INTRODUCTION

The Guide to Daily Operations describes the procedures Institutional Review Board (IRB) utilizes to adhere to its standard operating policies. The Guide to Daily Operations is the companion to the Standard Operating Policies. The procedures described herein, though based on policy, are flexible and take into account numerous details of the day-to-day activities of the IRB.

While this Guide is a Companion to the Standard Operating Policies, this Guide is organized in a different manner. This Guide is arranged in the following sections:

- **IRB Staff Administrative Processes:** Addresses maintenance of SOPs, training and management of IRB staff, the internal quality assurance and improvement program.

- **IRB Membership Administrative Processes:** Addresses the make-up and management of the IRB, membership training, and management of member conflicts of interest.

- **IRB Meeting Administrative Processes** Addresses meeting administration, submission requirements, and billing procedures.

- **Research Review Processes:** Addresses the procedures for initial and continuing review of research and for additional circumstances that require special considerations by the IRB.

- **Miscellaneous Processes and Procedures** Details tasks completed by IRB that are not previously described in earlier sections.
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Format

The majority of the sections in this document are arranged in the following manner --

- Process Overview – Defines the scope of the procedure
- Responsibility – Assigns roles
- Procedures Employed to Implement the Policy - Details the individuals and daily activities of IRB staff and members to carry out the requirements of the policy

Some sections are formatted differently in order to better detail procedures, activities, and guidance.
IRB Staff Administrative Processes

Policy and Procedures Maintenance

1. Process Overview

This section details the manner in which the IRB will ensure that its policies and procedures are up to date.

2. RESPONSIBILITY

Director
The Director is responsible for overseeing the policy review process. The Director designates staff to assist in the review and revision process. The Director reviews and approves the work to ensure that revisions are appropriate and accurately reflect the current policies.

Designated Staff
Staff members review and provide comments on policies and forms. Staff members may also create draft policies and forms as assigned. Staff work is submitted to the Director for review and approval.

3. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY

Policy Review Processes

Director, Associate Director and Assistant Director
The Director, Associate Director and Assistant Director are responsible for ensuring that the IRB maintains up-to-date policies and procedures that adhere to regulatory mandates and ethical principles. They will review Policies and designate appropriate staff to review policies at least every three years or more frequently on an as needed basis.

Director or designated staff
Staff will review the specific policies or policy sections assigned to them by the Director and provide feedback on which sections appear out of date in response to changes in regulations, federal guidance, and policies and procedures of the University of Pennsylvania. Staff will suggest revisions to appropriately update policies. Suggested revisions, comments, and questions will be sent to the Director, Associate Director or Assistant Director for consideration. If changes are warranted, changes to the policies will be made according to the policy revision processes.
Policy Revision Processes

Director
The Director will charge staff with drafting revised policies or creating new policies depending on the results of the policy review process. The Director will provide staff with needed background information to ensure that staff understands their assigned duties.

Designated Staff
Staff will work individually or as part of a team to create policies per the Director’s instructions. Draft materials will be provided to the Director for review and approval prior to incorporation into the SOPs.

Director
Director will review the draft to determine if it is satisfactory. Once revised policies are determined to be appropriate, the Director will determine if further review by the Institutional Official is necessary. In addition, if comments from other offices within the University of Pennsylvania are needed, the Director will solicit feedback. Additional revisions may be required and the Director will determine the appropriate course for completing those revisions.

Once draft review and revisions have been completed, the Policies will be finalized and published on the IRB website. Additional publication sources within the University may be utilized at the discretion of the Director.

Form Development and Revision Processes

Director, Associate Director and Assistant Director
The Director Associate Director and Assistant Director are responsible for ensuring that the forms, guidance, checklist, and worksheets can be appropriately used to ensure that policies are integrated into the daily operations of the IRB. They will review documents and designate appropriate staff to review forms on an as-needed basis.

Director or designated staff
Staff will review the specific documents assigned to them by the Director and provide feedback on whether these forms are optimal documents for ensuring meaningful reviews. Staff will suggest revisions to appropriately update documents. Suggested revisions, comments, and questions will be sent to the Director, Associate Director or Assistant Director for consideration. Forms will be updated in a manner similar to IRB Policies.
IRB Staff Administrative Processes

New Staff Education and Training

1. PROCESS OVERVIEW

This section details the processes for training new staff members on the policies and procedures of the IRB.

2. RESPONSIBILITY

Associate Director
The Associate Director develops the training program for all IRB staff and tailors the training program to the new staff's strengths and weaknesses. The Associate Director updates the Director on the progress of new staff as they move throughout the training program.

Associate Director or Designee
Staff designated by the Associate Director serve as trainers and mentors to new staff hires. They guide the new staff through the training program set by the Associate Director and seek to foster a collaborative and supportive atmosphere.

New Staff Member
The role of the new staff member during this education and training phase is to follow instructions provided by the Associate Director or designee. Due to the fluid nature of the training program, specific responsibilities are not detailed for the trainee in this section.

3. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY

Associate Director
The Associate Director is responsible for developing and implementing the new staff education and training program. The program is customized to new staff members and their strengths and weaknesses. While customizable, the program will always involve the completion of CITI human subjects' protections course, a 4 to 6 month probationary period, and a review session at the completion of the probationary period. The Associate Director may designate additional IRB staff to assist with the training program. Updates from the Associate Director to the Director will be provided throughout the training period.

Associate Director or Designee
Either the Associate Director or an appropriate designated staff member will be responsible for overseeing the training of a new staff member. The trainer(s) will provide support and mentorship throughout the probation period. The trainer(s) will provide updates to the Associate Director and Director as needed. If appropriate, the trainer(s) may suggest revisions to the
education and training plan set by the Associate Director in order to better tailor the program to
the new staff member.

The trainer(s) will ensure that the staff member has completed a basic human subjects'
protections course available online through the CITI program. Staff members who have not
previously completed the course are asked to complete the IRB member course. The
biomedical research course or social/behavioral research course may also be accepted if
previously completed as these courses are supplemented by additional orientation materials.
Staff members involved in the review of Department of Navy funded research are required to
complete additional training modules applicable to the review of these protocols.

New staff members are required to review existing IRB policies, guidance, and forms. The
trainer(s) will show staff where materials can be found and task staff with reviewing these
documents. The trainer(s) will provide more in depth review of policies and procedures as staff
move through probationary period.

The trainer(s) will guide the new staff member through a 4 to 6 month probationary period. The
educational approach focuses on developing a mastery of more basic skills before advancing to
more complex responsibilities. New staff will focus on one specific day to day function of the IRB
at a time in order to develop an understanding of the processes required to complete that task.
Staff will then move on to more complex assignments when basic skills are mastered. Finally,
multiple tasks will begin to be assigned to new staff in order to develop skills related to multi-
tasking and priority setting. The trainer(s) will monitor assignments to new staff and provide
guidance and feedback throughout the process in order to ensure that assignments are
completed in a timely and appropriate manner.

After four months, the trainer(s) and Associate Director will meet with new staff and review
progress made during the probationary period. If necessary, the probationary period may be
extended in order to provide new staff with additional training and skill development. If the
trainer(s) and Associate Director determine that the probationary period can end, the meeting
will focus on ongoing skill development and goal setting for the remainder of the University’s
performance period.
IRB Staff Administrative Processes

Ongoing Staff Education and Training

1. PROCESS OVERVIEW
IRB staff members receive education and training from senior staff on a regular basis. This section details the typical methods used to develop staff throughout the year.

2. RESPONSIBILITY

Director
The Director is responsible for establishing training requirements for IRB staff and for ensuring that requirements are met.

Associate Director and Desigenees
The Associate Director and any additional designated staff conduct ongoing training at the behest of the Director. They suggest, develop, and document ongoing training activities as they are conducted.

IRB Staff
The role of IRB staff that are receiving education and training phase is to follow instructions provided by the Associate Director or designee. Due to the fluid nature of the training program, specific responsibilities are not detailed for the trainee in this section.

3. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY

Staff Meetings

Associate Director and Desigenees
Weekly staff meetings may have an educational or training presentation. These presentations are often led by senior staff members or invited guests. Topics related to educational needs of the IRB staff are covered. Topics and presenters are selected by the Associate Director in consultation with the Director.

Individual Trainings

Associate Director and Desigenees
The Associate Director will determine when individual staff members will best benefit from one-on-one training on specific topics or procedures. These training sessions seek to develop new skills or expertise in an area related to human subjects' protections or IRB operations. The Associate Director may assign a specific mentor to the IRB staff that will provide support and guidance during the training. The mentor and Associate Director will determine when the IRB
staff member has developed the necessary competency to complete the tasks with minimal supervision and report the results of the training to the Director.

**External Conferences/Seminars:**

Staff members are encouraged to expand their knowledge base and subject-matter expertise by attending national and regional conferences that cover topic areas pertinent to human subjects’ protections. Staff members at all levels are afforded an opportunity to attend external educational opportunities. Permission for staff to attend conferences is granted by the Director. In order to ensure collective benefit from staff participation in these external activities, staff afforded an opportunity to attend are required to present the lessons learned from their participation/attendance at a staff meeting.
IRB Staff Administrative Processes

Staff Assessments

1. PROCESS OVERVIEW
This section details the process for assessing performance of IRB staff. Staff assessments are completed at least annually and additional assessments may be conducted as needed.

2. RESPONSIBILITY

Director
The Director, in consultation with the Vice Provost for Research, is responsible for determining the overall organizational structure of the IRB. Supervisory assignments are designated by the Director according to University Policy.

Supervising IRB Staff
Designated IRB staff will provide oversight and guidance as required by the Director and University Policy. Staff with supervisory responsibility will be responsible for ensuring that supervisees meeting office expectations. Staff with supervisory responsibility will inform the Director of any issues that need to be addressed.

3. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY

Annual Performance Reviews

Director
IRB staff members undergo a yearly performance review pursuant to University Policy. The Director establishes a timeline for completion of the performance review and informs the staff of their responsibilities and obligations during this process.

IRB Staff
IRB staff complete a self-assessment according to University Policies. The self-assessment details competencies demonstrated over the previous years, individual goals that have been completed, and upcoming goals for the following year. Once completed, this self-assessment is provided to the staff members’ supervisor.

Supervising IRB Staff
Supervising staff review the self-assessment and provide a review of the staff member’s performance over the past year. The supervisor(s) also comments on goals set by the supervisee and may provide additional goals for the coming year. The performance assessment is then provided to the Director for Review and Comment.
After receiving the Directors review, the supervisor(s) meet(s) in person with supervisee and discusses the performance assessment. The supervisee then signs the performance assessment. The signed performance assessment is then provided to the Director for filing according to University Policy.

**Performance Improvement Plans**

**Supervising IRB Staff**
Throughout the year, supervising IRB staff may need to document identified areas of improvement of staff members they oversee. Supervising staff will consult with Associate Director and Director when problems are identified and determine if a performance improvement plan is warranted. If necessary, staff will implement a plan in accordance with University Policies. Documentation of staff’s performance through the improvement plan will be generated by Supervisor. The documentation will then be provided to the Director who will store the documentation according to University Policies. If performance fails to meet expectations established in the performance plan, additional warning and disciplinary actions may be necessary. These actions will be documented and be made accessible to HR as applicable per University Policies.

**Informal Assessments**

**IRB Staff**
IRB staff members are encouraged to track and log any informal documentation related to their performance. This documentation is often received from colleagues, supervisors, and the research community. Staff members are also encouraged to share this information with supervisors and the Director in order to generate a comprehensive picture of staff strengths and weaknesses.
IRB Staff Administrative Processes

Signatory Authority Maintenance

1. PROCESS OVERVIEW

Authority to sign documents is designated according to IRB policies. The Director is charged with regularly reviewing and amending individual staff member authorizations.

2. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY

Authority to sign IRB documents is based on an individual staff member’s position, training and expertise. Staff responsibilities for signing documents often change after completion of probationary periods and at the time of promotion. The Director is to be kept apprised of staff members training and expertise and will revise staff’s signatory authority as appropriate. Signatory authority is documented by the Director.
IRB Staff Administrative Processes

Management of Conflicts of Interest: Staff

1. PROCESS OVERVIEW

This section discusses the procedures that will be implemented when a staff member identifies a potential conflict with a research protocol.

2. RESPONSIBILITY

Director and Associated Director
The Director and Associate Director are responsible for training and overseeing staff on the management of conflicts.

IRB Staff
Staff members are charged with identifying conflicts and taking necessary steps to manage them.

3. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY

Director and Associate Director
IRB leadership is charged with ensuring that staff members are informed of the University policies and the federal regulations on conflict of interest. The Director and Associate Director will provide education and training to staff on conflict of interest policies.

IRB Staff
All staff must familiarize themselves with University and federal regulations on conflict of interest.

Staff will self-identify any potential conflicting interests that appear during the course of day to day activities. If staff is conflicted with a protocol, they will remove themselves from consideration of any expedited or convened review of the protocol. The staff will also inform the Director of the conflict for development of a management plan, as applicable.
IRB Membership Administrative Processes

Membership Recruitment and Selection

1. PROCESS OVERVIEW

The Board Member recruitment process is flexible and Senior Staff tailor this process to the needs of the IRB and the potential members expressing interest in the IRB. This section discusses the general processes involved in identifying and recruiting new Board members.

2. RESPONSIBILITY

Senior IRB Staff
Senior staff interacts with potential new members and work with them to gauge interest in service on a Board.

3. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY

The overall Board Membership recruitment strategy is set by the Director in consultation with the Vice Provost for Research, if determined necessary. Strategies are based on the specific needs of the Boards at various points in time. Potential members are approached by senior members and staff of the IRB. More junior members and staff of the IRB staff are encouraged to discuss participation with potential members and then refer individuals to the Director, Associate Director or IRB Chairs.

Senior IRB Staff
After a potential member expresses interest in serving on a Board, the member is invited to observe an IRB meeting. Senior IRB staff set up a convenient time for the member to observe. The staff member informs the IRB administrator and assistant for that Board that a guest will be attending the meeting. The senior staff asks the potential member to provide a resume or CV for consideration.

At the meeting, the potential member first signs a Guest Confidentiality form. The potential member then receives a copy of the meeting agenda and observes the meeting. After the meeting is over, the potential member will sit down with the Senior IRB Staff member to discuss interest in serving on a Board. Other Board members and IRB staff may be invited into that discussion.

If the potential member expresses a desire to join the IRB, the senior staff and the potential member discuss which Board meetings the member would be able to regularly attend. After this
discuss the staff member forwards the information to the Director/Associate Director for review.

**Director/Associate Director**
The Director/Associate Director receives a copy of the potential members CV and a description of the Boards and membership slots that are available at this time. The Director/Associate Director considers the expertise of the member and the needs of the IRB when deciding whether to approve a term for the Member and the findings of the assessment are discussed with the IRB Chair, as applicable.

**Senior IRB Staff**
If the member is accepted, the Senior Staff member informs the Administrator for the Board who adds the member to the roster. Training for the new member is scheduled with the appropriate IRB personnel.

If the member is not accepted, the Senior Staff informs the potential member of the reason why he or she could not be accepted at this time.
IRB Membership Administrative Processes

Board Roster Maintenance

1. PROCESS OVERVIEW
The following procedures are implemented by IRB staff for creating Board membership rosters, maintaining the Board membership rosters, and ensuring the PennERA system provides the most current Board membership information to date.

2. RESPONSIBILITY

Director/Associate Director/Assistant Director
The Director/Associate Director/Assistant Director reviews IRB membership letters for IRB Members and once determined to be correct; a copy will be signed by the Director and provided to the designated IRB Administrator.

IRB Administrator
The IRB Administrator is responsible for the maintenance of each individual Board roster in Penn ERA and corresponds with the IRB Chair, the Board Members, and the IRB Administrative Assistant to ensure the most current Board membership information is captured in the appropriate record databases. The IRB Administrator is also responsible for corresponding with the appointed IRB personnel (noted below) to ensure that membership letters are sent to Board Members. The IRB administrator will maintain IRB membership documents for each member of the board which include their most current curriculum vitae, membership letters, background and experience, etc,

IRB Assistant
An appointed IRB Staff Member will draft and convert IRB membership letters for new and renewing Members.

3. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY

Adding New Members to Rosters

Senior IRB Staff
After a new Board Member has been accepted for a Board, the Senior IRB Staffer who worked on the recruitment project notifies the IRB Administrator for the Board the member is joining and notifies the IRB administrator to draft the IRB membership letter. The Senior Staffer provides both administrators with a copy of the Member’s resume, information on the role the Member will serve, and the length of the Member’s term.

IRB Administrator
The IRB Administrator updates PennERA to include the new member. The administrator navigates to the Human Subjects Administration – Board Administration fields and selects the appropriate roster. The member information is updated to include the new member and indicate the length of his term. The IRB Administrator also updates the Roster Spreadsheet for the Board. This roster is stored on the G: Drive and is updated to include the new member and detail the length of the member’s term.
The Administrator then works with Senior Staff to help the new member through the new member training process.

**Renewing Existing Membership Terms**

**IRB Administrator**
On a monthly basis, IRB members with terms that are set to expire in the near future are identified. The IRB Administrator compiles a list of the current Board Members who are set to expire and discusses this with the Director/Associate Director/Assistant Director to determine if the member should be invited for another term. The Chair of the Board may be queried as well.

After reviewing the roster and identifying expiring members the IRB Administrator contacts both the Board Chair and the Director and requests their determination on whether the member’s term should be renewed or expired. If the Chair and Director agree that the member should be asked to continue to serve for another term, the IRB Administrator asks the member if they are willing to serve for another term.

Once the member’s response has been received, the IRB Administrator informs the Assistant if a membership renewal or a thank you for your service letter should be generated. The IRB Administrator than updates the rosters in PennERA and the G: Drive to reflect the new or expiring term.

**Terminating Memberships**

**IRB Administrator**
If a Board Member resigns from the IRB or a decision is made to terminate a Board Member’s term prior to its expiration, the IRB Administrator is responsible for ensuring that the Director, and IRB Chair are all informed of termination. The IRB Administrator than updates the rosters in PennERA and the G: Drive to reflect the terminated term. The IRB administrator informs the IRB Assistant that a thank you for your service letter should be drafted for the member.

**Membership Letter Generation**

**IRB Assistant**
After receiving an email from the Administrator, the IRB Roster Assistant drafts initial, renewing, and thank you for your service Board Member letters. The letter should outline the membership action that is occurring and the effective date. These letters are converted into PDFs and sent to the IRB Administrator.

**IRB Administrator**
The IRB Administrator reviews the letters for accuracy and completeness. The letters are then forwarded to the Director for review and signature.

**Director**
The Director reviews and signs the IRB membership letters. Signed letters are then returned to the Administrator.
The Board Administrator and/or Assistant then upload all signed letters for storage on the G: Drive. New membership and renewal letters are combined with Confidentiality and Conflict of Interest Statements and sent to the Board Members. Members are asked to sign the statements and give them to the IRB administrator at the next board meeting. Signed statements are stored on the G: Drive along with the signed membership letters.
IRB Membership Administrative Processes

New Member Training

1. PROCESS OVERVIEW

The IRB has a variety of educational initiatives designed to orient new members to IRB review processes and the regulations governing human subjects' research. These activities are detailed below.

2. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY

Senior IRB Staff and IRB Administrator
The senior IRB staffer involved in recruitment of the member and the IRB administrator for the Board the member is joining, work together to make sure that the member completes the initial orientation process. Before new members are assigned primary or secondary reviews for agenda items, new members are required to observe at least two convened IRB meetings, including one meeting of the Board to which the member has been assigned.

In addition, IRB staff will provide new members with orientation materials including Amdur and Bankert’s IRB member handbook, applicable ethical and regulatory guidance materials, details regarding the Board’s roster and meeting schedule, and copies of the IRB’s reviewer forms/checklists.

All new members undergo a new member training session prior to serving as a member of a convened IRB. The new member training is led by Senior IRB staff with assistance from IRB administrators and provides instruction on the electronic application system, IRB agendas and minutes, reviewer guidance materials and checklists, the expected work of members prior to and during the convened meeting and applicable ethical and regulatory requirements with particular emphasis on the criteria for IRB approval.

At the time of the first direct review assignments, new members are also afforded an opportunity to walk through any questions/concerns they have with a member of the IRB staff to ensure all applicable criteria for approval have been appropriately considered by the member in the process of the review.

All IRB members are notified of the request to complete a basic human subjects’ protections course available online through the CITI program at [www.citiprogram.org](http://www.citiprogram.org). Members who have not previously completed the course (if they are not researchers at Penn) are asked to complete the IRB member course. The biomedical research course or social/behavioral research course may also be accepted if previously completed and applicable to the types of reviews that will be conducted by the Board to which the member has been assigned. Members who serve on Boards that review Department of Navy funded research are required to complete additional training modules applicable to the review of these protocols. The IRB administrator is responsible for informing members of the CITI training requirements and ensuring that required training has been completed.
The IRB offers a mentorship program for new IRB members. This program pairs new members with seasoned IRB members on the same Board when determined to be appropriate. New members are encouraged to share questions/concerns regarding their review assignments with their mentor. The mentor may also facilitate communications with the study team in advance of the meeting to gather information needed for the review process. IRB administrators assign reviews according to the mentorship program requirements. Mentors may be partnered with mentees for at least the initial three months of direct review assignments and longer if needed to meet the training needs of the new member.
IRB Membership Administrative Processes

Ongoing Member Training

1. PROCESS OVERVIEW
IRB Board Members are provided initial and ongoing training in the review and conduct of human subjects’ protections. IRB staff has the responsibility to create and present ongoing training through informative presentations on a regular monthly basis.

2. RESPONSIBILITY

IRB Administrator
The role of the IRB Administrator is to provide the Board Members the ongoing training presentation at IRB convened meetings. The IRB Administrator is also responsible for sending the ongoing training to Board Members and including a summary of the ongoing training in the finalized minutes.

IRB Staff Member
The role of the IRB Staff Member is to construct an ongoing training presentation that pertains to the review and conduct of human subjects’ protections. The IRB Staff Member is also responsible for demonstrating the ongoing training to IRB Administrators and providing a summary of the ongoing training to be included in the finalized minutes.

Senior Staff
The role of the Senior Staff is to designate an IRB Staff Member to construct an ongoing training presentation. The Senior Staff provides the designated IRB Staff Member with any appropriate guidance to assist in the completion of the ongoing training presentation.

3. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY

Senior Staff
The Senior Staff designates and informs an IRB Staff Member to construct an IRB Board Member ongoing training presentation for an upcoming IRB Board Member meeting. The Senior Administrator with the IRB Staff Member arranges a format in which the ongoing training will be presented and selects a topic for the ongoing training pertaining to human subjects’ protections.

IRB Staff
After being informed from the Senior Staff the IRB Staff Member begins the process for constructing an ongoing training presentation that is relevant to human subjects’ protection. The IRB Staff Member must complete a draft of the ongoing training in the time given by the Senior Staff Member. The IRB Staff Member prepares a draft of the presentation by utilizing institutional and software resources (e.g. library services and PowerPoint) while communicating to the Senior Staff about any issues or questions should they arise. In addition, the IRB Staff Member includes a brief summary about the ongoing training to be included in the finalized minutes. The IRB Staff Member sends the ongoing training and its summary to the Senior Staff Member for review.
Senior Staff
The Senior Staff reviews the IRB Staff Member’s ongoing training presentation. Any revisions and/or concerns are communicated to the IRB Staff Member.

IRB Staff Member
The IRB Staff Member makes any necessary revisions to his or her ongoing training presentation. The IRB Staff Member demonstrates the ongoing training presentation at an IRB Administrators meeting so that the IRB Administrator may be able to present the ongoing training at his or her respective board meeting.

The IRB Staff Member addresses any necessary revisions to the ongoing training that were voiced at the IRB Administrators meeting. Upon finalization of any revisions, the IRB Staff Member emails the ongoing training presentation, any supplemental documents, and the brief summary for the minutes to all IRB Administrators. Copies of the trainings are also stored on the G: Drive for future reference.

IRB Administrator
The IRB Administrator receives the ongoing training documents and includes the ongoing training in the agenda email to the Board Members. The ongoing training summary is saved for later inclusion into the finalized minutes. The IRB Administrator presents the ongoing training at the appropriate IRB convened meeting either before or after the agenda depending on time constraints. A summary of the ongoing training is included in the finalized minutes.
IRB Membership Administrative Processes

Member Assessments

1. PROCESS OVERVIEW

IRB Board membership is reviewed and assessed on an annual basis through a self-assessment completed by members and a general review completed by IRB staff. This process is done to ensure that Board members are appropriately trained and that Board Rosters consist of members who are able to make meaningful contributions to human subjects’ protections at Penn.

2. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY

IRB Member Self-Assessment

IRB Administrator
On a yearly basis, the IRB asks its members to complete a self-assessment form. This form is usually completed during a spring IRB meeting. The IRB administrator presents the self-assessment form to the members and conducts a training session on how to complete the form in the manner that will give the IRB the most useful information possible. The IRB administrator will email the self-assessment form to members who were not present at the meeting.

The form and training materials are drafted by Senior Staff and presented to the Administrators at a staff meeting. The form is revised on an annual basis to best suit the needs of the IRB but typically includes information on member training, level of comfort with various review activities, and experience conducting specific types of IRB review (subpart determinations, waiver of consent requests, etc.).

The IRB administrator collects the completed self-assessments and stores them on the G: Drive. Reminder emails are sent to any members who have not completed the form. Senior staff is notified once all self-assessments have been received.

IRB Board Review

Director, Associate Director, and IRB Administrator
After all self-assessments have been received and reviewed by senior IRB staff, the Director, Associate Director, and IRB administrator meet to informally discuss the Boards. The roster is reviewed and IRB staff discusses the previous year. The strengths and weaknesses of the Board are discussed. Membership recruitment goals for the coming year are outlined. IRB staff also determines if individual member training is needed and if targeted training to the Board as a
whole would be valuable.

**Expiration Review**

**Director, IRB Chair, and IRB Administrator**

When a Board members term is set to expire, the IRB administrator asks the Chair and Director to consider whether the member should be asked to return for another term. The Chair and Director review the members' expertise and contributions to the Board over the previous term. The Chair and Director also consider whether the member would benefit from additional training. The results of this review are given to the IRB administrator. If further training or actions are warranted, the administrator consults with the Associate Director and Director to determine the best course of action.

**Membership Feedback**

After IRB leadership has met to discuss the results of the member self-assessments, the findings are presented to the IRB chairs at the next available IRB Chairs Meeting. During that meeting, the Chairs are consulted on the recruitment and training goals of the Boards and specific members if needed. This feedback is then incorporated into the self-assessment findings.

The feedback provided by IRB leadership and the chairs are summarized and presented to the Board members. The presentation is given at convened IRB meetings and takes the place of that month’s member training presentation. If individualized feedback or training is appropriate for a member, it will be provided by either the Chair or IRB staff via a one on one discussion.
IRB Membership Administrative Processes

Management of Conflicts of Interest: Members and Consultants

1. PROCESS OVERVIEW

Conflicts of interest are defined by institutional policies and the federal regulations. Members are responsible for identifying conflicts and informing the IRB staff so that staff may take appropriate steps to allow IRB review to continue. The process for managing member conflicts is identified below.

2. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY

IRB Administrator and Assistant

Board Members are informed of the University Policies and the Federal Regulations related to conflicts of interest at the time they join or renew their membership on a Board. Members are given a statement regarding the conflict of interest policies that they must sign to indicate their understanding and agreement to abide by the policies. The IRB Administrator receives this signed form and will file accordingly.

While screening full board action items, the IRB Administrator and assistant review the protocol’s personnel list to see if any Board members are listed. If conflicts are identified during pre-screens the staff logs these conflicts. When the agenda is distributed via email, the Board Members are informed of all identified conflicts along with a request for members to inform the IRB staff of any un-identified conflicts.

Board members are required to self-identify their conflicts of interest for all reviews. During a convened review of any action, any member with a conflict must leave the room for the discussion and vote. Members with conflicts can only participate in the discussion if they are invited back into the meeting the Board to answer specific questions. The IRB Administrator and assistant should track all conflicts and document that the member left the room in the minutes for that review.

Members with conflicting interests do not count towards quorum and cannot conduct primary or secondary reviews. Therefore, IRB staff must ensure that a quorum is present for the discussion and during the review of a protocol with an identified conflict. In addition, if a member assigned a primary or secondary review identifies a conflict, the administrator must re-assign that review to an un-conflicted Board member.
Consultants cannot provide reviews for protocols with which they have a conflict. If a consultant review is requested and the consultant identifies a conflict, the IRB Administrator should notify the Director or Associate Director and discuss approaching another consultant. If a consult is present during the discussion of a protocol with which he or she is conflicted, the consultant must leave the room during the discussion and the vote.
IRB Meeting Administrative Processes

Convened Meeting Responsibilities

1. PROCESS OVERVIEW
This section describes IRB staff procedures for Convened Board Meetings. This section outlines agenda preparation and distribution, administrative activities during the convened Board meeting, and preparation and distribution of letters and minutes after the meeting.

2. RESPONSIBILITY

ORA Administrator
The role of the ORA Administrator is to check for incoming convened review actions and assign the actions to the appropriate IRB Administrator/Assistant for review.

IRB Administrator
The role of the IRB Administrator is to review the action, begin data entry processes, and assign the review action to the appropriate IRB board. The administrator drafts decision letters for actions, distributes signed letters to the study team, and provides assistance and oversight to the IRB Administrative Assistant as needed.

IRB Administrative Assistant
The role of the IRB Administrative Assistant is to complete data entry for the action, draft the IRB decision letter for the action, distribute the signed letter to the study team, and provide assistance to the IRB Administrator as needed.

IRB Senior Administrator
The role of the Senior Administrator is to provide support to the Administrator and Administrative Assistant as needed to ensure that the items scheduled for the meeting agenda have been screened and scheduled appropriately. The Senior Administrator may also review the minutes generated from the meeting.

IRB Regulatory Representative
The regulatory representative is a senior member of the IRB staff who attends the meeting and participates in the discussion. The regulatory representative often serves as a voting member. The regulatory representative also reviews the determination letters and minutes generated from the meeting in order to ensure that they are accurate description of the Board’s deliberations.
3. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY

A. Pre-Meeting Activities

i. Expiration Email Reminders

IRB Administrative Assistant

After the prior month’s IRB meeting has been completed and the minutes have been finalized, the IRB Administrative Assistant contacts study teams for protocols that are expiring within the next 2-3 months. These contacts are to inform the study team of the requirements for continuing review and the IRB’s preferred timeline for submission.

The Administrative Assistant runs a report in PennERA to detail the list of protocols that are expiring with the next 2-3 months. The Administrative Assistant then locates the email addresses for the PI and primary study contact by viewing the last IRB decision letter uploaded to the communications folder for each protocol in PennERA. The study personnel sections in the most recent HS-ERA submission may also be used to locate additional study contact information for electronic submissions if sufficient contact information has not been obtained from the most recent IRB decision letter.

The Administrative Assistant drafts an email addressed to the PI and study contact. The email informs the study team of the upcoming protocol expiration date and details the IRB’s preference for continuing reviews to be reviewed at the meeting scheduled a month prior to the study’s expiration date.

The Administrative Assistant creates a document tracking the continuing reviews that may be scheduled for the agenda. That document is updated to indicate that the study team was contacted regarding the protocol’s expiration date. In addition, the document is updated to reflect when continuing review submissions are received by the IRB and scheduled for the meeting agenda.

If an email response in regard to the protocol’s upcoming expiration has not been received or the submission has not yet been received by the IRB within a reasonable timeframe (e.g. three weeks after initial contact), the Administrative Assistant uses the study personnel sections in the most recent HS-ERA submission to notify alternative study contacts and the PI, once again.

The Administrative Assistant coordinates with the IRB Administrator throughout this process and consults the IRB Administrator if any questions or issues arise.
ii. Member Attendance

IRB Administrative Assistant

Approximately four weeks before the agenda date of the next IRB meeting, the IRB Administrative Assistant contacts the Board members via email to request their availability for the meeting. This email includes the date, time, and location of the meeting.

As each Board member responds with his or her availability for the meeting, the IRB Administrative Assistant updates a Board member attendance spreadsheet. The IRB Administrator is informed throughout this process in order to respond to any questions or issues as they arise.

IRB Administrative Assistant and IRB Administrator

Both the IRB Administrative Assistant and the IRB Administrator are responsible for ensuring that a quorum of members will be present at the meeting. A quorum consists of a majority of the IRB members present to discuss and vote on the convened board actions. A majority of the members is defined as at least half of the Board members plus one. For example, if there are 14 members on the Board’s roster, quorum is 8 members. If there are 15 members on the Board’s roster, quorum is still 8. If there are 16 members, quorum is 9. A quorum also requires a non-scientist member be present at the meeting. For FDA regulated research, a physician member must also be present. If the research being reviewed involves prisoners, a prisoner representative must be present for quorum. Alternate Board members share one roster position. If both members attend the meeting, only one Board member votes and only one vote is counted toward the quorum.

iii. Assignment Tracking

ORA Administrator

Convened review items are assigned to the IRB administrator and assistant based on IRB procedures.

IRB Administrator and Administrative Assistant

The IRB Administrator and Administrative Assistant track all incoming assignments for the convened agenda on a shared document in the G Drive. The document is updated throughout the preparation process and contains information on the type of submission, its status, and any questions or issues with the submission that have not yet been resolved.
iv. Reviewer Assignments

**IRB Administrator and Administrative Assistant**

After the agenda items have been scheduled and Board member availability has been determined, the IRB Administrator and Administrative Assistant assign reviewers for each submission going on the convened agenda.

The Administrative Assistant is responsible for assignment of primary reviewers for all continuing review submissions. The IRB Administrator is responsible for assignment of Primary and Secondary reviewers for all submissions for initial review. The IRB Administrator is also responsible for assignment of primary reviewers for all modification submissions and reportable events. The IRB Administrator and IRB Administrative Assistant collaborate as needed to complete review assignments.

When selecting the Primary Reviewer for any agenda item, IRB staff should ensure that the member has appropriate scientific or scholarly expertise to conduct the in-depth review of the protocol needed for the type of review requested. Administrators and Administrative Assistants should consult the IRB Rosters and the available Curriculum Vitae to determine appropriate professional experience. Previous IRB membership and other personal and professional experiences should be considered when determining assignments. IRB Senior Staff may also be consulted. Senior staff may recommend that a consultant review be obtained if outside expertise is necessary in order to ensure an appropriate review. Senior staff will work with the IRB administrator to obtain and document this consultant review.

The IRB Administrator and Administrative Assistant assign reviewers by navigating to the post-review page for each submission and selecting the appropriate reviewer. The assignment tracker is also revised to include the submission assignments. These assignments may be changed as additional items are scheduled for review or if the Board member(s) identify a conflict.

v. Agenda Generation, Review, and Distribution

**IRB Administrator**

Prior to generating the agenda, the IRB Administrator reviews the meeting agenda volume to ensure that the workload is appropriate given the member attendance for that meeting. Meeting agendas will generally be limited to 6 initial reviews, 10 continuing reviews, and 6 modifications. This limit may be altered in circumstances requiring a rush review from the investigators (i.e. patient safety notification, funding contingencies) or when complex reportable events are submitted for review. After the agenda items have been scheduled and assignments have been made, the IRB Administrator generates the meeting agenda to be sent to Board members.
PennERA is utilized to generate the agenda. The IRB Administrator navigates to the appropriate Board Meeting page in the Human Subjects Admin module in PennERA. The IRB Administrator then builds the agenda for the upcoming Board Meeting. The IRB Administrator then converts the built agenda into a word document.

The IRB Administrator reviews the agenda to ensure it appropriately details the time and location of the meeting. The IRB Administrator also ensures that all the items on the tracking document appear in the agenda with the correct reviewer assignments. The IRB Administrator makes any necessary formatting revisions to the agenda document in each individual item. Any additional expedited and/or duplicate items that populate in the agenda are removed from the agenda. Expedited items are reported to the Board with in the meeting minutes. The IRB administrator may consult with Senior Administrators or the Regulatory Representative as needed when finalizing the agenda.

Once the agenda is finalized, the IRB Administrator works with the Administrative Assistant to ensure that paper submission materials are ready for distribution. The IRB Administrator sends the agenda to the Board members in an email along with the minutes from the previous month’s meeting. The email should also direct members to the appropriate worksheets and guidance documents for Board members to utilize during their reviews. Previously identified Board member conflicts of interest should be shared with members along with a request for members to inform the IRB of any additional conflicts they identify.

All members are provided the following materials through the electronic submission system, HS-ERA:

- Full protocol and application containing the relevant information to determine whether the proposed research fulfills the criteria for approval
- Proposed consent document
- Recruitment materials (if applicable)
- Investigator’s Brochure (if applicable)
- Relevant grant applications (when applicable)
- Sample informed consent form and/or protocol (when applicable)

*NOTE: Only the Chair, Primary and Secondary Reviewers are expected to review the full protocol and investigator’s brochure
*NOTE: All review materials are available to all members of the convened board.

**IRB Administrative Assistant**

After receiving the finalized agenda, the IRB Administrative Assistant closes the agenda in PennERA. The Administrative Assistant performs this action by navigating to the appropriate Board Meeting page in the Human Subjects Admin module in PennERA. Then Administrative Assistant then checks the meeting date as closed and informs the IRB staff that future items should be assigned to the next month’s agenda.
The Administrative Assistant then prepares any paper submissions scheduled for review. Each Board member who has confirmed attendance will receive a packet with documents for each submission. The IRB Chair’s packet includes all submitted review materials for paper actions. IRB Board members receive all submitted review materials for any actions for which the member is a primary or secondary reviewer. If the member is not the designated reviewer, then he/she receives a partial packet for that item.

Partial packets for continuing review submissions contain the Protocol Summary, the Continuing Review Form, the Progress Report (noting any subject complaints occurring during the last approval and any Investigator-identified revisions to the current risk-potential benefit assessment, based on current study information) and the Informed Consent Form. Partial Packets for modification submissions contain the Modification Form, the Modification Summary document(s), and the Revised Informed Consent form.

The Administrative Assistant arranges the packet materials in the order the paper submissions are listed on the final agenda. The Administrative Assistant arranges for packets to be delivered by Timecycle or by IRB staff. If there are 3 or fewer paper items scheduled for review, the Administrative Assistant may scan and send PDF copies of the documents to the Board members via email.

vi. Ordering Food, Regulatory Representative Consult, Prep Meetings, Skeleton Minutes

IRB Administrative Assistant

The Administrative Assistant determines the food order for the Board Meeting. The Administrative Assistant emails the appropriate staff member with ProCard responsibility to place the food order. The email includes the meal menu, the number of meeting attendees, and the cost of the meal. Any issues related to menu selection, including cost constraints, may involve the ProCard staffer and the IRB Administrator.

IRB Administrator and Administrative Assistant

During their screening and scheduling of convened action items, the IRB Administrator and Administrative Assistant may identify questions or concerns related to the protocols that are not related to the criteria for determining if a submission is ready for convened review. When this occurs the IRB Administrator and/or Administrative Assistant should relay these questions and concerns to the Regulatory Representative scheduled to attend the meeting.

Regulatory Representative

The Regulatory Representative will review the issues raised by the IRB Administrator and Administrative Assistant as part of his/her preparation for the Board meeting. In the same manner as all Board Members, the Regulatory Representative may share comments or questions raised during review of the agenda with the administrative staff, the Chair, other IRB
IRB Administrative Assistant and Administrator

If Board members contact the IRB Administrative Assistant with any questions or issues related to their reviews, the Administrative Assistant should attempt to resolve the concerns as quickly as possible. The Administrative Assistant may forward any correspondence with members to the IRB Administrator as necessary. If the Administrative Assistant resolves a board member’s concern, then he/she should inform the IRB Administrator.

IRB Administrator and Administrative Assistant

The IRB Administrator and Administrative Assistant will receive comments and questions from Board members as they review studies prior to the meeting. The IRB Administrator and Administrative Assistant should respond to questions as quickly as possible and work together to ensure that Board members’ issues are addressed. The Senior Administrator, Regulatory Representative, and/or Directors may be consulted to ensure issues are responded to appropriately. The IRB Administrator is responsible for compiling all comments.

IRB Administrators, Administrative Assistant, and Senior Administrator

Prior to the convened meeting, the IRB Staff attending the meeting and the appropriate Senior Administrator and/or Regulatory Representative may meet to discuss the Board meeting’s agenda. The attendees discuss each agenda item. Comments received by the members, special circumstances for the item, and any other issues related to the convened actions are described. If there are issues that can be resolved prior to the meeting, the attendees determine an appropriate course of action. The administrator creates an agenda summary document with all the issues pertaining to each agenda item along with the status of those issues and sends this document to the Chair and Regulatory Representative for review prior to the meeting. The Administrator identifies any regulatory determinations that must be made during the meeting and notifies the assistant to ensure that appropriate determination worksheets are available during the meeting. The Primary IRB Administrator is responsible for ensuring that the course of action is adhered to unless this responsibility is delegated to another IRB staff member.

IRB Administrator

On the morning of the meeting, the IRB Administrator drafts the skeleton minutes template for the convened meeting and sends this minute template to the Administrative Assistant(s), and regulatory representative(s). The IRB Administrator performs this action by navigating to the appropriate Board Meeting page in the Human Subjects Admin module in PennERA. Then, the IRB Administrator builds the template minutes for the Board Meeting. The IRB Administrator then converts the built template into a Word document. Any appropriate comments from the Board members are added to the template.
vii. Location Setup

IRB Administrative Assistant

Approximately 1 hour before the meeting, the Administrative Assistant prepares the meeting location for the Board Members. The Administrative Assistant ensures that the ORA laptops and iPads are set up for the Board members and the IRB staff and that a projector is available for Board member training.

If guests are attending the meeting, the IRB Administrative Assistant compiles any confidentiality forms and copies of the agenda for distribution to the guests. If supplemental forms, worksheets, or guidance documents are needed, the IRB Administrative Assistant ensures that they are available for the Board members.

When the food arrives to the meeting location, the IRB Administrative Assistant makes any necessary food preparations and retains a copy of the receipt for the ProCard staffer.

B. In-Meeting Activities

IRB Administrator

The IRB Administrator is responsible for presenting the monthly “IRB Member Training” either directly before or after the convened meeting. Additionally, the Administrator is responsible for determining that quorum is met prior to the start of the meeting. Once quorum has been determined to be met, the IRB Chair will call the meeting to order. The Chair may begin by making a motion for the Board to accept the meeting minutes from the previous month’s meeting (Please note that this motion can be made at any time during the meeting). The Administrator records the Board’s acceptance of the previous month’s minutes or documents any changes required to the minutes as specified by the Board. If any another administrative announcements are necessary, either the IRB Administrator or the IRB Chair will inform the Board at this time.

The IRB Chair then directs the Board through the meeting’s agenda items. The order of review is done at the Chair’s discretion. Reviews begin with presentations by the primary reviewer for the assignment. As the primary and, if appropriate, secondary reviewers present their assessment of the proposed research the IRB Administrative staff actively listens to the discussion and records the concerns in the meeting skeleton minutes. The IRB Administrator is responsible for accurately recording the discussion and concerns raised by the Board. If the staff has difficulty following the Board’s deliberations, they are encouraged to ask for additional clarification and explanation. The IRB Administrative staff is encouraged to engage the Board to provide supplementary documentation of their review and concerns (i.e. marked consent form).
The information captured in the minutes should include a brief overview of the reviewer’s summary of the proposed research, a specific description of the concerns raised during the review, tracking the members who have left the room or meeting to be sure quorum is not lost, (noting the time of the member entered/exited the conference room), tracking any member who has a conflict with any protocol review on the agenda so the member can exit the room during the discussion and vote, the order of the protocols reviewed, and the Board’s vote determination.

In the case that the agenda item requires special review determinations (i.e. Sub-part determination or NSR) the supplemental forms should be referred to during the review and utilized as a guide for the determination. The minutes should accurately reflect the Board’s determination.

If the Principal Investigator/Research Staff is present for the meeting to clarify any of the Board’s concerns for their proposed research project, the IRB Administrator will invite them into the meeting to answer and clarify any of the Board’s concerns. The PI/Research Staff will exit the meeting once the Board has completed their questioning. The Board will consider the PI/Research Staff commentary to include with their discussion and review of the proposed research.

IRB Administrative Assistant:

The Administrative Assistant is responsible for accurately recording the discussion and concerns raised by the Board for all agenda items, including the initial reviews. The Assistant should ask the Board questions if their reviews for the Continuing Review and/or Modifications are not clear, to be sure that the discussion is accurately captured in the meeting minutes.

IRB Chair:

The IRB Chair is responsible for a complete review of each agenda item, running the meeting in a timely and efficient manner, and guiding the Board to present clear and efficient reviews of their reviewer assignments. After the discussion of a review has been completed, the Chair will provide a brief summary of the Board’s determinations and call for a vote.

IRB Regulatory Representative:

The IRB Regulatory Representative role is as a Board member. In addition, when necessary, the regulatory representative may provide support to the Chair and Board Members regarding regulatory requirements for specific determinations and for insight into previous determinations made by other Boards.

C. Post-Meeting Activities

IRB Administrator:
Once the convened meeting adjourns, the IRB Administrative staff is responsible for emailing their draft minutes to each of the Administrative staff present at the meeting before exiting the conference room. The letter and minute drafting responsibilities for initial reviews and reportable events are the responsibility of the administrator. The assistant is responsible for drafting letters and minutes for continuing reviews and modifications. The IRB Administrator will discuss the Continuing Review and Modification reviews with the Assistant to determine a plan for which actions have priority (i.e. CR lapsing in approval). In special cases it can be determined appropriate to distribute the CR and Modification minutes and letters to the IRB Assistant staff due to volume and time constraints at the discretion of the IRB Administrator/Regulatory Representative. The IRB Administrator is responsible for reviewing the minutes, stipulations, and letters produced by the Assistant.

**IRB Administrative Assistant:**

After the convened meeting adjourns, the IRB Administrative Assistant collects and saves all marked Board Member documents, unmarked documents, and guest permission forms. In addition, the IRB Administrative Assistant cleans any food waste and dining materials left in the meeting room and ensures any electrical equipment and hardware (e.g. extension cords or ORA laptops) is securely put away. The IRB Administrative Assistant may supply the IRB Staff with the Board Member’s marked documents to assist with minute writing.

The IRB Administrative Assistant will dispose of all the collected paper materials from the convened meeting in the proper disposal receptacle.

**IRB Administrators and Assistants:**

The staff present at the meeting will generate letters and minutes for the convened Board actions per the processes described in the later sections of this document.

**IRB Administrator**

After all minutes and letters for the convened Board actions have been finalized and uploaded, the IRB administrator will generate the official minutes for that months' Board Meeting. The meeting minutes will be built using Board Administrator fields in PennERA. The generated minutes will be converted into a Word document. The Administrator will add sections documenting member attendance, the order of review, ongoing member training, and other administrative actions. The Administrator will also review the minutes to ensure items populated correctly and are appropriately formatted. Once complete, the Administrator will send the minutes to the QA coordinator, for review.

**QA Coordinator:**

The QA Coordinator will review the finalized meeting minutes to identify any potential errors and omissions. QA Coordinator provides comments and questions to the Administrator so that revisions can be made.

**IRB Administrator**
Once the QA coordinator’s review has been completed, the minutes are uploaded to the G: Drive. The minutes will also be sent to the Board members for review and acceptance at the next month’s meeting. Accepted minutes will be stamped by the administrator and uploaded to the Board Administration section of PennERA and the Minutes folder on the G: Drive. Monthly, after the minutes are accepted by the convened IRB, the Associate Vice Provost for Human Research is notified via email that the minutes are available for review. Any issues identified are shared with the Director and/or Associate Director; substantive concerns will be reviewed by the convened IRB.
IRB Meeting Administrative Processes

Revising Convened Meeting Dates

1. PROCESS OVERVIEW

This section details the processes that must be completed if the date of an IRB meeting is changed or a meeting is cancelled.

3. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY

IRB Administrator and Assistant

After the Director has approved a request to change a meeting date or cancel a Board meeting, the IRB Administrator and Assistant contact the Board members to inform them of the change. They should also inform the Board members of the next meeting and confirm whether a quorum will be present. The IRB Administrator and Assistant should shift all scheduled full board action items to the agenda designated by the Director.

Processes for a Cancelled Meeting

IRB Administrator

The IRB Administrator should immediately close the agenda for the cancelled meeting in order to prevent the assignment of any new full or expedited actions. The IRB Administrator should then run the minutes for that agenda in order to compile the expedited actions. That list should be forwarded to the Board along with the agenda for the next month’s meeting.

Processes for a Re-Scheduled Meeting

IRB Administrator

The IRB Administrator should revise the agenda to reflect the new meeting date and any changes in assignments that results for the re-scheduling. A new agenda date should be made in PennERA using the Board Administrator fields. The IRB Administrator should then run the minutes for the older agenda date in order to compile the expedited actions referred to that meeting date. Those actions will then be combined with the minutes built for the rescheduled date and sent to the Board for their review.
IRB Meeting Administrative Processes

Documentation and Document Management

1. PROCESS OVERVIEW

IRB Protocol files are stored in either the IRB file room or the electronic submission system (HS-ERA). In addition, most of the other documents related to IRB processes are stored on the IRB’s servers (G: Drive). This section details the processes in place to ensure that documents are stored and maintained appropriately in these locations.

2. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY

Paper File Maintenance

IRB Administrative Assistant

After a review has been completed and a decision letter has been sent to the study team, the IRB Administrative Assistant is responsible for adding the decision to the file. The IRB Assistant reviews the submission to make sure that all controlled documents are included and all uncontrolled documents have been removed. The IRB Assistant then places the submission and a copy of the determination letter in the file. The IRB Assistant reviews the protocol file in its entirety to ensure that all previous reviews are arranged in chronological order and the file is organized according to IRB standards. If changes are made, the assistant updates the file before returning it to the file room.

Once the file is updated, the assistant returns it to the file room. The file room is arranged in alphabetical order based on the last name of the Principal Investigator and then by protocol number. Expedited and convened protocol files are located in one section while exempt protocols and other administrative reviews are located in another.

Records Specialist

The Records Specialist is responsible for file room maintenance and will regularly check the file room in order to ensure that it is organized correctly. In addition, when a study is closed or IRB approval has expired and is not likely to be renewed, the records specialist will archive the file. The Records Specialist updates PennERA to detail where in the archives the file will be stored. In the event that a file must be recalled from archives, the Records Specialist will have it returned to the IRB.
Electronic File Maintenance

The electronic submission system (HS-ERA) also serves as the protocol file. Once a submission is received by the IRB, the submission becomes a permanent part of the electronic protocol file regardless of whether it is approved or returned for revision.

After a review has been completed, the IRB administrator and assistant will review the electronic submission while generating and forwarding the decision letter. During that review, any uncontrolled documents or comments that should not be added to the file are deleted by IRB staff.

The electronic system serves as its own archives. IRB staff can locate closed and expired protocols by searching HS-ERA in the same manner they search for current protocols.

Documentation of Agendas and Minutes
All finalized versions of the Agendas and Minutes for IRB meetings are stored in both PennERA and the G: Drive in designated folders. The IRB administrator and assistant are responsible for ensuring that these documents are stored in both locations.

Member Documents
Membership letters and current curriculum vitae for each ember are stored on the G: Drive in designated folders. The IRB Administrator and Roster Assistant are responsible for ensuring that these documents are stored properly.

IRB Rosters
Rosters are updated on a monthly basis. The Roster for each IRB for each month is stored on the G: Drive in designated folders. The IRB Administrator and Administrative Assistant are responsible or ensuring that these documents are stored properly.

Standard Operating Policies Documentation
The current version of the Standard Operating Policies is published on the IRB website. The current version and previous version of the Policies is stored on the G: Drive in designated folder. The IRB Director is responsible for ensuring that these documents are stored properly.
IRB Meeting Administrative Processes

IRB Billing

1. PROCESS OVERVIEW

The IRB charges a review fee when conducting initial and continuing reviews for industry sponsored protocols. Designated IRB staff member(s) assist the Budget Office in identifying and invoicing protocols that are eligible for IRB fees. The steps taken by IRB staff for this process are described below.

2. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY

The IRB Administrator tracks protocols that are eligible for IRB fees. Two methods are used to track these protocols. The IRB Administrator reviews the agenda and identifies any industry sponsored protocols that are undergoing initial and continuing review. On a regular basis, the IRB Administrator sends a list of protocols that are eligible to be charged IRB fees to the IRB Budget Support Staff in the IRB, who shares this information with the IRB Billing Coordinator in the Office of the Vice Provost for Research. This list of protocols also contains information related to the industry sponsor that will be billed.

The Billing Coordinator reviews the contract to determine if it contains language related to IRB fees. The Billing Coordinator also reviews the contract to ensure that the language related to IRB fees is correct and in line with the fees the IRB charges for initial and continuing review. Any issues noted during this review are sent to the IRB Budget Support Staff.
Research Review Processes – Initial Reviews

Non-Human Subjects Research Reviews

1. PROCESS OVERVIEW
Activities that do not meet the HHS and FDA definitions of human subjects research do not require submission to the IRB. However, investigators may request that the IRB make an official determination as to whether a submission meets the definitions of human subjects research. Reviewers may request revisions to the submitted documents and review the revisions prior to forwarding the submission to the Director or Designee for the final determination. Investigators will be notified in writing if activities do or do not meet the definition of human subjects research.

2. RESPONSIBILITY
ORA Administrator
The role of the ORA Administrator is to check for incoming initial reviews and assign to the appropriate IRB Administrator for review.

IRB Administrator
The role of the IRB Administrator is to review the initial action, begin data entry processes, and assign the review action to the appropriate IRB board.

IRB Administrative Assistant
The role of the IRB Administrative Assistant is to complete data entry for the review action, draft the IRB approval letter for the action, distribute the signed letter to the study team, and provide assistance to the IRB Administrator as needed.

Director or Designee
The Director or designee (“Final Approver”) completes a secondary review of the initial action and makes a final determination.

3. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY

ORA Administrator
The submission is received in the HS-ERA IRB queue once approved by the Principal Investigator. Upon receipt in the IRB queue, the status of the submission is changed from “Pending review by (Principal Investigator’s Name)” to “Accepted and submitted for review”.

The ORA Administrator identifies incoming initial non-human subjects research review (NHSR) actions and assigns those actions to the appropriate IRB Administrator for review. The ORA Administrator utilizes the “Assign to IRB” section of HS-ERA and sorts submissions by Status so that all submissions with an “accepted and submitted for review status” appear first. The ORA Administrator uses the assign field for the submission and adds a comment to the submission detailing the type of submission and any deadlines for review. The ORA Administrator may utilize the HS-ERA Submission when assessing the appropriate level of review.
The IRB Administrator receives a notification email detailing the assignment and deadline for completion and locates the submission in the Assign to IRB section of HS-ERA. The administrator assigns the application to an appropriate board by selecting IRB 7 or 8 on the HS-ERA Assign to the IRB page. Biomedical applications are assigned to IRB 7. Social and behavioral applications are assigned to IRB 8. Assigning the application to IRB 7 or 8 will create a new PennERA action including a new Protocol Number.

The IRB Administrator conducts the initial review examining the HS-ERA application and any submitted study documents to determine if the application meets the HHS and FDA definitions of human subjects research. Concurrently, any issues or concerns with the application or study documents (or lack thereof) should be noted within a problems/Issues document and the human subjects determination worksheet. This problems/issues document should also include any recommendations, comments on review status, and questions for the study team.

If the IRB Administrator determines that the study meets either the HHS or FDA definition of human subjects' research, the study team is contacted and provided the rationale for this determination. The NHSR application is insufficient for exempt, expedited, and convened review. The study team should be provided instructions for completing a new application and the submission is withdrawn. The IRB Administrator then adds a comment to HS-ERA to indicate that the submission does not qualify for NHSR acknowledgement and withdraws the submission. The Summary, Review (general) and post review pages in PennERA are updated to reflect the withdrawal of the submission.

If the IRB Administrator has identified issues with the submission that must be addressed before a final determination can be made, the administrators should return the submission. To return the submission to the study team, the IRB Administrator revises the PennERA action to detail the status as “Issue Identified” and revises the Review (general) page to record the issues noted for the application, if any. The Post-Review page in PennERA should be revised to also list the status as “Issue Identified.” The IRB Administrator uses the HS-ERA Assign to the IRB page to add a comment detailing any issues noted during the review, and return the application. The HS-ERA application is returned for response without PI approval.

ORA Administrator
By returning the submission, the application is opened to the research staff to address the concerns noted during review. When the research team returns the application to the IRB, the ORA Administrator assigns the application to the IRB Administrator who completed the initial review in the manner previously described.

IRB Administrator
If no issues were noted during the initial review or if the issues raised by the administrator have been resolved, then the application is re-assigned to the appropriate board and assigned a final reviewer for a determination that the study does not meet the definition of human subjects research. The IRB Administrator should attach the NHSR worksheet, any documents/emails submitted outside of HS-ERA, and a document summarizing any issues raised and how they
were resolved to the HS-ERA application. The IRB Administrator should revise or note any changes to his/her recommendations and categories to respond to the research team’s reply as needed. PennERA is revised to list the application as “Pending” on the Submissions page and Post-Review page. The PennERA Post-Review Page is also updated to select the Executive Chair or Designee who will review the study and is referred to as the “Final Approver” throughout this section. The Review (General) review activities field should state that a reviewer has been assigned.

**Director or Designee**
The Final Approver finds the submission in HS-ERA by opening the My Submissions Approvals – view assigned section. The Final Approver reviews the application to make the final NHSR determination. If any questions or concerns related to submission are identified, the approver communicates these issues to the IRB administrator. If no concerns are raised or the issues raised by the approver are appropriately addressed, the Final Approver then acknowledges the determination for the submission in the My Submissions Approvals – view assigned section by submitting a decision for this protocol.

**IRB Administrator**
If issues are raised by the final approver, the administrator relays those issues to the study team and may return the submission in HS-ERA if appropriate.

**ORA Administrator**
The determination will be reflected in the follow day’s letter generation report which is forwarded to the Director and designated ORA Administrators.

The ORA Administrator assigns the submission to an IRB Administrative Assistant based on the previously completed letter generation report. The ORA Administrator utilizes the Assign to IRB admin section of HS-ERA and locates submissions by filtering based on the protocol number or confirmation code provided in the letter generation report. The ORA Administrator uses the assign field for the submission and adds a comment to the submission detailing the type of assignment and any deadlines for completion.

**IRB Administrative Assistant**
The IRB Administrative Assistant receives a notification email detailing the assignment and deadline for completion and locates the submission in the Assign to IRB section of HS-ERA and in PennERA.

The IRB Administrative Assistant completes the data entry, as needed. The IRB Administrative Assistant uses the HS-ERA submission’s eyeglass and/or review views to identify all documents submitted for review and list them into the review (general) page in PennERA. The Administrative Assistant reviews the HS-ERA comments section to determine if any notes should be added to the determination letter and lists those comments on the Post-Review page. The overall summary page of PennERA and the submission is updated to reflect that no continuing review should occur. The Administrative Assistant reviews the PennERA protocol’s management folders and updates sections, when appropriate, to ensure the protocol and status accurately reflect the determination.

The IRB Administrative Assistant generates the determination letter by using the communications folder for this review action. The administrative assistant selects the appropriate letter template and builds the letter. The assistant then transfers the letter into a
The IRB Administrator reviews the letter to ensure that the information contained is accurate and appropriately formatted. The Administrator may refer to the submission in HS-ERA to verify the accuracy of the letter. The Administrator reviews the protocol in PennERA to ensure that the record was appropriately updated to reflect the new approval. If revisions to the letter are necessary the administrator informs the assistant of the required revisions and deletes the PDF of the approval letter. If revisions to the letter are not required, the IRB administrator electronically signs the PDF and saves the signed letter in the IRB Administrative Assistant Letters Signed Folder on the G: Drive. The IRB Administrator updates the PennERA review activities section for the submission to indicate that the letter has been signed.

IRB Administrative Assistant
The IRB Administrative Assistant locates the signed letter from the IRB Administrator in the Signed Folder on the G: Drive. The HS-ERA submission’s Review Page is utilized to upload the signed letter in the add decision document page. After the review decision and signed letter are selected, the letter is uploaded.

The IRB Administrative Assistant uploads the signed letter in the communications folder in the PennERA communication section and updates the review activities to indicate the letter has been signed and forwarded. An email with the signed letter and an explanation of its contents is sent to the PI, appropriate study contacts, and any other designated recipients. The signed letter is removed from the Signed Folder on the G: Drive.
Research Review Processes – Initial Reviews

Exempt Research Reviews

1. PROCESS OVERVIEW
Experienced IRB staff review protocols to determine if they meet the regulatory and institutional criteria for exemption from IRB review. Exempt reviewers may request revisions to the submitted documents and review the revisions prior to forwarding the submission to the Director or Designee for the final determination.

2. RESPONSIBILITY

ORA Administrator
The role of the ORA Administrator is to check for incoming initial reviews and assign to the appropriate IRB Administrator for review.

IRB Administrator
The role of the IRB Administrator is to review the initial action, begin data entry processes, and assign the review action to the appropriate IRB board.

IRB Administrative Assistant
The role of the IRB Administrative Assistant is to complete data entry for the initial review action, draft the IRB approval letter for the action, distribute the signed letter to the study team, and provide assistance to the IRB Administrator as needed.

Director or Designee
The Director or designee (“Final Approver”) completes a secondary review of the initial action and determines if it qualifies for exempt approval.

3. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY

ORA Administrator
The submission is received in the HS-ERA IRB queue once approved by the Principal Investigator and Department Chair. Upon receipt in the IRB queue, the status of the submission is changed from “Pending review by (Principal Investigator’s or Department Chair’s name)” to “Accepted and submitted for review”.

The ORA Administrator identifies incoming initial exempt actions and assigns those actions to the appropriate IRB Administrator reviewer. The administrator utilizes the Assign to IRB admin section of HS-ERA and sorts submissions by Status so that all submissions with an “accepted and submitted for review status” appear first. The ORA Administrator uses the assign field for the submission and adds a comment to the submission detailing the type of submission and any deadlines for review. The ORA Administrator may utilize the HS-ERA Submission when assessing the appropriateness of the level of review.
The IRB Administrator receives a notification email detailing the assignment and deadline for completion and locates the submission in the Assign to IRB section of HS-ERA. The administrator assigns the application to an appropriate board by selecting IRB 7 or 8 on the HS-ERA Assign to the IRB page. Biomedical applications are assigned to IRB 7. Social and behavioral applications are assigned to IRB 8. Assigning the application to IRB 7 or 8 will create a new PennERA action including a new Protocol Number.

The IRB Administrator conducts the initial review examining the HS-ERA application and any submitted study documents to determine if the application meets the criteria for exemption from IRB review. The IRB Administrator confirms that the application satisfies the ethical considerations for exempt research and completes the exempt worksheet. Concurrently, any issues or concerns with the application or study documents (or lack thereof) affecting the criteria for exemption should be noted within a problems/Issues document and the exempt worksheet. This problems/issues document should also include any recommendations, comments on review status, and questions for the study team.

If the IRB Administrator determines that the study requires expedited review, he/she should continue to process this submission according to the procedures for expedited review. If applicable, the electronic submission may be returned to the submitter to complete additional sections required for expedited applications. If convened IRB review is required, the submission will be returned to the study team to provide any additional information needed for the convened review.

The IRB Administrator verifies that the required human subjects' training is present for all research personnel. If training is expired or not completed, a request is made to provide a training certificate (if not located in the CITI system) or to complete the training and provide the certificate upon completion.

If the administrator has identified issues with the submission that must be addressed before final review can occur, the administrators should return the submission. To return the submission to the study team, the IRB Administrator revises the PennERA action to detail the status as “Issue Identified” and revises the Review (general) page to record the issues noted for the application, if any. The Review (review) page in PennERA should be revised to also list the status as “Issue Identified.” The Administrator uses to the HSERA – Assign to the IRB page to add a comment detailing any issues noted during the review, and return the application. The HS-ERA application is returned for response without PI approval. If the submission is to be returned so the study team can complete the application for expedited or convened review, the Exempt Review Field should be changed to No before the return for response without approval option is selected.

ORA Administrator
By returning the submission, the application is opened to the research staff to address the concerns noted during review. When the research team returns the application to the IRB, the
ORA Administrator assigns the application to the IRB Administrator who completed the initial review per the process above.

**IRB Administrator**

If the application is returned to the IRB Administrator where all concerns noted during the initial review are addressed, the application is reassigned to the appropriate board.

If no issues were noted during the initial review or if the issues raised by the administrator have been resolved, then the application is assigned to the final reviewer for approval. The IRB Administrator should attach the exempt worksheet, any documents/emails submitted outside of HS-ERA, and a document summarizing any issues raised and how they were resolved to the HS-ERA application. The IRB Administrator should revise or note any changes to his/her recommendations and categories to respond to the research team's reply as needed. PennERA is revised to list the application as “Pending” on the Submissions page and Post-Review page. PennERA Post-Review Page is also updated to select the Executive Chair or Designee who will review the study and is referred to as the “Final Approver” throughout this section. The Review (General) page should be revised to indicate the exempt review category and the review activities field should state that a reviewer has been assigned.

**Director or Designee**

The Final Approver finds the submission in HS-ERA by opening the My Submissions Approvals – view assigned section. The Final Approver reviews the application to determine if the criteria for exemption have been met. If any questions or concerns related to the criteria for exemption are identified, the approver communicates these issues to the IRB administrator. If no concerns are raised or the issues raised by the approver are appropriately addressed, the Final Approver then approves the submission in My Submissions Approvals – view assigned section by submitting a decision for this protocol.

**IRB Administrator**

If issues are raised by the final approval, the IRB Administrator relays those issues to the study team and may return the submission in HS-ERA if appropriate.

**ORA Administrator**

The approval will be reflected in the follow day’s letter generation report which is forwarded to the Director and designated ORA Administrators.

The ORA Administrator assigns the submission to an IRB Administrative Assistant based on the previously completed letter generation report. The ORA Administrator utilizes the Assign to IRB admin section of HS-ERA and locates submissions by filtering based on the protocol number or confirmation code provided in the letter generation report. The ORA Administrator uses the assign field for the submission and adds a comment to the submission detailing the type of assignment and any deadlines for completion.

**IRB Administrative Assistant**

The IRB Administrative Assistant receives a notification email detailing the assignment and deadline for completion and locates the submission in the Assign to IRB section of HS-ERA and in PennERA.

The IRB Administrative Assistant completes the data entry, as needed. The IRB Administrative Assistant uses the HS-ERA submission’s eyeglass and/or review views to identify all documents.
submitted for review and list them into the review (general) page and Post-Review page in PennERA. The Administrative Assistant reviews the HS-ERA comments section to determine if any notes should be added to the approval letter and lists those comments on the Post-Review page. The overall summary page of PennERA and the submission is updated to reflect that no continuing review should occur. The Administrative Assistant reviews the PennERA protocol’s management folders and updates sections, when appropriate, to ensure the protocol and status accurately to reflect the new approval.

The IRB Administrative Assistant generates the approval letter by using the communications folder for this review action. The Administrative Assistant selects the appropriate letter template and builds the letter. The Administrative Assistant then transfers the letter into a word document and makes revisions to ensure that the letter is appropriately formatted and accurately documents the outcome of the IRB’s review. The letter is then converted into an Adobe PDF and is placed in the appropriate IRB Administrator Letters to be Signed folder on the G: Drive.

**IRB Administrator**
The IRB Administrator reviews the letter to ensure that the information contained is accurate and appropriately formatted. The Administrator may refer to the submission in HS-ERA to verify the accuracy of the letter. The Administrator reviews the protocol in PennERA to ensure that the record was appropriately updated to reflect the new approval. If revisions to the letter are necessary the administrator informs the assistant of the required revisions and deletes the PDF of the approval letter. If revisions to the letter are not required, the IRB administrator electronically signs the PDF and saves the signed letter in the IRB Administrative Assistant Letters Signed Folder on the G: Drive. The IRB administrator updates the PennERA review activities section for the submission to indicate that the letter has been signed.

**IRB Administrative Assistant**
The IRB Administrative Assistant locates the signed letter from the IRB Administrator in the Signed Folder on the G: Drive. The HS-ERA submission’s Review Page is utilized to upload the signed letter in the add decision document page. After the review decision and signed letter are selected, the letter is uploaded.

The IRB Administrative Assistant uploads the signed letter in the communications folder in the PennERA communication section and updates the review activities to indicate the letter has been signed and forwarded. An email with the signed letter and an explanation of its contents is sent to the PI, appropriate study contacts, and any other designated recipients. The signed letter is removed from the Signed Folder on the G: Drive.
Research Review Processes – Initial Reviews

Prime/Umbrella Grant/Just in Time (JIT) reviews

1. PROCESS OVERVIEW
Experienced IRB member reviewers conduct the determination for Prime reviews. Expedited reviewers may request revisions to the submitted documents and review the revisions prior to forwarding the submission to the Director or Designee for approval of the concept in principle.

2. RESPONSIBILITY
ORA Administrator
The role of the ORA Administrator is to check for incoming initial reviews and assign to the appropriate IRB Administrator for review.

IRB Administrator
The role of the IRB Administrator is to review the initial action, begin data entry processes, and assign the review action to the appropriate IRB board.

IRB Administrative Assistant
The role of the IRB Administrative Assistant is to complete data entry for the review action, draft the IRB approval letter for the action, distribute the signed letter to the study team, and provide assistance to the IRB Administrator as needed.

Director or Designee
The Director or designee (“Final Approver”) completes a secondary review of the initial action and approves the action.

3. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY

ORA Administrator
The submission is received in the HS-ERA IRB queue once approved by the Principal Investigator and Department Chair. Upon receipt in the IRB queue, the status of the submission is changed from “Pending review by (Principal Investigator’s or Department Chair’s name)” to “Accepted and submitted for review”.

The ORA Administrator identifies incoming prime/JIT/umbrella grant actions and assigns those actions to the appropriate IRB Administrator reviewer. Prime grants/JIT reviews, and umbrella grants will be referred to as "prime reviews" throughout this section. The administrator utilizes the Assign to IRB admin section of HS-ERA and sorts submissions by Status so that all submissions with an “accepted and submitted for review status” appear first. The ORA Administrator uses the assign field for the submission and adds a comment to the submission detailing the type of submission and any deadlines for review. The ORA Administrator may utilize the HS-ERA Submission when assessing the appropriateness of the level of review.
Note: If this submission is received via a paper or email submission process, a protocol will be created in the IRB database (PennERA) and the documents will be uploaded and Senior Staff will be notified that the submission is ready for review.

**IRB Administrator**

The IRB Administrator receives a notification email detailing the assignment and deadline for completion and locates the submission in the Assign to IRB section of HS-ERA. The administrator assigns the application to an appropriate board by selecting IRB 7 or 8 on the HS-ERA Assign to the IRB page. Biomedical applications are assigned to IRB 7. Social and behavioral applications are assigned to IRB 8. Assigning the application to IRB 7 or 8 will create a new PennERA action including a new Protocol Number.

The IRB Administrator conducts an initial review examining the HS-ERA application and any submitted study documents to determine if the concept of the project can be approved. Submitters are required to complete the HS-ERA application and upload a copy of the grant application. The IRB Administrator reviews these documents to determine if this protocol will be able to be conducted in accordance with the federal regulations and institutional policies. Any issues or concerns with the application or study documents (or lack thereof) hindering the approval in concept should be noted within a problems/Issues document. This problems/issues document should also include any recommendations, comments on review status, and questions for the study team.

If the IRB Administrator unsure if the project would be approved for the enrollment of human subjects, he/she should consult with the Director/designee and/or the IRB chair for the assigned board.

If the IRB Administrator has identified issues with the submission that must be addressed before final prime review can occur, the administrators should return the submission. To return the submission to the study team, the IRB Administrator revises the PennERA action to detail the status as “Issue Identified” and revises the Review (general) page to record the issues noted for the application, if any. The Review (review) page in PennERA should be revised to also list the status as “Issue Identified.” The Administrator uses to the HSERA – Assign to the IRB page to add a comment detailing any issues noted during the review, and return the application. The HS-ERA application is returned for response without PI approval.

**ORA Administrator**

By returning the submission, the application is opened to the research staff to address the concerns noted during review. When the research team returns the application to the IRB, the ORA Administrator assigns the application to the IRB Administrator who completed the initial review per the process above.
If no issues were noted during the initial review or if the issues raised by the administrator have been resolved, then the application is re-assigned to the appropriate Board and assigned to the final reviewer for approval. The IRB Administrator should document why a determination that approval of the prime review is appropriate. In addition, the administrator should attach any documents/emails submitted outside of HS-ERA, and a document summarizing any issues raised and how they were resolved to the HS-ERA application. The IRB Administrator should revise or note any changes to his/her recommendations to respond to the research team’s reply as needed. PennERA is revised to list the application as “Pending” on the Submissions page and Post-Review page. PennERA Post-Review Page is also updated to select the Executive Chair or Designee who will review the study and is referred to as the “Final Approver” throughout this section. The Review (General) review activities field should state that a reviewer has been assigned. An exempt/expedited review category should not be assigned for prime reviews.

**Director or Designee**

The Final Approver finds the submission in HS-ERA by opening the My Submissions Approvals – view assigned section. The Final Approver reviews the application to determine if the prime review is approvable. If any questions or concerns related to the submission are identified, the approver communicates these issues to the IRB administrator. If no concerns are raised or the issues raised by the approver are appropriately addressed, the Final Approver then approves the prime review in the My Submissions Approvals – view assigned section by submitting a decision for this protocol.

**IRB Administrator**

If issues are raised by the final approver, the administrator relays those issues to the study team and may return the submission in HS-ERA if appropriate.

**ORA Administrator**

The IRB Administrator and/or the Director may also directly assign this letter to an IRB Administrative Assistant in advance of the letter generation report.

The ORA Administrator assigns the submission to the IRB Administrative Assistant designated by the IRB Administrator. The ORA Administrator utilizes the Assign to IRB admin section of HS-ERA and locates submissions by filtering based on the protocol number or confirmation code provided in the letter generation report. The ORA Administrator uses the assign field for the submission and adds a comment to the submission detailing the type of assignment and any deadlines for completion.

**IRB Administrative Assistant**

The IRB Administrative Assistant receives a notification email detailing the assignment and deadline for completion and locates the submission in the Assign to IRB section of HS-ERA and in PennERA.

The IRB Administrative Assistant completes the data entry, as needed. The IRB Administrative Assistant uses the HS-ERA submission’s eyeglass and/or review views to identify all documents submitted for review and list them into the review (general) page in PennERA. The Administrative Assistant reviews the HS-ERA comments section to determine if any notes should be added to the approval letter and lists those comments on the Post-Review page. The
The IRB Administrative Assistant generates the approval letter by using the communications folder for this review action. The administrative assistant selects the appropriate letter template and builds the letter. The assistant then transfers the letter into a word document and makes revisions to ensure that the letter is appropriately formatted and accurately documents the outcome of the IRB’s review. The letter is then converted into an Adobe PDF and is placed in the appropriate IRB Administrator Letters to be Signed folder on the G: Drive.

**IRB Administrator**

The IRB Administrator reviews the letter to ensure that the information contained is accurate and appropriately formatted. The Administrator may refer to the submission in HS-ERA to verify the accuracy of the letter. The Administrator reviews the protocol in PennERA to ensure that the record was appropriately updated to reflect the new approval. If revisions to the letter are necessary the administrator informs the assistant of the required revisions and deletes the PDF of the approval letter. If revisions to the letter are not required, the IRB Administrator electronically signs the PDF and saves the signed letter in the IRB Administrative Assistant Letters Signed Folder on the G: Drive. The IRB administrator updates the PennERA review activities section for the submission to indicate that the letter has been signed.

**IRB Administrative Assistant**

The IRB Administrative Assistant locates the signed letter from the IRB Administrator in the Signed Folder on the G: Drive. The HS-ERA submission’s Review Page is utilized to upload the signed letter in the add decision document page. After the review decision and signed letter are selected, the letter is uploaded.

The IRB Administrative Assistant uploads the signed letter in the communications folder in the PennERA communication section and updates the review activities to indicate the letter has been signed and forwarded. An email with the signed letter and an explanation of its contents is sent to the PI, appropriate study contacts, and any other designated recipients. The signed letter is removed from the Signed Folder on the G: Drive.
Research Review Processes – Initial Reviews

Expanded Access Protocols of Investigational Drugs or Devices - Expedited Review

1. PROCESS OVERVIEW
In some instances, protocols designed to provide expanded access of investigational drugs or devices may undergo an expedited review procedure. These typically involve compassionate and treatment use protocols designed to treat one specific participant. Experienced IRB staff may review these protocols to determine if the submission is complete. Staff may request revisions to the submitted documents and review the revisions prior to forwarding the submission to an IRB Chair or other member with sufficient expertise to conduct the review. The Chair or designee may exercise all of the authorities of the IRB, except that he/she may not disapprove the research.

2. RESPONSIBILITY

ORA Administrator
The role of the ORA Administrator is to check for identifying these protocols and assigning them to the appropriate IRB Administrator for review.

IRB Administrator
The role of the IRB Administrator is to review the initial action, complete data entry, and assign the review action to the appropriate IRB board.

IRB Administrative Assistant
The role of the IRB Administrative Assistant is to provide assistance to the IRB Administrator as needed for completion of data entry for the initial review action. The Administrative Assistant is also responsible for drafting the IRB approval letter for the action.

Director or Designee
The Director or designee (“Final Approver”) completes a secondary review of the initial action and approves the action.

3. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY

ORA Administrator
The submission is received in the HS-ERA IRB queue once approved by the Principal Investigator and Department Chair. Upon receipt in the IRB queue, the status of the submission is changed from “Pending review by (Principal Investigator’s or Department Chair’s name)” to “Accepted and submitted for review”.

The ORA Administrator identifies incoming initial expanded access protocol and assigns it to appropriate IRB Administrator reviewer. The Director or Associate Director may be consulted in order to determine the appropriate IRB administrator to review the protocol. The ORA administrator utilizes the Assign to IRB admin section of HS-ERA and sorts submissions by Status so that all submissions with an “accepted and submitted for review status” appear first. The ORA Administrator uses the assign field for the submission and adds a comment to the submission detailing the type of submission and any deadlines for review.
The ORA Administrator may utilize the HS-ERA Submission when assessing the appropriateness of the level of review.

**IRB Administrator**
The IRB Administrator receives a notification email detailing the assignment and deadline for completion and locates the submission in the Assign to IRB section of HS-ERA and PennERA. The expedited reviewer assigns the application to an appropriate board using the HS-ERA – Assign to the IRB page.

The IRB Administrator conducts the initial review examining the HS-ERA application and any submitted study documents. The IRB Administrator confirms that the application is complete and meets the criteria for expedited review. Concurrently, any issues or concerns noted during completeness assessment should be noted. The IRB Administrator should verify the status of the FDA review and approval of the protocol. The IRB Administrator should also ensure that rationale for why the patient qualifies for the study is provided and that the consent form appropriate describes the procedure as treatment and not a research study.

The IRB Administrator verifies that the required human subjects’ training is present for all research personnel. If training is expired or not completed, a request is made to provide the CITI certificate (if the system is outdated) or to complete the training and provide the certificate upon completion.

If the IRB Administrator has identified issues with the submission that must be addressed before final review can occur, the administrator should request additional information via email, or if necessary, return the submission to address issues (after discussing with a member of the Senior Staff). To return the submission to the study team, the IRB Administrator revises the PennERA action to detail the status as “Issue Identified” and revises the Review (general) page to record the issues noted for the application, if any. The Post-Review page in PennERA should be revised to also list the status as “Issue Identified.” The Administrator utilizes the HSERA – Assign to the IRB page to add a comment detailing any issues noted during the review and return the application. The HS-ERA application is returned for response without PI approval. If additional information is received via email, the administrator uploads the documents to the Comments section in HS-ERA.

**ORA Administrator**
By returning the submission, the application is opened to the research staff to address the concerns noted during review. When the research team returns the application to the IRB, the ORA Administrator assigns the application to the IRB Administrator who completed the initial review per the process above.

**IRB Administrator**
If no issues were noted during the initial review or if the issues raised by the administrator have been resolved, then the application is re-assigned to the appropriate board and assigned to the final reviewer for approval. The IRB Administrator should provide a brief summary of the submission and any issues raised and how they were resolved. PennERA is revised to list the application as “Pending” on the Submissions page and Post-Review page. PennERA Post-Review Page is also updated to select the Executive Chair or Designee who will review the study and is referred to as the “Final Approver” throughout this section. The review activities field should state that a reviewer has been assigned.
**Director or Designee**
The Final Approver, an appropriately trained member of the IRB staff or an IRB member, finds the submission in HS-ERA by opening the My Submissions Approvals – view assigned section. The Final Approver reviews the application to determine if the criteria for expedited approval have been met. If any questions or concerns are identified, the approver communicates these issues to the IRB Administrator. If no concerns are raised or the issues raised by the approver are appropriately addressed, the Final Approver then approves the submission in My Submissions Approvals – view assigned section by submitting a decision for this protocol.

**IRB Administrator**
If issues are raised by the final approver, the administrator relays those issues to the study team and may return the submission in HS-ERA if appropriate.

If at any point in the above processes, the IRB Administrator or Final Approver determines that the study requires convened IRB review, a Senior IRB Administrator is notified that he/she should schedule the study for convened IRB review. The IRB Administrator should share his/her notes or comments about the study with appropriate IRB staff. The IRB Administrator may complete the Completeness Checklist and Agenda Notes for the convened IRB’s review. Expanded Access Protocols that require convened review are processed in a manner similar to other protocols that require convened initial review.

**IRB Administrator**
The approval will be reflected in the following day’s letter generation report which is forwarded to the Director and designated ORA Administrators. However, due to the often-emergent nature of these requests, the IRB administrator typically assigns the letter to an Administrative Assistant immediately after the protocol has been approved. The IRB Administrator will inform the ORA Administrator of the appropriate IRB Administrative Assistant who should be assigned the letter.

**ORA Administrator**
The ORA Administrator utilizes the Assign to IRB admin section of HS-ERA and locates submissions by filtering based on the protocol number or confirmation code provided by the Administrator. The ORA Administrator uses the assign field for the submission and adds a comment to the submission detailing the type of assignment and any deadlines for completion.

**IRB Administrative Assistant**
The IRB Administrative Assistant receives a notification email detailing the assignment and deadline for completion and locates the submission in assign to IRB section of HS-ERA and PennERA.

The IRB Administrative Assistant completes the data entry, as needed. The IRB Administrative Assistant uses the HS-ERA submission’s eyeglass and/or review views to identify all documents submitted for review and list them into the review (general) page and Post-Review page in PennERA. The Administrative Assistant reviews the HS-ERA comments section to determine if any notes should be added to the approval letter and lists those comments on the Post-Review page. The overall summary page of PennERA and the submission is updated to reflect the approval and the expiration dates. The Administrative Assistant reviews the PennERA protocol’s management folders and updates sections, when appropriate, to ensure the protocol and status
The IRB Administrative Assistant generates the approval letter by using the communications folder for this review action. The administrative assistant selects the appropriate letter template and builds the letter. The Administrative Assistant then transfers the letter into a word document and makes revisions to ensure that the letter is appropriately formatted and accurately documents the outcome of the IRB’s review. The letter is then converted into an Adobe PDF and combined with any applicable consent forms that receive and IRB approval stamp labeled Single Patient Only. The letter is then converted into an Adobe PDF and is placed in the appropriate IRB Administrator Letters to be Signed folder on the G: Drive.

**IRB Administrator**
The IRB Administrator reviews the letter to ensure that the information contained is accurate and appropriately formatted. The IRB Administrator may refer to the submission in HS-ERA to verify the accuracy of the letter. The IRB Administrator reviews the protocol in PennERA to ensure that the record was appropriately updated to reflect the new approval. If revisions to the letter are necessary the administrator informs the assistant of the required revisions and deletes the PDF of the approval letter. If revisions to the letter are not required, the IRB Administrator electronically signs the PDF and saves the signed letter in the IRB Administrative Assistant Letters Signed Folder on the G: Drive. The IRB Administrator updates the PennERA review activities section for the submission to indicate that the letter has been signed.

**IRB Administrative Assistant**
The IRB Administrative Assistant locates the signed letter from the IRB Administrator in the Signed Folder on the G: Drive. The HS-ERA submission’s Review Page is utilized to upload the signed letter in the add decision document page. After the review decision and signed letter are selected, the letter is uploaded.

The IRB Administrative Assistant uploads the signed letter in the communications folder in the PennERA communication section and updates the review activities to indicate the letter has been signed and forwarded. An email with the signed letter and an explanation of its contents is sent to the PI, appropriate study contacts, and any other designated recipients. The signed letter is removed from the Signed Folder on the G: Drive.

**NOTE:** The IRB accepts expanded use protocols via email when timing or other special circumstances do not allow for study team to easily access or submit the request through HS-ERA. The emailed documents would be reviewed outside of HS-ERA. Upon completion of the review, the administrative assistant would create a paper file which would be stored in the file room according to IRB policies.
Research Review Processes – Initial Reviews

Expedited Initial Reviews

1. PROCESS OVERVIEW
Experienced IRB member reviewers conduct expedited initial review. Expedited reviewers may request revisions to the submitted documents and review the revisions prior to forwarding the submission to the Director or Designee for approval. The Director or designee may exercise all of the authorities of the IRB, except that he/she may not disapprove the research.

2. RESPONSIBILITY

ORA Administrator
The role of the ORA Administrator is to check for incoming initial reviews and assign to the appropriate IRB Administrator for review.

IRB Administrator
The role of the IRB Administrator is to review the initial action, complete data entry, and assign the review action to the appropriate IRB board.

IRB Administrative Assistant
The role of the IRB Administrative Assistant is to provide assistance to the IRB Administrator as needed for completion of data entry for the initial review action. The Administrative Assistant is also responsible for drafting the IRB approval letter for the action.

Director or Designee
The Director or designee (“Final Approver”) completes a secondary review of the initial action and approves the action.

3. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY

ORA Administrator
The submission is received in the HS-ERA IRB queue once approved by the Principal Investigator and Department Chair. Upon receipt in the IRB queue, the status of the submission is changed from “Pending review by (Principal Investigator’s or Department Chair’s name)” to “Accepted and submitted for review”.

The ORA Administrator identifies incoming initial expedited actions and assigns those actions to the appropriate IRB Administrator reviewer. The ORA administrator utilizes the Assign to IRB admin section of HS-ERA and sorts submissions by Status so that all submissions with an “accepted and submitted for review status” appear first. The ORA Administrator uses the assign field for the submission and adds a comment to the submission detailing the type of submission and any deadlines for review. The ORA Administrator may utilize the HS-ERA Submission when assessing the appropriateness of the level of review.

IRB Administrator
The IRB Administrator receives a notification email detailing the assignment and deadline for completion and locates the submission in the Assign to IRB section of HS-ERA and PennERA.
The expedited reviewer assigns the application to an appropriate board by selecting IRB 7 or 8 on the HS-ERA – Assign to the IRB page. Biomedical applications are assigned to IRB 7. Social and behavioral applications are assigned to IRB 8. Assigning the application to IRB 7 or 8 will create a new PennERA action including a new Protocol Number.

The IRB Administrator conducts the initial review examining the HS-ERA application and any submitted study documents. The IRB Administrator confirms that the application satisfies the criteria for approval and completes the expedited worksheet noting how the application satisfies these criteria. Concurrently, any issues or concerns with the application or study documents (or lack thereof) affecting the criteria for approval should be noted within a problems/Issues document and the expedited worksheet. This problems/issues document should also include any recommendations, comments on review status, and questions for the study team.

The IRB Administrator verifies that the required human subjects' training is present for all research personnel. If training is expired or not completed, a request is made to provide the CITI certificate (if the system is outdated) or to complete the training and provide the certificate upon completion.

If the IRB Administrator has identified issues with the submission that must be addressed before final review can occur, the administrator should return the submission. To return the submission to the study team, the IRB Administrator revises the PennERA action to detail the status as “Issue Identified” and revises the Review (general) page to record the issues noted for the application, if any. The Post-Review page in PennERA should be revised to also list the status as “Issue Identified.” The IRB Administrator utilizes the HSERA – Assign to the IRB page to add a comment detailing any issues noted during the review and return the application. The HS-ERA application is returned for response without PI approval.

ORA Administrator
By returning the submission, the application is opened to the research staff to address the concerns noted during review. When the research team returns the application to the IRB, the ORA Administrator assigns the application to the IRB administrator who completed the initial review per the process above.

IRB Administrator
If no issues were noted during the initial review or if the issues raised by the administrator have been resolved, then the application is re-assigned to the appropriate board and assigned to the final reviewer for approval. The IRB Administrator should attach the expedited worksheet, any documents/emails submitted outside of HS-ERA, and a document summarizing any issues raised and how they were resolved to the HS-ERA application. The IRB Administrator should revise or note any changes to his/her recommendations and categories to respond to the research team’s reply as needed. PennERA is revised to list the application as “Pending” on the Submissions page and Post-Review page. PennERA Post-Review Page is also updated to select the Executive Chair or Designee who will review the study and is referred to as the “Final Approver” throughout this section. The Review (General) page should be revised to indicate the expedited review category and the review activities field should state that a reviewer has been assigned.

Director or Designee
The Final Approver finds the submission in HS-ERA by opening the My Submissions Approvals – view assigned section. The Final Approver reviews the application to determine if the criteria
for expedited approval have been met. If any questions or concerns related to the criteria for approval are identified, the approver communicates these issues to the IRB administrator. If no concerns are raised or the issues raised by the approver are appropriately addressed, the Final Approver then approves the submission in My Submissions Approvals – view assigned section by submitting a decision for this protocol.

**IRB Administrator**
If issues are raised by the final approver, the administrator relays those issues to the study team and may return the submission in HS-ERA if appropriate.

If at any point in the above processes, the administrator or final approver determines that the study requires convened IRB review, a Senior IRB Administrator is notified that he/she should schedule the study for convened IRB review. The IRB Administrator should share his/her notes or comments about the study with appropriate IRB staff. The administrator may complete the Completeness Checklist and Agenda Notes for the convened IRB’s review.

**ORA Administrator**
The approval will be reflected in the following day’s letter generation report which is forwarded to the Director and designated ORA Administrators.

The ORA Administrator assigns the submission to an IRB Administrative Assistant based on the previously completed letter generation report. The ORA Administrator utilizes the Assign to IRB admin section of HS-ERA and locates submissions by filtering based on the protocol number or confirmation code provided in the letter generation report. The ORA Administrator uses the assign field for the submission and adds a comment to the submission detailing the type of assignment and any deadlines for completion.

**IRB Administrative Assistant**
The IRB Administrative Assistant receives a notification email detailing the assignment and deadline for completion and locates the submission in assign to IRB section of HS-ERA and PennERA.

The IRB Administrative Assistant completes the data entry, as needed. The IRB Administrative Assistant uses the HS-ERA submission’s eyeglass and/or review views to identify all documents submitted for review and list them into the review (general) page and Post-Review page in PennERA. The Administrative Assistant reviews the HS-ERA comments section to determine if any notes should be added to the approval letter and lists those comments on the Post-Review page. The overall summary page of PennERA and the submission is updated to reflect the approval and the expiration dates. The Administrative Assistant reviews the PennERA protocol’s management folders and updates sections, when appropriate, to ensure the protocol and status accurately to reflect the new approval.

The IRB Administrative Assistant generates the approval letter by using the communications folder for this review action. The IRB Administrative Assistant selects the appropriate letter template and builds the letter. The Administrative Assistant then transfers the letter into a word document and makes revisions to ensure that the letter is appropriately formatted and accurately documents the outcome of the IRB’s review. The letter is then converted into an Adobe PDF and is placed in the appropriate IRB Administrator Letters to be Signed folder on the G: Drive.
IRB Administrator
The IRB Administrator reviews the letter to ensure that the information contained is accurate and appropriately formatted. The IRB Administrator may refer to the submission in HS-ERA to verify the accuracy of the letter. The IRB Administrator reviews the protocol in PennERA to ensure that the record was appropriately updated to reflect the new approval. If revisions to the letter are necessary the administrator informs the assistant of the required revisions and deletes the PDF of the approval letter. If revisions to the letter are not required, the IRB Administrator electronically signs the PDF and saves the signed letter in the IRB Administrative Assistant Letters Signed Folder on the G: Drive. The IRB Administrator updates the PennERA review activities section for the submission to indicate that the letter has been signed.

IRB Administrative Assistant
The IRB Administrative Assistant locates the signed letter from the IRB Administrator in the Signed Folder on the G: Drive. The HS-ERA submission’s Review Page is utilized to upload the signed letter in the add decision document page. After the review decision and signed letter are selected, the letter is uploaded.

The IRB Administrative Assistant uploads the signed letter in the communications folder in the PennERA communication section and updates the review activities to indicate the letter has been signed and forwarded. An email with the signed letter and an explanation of its contents is sent to the PI, appropriate study contacts, and any other designated recipients. The signed letter is removed from the Signed Folder on the G: Drive.
Research Review Processes – Initial Reviews

1. PROCESS OVERVIEW
This procedure outlines the review processes for protocol submissions that require review by the convened IRB. Use of the HS-ERA electronic submission system is mandatory for all initial submissions.

2. RESPONSIBILITY

IRB Administrator
The role of the IRB Administrator is to screen the convened initial protocol assigned to them for processing, assess for completeness of the application, complete data entry, and assign the review action to the appropriate meeting agenda and reviewers. The IRB Administrator is also responsible for compilation of initial review of minutes and letters for the convened initial protocol review action.

ORA Administrator
The role of the ORA Administrator is to check for incoming convened initial protocols and assign to the appropriate IRB Administrator for screening and scheduling for the next appropriate board. The ORA Administrator is also responsible for re-assignment of convened initial protocols to the IRB Administrator for re-submitted protocols.

IRB Senior Administrator
The IRB Senior Administrator is responsible for supporting the IRB administrator as needed. The Senior Administrator may consult to ensure that protocols on the agenda were appropriately scheduled and that the submission is not eligible for expedited review.

IRB Board Members
The role of the IRB Board Member is to review the protocol submission to determine if the criteria for approval have been met, assess the protocol for any controverted issues and raise the issues for discussion during the meeting, along with their resolutions, and vote on the risk assessment and final review decision.

Regulatory Representative
The regulatory representative is a senior member of the IRB staff (typically the Director or Associate Director) who serves as an IRB Board Member. In addition to Board Member duties the Regulatory Representative also provides expertise on federal regulations and Penn policy and provides guidance in order to ensure that policies are applied consistently across all Penn Boards. The regulatory representative also provides assistance to the IRB Administrator by discussing potential issues prior to the meeting and reviewing minutes and letters generated after the meeting.
3. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY

ORA Administrator
The initial convened protocol submission is received in the HS-ERA IRB queue once approved by the Principal Investigator and the Department approver. Upon receipt in the IRB queue, the status of the submission is changed from “Pending review by (Department approver name)” to “Accepted and submitted for review”.

The ORA Administrator identifies incoming initial convened submissions that are labeled for full board review and assigns to the appropriate IRB Administrator for screening. The administrator utilizes the Assign to IRB admin section of HS-ERA and sorts submissions by Status so that all submissions with an “accepted and submitted for review status” appear first. The ORA Administrator uses the assign field for the submission and adds a comment to the submission detailing the type of submission and any deadlines for review. The Senior Administrator conducts an initial pre-screen of the protocol and assess for appropriateness of level of review required. The ORA Administrator also considers the volume of actions scheduled and the expertise of the Board when determining which Board should review the protocol.

IRB Administrator
Upon receipt of the assignment, the IRB Administrator assigns the protocol to the designated board per the ORA Administrator’s comment in HS-ERA using the HS-ERA assign field for the submission. Assigning the application to a Board will create a new PennERA action including a new Protocol Number.

The IRB Administrator screens the protocol submission for completeness using the IRB completeness check tool to guide in the completion of review. To determine if the submission is ready for scheduling on the agenda, the administrator looks over the online application and any attached documents under the HS-ERA Review field. During the screening of the protocol, the IRB administrator should verify the submission requires convened review. The IRB Administrator should also ensure that the submission contains sufficient information for the Board to consider whether the study meets the criteria for approval.

The IRB Administrator creates a separate word document in concurrence with the IRB completeness check to document the Administrator’s findings. If the protocol involves the use of investigational device/ drugs, administrator completes the Drug/Device/Biologic checklist to describe the status of the submission in meeting the regulatory requirements and including appropriate documentation pertaining to the use of drugs/devices/biologics in research. The Administrator uploads completed staff screening tools and initial screening notes in the Comments section of HSERA so that it is accessible to IRB members and staff.

The IRB Administrator verifies that the required human subjects’ training is present for all research personnel. If training is expired or not completed, a request is made to provide the CITI certificate (if the system is outdated) or to complete the training and provide the certificate upon completion.

Senior Administrator/Regulatory Representative
The Senior Administrator and/or Regulatory Representative support the IRB Administrator if needed. The Senior Administrator may review the IRB Administrator’s findings and confirms whether the study is ready to be scheduled for review or if it must be returned to the submitter. The Senior Administrator may also provide guidance on which of the IRB Administrator’s findings require resolution prior to the agenda being finalized, which issues can be forwarded to the reviewers for consideration prior to the meeting, and which issues can be raised during the Board discussion.

**IRB Administrator**

If the IRB Administrator determines the submission is incomplete or not yet ready to be reviewed, the submission is returned to the submitter for “response without approval” using the assign field following the addition of a comment regarding the issues to be addressed. Before the submission is returned, the IRB Administrator updates the decision of the review from “logged” to “issues identified” using the review field of PennERA and ensures that the updated decision is reflected in HS-ERA before returning. A copy of the email correspondence sent to the study team outlining the issues that need to be addressed prior to convened review assignment must also be uploaded in the Comments section of the submission. The Administrator will also provide the study team with the deadline for re-submitting the application if the study is to be scheduled for review at a certain IRB meeting.

**ORA Administrator**

By returning the submission, the application is opened to the research staff to address the concerns noted during review. When the research team returns the application to the IRB, the ORA Administrator assigns the application to the IRB Administrator who completed the initial review per the process above or another appropriate IRB staff member, if needed, for timeliness of IRB review of the response submission.

**IRB Administrator**

If no issues requiring returning of the submission were noted during the initial screen or if the issues raised by the IRB Administrator upon returning of the submission have been resolved, the IRB Administrator finalizes the assignment to the appropriate board by updating the PennERA Summary and Review page. The IRB Administrator updates the PennERA Summary to reflect any other ancillary reviews required (EHRS, CTSRMC, etc.), funding status (industry sponsored or federally funded), subpart determinations, authorization agreements, and contract status if industry sponsored. The IRB Administrator completes the agenda entry in PennERA by locating the review action in the Submissions page. The IRB Administrator uses the edit field to update the agenda entry description field, review activities, post review, and summary pages to reflect the review action has been scheduled. The administrator adds a comment in HS-ERA detailing which IRB meeting agenda the review has been scheduled for. The completeness check tool and initial screening notes document are then uploaded to the HS-ERA comments section to detail the administrator’s screening and any issues for consideration by the convened board. If a separate word document documenting the review finding was created by the IRB Administrator in concurrence with the completeness check, and Senior Administrator oversight/input is needed, the document is then forwarded to the Senior Administrator via email.
If at any point in the above processes, the IRB Administrator, Senior Administrator, or Regulatory Representative determines that the study is eligible for expedited IRB review, the study is then reviewed according to the procedures described in the Initial Review – Expedited Review Section.

Board Members
When conducting initial protocol review at a convened IRB, Penn uses a dual reviewer system for initial protocol review. The primary and secondary reviewers present their findings to the convened IRB based on their review of the protocol submission. The Board discusses any issues with the submission raised by the primary and secondary reviewer as well as any potential issues or questions that may be raised by other members of the board. The convened IRB considers the findings presented and makes a determination for approval, withheld approval, tabling, or disapproval of the protocol.

IRB Administrator and Administrative Assistant
For all voting actions, the IRB Administrator and Administrative Assistant present at the meeting ensure a quorum is present for the discussion and vote.

The IRB Administrator and Administrative Assistant take minutes during the discussion of the review. The minutes taken include an overview of the review discussion by the Board, including a summary of the proposed protocol design, any controverted issues and their resolutions, assessment of risk determination, and final decision and vote counts.

IRB Administrator:
At the conclusion of the meeting the IRB Administrator collects any notes and/or marked documents provided by the members to supplement the minutes taken during the Board’s discussion of the protocol.

After the meeting, the IRB Administrator uses the notes taken during the meeting and any additional comments provided by Board Members to compile a draft of the minutes and stipulations. The information that is captured in the minutes should mirror the Board’s discussion and concerns. The minutes are not a transcript of the Board’s discussion but rather a summary of the discussion including descriptions of controverted issues raised by members and the resolution of those issues. The stipulations and recommendations should be directive statements written to the study team informing them how to revise their submission to meet the Board’s requirements, if the decision reached by the convened IRB was a status of withheld approval. If the submission was tabled, the stipulations should be instructional for the study team in order to provide guidance for how to revise the submission to meet the approval criteria.

If the IRB Chair, primary and/or secondary reviewers provide marked copies of the consent form containing additional editorial/administrative changes, the Administrator should compile the reviewer’s comments/revisions on a marked consent form to provide to the Regulatory
Once the first draft of the minutes have been written in a word document, the IRB Administrator emails the word document containing the minutes and the marked consent form (if applicable) to the Regulatory Representative/Chair who attended the meeting.

**Regulatory Representative/Chair/Senior Staff Members**

The Regulatory Representative reviews the document and either approves the language or requests revisions, as needed. The Regulatory Representative reviews the document to ensure that it is complete and accurately reflects the Board’s review of the protocol.

**IRB Administrator**

The Administrator makes the appropriate revisions to the minute’s document based on the Regulatory Representative’s comments. The Regulatory Representative will communicate to the Administrator whether additional drafts of the minutes will be required to be reviewed again by the Regulatory Representative. If so, the draft of the minute word document will be required to be sent to the Regulatory Representative for an additional review once completed.

Once determined to be appropriate by the Regulatory Representative, the Administrator enters the final version of the minutes and any stipulations in the post review page of PennERA and generates the letter for the administrator to sign.

The IRB Administrator uses the Submissions page to locate the review action in PennERA and enters the finalized minutes, review decision, and vote count in the post review page, as well as updating the review activities page to reflect the completed action. The overall summary page of PennERA and the submission is updated to reflect the changes from the Board’s decision. The Administrator reviews the PennERA protocol’s management folders and updates any applicable fields to reflect the Board’s decision.

The IRB Administrator generates the decision letter by using the communications folder for this review action. The IRB Administrator selects the appropriate letter template and builds the letter. The administrator then transfers the letter into a word document and makes revisions to ensure that the letter is appropriately formatted and accurately documents the outcome of the IRB’s review. The letter is then converted into an Adobe PDF and combined with any tracked documents outlining additional changes not captured in the stipulations, if needed.

**IRB Administrator**

IRB Administrator electronically signs the PDF and saves the signed letter. The IRB Administrator updates the PennERA review activities section for the submission to indicate that the letter has been signed.

The IRB Administrator accesses the HS-ERA modification review submission to upload the signed letter in the add decision document page. After the review decision and signed letter are
selected, the letter is uploaded. The IRB Administrator uploads the signed letter in the communications folder in the PennERA communication section and updates the review activities to indicate the letter has been signed and forwarded. An email with the signed letter and an explanation of its contents is sent to the PI, appropriate study contacts, and any other designated recipients. The HS-ERA submission is returned the submission for response using the “assign to IRB” field in HS-ERA. Studies that are tabled by the Board are returned for “response with approval.” Studies that receive withheld approval are returned for response without approval. Studies that receive outright approval are not returned to the study team.
Research Review Processes – Initial Reviews

Expedited Responses to Convened Initial Reviews

1. PROCESS OVERVIEW
This procedure outlines the review processes for responses to stipulations raised during review by the convened IRB. This section applies to responses that are eligible for expedited review. Use of the HS-ERA electronic submission system is mandatory for all initial submissions and therefore, all responses will be submitted through HS-ERA.

2. RESPONSIBILITY

ORA Administrator
The role of the ORA Administrator is to check for incoming response submissions and assign to the appropriate IRB Administrator for review.

IRB Administrator
The role of the IRB Administrator is to review the response, complete data entry, and assign the review action to the appropriate IRB board.

IRB Administrative Assistant
The role of the IRB Administrative Assistant is to provide assistance to the IRB Administrator as needed for completion of data entry for the initial review action. The Administrative Assistant is also responsible for drafting the IRB approval letter for the action.

IRB Chair or Designee
The IRB Chair or designee completes a secondary review of the action and approves the action.

3. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY

ORA Administrator
The response submission to Initial Protocol withheld approval decisions is received in the HS-ERA IRB queue once accepted by the submitter for submission to the IRB. Once accepted for submission to the IRB, the status of the submission is updated from “draft” to “accepted and submitted for review”.

The ORA Administrator identifies incoming response submissions to IRB withheld approval decisions and assigns to the appropriate IRB Administrator for screening. The administrator utilizes the Assign to IRB admin section of HS-ERA and sorts submissions by Status so that all submissions with an “accepted and submitted for review status” appear first. The ORA Administrator uses the view icon next to the submission to identify who the response submission should be assigned to. The administrator uses the assign field for the submission and adds a comment to the submission detailing the type of submission and any deadlines for review.
IRB Administrator
The IRB Administrator screens the response submission for completeness. The IRB Administrator uses the Response to Withheld Worksheet to create a summary document that outlines the stipulations raised by the Board in the manner in which they appear in the initial withheld approval letter. Below each stipulation, the administrator should clearly indicate whether the stipulation was addressed or not, summarize the response provided by the study team and any comments that should be brought to the reviewer’s attention.

The IRB Administrator verifies that the required human subjects’ training is present for all research personnel. If training is expired or not completed, a request is made to provide the CITI certificate (if the system is outdated) or to complete the training and provide the certificate upon completion.

To determine if the response submission is ready for final review, the administrator utilizes the online application and any attached documents under the HS-ERA Review field, ensuring that all required revisions were incorporated, as well as tracked/clean copies of any revised documents.

During the screening of the response submission, the IRB Administrator should verify the submission is eligible for expedited review. Consult may be sought from the Senior IRB Administrator in assessing whether the response requires review by the convened IRB.

If the IRB Administrator (with consult from the Senior Administrator if needed) determines the submission is incomplete or not yet ready for final review, the submission is returned to the submitter for response without approval using the assign field following the addition of a comment regarding the issues to be addressed. If the issues were identified after the response submission has been assigned to the board, the IRB administrator updates the decision of the review from “logged” to “issue identified” using the review field of the PennERA and ensures that the updated decision is reflected in HS-ERA before returning.

ORA Administrator
By returning the submission, the application is opened to the research staff to address the concerns noted during review. When the research team returns the application to the IRB, the ORA Administrator assigns the application to the IRB administrator who completed the initial review of the response submission per the process above.

IRB Administrator
If no issues requiring returning of the submission were noted during the initial screen or if the issues raised by the administrator upon returning of the submission have been resolved, the IRB Administrator finalizes the assignment to the IRB Chair or designee by updating the PennERA Summary and Review page. The IRB Administrator completes the agenda entry in PennERA by locating the review action in the Submissions page. The IRB Administrator uses the edit field to update the agenda entry description field, review activities, and post review pages to reflect the review action has been assigned to the IRB Chair or designee.
The IRB Administrator ensures the data entry is complete in PennERA and is reflective of the review notes as outlined in the HS-ERA pre-review notes and includes appropriate language and notes regarding pending reviews (e.g. CTSRMC, finalized contract, etc.) for inclusion in the final approval letter.

The IRB Administrator adds a comment in HS-ERA detailing the submission is ready for final review and uploads a copy of the response summary document. The IRB Chair or Designee is then notified via email for final review.

**IRB Chair or Designee**
The IRB Chair or Designee is notified of the pending assignment upon receipt of email notification from the IRB Administrator. The reviewer locates the submission in HS-ERA by opening the My Submissions Approvals – view assigned section. The reviewer reviews the application to determine concurrence with the IRB Administrator’s assessment that all stipulations have been appropriately addressed. If any questions or concerns related to the response submission are identified, the approver communicates these issues to the IRB administrator. If no concerns are raised and the issues raised by the IRB Administrator upon pre-review are appropriately addressed, the reviewer then approves the submission in My Submissions Approvals – view assigned section by submitting a decision for this protocol.

**IRB Administrator**
If issues are raised by the reviewer, the IRB Administrator relays those issues to the study team and may return the submission in HS-ERA for response without approval if appropriate.

If the response submission introduces a component of the research which warrants convened board review or if the study team refuses to address the Board’s stipulations, the IRB administrator would then follow the procedures for processing convened responses to initial protocols. If at any point in the above processes, the IRB Administrator or Chair/designee determines that the study requires convened IRB review, the Senior IRB Administrator is notified that the response submission will need to be scheduled for convened IRB review.

**ORA Administrator**
The approval will be reflected in the follow day letter generation report which is forwarded to the Director and designated ORA administrators.

The ORA Administrator assigns the submission to an IRB Administrative Assistant based on the previously completed letter generation report. The ORA administrator utilizes the Assign to IRB admin section of HS-ERA and locates submissions by filtering based on the protocol number or confirmation code provided in the letter generation report. The ORA Administrator uses the assign field for the submission and adds a comment to the submission detailing the type of assignment and any deadlines for completion.
The IRB Administrative Assistant receives a notification email detailing the assignment and deadline for completion and locates the submission in assign to IRB section of HS-ERA and PennERA.

The IRB Administrative Assistant completes the data entry, as needed. The IRB Administrative Assistant uses the HS-ERA submission’s eyeglass and/or review view to identify all documents submitted for review and verifies the document listing provided by the IRB Administrator in the review (general) page and Post-Review page in PennERA. The Administrative Assistant reviews the HS-ERA comments section to determine if any notes or supplemental language should be added to the approval letter and ensures those comments are listed on the Post-Review page. The overall summary page of PennERA and the submission is updated to reflect the changes from the new approval. The Administrative Assistant reviews the PennERA protocol’s management folders and updates any applicable fields to reflect the protocol approval.

The IRB Administrative Assistant generates the approval letter by using the communications folder for this review action. The Administrative Assistant selects the appropriate letter template and builds the letter. The assistant then transfers the letter into a word document and makes revisions to ensure that the letter is appropriately formatted and accurately documents the outcome of the IRB’s review. The letter is then converted into an Adobe PDF and combines any applicable study documents with an appropriate stamp, if needed. The letter is placed in the appropriate IRB Administrator Letters to be Signed folder on the G: Drive.

The IRB Administrative Assistant locates the signed letter from the IRB Administrator in the Signed Folder on the G: Drive. The HS-ERA modification Submission is accessed to upload the signed letter in the add decision document page. After the review decision and signed letter are selected, the letter is uploaded.

The IRB Administrative Assistant uploads the signed letter in the communications folder in the
PennERA communication section and indicates through the review activities as sent and uploaded. An email with the signed letter and an explanation of its contents is sent to the PI, appropriate study contacts, and any other designated recipients. The signed letter is removed from the Signed Folder on the G: Drive.
Research Review Processes – Initial Reviews

Convened Responses to Convened Initial Reviews

1. PROCESS OVERVIEW
This procedure outlines the review processes for responses to stipulations raised during review by the convened IRB. This section applies to responses that require convened review. Use of the HS-ERA electronic submission system is mandatory for all initial submissions and therefore, all responses will be submitted through HS-ERA.

2. RESPONSIBILITY

IRB Administrator
The role of the IRB Administrator is to screen the convened response assigned to them for processing, assess for completeness of the application, complete data entry, and assign the review action to the appropriate meeting agenda and reviewer. The IRB Administrator is also responsible for completion of minutes and letters for the response review action.

ORA Administrator
The role of the ORA Administrator is to check for incoming convened responses and assign to the appropriate IRB Administrator for screening and scheduling for the next appropriate board. The ORA Administrator is also responsible for re-assignment of convened responses to the IRB Administrator for re-submitted protocols.

IRB Senior Administrator
The IRB Senior Administrator is responsible for supporting the IRB administrator as needed. The Senior Administrator may consult to ensure that protocols on the agenda were appropriately scheduled and that the submission is not eligible for expedited review.

IRB Board Members
The role of the IRB Board Member is to review the protocol submission to determine if the criteria for approval have been met, assess the protocol for any controverted issues and raise the issues for discussion during the meeting, along with their resolutions, and vote on the risk assessment and final review decision.

Regulatory Representative
The Regulatory Representative is a senior member of the IRB staff (typically the Director or Associate Director) who serves as an IRB Board Member. In addition to Board Member duties the Regulatory Representative also provides expertise on federal regulations and Penn policy and provides guidance in order to ensure that policies are applied consistently across all Penn Boards. The Regulatory Representative also provides assistance to the IRB Administrator by discussing potential issues prior to the meeting and reviewing minutes and letters generated after the meeting.
3. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY

ORA Administrator:
The ORA Administrator identifies incoming response submission that is labeled for full board review and assigns to the appropriate IRB Administrator for screening. The ORA Administrator utilizes the Assign to IRB admin section of HS-ERA and sorts submissions by Status so that all submissions with an “accepted and submitted for review status” appear first. The Senior Administrator uses the assign field for the submission and adds a comment to the submission detailing the type of submission and any deadlines for review.

IRB Administrator:
Upon receipt of the assignment, the IRB Administrator assigns the re-submission to the designated board per the ORA Administrator’s comment in HS-ERA using the HS-ERA assign field for the re-submission.

Responses to submissions that are tabled by the convened IRB at the time of review require Convened Board review. Responses to submission that receive Withheld Approval by the Convened IRB at the time of review require Convened Board review when the Board’s stipulations have not been addressed or an additional substantive modification has been submitted for concurrent review. The IRB Administrator should consult with the Senior Administrator to verify that the Response to Withheld re-submission requires Convened Board review.

The IRB Administrator screens the response submission for completeness. The IRB Administrator creates a summary document that outlines the stipulations raised by the Board in the manner in which they appear in the initial letter. Below each stipulation, the administrator should summarize the response provided by the study team and any comments that should be brought to the convened board’s attention. The summary document should also include the minutes from the Board’s initial review of the submission.

To determine if the response submission is ready for convened review, the IRB Administrator reviews the online application and any attached documents under the HS-ERA Review field, ensuring that the required revisions were made, as well as presence of any tracked/clean copies of any revised documents.

The IRB Administrator verifies that the required human subjects’ training is present for all research personnel. If training is expired or not completed, a request is made to provide the CITI certificate (if the system is outdated) or to complete the training and provide the certificate upon completion.

Senior Administrator/Regulatory Representative
The Senior Administrator or Regulatory Representative provides consult to the IRB Administrator as required. The Senior Administrator may review the IRB administrator’s findings
and confirm whether the study is ready to be scheduled for review or if it must be returned to the submitter.

**IRB Administrator**
If the IRB Administrator determines the submission is incomplete or not yet ready to be reviewed, the submission is returned to the submitter for response without approval using the assign field following the addition of a comment regarding the issues to be addressed. If necessary, the IRB Administrator updates the decision of the review from “logged” to “issues identified” using the review field of PennERA and ensures that the updated decision is reflected in HS-ERA before returning.

**ORA Administrator**
By returning the submission, the application is opened to the research staff to address the concerns noted during review. When the research team returns the application to the IRB, the ORA Administrator assigns the application to the IRB administrator who completed the initial review per the process above.

**IRB Administrator**
If no issues requiring returning of the submission were noted during the initial screen or if the issues raised by the administrator upon returning of the submission have been resolved, the IRB Administrator finalizes the assignment to the appropriate board by updating the PennERA Summary and Review page. The IRB Administrator completes the agenda entry in PennERA by locating the review action in the Submissions page. The IRB Administrator uses the edit field to update the agenda entry description field, review activities, post review, and summary pages to reflect the review action has been scheduled. The IRB Administrator adds a comment in HS-ERA detailing why the protocol requires convened review and which IRB meeting agenda the review has been scheduled for. The submission summary document is then uploaded to the HS-ERA comments section to detail the IRB Administrator’s screening and any issues for consideration by the convened board.

If at any point in the above processes the IRB Administrator, Senior Administrator, or Regulatory Representative determines that the study is eligible for expedited IRB review, the study is then placed up for expedited review according to the procedures described in the Expedited Responses to Convened Initial Review Section.

**Board Members**
When conducting the response review at a convened IRB, Penn uses a primary reviewer system for protocol review. The primary reviewer (which should be the original reviewer, if present at the meeting, or the Chair) presents their findings to the convened IRB based on his/her review of the protocol submission. The Board discusses any issues with the submission raised by the primary reviewer as well as any potential issues or questions that may be raised by other members of the board. The convened IRB considers the findings presented and makes a determination for approval, withheld approval, tabling, or disapproval of the protocol.
For all voting actions, the IRB Administrator and Assistant present at the meeting ensure a quorum is present for the discussion and vote.

The IRB Administrator and Administrative Assistant take minutes during the discussion of the review. The minutes taken include an overview of the review discussion by the Board, including a summary of the proposed protocol design, any controverted issues and their resolutions, assessment of risk determination, and final decision and vote counts.

**IRB Administrator:**
At the conclusion of the meeting the IRB Administrator collects any notes and/or marked documents from the members to supplement the minutes taken during the Board’s discussion of the protocol.

After the meeting, the IRB Administrator uses the notes taken during the meeting and any additional comments provided by Board Members to compile a draft of the minutes and stipulations. The information that is captured in the minutes should mirror the Board’s discussion and concerns. The minutes are not a transcript of the Board’s discussion but rather a summary of the discussion including descriptions of controverted issues raised by members and the resolution of those issues. The stipulations and recommendations are directive statements written to the study team informing them how to revise their submission to meet the Board’s requirements.

If the IRB Chair and/or primary reviewer provide marked copies of the consent form containing additional editorial/administrative changes, the IRB Administrator should compile the reviewer’s comments/revisions on a marked consent form to provide to the Regulatory Representative concurrently for review with the minutes/stipulations word document.

Once the first draft of the minutes have been written in a word document, the IRB Administrator emails the word document containing the minutes and the marked consent form (if applicable) to the Regulatory Representative who attended the meeting.

**Regulatory Representative/IRB Senior Staff/IRB Chair**
The Regulatory Representative reviews the document and either approves the language or requests revisions, as needed. The Regulatory Representative reviews the document to ensure that it is complete and accurately reflects the Board’s review of the protocol.

**IRB Administrator**
The IRB Administrator makes the appropriate revisions to the minute’s document based on the Regulatory Representative’s comments. The Regulatory Representative will communicate to the Administrator whether additional drafts of the minutes will be required to be reviewed again by the Regulatory Representative. If so, the draft of the minute word document will be required to be sent to the Regulatory Representative for an additional review once completed.
Once determined to be appropriate by the Regulatory Representative, the Administrator enters the final version of the minutes and any stipulations in the post review page of PennERA and generates the letter for the administrator to sign.

The IRB Administrator uses the Submissions page to locate the review action in PennERA and enters the finalized minutes, review decision, and vote count in the post review page, as well as updating the review activities page to reflect the completed action. The overall summary page of PennERA and the submission is updated to reflect the changes from the Board’s decision. The Administrator reviews the PennERA protocol’s management folders and updates any applicable fields to reflect the Board’s decision.

The IRB Administrator generates the decision letter by using the communications folder for this review action. The IRB Administrator selects the appropriate letter template and builds the letter. The administrator then transfers the letter into a word document and makes revisions to ensure that the letter is appropriately formatted and accurately documents the outcome of the IRB’s review. The letter is then converted into an Adobe PDF and combined with any tracked documents outlining additional changes not captured in the stipulations, if needed.

**IRB Administrator**
The IRB Administrator electronically signs the PDF and saves the signed letter. The IRB Administrator updates the PennERA review activities section for the submission to indicate that the letter has been signed.

The IRB Administrator accesses the HS-ERA modification review submission to upload the signed letter in the add decision document page. After the review decision and signed letter are selected, the letter is uploaded. The IRB Administrator uploads the signed letter in the communications folder in the PennERA communication section and updates the review activities to indicate the letter has been signed and forwarded. An email with the signed letter and an explanation of its contents is sent to the PI, appropriate study contacts, and any other designated recipients. The HS-ERA submission is returned for response using the assign to IRB field in HS-ERA. Studies that are tabled by the Board are returned for response with approval. Studies that receive withheld approval are returned for response without approval. Studies that receive outright approval are not returned to the study team.

**Research Review Processes – Continuing Review**

**Expedited Continuing Reviews**

1. **PROCESS OVERVIEW**
This procedure outlines the processes for continuing reviews that meet the criteria for expedited review. Applications are submitted via the HS-ERA electronic submission system and the Paper Submission Process.
2. RESPONSIBILITY

IRB Front Desk Administrative Assistant
The role of the IRB FD Administrative Assistant is to receive incoming paper actions, log the submission in PennERA, and place the action on the designated assignment shelf for distribution by the ORA Administrator.

ORA Administrator
The role of the ORA Administrator is to check for incoming reviews and assign to the appropriate IRB Administrator/Appropriate IRB Staff Member for review.

IRB Administrator/Appropriate IRB Staff
The role of the IRB Administrator is to review the action, complete preliminary data entry, and assign the review action to the appropriate IRB board. IRB Administrative Assistants can be designated as appropriate IRB staff after undergoing appropriate training.

IRB Administrative Assistant
The role of the IRB Administrative Assistant is to provide assistance to the IRB Administrator as needed for completion of data entry for the review action. The IRB Administrative Assistant is also responsible for drafting the IRB approval letter for the action.

Director or Designee
The Director or designee ("reviewer") completes a secondary review of the action and approves the action.

3A. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY - HS-ERA Applications

ORA Administrator
The expedited continuing review submission is received in the HS-ERA IRB queue once approved by the Principal Investigator. Upon receipt in the IRB queue, the status of the submission is changed from “Pending review by (Principal Investigator’s name)” to “Accepted and submitted for review”.

The ORA Administrator identifies incoming continuing reviews that are labeled for expedited review and assigns to the appropriate IRB Staff for screening. The ORA Administrator utilizes the Assign to IRB admin section of HS-ERA and sorts submissions by Status so that all submissions with an “accepted and submitted for review status” appear first. The ORA Administrator uses the assign field for the submission and adds a comment to the submission detailing the type of submission and any deadlines for review. The ORA Administrator may utilize the HS-ERA Continuing Review Submission and the PennERA Protocol Status when assessing the appropriateness of expedited review.

IRB Administrator/Appropriate IRB Staff
The IRB Administrator or Appropriate IRB Staff (referred to as IRB Administrator throughout this section) screens the expedited continuing review submission for completeness. PennERA, the
HS-ERA continuing review submission, and previous HS-ERA submission for the protocol may all be utilized to assist the administrator in his/her assessment. The IRB Administrator should determine the appropriate expedited review category and that the criteria for re-approval are met. The IRB Administrator should verify that the enrollment numbers are consistent with previous protocol submissions, that any issues raised within the continuing review submission are appropriately addressed by the study team, and that the study documents uploaded are the most recent IRB approved versions.

The IRB Administrator verifies that the required human subjects’ training is present for all research personnel. If training is expired or not completed, the IRB Administrator will notify the study team and inform them that the affected research staff cannot conduct research related activity until the training has been completed.

If the IRB Administrator determines the submission is incomplete or not yet ready to be reviewed, the submission is returned to the submitter for revision without approval using the assign field following the addition of a comment regarding the issues to be addressed.

ORA Administrator
By returning the submission, the application is opened to the research staff to address the concerns noted during review. When the research team returns the application to the IRB, the ORA Administrator assigns the application to the IRB Administrator who completed the initial review per the process above.

IRB Administrator/Appropriate IRB Staff
If no issues were noted during the initial review or if the issues raised by the IRB Administrator have been resolved, the IRB Administrator assigns the review action to the appropriate board using the HS-ERA assign field for the submission and adds a comment summarizing their findings. An expedited continuing review worksheet may be uploaded in the comments section.

- The IRB Administrator places the submission up for expedited review in PennERA by locating the review action in the Submissions page. The IRB Administrator updates the review activities section to indicate that the review has been assigned and may select the expedited category. The IRB Administrator then navigates to the post-review page and assigns the review action to the Executive Chair (or authorized designee), who will be referred to moving forward as the “reviewer.”

Director or Designee
The reviewer finds the submission in HS-ERA by opening the My Submissions Approvals – view assigned section. The reviewer reviews the application to determine if the criteria for expedited re-approval have been met. If any questions or concerns related to the criteria for re-approval are identified, the approver communicates these issues to the IRB Administrator/IRB Staff. If no concerns are raised or the issues raised by the reviewer are appropriately addressed, the reviewer then approves the submission in My Submissions Approvals – view assigned section by submitting a decision for this protocol.

IRB Administrator/Appropriate IRB Staff
If issues are raised by the reviewer, the IRB Administrator relays those issues to the study team and may return the submission in HS-ERA if appropriate.

If at any point in the above processes, the administrator or reviewer determines that the study requires convened IRB review, a Senior IRB Administrator is notified that he/she should schedule the study for convened IRB review. The IRB Administrator should share his/her notes or comments about the submission with appropriate IRB staff.

ORA Administrator
The approval will be reflected in the following day’s letter generation report which is forwarded to the Director and designated ORA administrators.

The ORA Administrator assigns the submission to an IRB Administrative Assistant based on the previously completed letter generation report. The ORA administrator utilizes the Assign to IRB admin section of HS-ERA and locates submissions by filtering based on the protocol number or confirmation code provided in the letter generation report. The ORA Administrator uses the assign field for the submission and adds a comment to the submission detailing the type of assignment and any deadlines for completion.

IRB Administrative Assistant
The IRB Administrative Assistant receives a notification email detailing the assignment and deadline for completion and locates the submission in assign to IRB section of HS-ERA and PennERA.

The IRB Administrative Assistant completes the data entry, as needed. The IRB Administrative Assistant uses the HS-ERA submission’s eyeglass and/or review views to identify all documents submitted for review and list them into the review (general) page and Post-Review page in PennERA. The IRB Administrative Assistant reviews the HS-ERA comments section to determine if any notes should be added to the approval letter and lists those comments on the Post-Review page. The overall summary page of PennERA and the submission is updated to reflect the approval period. The IRB Administrative Assistant reviews the PennERA protocol’s management folders and updates sections, when appropriate, to ensure the protocol and status accurately to reflect the new approval.

The IRB Administrative Assistant generates the approval letter by using the communications folder for this review action. The IRB Administrative Assistant selects the appropriate letter template and builds the letter. The IRB Administrative Assistant then transfers the letter into a word document and makes revisions to ensure that the letter is appropriately formatted and accurately documents the outcome of the IRB’s review. The letter is then converted into an Adobe PDF and combined with any applicable study documents with an IRB approval stamp, if needed. The letter is placed in the appropriate IRB Administrator Letters to be Signed folder on the G: Drive.

IRB Administrator
The IRB Administrator reviews the letter to ensure that the information contained is accurate and appropriately formatted. The Administrator may refer to the submission in HS-ERA to verify
the accuracy of the document listing and template language. The administrator also ensures that the appropriate documents are attached to the letter and accurately stamped and that PennERA has been correctly updated to reflect the new approval. If revisions to the letter are necessary the administrator informs the assistant of the required revisions and deletes the PDF of the approval letter. If revisions to the letter are not required, the IRB administrator electronically signs the PDF and saves the signed letter in the IRB Administrative Assistant Letters Signed Folder on the G: Drive. The IRB administrator updates the PennERA review activities section for the submission to indicate that the letter has been signed.

IRB Administrative Assistant
The IRB Administrative Assistant locates the signed letter from the IRB Administrator in the Signed Folder on the G: Drive. The HS-ERA continuing review submission is accessed to upload the signed letter in the add decision document page. After the review decision and signed letter are selected, the letter is uploaded.

The IRB Administrative Assistant uploads the signed letter in the communications folder in the PennERA communication section and updates the review activities to indicate the letter has been signed and forwarded. An email with the signed letter and an explanation of its contents is sent to the PI, appropriate study contacts, and any other designated recipients. The signed letter is removed from the Signed Folder on the G: Drive.

3B. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY – Paper Applications

IRB Front Desk Administrative Assistant
The expedited continuing review submission is received in the IRB office once signed-off by the Principal Investigator. Upon receipt in the IRB queue, the IRB Front Desk Administrative Assistant date stamps and logs the submission in PennERA for tracking purposes. The IRB Front Desk Administrative Assistant utilizes the “Add new” field in the Submissions page to create a new Review record in PennERA. Once a new Review record is created, the front desk assistant uploads the signed letter in the communications folder in the PennERA communication section and updates the review activities to indicate the letter has been signed and forwarded. An email with the signed letter and an explanation of its contents is sent to the PI, appropriate study contacts, and any other designated recipients. The signed letter is removed from the Signed Folder on the G: Drive.

ORA Administrator
The ORA administrator checks the distribution shelf and assigns the submission to the appropriate IRB Staff for screening. The ORA Administrator writes the type of assignment and deadlines for completion on the paper submission. The reviewer places the submission and protocol file in the IRB Administrator’s designated area for new expedited screening assignments.

IRB Administrator/Appropriate IRB Staff
The IRB Administrator or Appropriate IRB Staff (referred to as IRB administrator throughout this section) screens the expedited continuing review submission for completeness. PennERA, the continuing review submission, and previous submissions in the protocol file may be utilized to
assist the IRB Administrator in his/her assessment. The IRB Administrator should determine the appropriate expedited review category and that the criteria for re-approval are met. The IRB Administrator should verify that the enrollment numbers are consistent with previous protocol submission, that any issues raised within the continuing review submission are appropriately addressed by the study team, and that the study documents provided are the most recent IRB approved versions.

The IRB Administrator verifies that the required human subjects' training is present for all research personnel. If training is expired or not completed, the IRB Administrator will notify the study team and inform them that the affected research staff cannot conduct research related activity until the training has been completed.

If the IRB Administrator determines the submission is incomplete or not yet ready to be reviewed, the submitter is emailed a notification with the issues to be addressed. The review activities field for the submission in PennERA should be updated to document the issues raised with the study team. The email correspondence with the study team and any additional documents provided are incorporated into the paper submission.

If the submission is ready for review or the issues raised by the IRB Administrator have been appropriately addressed, the IRB Administrator places the submission up for expedited review in PennERA by locating the review action in the Submissions page. The IRB Administrator updates the review activities section to indicate that the review has been assigned. The administrator then navigates to the post-review page and assigns the review action to the Executive Chair (or authorized designee), who will be referred to moving forward as the “reviewer.” The submission and the file are then placed in the designated location for expedited paper reviews.

**Director or Designee**

The reviewer checks the location for expedited paper reviews and determines if the criteria for expedited re-approval have been met. If any questions or concerns related to the criteria for approval are identified, the approver communicates these issues to the IRB Administrator and returns the submission and protocol file. If no concerns are raised or the issues raised by the reviewer are appropriately addressed, the reviewer affix his/her approval comments and signature.

**IRB Administrator**

If issues are raised by the reviewer, the IRB Administrator relays those issues to the study team. The study team’s response and any additional documents are incorporated into the submission and the submission and file are returned to the designated location for expedited reviews.

If at any point in the above processes, the administrator or reviewer determines that the study requires convened IRB review, a Senior IRB Administrator is notified that he/she should schedule the study for convened IRB review. The IRB Administrator should share his/her notes or comments about the submission with appropriate IRB staff.

**ORA Administrator/Senior IRB Staff**
After the submission is approved, the reviewer assigns the submission to an IRB Administrative Assistant for letter generation. The reviewer writes the type of assignment and deadlines for completion on the paper submission. The reviewer places the submission and protocol file in the assistants designated area for letter generation assignments.

**IRB Administrative Assistant**
The IRB Administrative Assistant retrieves the continuing review from his/her designated area and locates the submission in PennERA.

The IRB Administrative Assistant completes the data entry, as needed. The IRB Administrative Assistant reviews the paper documents and lists them into the review (general) page and Post-Review page in PennERA. The Administrative Assistant reviews the documents to determine if any notes or supplemental language should be added to the approval letter and lists those comments on the Post-review page. The overall summary page of PennERA and the submission is updated to reflect the new approval period. The Administrative Assistant reviews the PennERA protocol's management folders and updates sections, when appropriate, to ensure the protocol and status accurately to reflect the new approval.

The IRB Administrative Assistant generates the approval letter by using the communications folder for this review action. The Administrative Assistant selects the appropriate letter template and builds the letter. The assistant then transfers the letter into a word document and makes revisions to ensure that the letter is appropriately formatted and accurately documents the outcome of the IRB’s review. The letter is then converted into an Adobe PDF. Any applicable study documents are scanned into PDF and affixed with an appropriate stamp, if needed. The letter and scanned documents are combined and placed in the appropriate IRB Administrator Letters to be Signed folder on the G: Drive. The paper submission and protocol file are placed in the IRB Administrator’s designated area for letters to be signed.

**IRB Administrator**
The IRB Administrator reviews the letter to ensure that the information contained is accurate and appropriately formatted. The Administrator may refer to the paper submission to verify the accuracy of the document listing and template language. The IRB Administrator also ensures that the appropriate documents are attached to the letter and accurately stamped and that PennERA has been correctly updated to reflect the new approval. If revisions to the letter are necessary the administrator informs the assistant of the required revisions, deletes the PDF of the approval letter, and returns the submission and protocol file to the IRB administrative assistant. If revisions to the letter are not required, the IRB administrator electronically signs the PDF and saves the signed letter in the IRB Administrative Assistant Letters Signed Folder on the G: Drive. The IRB Administrator updates the PennERA review activities section for the submission to indicate that the letter has been signed. A copy of the signed letter is printed and attached to the paper submission and protocol file. The submission is then returned to the administrative assistant for forwarding.

**IRB Administrative Assistant**
The IRB Administrative Assistant locates the signed letter from the IRB Administrative Assistant Signed Letters Folder on the G: Drive. The IRB Administrative Assistant uploads the signed letter in the communications folder in the PennERA communication section and updates the
review activities to indicate the letter has been signed and forwarded. An email with the signed letter and an explanation of its contents is sent to the PI, appropriate study contacts, and any other designated recipients. The signed letter is removed from the Signed Folder on the G: Drive. The approval letter and submission documents are placed in the paper protocol file. The assistant conducts a quality assurance review of the file to ensure that actions are organized appropriately. The assistant then returns the file to the file room.
Convened Continuing Reviews

1. **PROCESS OVERVIEW** This procedure outlines the review of convened continuing reviews submitted via the HS-ERA electronic submission system and the paper submission process.

2. **RESPONSIBILITY**

   **IRB Front Desk Administrative Assistant**
   The role of the FD IRB Administrative Assistant is to receive incoming paper actions, complete initial data entry into PennERA and place them in the designated area for distribution by the ORA Administrator.

   **ORA Administrator**
   The role of the ORA Administrator is to check for incoming convened continuing reviews and assign to the appropriate IRB Administrative Assistant for screening and scheduling for the next appropriate board.

   **IRB Administrative Assistant**
   The role of the IRB Administrative Assistant is to screen the convened continuing reviews assigned to them for processing, assess for completeness of the application, complete data entry, and assign the review action to the appropriate meeting agenda and reviewer. The IRB Administrative Assistant is also responsible for drafting the minutes and letters for the convened continuing review.

   **IRB Administrator**
   The role of the IRB Administrator is to review the Administrative Assistants completeness checklist and confirm that the action is appropriately scheduled for the convened IRB review. The Administrator is also responsible for reviewing the initial draft of the minutes and letters completed by the IRB Administrative Assistant for the convened continuing review action to assess for appropriateness and accuracy of content.

   **Board Members**
   The role of the board member is to review the action prior to the IRB meeting, discuss the action during the meeting, and ultimately make a final determination about the action. The member can contact the research team prior to the meeting to have questions about the action addressed for use during the discussion.
3A. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY - HS-ERA Applications

ORA Administrator
The convened continuing review submission is received in the HS-ERA IRB queue once approved by the Principal Investigator. Upon receipt in the IRB queue, the status of the submission is changed from "Pending review by (Principal Investigator’s name)" to “Accepted and submitted for review”.

The ORA Administrator identifies incoming continuing reviews that are labeled for full board review and assigns to the appropriate IRB Administrative Assistant for screening for the next available meeting agenda. Assignments are made based what board initially reviewed the protocol, the continuing review submission’s expiration date, and agenda volume. The Senior Administrator utilizes the Assign to IRB admin section of HS-ERA and sorts submissions by status so that all submissions with an “accepted and submitted for review status” appear first. The Senior Administrator uses the assign field for the submission and adds a comment to the submission detailing the type of submission and any deadlines for review. The Senior Administrator may utilize the HS-ERA Continuing Review Submission and the PennERA Protocol Status when assessing the appropriateness of full board review.

IRB Administrative Assistant
The IRB Administrative Assistant screens the convened continuing review submission for completeness. PennERA, the HS-ERA continuing review submission, and previous HS-ERA submissions for the protocol may all be utilized to assist the IRB Administrative Assistant in his/her assessment. To screen the continuing review submission, the IRB Administrative Assistant utilizes the Assign to IRB section of HS-ERA and sorts submissions by Status so that all submissions with an “assign to (IRB administrator name)” appear first or via a search of the submission using the confirmation code and/or protocol number from the email notification provided at receipt of the assignment. The IRB Administrative Assistant uses the Eyeglass field for the submission and completes the screening.

The IRB Administrative Assistant uses the convened continuing review completeness checklist to ensure the continuing review submission has sufficient information for the Board’s consideration. This process includes, but is not limited to, verification that the enrollment numbers are consistent with previous protocol submissions, that any outstanding issues identified from previous reviews have been resolved, and that any issues raised within the continuing review submission are appropriately addressed by the study team. The IRB Administrative Assistant reviews the submission to determine if the study team has reported any complaints about the research and requests a summary of the complaints if needed. The IRB Administrative Assistant verifies that no modifications are incorporated into the continuing review submission. When a modification is included within a continuing review submission, the IRB Administrative Assistant consults with the IRB Administrator to determine an appropriate course of action.
The IRB Administrator verifies that the required human subjects’ training is present for all research personnel. If training is expired or not completed, the IRB Administrator will notify the study team and inform them that the affected research staff cannot conduct research related activity until the training has been completed.

If the IRB Administrative Assistant determines the submission is incomplete or not yet ready to be scheduled on the next appropriate meeting agenda, he/she consults with the IRB Administrator to determine if returning the submission is appropriate. If the IRB Administrator determines it is appropriate, the submission is returned to the submitter for revision without approval using the assign field following addition of a comment regarding the issues to be addressed.

ORA Administrator
By returning the submission, the application is opened to the research staff to address the concerns noted during review. When the research team returns the application to the IRB, the ORA Administrator assigns the application to the IRB Administrative Assistant who completed the initial review per the process above.

IRB Administrative Assistant
If no issues were noted during the initial review or if the issues raised by the IRB Administrative Assistant have been resolved, the IRB Administrative Assistant assigns the review action to the appropriate board using the HS-ERA assign field for the submission and adds a comment summarizing their findings. A convened continuing review completeness checklist may be uploaded in the comments section and is provided to the IRB Administrator for review.

Once it has been determined that the continuing review submission is complete and requires convened review, the IRB Administrative Assistant completes the agenda entry, as needed. The IRB Administrative Assistant places the submission up for convened review in PennERA by locating the review action in the Submissions page. The IRB Administrative Assistant updates the review activities section to indicate that the review has been assigned and may select the appropriate agenda date. The IRB Administrative Assistant then navigates to the post-review page and assigns the review action to the Board Member.

IRB Administrator
The IRB Administrator reviews the convened continuing review checklist and the agenda entry for the continuing review once he/she receives the document from the IRB Administrative Assistant. The IRB Administrator ensures that the convened continuing review checklist and the agenda entry are completed correctly. Any necessary revisions are conveyed to the IRB Administrative Assistant. If no revisions are required, the IRB Administrator signs the convened continuing review checklist and uploads it to the submission activities page of HS-ERA in the comments section. If revisions are required, the IRB Administrator ensures the revisions have been incorporated by the Administrative Assistant appropriately. The IRB Administrator then signs the convened continuing review checklist and uploads it to the submission activities page of HS-ERA in the comments section.
If at any point in the above processes, the IRB Administrator, Senior Administrator, or Regulatory Representative determines that the study is eligible for expedited IRB review, the study is then placed up for expedited review according to the procedures described in the expedited continuing reviews section.

Board Members
When conducting continuing reviews at a convened IRB, Penn uses a primary reviewer system. The primary reviewer presents his/her findings to the convened IRB based on their review of the continuing review request. The board considers the study progress reported in the submission and whether the information has the potential to alter the most recent risk-benefit assessment made by the investigator. If complaints have been made about the research, the board considers whether they were appropriately resolved. The board discusses any issues with the submission raised by the primary reviewer as along with any potential issues or questions that may be raised by other members of the board. The convened IRB considers the findings presented and makes a determination for approval, conditional re-approval, or suspension of the research.

IRB Administrator and Administrative Assistant
For all voting actions, the IRB Administrator and Assistant present at the meeting ensure a quorum is present for the discussion and vote.

The IRB Administrator and Administrative Assistant take minutes during the discussion of the review, and generate final minutes and IRB decision letters collaboratively based on the convened meeting discussion. The minutes taken includes an overview of the review discussion by the Board, including the study's progress to date, any relevant new findings, any controverted issues and their resolutions, re-assessment of risk determination, considerations for subpart reviews, final decision, and vote counts.

IRB Administrative Assistant
After the meeting, the IRB Administrative Assistant uses the notes taken during the meeting and any additional comments provided by Board Members to compile a draft of the minutes and stipulations. This draft is then sent to the IRB Administrator as a single word document.

IRB Administrator
The IRB Administrator reviews the document and either approves the language or requests revisions, as needed. The Senior Administrator or regulatory representative/Chair may be consulted in order to clarify any controverted issues regarding the Board's determination.

IRB Administrative Assistant
Once determined to be appropriate by the IRB Administrator, the IRB Administrative Assistant enters the final version of the minutes and any stipulations in the post review page of PennERA and generates the letter for the administrator to sign.
The IRB Administrative Assistant uses the Submissions page to locate the review action in PennERA and enters the finalized minutes, review decision, and vote accounts in the post review page, as well as updating the review activities page to reflect the completed action. The overall summary page of PennERA and the submission is updated to reflect the Board’s decision. The Administrative Assistant reviews the PennERA protocol's management folders and updates any applicable fields to reflect the Board’s decision.

The IRB Administrative Assistant generates the decision letter by using the communications folder for this review action. The IRB Administrative Assistant selects the appropriate letter template and builds the letter. The IRB Administrative Assistant then transfers the letter into a word document and makes revisions to ensure that the letter is appropriately formatted and accurately documents the outcome of the IRB’s review. The letter is then converted into an Adobe PDF and combines any applicable study documents with an appropriate stamp, if needed. The letter is placed in the appropriate IRB Administrator Letters to be Signed folder on the G: Drive.

IRB Administrator
The IRB Administrator reviews the letter to ensure that the information contained is accurate and appropriately formatted. The IRB Administrator may refer to the submission in HS-ERA to verify the accuracy of the document listing and template language. The IRB Administrator also ensures that the appropriate documents are attached to the letter, accurately stamped, and that PennERA has been correctly updated to reflect the new approval. If revisions to the letter are necessary the IRB Administrator informs the IRB Administrative Assistant of the required revisions and deletes the PDF of the approval letter. If revisions to the letter are not required, the IRB administrator electronically signs the PDF and saves the signed letter in the IRB Administrative Assistant Letters Signed Folder on the G: Drive. The IRB Administrator updates the PennERA review activities section for the submission to indicate that the letter has been signed.

IRB Administrative Assistant
The IRB Administrative Assistant locates the signed letter from the IRB Administrator in the Letters Signed Folder on the G: Drive. The HS-ERA modification review submission is accessed to upload the signed letter in the add decision document page. After the review decision and signed letter are selected, the letter is uploaded.

The IRB Administrative Assistant uploads the signed letter in the communications folder in the PennERA communication section and updates the review activities to indicate the letter has been signed and forwarded. An email with the signed letter and an explanation of its contents is sent to the PI, appropriate study contacts, and any other designated recipients. The signed letter is removed from the Signed Folder on the G: Drive. In certain situations, the Board’s decision may require that the continuing review submission be returned for response without approval. The IRB Administrative Assistant will return this submission after consultation with the IRB Administrator. The submission is returned using the assign to IRB field in HS-ERA.
QA Coordinator
The QA Coordinator reviews the minutes and stipulations for the continuing review once he/she receives the finalized minutes from the IRB Administrator. The QA Coordinator ensures that the minutes clearly and accurately convey the Board’s discussion and determination. Any necessary revisions to the minutes are conveyed to the IRB Administrator.
3B. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY - Paper Applications

IRB Front Desk Administrative Assistant
The convened continuing review submission is received in the IRB office once signed-off by the Principal Investigator. Upon receipt in the IRB queue, the IRB Front Desk Administrative Assistant date stamps and logs the submission in PennERA for tracking purposes. The IRB Front Desk Administrative Assistant pulls the protocol's most current file and places both the continuing review submission and file together on the distribution shelf for assignment by the Senior Administrator.

The IRB Front Desk Administrative Assistant utilizes the “Add new” field in the Submissions page to create a new Review record in PennERA. Once a new review record is created, the front desk assistant updates the review activities page to reflect this and places the submission on the distribution shelf for the Senior Administrator to assign to the appropriate IRB Administrative Assistant for screening.

ORA Administrator
The ORA Administrator checks the distribution shelf and assigns the continuing review to the appropriate IRB Administrative Assistant for screening on the next appropriate board. Once the board determination is complete, the continuing review submission is placed on the convened board shelf for the appropriate assistant for processing. The ORA Administrator notifies the assistant and IRB administrator of the new assignment via email, detailing the type of submission and any deadlines for review. The ORA Administrator may utilize the Continuing Review Submission and the PennERA Protocol Status when assessing the appropriateness of full board review.

IRB Administrative Assistant
The IRB Administrative Assistant screens the convened continuing review submission for completeness. PennERA, the continuing review submission, and previous paper submissions for the protocol are utilized to assist the IRB Administrative Assistant in his/her assessment for processing the submission.

The IRB Administrative Assistant uses the convened continuing review completeness checklist to ensure the continuing review submission has sufficient information for the Board’s consideration. This process includes, but is not limited to, verification that the enrollment numbers are consistent with previous protocol submissions and that any issues raised within the continuing review submission are appropriately addressed by the study team. The IRB Administrative Assistant verifies that no modifications are incorporated into the continuing review submission. When a modification is included within a continuing review submission, the IRB Administrative Assistant consults with the IRB Administrator to determine an appropriate course of action.

Once the IRB Administrative Assistant completes the convened review checklist, the checklist is
The IRB Administrator verifies that the required human subjects' training is present for all research personnel. If training is expired or not completed, the IRB Administrator will notify the study team and inform them that the affected research staff cannot conduct research related activity until the training has been completed.

If the IRB Administrative Assistant determines the submission is incomplete or not yet ready to be scheduled on the next appropriate meeting agenda, the submitter is emailed in notification with the issues to be addressed. The review activities field for the submission in PennERA should be updated to document the issues raised with the study team. The email correspondence with the study team and any additional documents provided are incorporated into the paper submission.

If the continuing review submission is determined to be ready for convened review, the submission is scheduled on the next appropriate meeting agenda. The IRB Administrative Assistant assigns the review action to the appropriate board and completes the agenda entry in PennERA. The IRB Administrative Assistant completes the agenda entry in PennERA by locating the review action in the Submissions page. To complete the agenda entry, the IRB Administrative Assistant uses the edit field to update the agenda entry description field, review activities, and Post-Review page to reflect the review action has been completed. Upon completion, the IRB Administrative Assistant places the continuing review submission with the checklist and study file on the convened board shelf to be verified by the appropriate IRB Administrator for the submission’s accuracy and completeness.

**IRB Administrator**
The IRB Administrator reviews the convened continuing review checklist and the agenda entry for the continuing review once he/she receives the document from the IRB Administrative Assistant. The IRB Administrator ensures that the convened continuing review checklist and the agenda entry are completed correctly. Any necessary revisions are conveyed to the IRB Administrative Assistant. If no revisions are required, the IRB Administrator signs the convened continuing review checklist and uploads it to the submission activities page of HS-ERA in the comments section. If revisions are required, the IRB Administrator ensures the revisions have been incorporated by the Administrative Assistant appropriately. The IRB Administrator then signs the convened continuing review checklist and uploads it to the submission activities page of HS-ERA in the comments section.

If at any point in the above processes, the IRB Administrator, Senior Administrator, or Regulatory Representative determines that the study is eligible for expedited IRB review, the study is then placed up for expedited review according to the procedures described in the expedited continuing reviews section.

**Board Members**
When conducting continuing reviews at a convened IRB, Penn uses a primary reviewer system. The primary reviewer presents his/her findings to the convened IRB based on their review of the
continuing review request. The Board discusses any issues with the submission raised by the primary reviewer as well as any potential added issues or questions that may be raised by other members of the board. The convened IRB considers the findings presented and makes a determination for approval, conditional re-approval, or suspension.

**IRB Administrator and Administrative Assistant**

For all voting actions, the attending IRB Administrator and Administrative Assistant ensure a quorum is present for the discussion and vote.

During the meeting, the IRB Administrator and Administrative Assistant take minutes during the discussion of the review, and generate final minutes and IRB decision letters collaboratively based on the convened meeting discussion. The minutes taken includes an overview of the review discussion by the Board, including a summary of the proposed modification request and rationale, any controverted issues and their resolutions, re-assessment of risk determination, considerations for subpart reviews and plan for re-consent (if applicable), final decision and vote counts.

**IRB Administrative Assistant**

After the meeting, the IRB Administrative Assistant uses the draft minutes taken during the meeting and any notes provided by Board Members to compile a draft of the minutes and stipulations. The draft is then sent to the IRB Administrator as a single word document.

**IRB Administrator**

The Administrator reviews the document and either approves the language or requests revisions, as needed. The senior administrator or regulatory representative/Chair may be consulted in order to clarify any controverted issues regarding the Board’s determination.

**IRB Administrative Assistant**

Once determined to be appropriate by the administrator, the assistant enters the final version of the minutes and any stipulations in the post review page of PennERA and generates the letter for the IRB Administrator to sign.

The IRB Administrative Assistant uses the Submissions page to locate the review action in PennERA and enters the finalized minutes, review decision, and vote counts in the post review page, as well as updating the review activities page to reflect the completed action. The overall summary page of PennERA and the submission is updated to reflect the changes from the Board’s decision. The Administrative Assistant reviews the PennERA protocol’s management folders and updates any applicable fields to reflect the Board’s decision.

The IRB Administrative Assistant generates the decision letter by using the communications folder for this review action. The Administrative Assistant selects the appropriate letter template and builds the letter. The Administrative Assistant then transfers the letter into a word document and makes revisions to ensure that the letter is appropriately formatted and accurately documents the outcome of the Board’s review. The letter is then converted into an Adobe PDF.
and combines any applicable study documents with an appropriate stamp, if needed. The letter is placed in the appropriate IRB Administrator Letters to be Signed folder on the G: Drive. The continuing review submission and the protocol file are placed in the IRB Administrator’s designated area for letters for signature.

**IRB Administrator**

The IRB Administrator reviews the letter to ensure that the information contained is accurate and appropriately formatted. The IRB Administrator may refer to the continuing review submission to verify the accuracy of the document listing and template language. The IRB Administrator also ensures that the appropriate documents are attached to the letter and accurately stamped and that PennERA has been correctly updated to reflect the Board’s decision. If revisions to the letter are necessary the IRB Administrator informs the IRB Administrative Assistant of the required revisions and deletes the PDF of the approval letter. If revisions to the letter are not required, the IRB administrator electronically signs the PDF and saves the signed letter in the IRB Administrative Assistant Letters Signed Folder on the G: Drive. The IRB Administrator updates the PennERA review activities section for the submission to indicate that the letter has been signed. A copy of the signed letter is printed and attached to the paper submission and protocol file. The submission is then returned to the IRB Administrative Assistant for forwarding.

**IRB Administrative Assistant**

The IRB Administrative Assistant locates the signed letter from the IRB Administrative Assistant Signed Letters Folder on the G: Drive. The IRB Administrative Assistant uploads the signed letter in the communications folder in the PennERA communication section and updates the review activities to indicate the letter has been signed and forwarded. An email with the signed letter and an explanation of its contents is sent to the PI, appropriate study contacts, and any other designated recipients. The signed letter is removed from the Signed Folder on the G: Drive. The approval letter and submission documents are placed in the paper protocol file. The IRB Administrative Assistant conducts a quality assurance review of the file to ensure that actions are organized appropriately. The IRB Administrative Assistant then returns the file to the file room.

**QA Coordinator**

The QA Coordinator reviews the minutes and stipulates for the modification once he/she receives the finalized minutes from the IRB administrator. The QA Coordinator ensures that the minutes clearly and accurately convey the Board’s discussion and determination. Any necessary revisions to the minutes are conveyed to the IRB administrator.
Research Review Processes – Modification Reviews

Modifications for Exempt Protocols

1. PROCESS OVERVIEW
This procedure outlines the review of modifications to protocols determined to meet the criteria for exemption from IRB review. Typically, the IRB does not review modifications to protocols that meet the exemption criteria. However, if the modification increases risk to subjects or increase the interaction with subjects, IRB review will be needed. The IRB may receive modifications via paper or HS-ERA depending on how the protocol was originally submitted.

2. RESPONSIBILITY
IRB Front Desk Administrative Assistant
The role of the IRB Front Desk Administrative Assistant is to receive incoming paper actions, complete initial data entry into PennERA and to place them in the designated area for distribution by the ORA Administrator.

ORA Administrator
The role of the ORA Administrator is to check for incoming modifications and assign to the appropriate IRB Staff for screening.

IRB Administrator/Appropriate IRB Staff
The role of the IRB Administrator/IRB staff person is to screen the changes to determine if the application exempt criteria still apply to the application. IRB Administrative Assistants can be designated as appropriate IRB staff after undergoing appropriate training.

IRB Administrative Assistant
The role of the IRB Administrative Assistant is to provide assistance to the IRB Administrator as needed for completion of data entry for the modification review action.

Director or Designee
The Director or designee ("reviewer") completes a secondary review of the initial action and approves the action.

3A. Procedures Employed to Implement this Policy – For HS-ERA Applications
IRB Administrator/IRB Staff person
Exempt protocols are listed as with a summary status of “No Continuing Review Required” in PennERA. This status does not allow submitters to create modifications to the protocol in HS-ERA. Because of this procedure, an IRB Administrator will typically be contacted about the process for submitting an amendment to an exempt study.

The IRB Administrator should correspond with the research regarding changes to the protocol. The IRB Administrator should determine whether the modification increases the risk to subjects.
or increase the interaction with subjects in a way which would increase the level of review to the expedited level. The IRB Administrator may consult a Senior Administrator or the Director of the IRB if there are questions regarding his determination. If no increase in risk or interaction is present in the modification, then submission to the IRB is not necessary. The IRB Administrator will inform the study team that they can incorporate their modification into the study without IRB review. If the noted changes would revise the application so that it falls within the expedited categories, the IRB Administrator should update Summary Page of PennERA to list the application as “Approved” and explain to the research team that when and how they should submit the modification in HSERA.

**ORA Administrator**

The expedited modification submission is received in the HS-ERA IRB queue once approved by the Principal Investigator. Upon receipt in the IRB queue, the status of the submission is changed from “Pending review by (Principal Investigator’s name)” to “Accepted and submitted for review”.

The ORA Administrator identifies incoming modifications that are labeled for expedited review and assigns to the appropriate IRB Administrator for screening. If possible, the modification should be routed to the administrator who completed the initial determination that the exemption should now be reviewed as expedited. The ORA Administrator utilizes the Assign to IRB admin section of HS-ERA and sorts submissions by Status so that all submissions with an “accepted and submitted for review status” appear first. The ORA Administrator uses the assign field for the submission and adds a comment to the submission detailing the type of submission and any deadlines for review. The ORA Administrator may utilize the HS-ERA Modification Submission and the PennERA Protocol Status when assessing the appropriateness of expedited review.

**IRB Administrator/Appropriate IRB Staff**

The IRB Administrator or Appropriate IRB Staff (referred to as IRB Administrator throughout this section) screens the expedited modification submission for completeness to the noted changes detailed during the conversation with the research team. PennERA, the HS-ERA modification submission, and previous HS-ERA submissions for the protocol may all be utilized to assist the administrator in his/her assessment. To determine if the submission is ready for review, the administrator looks over the modification summary, tracked changes to the online application, and any attached documents under the Review field.

The administrator should verify the submission is eligible for expedited review. In addition to this the administrator should identify new expedited categories for approval. The administrator should also make sure that there is sufficient rationale to justify any changes to the study documents and that the revisions are made consistently throughout the application. If the IRB Administrator determines the submission is incomplete or not yet ready to be reviewed, the submission is returned to the submitter for revision without approval using the assign field following the addition of a comment regarding the issues to be addressed.

**ORA Administrator**

By returning the submission, the application is opened to the research staff to address the concerns noted during review. When the research team returns the application to the IRB, the
ORA Administrator assigns the application to the IRB administrator who completed the initial review per the process above.

**IRB Administrator**
If no issues were noted during the initial review or if the issues raised by the administrator have been resolved, the IRB Administrator assigns the review action to the appropriate board using the HS-ERA assign field for the submission and adds a comment summarizing his/her findings. A modification worksheet may be uploaded in the comments section to detail the administrator’s screening and any issues raised with the study team.

The IRB Administrator places the modification submission up for expedited review in PennERA by locating the review action in the Submissions page. New categories of approval should be set on this page. The Administrator updates the review activities section to indicate that the review has been assigned. The Administrator then navigates to the post-review page and assigns the review action to the Executive Chair (or authorized designee), who will be referred to moving forward as the “reviewer.”

**Director or Designee**
The reviewer finds the submission in HS-ERA by opening the My Submissions Approvals – view assigned section. The reviewer reviews the application to determine if the criteria for expedited approval have been met and concurs with the new expedited categories. If any questions or concerns related to the criteria for approval are identified, the approver communicates these issues to the IRB Administrator. If no concerns are raised or the issues raised by the reviewer are appropriately addressed, the reviewer then approves the submission in My Submissions Approvals – view assigned section by submitting a decision for this protocol.

**IRB Administrator**
If issues are raised by the reviewer, the administrator relays those issues to the study team and may return the submission in HS-ERA if appropriate.

If at any point in the above processes, the administrator or reviewer determines that the study requires convened IRB review, a Senior IRB Administrator is notified that he/she should schedule the study for convened IRB review. The IRB Administrator should share his/her notes or comments about the submission with appropriate IRB staff.

**ORA Administrator**
The approval will be reflected in the follow day letter generation report which is forwarded to the Director and designated ORA administrators.

The ORA Administrator assigns the submission to an IRB Administrative Assistant based on the previously completed letter generation report. The ORA administrator utilizes the Assign to IRB admin section of HS-ERA and locates submissions by filtering based on the protocol number or confirmation code provided in the letter generation report. The ORA Administrator uses the assign field for the submission and adds a comment to the submission detailing the type of assignment and any deadlines for completion.
The IRB Administrative Assistant receives a notification email detailing the assignment and deadline for completion and locates the submission in assign to IRB section of HS-ERA and PennERA.

The IRB Administrative Assistant completes the data entry, as needed. The IRB Administrative Assistant uses the HS-ERA submission’s eyeglass and/or review view to identify all documents submitted for review and lists them into the review (general) page and Post-Review page in PennERA. The Administrative Assistant reviews the HS-ERA comments section to determine if any notes or supplemental language should be added to the approval letter and lists those comments on the Post-Review page. The overall summary page of PennERA and the submission is updated to reflect the changes from the modification submission. The Administrative Assistant reviews the PennERA protocol’s management folders and updates any applicable fields to reflect the modification approval.

The IRB Administrative Assistant generates the approval letter by using the communications folder for this review action. The Assistant selects the appropriate letter template and builds the letter. The assistant then transfers the letter into a word document and makes revisions to ensure that the letter is appropriately formatted and accurately documents the outcome of the IRB’s review. The letter is then converted into an Adobe PDF and combines any applicable study documents with an appropriate stamp, if needed. The letter is placed in the appropriate IRB Administrator Letters to be Signed folder on the G: Drive.

The IRB Administrative Assistant locates the signed letter from the IRB Administrator in the Signed Folder on the G: Drive. The HS-ERA modification Submission is accessed to upload the signed letter in the add decision document page. After the review decision and signed letter are selected, the letter is uploaded.

The IRB Administrative Assistant uploads the signed letter in the communications folder in the
PennERA communication section and indicates through the review activities as sent and uploaded. An email with the signed letter and an explanation of its contents is sent to the PI, appropriate study contacts, and any other designated recipients. The signed letter is removed from the Signed Folder on the G: Drive.

3B. Procedures Employed to Implement this Policy for Paper Applications

IRB Front Desk Administrative Assistant
The exempt modification submission is received in the IRB office once signed-off by the Principal Investigator. Upon receipt in the IRB queue, the IRB Front Desk Administrative Assistant date stamps and logs the submission in PennERA for tracking purposes. The IRB Front Desk Administrative Assistant utilizes the “Add new” field in the Submissions page to create a new Amendment record in PennERA. Once a new Review record is created, the front desk assistant updates the review activities page to reflect the action is complete. The IRB Front Desk Administrative Assistant pulls the protocol’s most current file and places both the modification submission and file together on the distribution shelf for assignment by the ORA Administrator.

ORA Administrator
The ORA administrator checks the distribution shelf and assigns the submission to IRB Staff for screening. The ORA Administrator writes the type of assignment and deadlines for completion on the paper submission. The reviewer places the submission and protocol file in the IRB Administrator’s designated area for new expedited screening assignments.

IRB Administrator/Appropriate IRB Staff
The IRB Administrator or Appropriate IRB Staff (referred to as IRB Administrator throughout this section) reviews the modification to determine if the modification increase the risk to subjects or increase the interaction in such a way as to change this application fall within the expedited categories for review. The administrator should communicate with the research team to obtain further information if the noted changes are not clear or if additional information is necessary to make the determination. If the modification changes allow the application to remain within the exempt categories, the IRB administrator notifies the research team via email to explain that the submission was not required and destroys the paper documents.

If the modification does increase the application to the expedited categories, the IRB administrator guides the research team to submit a new initial application within the HSERA system and the procedures outlined in the new initial expedited reviews should be followed once the new application is submitted to the IRB.
Research Review Processes – Modification Reviews

Modifications Eligible for Expedited Review

1. PROCESS OVERVIEW
This procedure outlines the review of expedited modifications submitted via the HS-ERA electronic submission system and the paper submission process.

2. RESPONSIBILITY

IRB Front Desk Administrative Assistant
The role of the FD IRB associate is to receive incoming paper actions, complete initial data entry into PennERA and to place them in the designated area for distribution by the ORA Administrator.

ORA Administrator
The role of the ORA Administrator is to check for incoming modifications and assign to the appropriate IRB Administrator/Staff person for review.

IRB Administrator/Appropriate IRB Staff
The role of the IRB Administrator/IRB staff person is to review the action, complete preliminary data entry, and assign the review action to the appropriate IRB board. IRB Administrative Assistants can be designated as appropriate IRB staff after undergoing appropriate training.

IRB Administrative Assistant
The role of the IRB Administrative Assistant is to provide assistance to the IRB Administrator as needed for completion of data entry for the review action. The Administrative Assistant is also responsible for drafting the IRB approval letter for the action.

Director or Designee
The Director or designee completes a secondary review of the action and approves the action.

3A. Procedures Employed to Implement this Policy – For HS-ERA Applications

ORA Administrator
The expedited modification submission is received in the HS-ERA IRB queue once approved by the Principal Investigator. Upon receipt in the IRB queue, the status of the submission is changed from “Pending review by (Principal Investigator’s name)” to “Accepted and submitted for review”.

The ORA Administrator identifies incoming modifications that are labeled for expedited review and assigns to the appropriate IRB Staff for screening. The administrator utilizes the Assign to IRB admin section of HS-ERA and sorts submissions by Status so that all submissions with an “accepted and submitted for review status” appear first. The ORA Administrator uses the assign...
field for the submission and adds a comment to the submission detailing the type of submission and any deadlines for review. The ORA Administrator may utilize the HS-ERA Modification Submission and the PennERA Protocol Status when assessing the appropriateness of expedited review.

**IRB Administrator/Appropriate IRB Staff**

The IRB Administrator or Appropriate IRB Staff (referred to as IRB Administrator throughout this section) screens the expedited modification submission for completeness. PennERA, the HS-ERA modification submission, and previous HS-ERA submissions for the protocol may all be utilized to assist the administrator in his/her assessment. To determine if the submission is ready for review, the administrator looks over the modification summary, tracked changes to the online application, and any attached documents under the Review field.

The administrator should verify the submission is eligible for expedited review and that the revised application continues to meet the criteria for approval. The IRB Administrator should also ensure that there is sufficient rationale to justify the changes to the study documents and that the revisions are made consistently throughout the application.

The IRB Administrator verifies that the required human subjects’ training is present for all research personnel. If training is expired or not completed, the IRB Administrator will notify the study team and inform them that the affected research staff cannot conduct research related activity until the training has been completed.

If the IRB Administrator determines the submission is incomplete or not yet ready to be reviewed, the submission is returned to the submitter for revision without approval using the assign field following the addition of a comment detailing the issues to be addressed.

**ORA Administrator**

By returning the submission, the application is opened to the research staff to address the concerns noted during review. When the research team returns the application to the IRB, the ORA Administrator assigns the application to the IRB administrator who completed the initial review per the process above.

**IRB Administrator/Appropriate IRB Staff Person**

If no issues were noted during the initial review or if the issues raised by the administrator have been resolved, the IRB Administrator/Appropriate IRB staff person assigns the review action to the appropriate board using the HS-ERA assign field for the submission and adds a comment summarizing his/her findings. A modification worksheet may be uploaded in the comments section to detail the IRB Staff’s screening and any issues identified with the study team.

The IRB staff member places the modification submission up for expedited review in PennERA by locating the review action in the Submissions page. The staff member updates the review activities section to indicate that the reviewer has been assigned. The staff member then navigates to the post-review page and assigns the review action to the Executive Chair (or
Director or Designee
The reviewer finds the submission in HS-ERA by opening the My Submissions Approvals – view assigned section. The reviewer reviews the application to determine if the criteria for expedited approval have been met. If any questions or concerns related to the criteria for approval are identified, the approver communicates these issues to the IRB administrator. If no concerns are raised or the issues raised by the reviewer are appropriately addressed, the reviewer then approves the submission in My Submissions Approvals – view assigned section by submitting a decision for this protocol.

IRB Administrator
If issues are raised by the reviewer, the administrator relays those issues to the study team and may return the submission in HS-ERA if appropriate.

If at any point in the above processes, the administrator or reviewer determines that the study requires convened IRB review, a Senior IRB Administrator is notified that he/she should schedule the study for convened IRB review. The IRB Administrator should share his/her notes or comments about the submission with appropriate IRB staff.

ORA Administrator
The approval will be reflected in the follow day’s letter generation report which is forwarded to the Director and designated ORA Administrators.

The ORA Administrator assigns the submission to an IRB Administrative Assistant based on the previously completed letter generation report. The ORA Administrator utilizes the Assign to IRB admin section of HS-ERA and locates submissions by filtering based on the protocol number or confirmation code provided in the letter generation report. The ORA Administrator uses the assign field for the submission and adds a comment to the submission detailing the type of assignment and any deadlines for completion.

IRB Administrative Assistant
The IRB Administrative Assistant receives a notification email detailing the assignment and deadline for completion and locates the submission in assign to IRB section of HS-ERA and PennERA.

The IRB Administrative Assistant completes the data entry, as needed. The IRB Administrative Assistant uses the HS-ERA submission’s eyeglass and/or review view to identify all documents submitted for review and lists them into the review (general) page and Post-Review page in PennERA. The Administrative Assistant reviews the HS-ERA comments section to determine if any notes or supplemental language should be added to the approval letter and lists those comments on the Post-Review page. The overall summary page of PennERA and the submission is updated to reflect the changes from the modification submission. The Administrative Assistant reviews the PennERA protocol’s management folders and updates any applicable fields to reflect the modification approval.
The IRB Administrative Assistant generates the approval letter by using the communications folder for this review action. The Assistant selects the appropriate letter template and builds the letter. The assistant then transfers the letter into a word document and makes revisions to ensure that the letter is appropriately formatted and accurately documents the outcome of the IRB’s review. The letter is then converted into an Adobe PDF and combines any applicable study documents with an appropriate stamp, if needed. The letter is placed in the appropriate IRB Administrator Letters to be Signed folder on the G: Drive.

IRB Administrator
The IRB Administrator reviews the letter to ensure that the information contained is accurate and appropriately formatted. The Administrator may refer to the submission in HS-ERA to verify the accuracy of the document listing and template language. The Administrator also ensures that the appropriate documents are attached to the letter and accurately stamped and that PennERA has been correctly updates to reflect the new approval. If revisions to the letter are necessary the Administrator informs the Assistant of the required revisions and deletes the PDF of the approval letter. If revisions to the letter are not required, the IRB administrator electronically signs the PDF and saves the signed letter in the IRB Administrative Assistant Letters Signed Folder on the G: Drive. The IRB administrator updates the PennERA review activities section for the submission to indicate that the letter has been signed.

IRB Administrative Assistant
The IRB Administrative Assistant locates the signed letter from the IRB Administrator in the Signed Folder on the G: Drive. The HS-ERA modification Submission is accessed to upload the signed letter in the add decision document page. After the review decision and signed letter are selected, the letter is uploaded.

The IRB Administrative Assistant uploads the signed letter in the communications folder in the PennERA communication section and indicates through the review activities as sent and uploaded. An email with the signed letter and an explanation of its contents is sent to the PI, appropriate study contacts, and any other designated recipients. The signed letter is removed from the Signed Folder on the G: Drive.
3B. Procedures Employed to Implement this Policy for Paper applications

IRB Front Desk Administrative Assistant
The expedited modification submission is received in the IRB office once signed-off by the Principal Investigator. Upon receipt in the IRB queue, the IRB Front Desk Administrative Assistant date stamps and logs the submission in PennERA for tracking purposes. The IRB Front Desk Administrative Assistant utilizes the “Add new” field in the Submissions page to create a new Amendment review record in PennERA. Once a new amendment record is created, the front desk assistant updates the review activities page to reflect this. The IRB Front Desk Administrative Assistant pulls the protocol’s most current file and places both the modification submission and file together on the distribution shelf for assignment by the ORA Administrator.

ORA Administrator
The ORA administrator checks the distribution shelf and assigns the submission to IRB staff for screening. The ORA Administrator writes the type of assignment and deadlines for completion on the paper submission. The reviewer places the submission and protocol file in the IRB administrators designated area for new expedited screening assignments.

IRB Administrator/Appropriate IRB Staff
The IRB Administrator or Appropriate IRB Staff (referred to as IRB Administrator throughout this section) screens the expedited modification submission for completeness. PennERA, the modification submission, and previous submissions in the protocol file may all be utilized to assist the administrator in his/her assessment. The IRB Administrator should verify the submission is eligible for expedited review and that the revised application continues to meet the criteria for approval. The IRB Administrator should also make sure that there is sufficient rationale to justify any changes to the study documents and that the revisions are made consistently throughout the application.

If the IRB Administrator determines the submission is incomplete or not yet ready to be reviewed, the submitter is emailed a notification with the issues to be addressed. The review activities field for the submission in PennERA should be updated to document the issues raised with the study team. The email correspondence with the study team and any additional documents provided are incorporated into the paper submission.

The IRB Administrator verifies that the required human subjects’ training is present for all research personnel. If training is expired or not completed, the IRB Administrator will notify the study team and inform them that the affected research staff cannot conduct research related activity until the training has been completed.

If no concerns are raised or the issues raised by the administrator have been appropriately addressed, the IRB Administrator places the submission up for expedited review in PennERA by
locating the review action in the Submissions page. The IRB Administrator updates the review activities section to indicate that the reviewer has been assigned. The administrator then navigates to the post-review page and assigns the review action to the Executive Chair (or authorized designee), who will be referred to moving forward as the “reviewer.” The submission and the file are then placed in the designated location for expedited paper reviews.

**Director or Designee**
The reviewer checks the location for expedited paper reviews and determines if the criteria for expedited approval have been met. If any questions or concerns related to the criteria for approval are identified, the approver communicates these issues to the IRB Administrator and returns the submission and protocol file. If no concerns are raised or the issues raised by the reviewer are appropriately addressed, the reviewer affixes his/her approval comments and signature.

**IRB Administrator**
If issues are raised by the reviewer, the administrator relays those issues to the study team. The study team’s response and any additional documents are incorporated into the submission and the submission and file are returned to the designated location for expedited reviews. If at any point in the above processes, the administrator or reviewer determines that the study requires convened IRB review, a Senior IRB Administrator is notified that he/she should schedule the study for convened IRB review. The IRB Administrator should share his/her notes or comments about the submission with appropriate IRB staff.

**ORA Administrator/IRB Senior Staff**
After the submission is approved, the reviewer assigns the submission to an IRB Administrative Assistant for letter generation. The reviewer writes the type of assignment and deadlines for completion on the paper submission. The reviewer places the submission and protocol file in the assistants designated area for letter generation assignments.

**IRB Administrative Assistant**
The IRB Administrative Assistant retrieves the modification from his/her designated area and locates the submission in PennERA.

The IRB Administrative Assistant completes the data entry, as needed. The IRB Administrative Assistant reviews the paper documents and lists them into the review (general) page and Post-Review page in PennERA. The IRB Administrative Assistant reviews the documents to determine if any notes or supplemental language should be added to the approval letter and lists those comments on the Post-review page. The overall summary page of PennERA and the submission is updated to reflect the changes from the modification submission. The Administrative Assistant reviews the PennERA protocol’s management folders and updates any applicable fields to reflect the modification approval.

The IRB Administrative Assistant generates the approval letter by using the communications
folder for this review action. The IRB Administrative Assistant selects the appropriate letter template and builds the letter. The IRB Administrative Assistant then transfers the letter into a word document and makes revisions to ensure that the letter is appropriately formatted and accurately documents the outcome of the IRB's review. The letter is then converted into an Adobe PDF. Any applicable study documents are scanned into PDFs and affixed with an appropriate stamp, if needed. The letter and scanned documents are combined and placed in the appropriate IRB Administrator Letters to be Signed folder on the G: Drive. The paper submission and protocol are file are placed in the IRB Administrator's designated area for letters to be signed.

IRB Administrator
The IRB Administrator reviews the letter to ensure that the information contained is accurate and appropriately formatted. The Administrator may refer to the paper submission to verify the accuracy of the document listing and template language. The administrator also ensures that the appropriate documents are attached to the letter and accurately stamped and that PennERA has been correctly updated to reflect the new approval. If revisions to the letter are necessary the administrator informs the assistant of the required revisions, deletes the PDF of the approval letter, and returns the submission and protocol file to the IRB administrative assistant. If revisions to the letter are not required, the IRB administrator electronically signs the PDF and saves the signed letter in the IRB Administrative Assistant Letters Signed Folder on the G: Drive. The IRB Administrator updates the PennERA review activities section for the submission to indicate that the letter has been signed. A copy of the signed letter is printed and attached to the paper submission and protocol file. The submission is then returned to the Administrative Assistant for forwarding.

IRB Administrative Assistant
The IRB Administrative Assistant locates the signed letter from the IRB Administrative Assistant Signed Letters Folder on the G: Drive. The IRB Administrative Assistant uploads the signed letter in the communications folder in the PennERA communication section and updates the review activities to indicate the letter has been signed and forwarded. An email with the signed letter and an explanation of its contents is sent to the PI, appropriate study contacts, and any other designated recipients. The signed letter is removed from the Signed Folder on the G: Drive. The approval letter and submission documents are placed in the paper protocol file. The Assistant conducts a quality assurance review of the file to ensure that actions are organized appropriately. The Assistant then returns the file to the file room.
Research Review Processes – Modification Reviews

Modifications Requiring Convened Review

1. PROCESS OVERVIEW
This procedure outlines the review of amendments that require convened review for ongoing projects that have already approved by the IRB and were submitted within the HS-ERA electronic submission system and paper submission process.

2. RESPONSIBILITY

IRB Front Desk Administrative Assistant
The role of the IRB Desk Front Administrative Assistant is to receive incoming paper actions, complete initial data entry into PennERA and to place the action in the designated area for distribution by the ORA Administrator.

ORA Administrator
The role of the ORA Administrator is to check for incoming convened modifications and assign to the appropriate IRB Administrator for screening and scheduling for the next appropriate board. The ORA Administrator is also responsible for re-assignment of convened modifications to the IRB Administrative Assistant for post-meeting follow-up.

IRB Administrator
The role of the IRB Administrator is to screen the convened modification assigned to them for processing, assess for completeness of the application, complete data entry, and assign the review action to the appropriate meeting agenda and reviewer. The IRB Administrator is also responsible for initial review of minutes and letters completed by the IRB Administrative Assistant for the convened modification review action to assess for appropriateness and accuracy of content.

IRB Administrative Assistant
The role of the IRB Administrative Assistant is to provide assistance to the IRB Administrator as needed for completion of data entry for the convened modification review action. The Administrative Assistant is also responsible for completion of minutes for the convened modification action as well as drafting the IRB decision letter for the convened modification review.

Senior Administrator
The Senior Administrator is responsible for supporting the IRB administrator as needed. The Senior Administrator may be consulted to ensure that modifications are appropriate to schedule for convened review.

Board Members
The role of the board member is to review the action prior to the IRB meeting, discuss the action during the meeting, and ultimately make a final determination about the action. The member can contact the research team prior to the meeting to have questions about the action addressed for use during the discussion.

3A. Procedures Employed to Implement this Policy For HS-ERA applications

ORA Administrator
The convened modification submission is received in the HS-ERA IRB queue once approved by the Principal Investigator. Upon receipt in the IRB queue, the status of the submission is changed from “Pending review by (Principal Investigator’s name)” to “Accepted and submitted for review”.

The ORA Administrator identifies incoming modifications that are labeled for full board review and assigns to the appropriate IRB Administrator for screening on the next available meeting agenda. The ORA Administrator utilizes the Assign to IRB admin section of HS-ERA and sorts submissions by Status so that all submissions with an “accepted and submitted for review status” appear first. The ORA Administrator uses the assign field for the submission and adds a comment to the submission detailing the type of submission and any deadlines for review. The ORA Administrator may utilize the HS-ERA Modification Submission and the PennERA Protocol Status when assessing the appropriateness of full board review. The ORA Administrator also considers the volume of actions scheduled and the expertise of the Board when determining which Board should review the modification.

IRB Administrator
The IRB Administrator screens the convened modification action for completeness and determines if the submission is ready for scheduling on the next available meeting agenda.

To screen the modification submission, the administrator utilizes the Assign to IRB section of HS-ERA and sorts submissions by Status so that all submissions with an “assign to (IRB administrator name)” appear first or via a search of the submission using the confirmation code and/or protocol number from the email notification provided at receipt of the assignment. The administrator uses the Review field for the submission and completes the screening.

To determine if the submission is ready for review, the IRB Administrator looks over the modification summary, tracked changes to the online application, and any attached documents under the Review field. The IRB Administrator should ensure the submission has sufficient information for the Board’s consideration including a summary of changes for the modification request, rationale for the proposed revisions, and tracked/clean version of the revised documents.

The IRB Administrator verifies that the required human subjects’ training is present for all research personnel. If training is expired or not completed, the IRB Administrator will notify the study team and inform them that the affected research staff cannot conduct research related activity until the training has been completed.

If the IRB Administrator determines the submission is incomplete or not yet ready to be
scheduled on the next appropriate meeting agenda, the submission is returned to the submitter for revision without approval using the assign field following addition of a comment regarding the issues to be addressed.

**ORA Administrator**

By returning the submission, the application is opened to the research staff to address the concerns noted during review. When the research team returns the application to the IRB, the ORA Administrator assigns the application to the IRB Administrator who completed the initial review per the process above.

**IRB Administrator**

If no issues were noted or if the issues raised by the IRB Administrator have been resolved, the IRB Administrator scheduled the submission for the next available meeting agenda. The administrator assigns the review action to the appropriate board using the HS-ERA assign field for the submission and adds a comment detailing why the modification requires convened review and which IRB meeting agenda the review has been scheduled for.

The IRB Administrator begins the agenda entry in PennERA by locating the review action in the Submissions page. The IRB Administrator uses the edit field to update the agenda entry description field, review activities, and post review pages to reflect that the review action has been scheduled.

**ORA Administrator**

The IRB Administrative Assistant may be asked to assist the administrator in completion of the agenda entry, as needed, upon which an ORA Administrator is notified to re-assign the full board modification in HS-ERA to the assistant to complete data entry.

**IRB Administrative Assistant**

Upon notification of the assignment, the assistant locates the review action in the Submissions page in PennERA and uses the edit field to update the agenda entry description field, review activities, and post review pages to reflect the review action has been completed.

If at any point in the above processes, the IRB Administrator, Senior Administrator, or Regulatory Representative determines that the study requires expedited IRB review, the study is then placed up for expedited review according to the procedures described in the expedited modifications section.

**Board Members**

When conducting modification review at a convened IRB, Penn uses a primary reviewer system for modification review. The primary reviewer presents their findings to the convened IRB based on their review of the modification request. The Board discusses any issues with the submission raised by the primary reviewer as well as any potential issues or questions that may be raised by other members of the Board. The convened IRB considers the findings presented and makes a determination for approval, withheld approval, tabling, or disapproval of the
IRB Administrator and Administrative Assistant
For all voting actions, the IRB Administrator and Assistant present at the meeting ensure a quorum is present for the discussion and vote.

The IRB Administrator and Administrative Assistant take minutes during the discussion of the review, and generate final minutes and IRB decision letters collaboratively based on the convened meeting discussion. The minutes taken include an overview of the review discussion by the Board, including a summary of the proposed modification request and rationale, any controverted issues and their resolutions, re-assessment of risk determination, considerations for subpart reviews and plan for re-consent (if applicable), final decision and vote counts.

IRB Administrative Assistant
After the meeting, the IRB Administrative Assistant uses the notes taken during the meeting and any additional comments provided by Board Members to compile a draft of the minutes and stipulations. This draft is then sent to the IRB Administrator as a single word document.

IRB Administrator
The IRB Administrator reviews the document and either approves the language or requests revisions, as needed. The senior administrator or regulatory representative/Chair may be consulted in order to clarify any controverted issues regarding the Board’s determination.

IRB Administrative Assistant
Once determined to be appropriate by the administrator; the assistant enters the final version of the minutes and any stipulations in the post review page of PennERA and generates the letter for the administrator to sign.

The IRB Administrative Assistant uses the Submissions page to locate the review action in PennERA and enters the finalized minutes, review decision, and vote accounts in the post review page, as well as updating the review activities page to reflect the completed action. The overall summary page of PennERA and the submission is updated to reflect the changes from the Board’s decision. The IRB Administrative Assistant reviews the PennERA protocol’s management folders and updates any applicable fields to reflect the Board’s decision.

The IRB Administrative Assistant generates the decision letter by using the communications folder for this review action. The IRB Administrative Assistant selects the appropriate letter template and builds the letter. The IRB Administrative Assistant then transfers the letter into a word document and makes revisions to ensure that the letter is appropriately formatted and accurately documents the outcome of the IRB’s review. The letter is then converted into an Adobe PDF and combines any applicable study documents with an appropriate stamp, if needed. The letter is placed in the appropriate IRB Administrator Letters to be Signed folder on the G: Drive.
IRB Administrator

The IRB Administrator reviews the letter to ensure that the information contained is accurate and appropriately formatted. The Administrator may refer to the submission in HS-ERA to verify the accuracy of the document listing and template language. The administrator also ensures that the appropriate documents are attached to the letter and accurately stamped and that PennERA has been correctly updated to reflect the new approval. If revisions to the letter are necessary the administrator informs the assistant of the required revisions and deletes the PDF of the approval letter. If revisions to the letter are not required, the IRB administrator electronically signs the PDF and saves the signed letter in the IRB Administrative Assistant Letters Signed Folder on the G: Drive. The IRB administrator updates the PennERA review activities section for the submission to indicate that the letter has been signed.

IRB Administrative Assistant

The IRB Administrative Assistant locates the signed letter from the IRB Administrator in the Letters Signed Folder on the G: Drive. The HS-ERA modification review submission is accessed to upload the signed letter in the add decision document page. After the review decision and signed letter are selected, the letter is uploaded.

The IRB Administrative Assistant uploads the signed letter in the communications folder in the PennERA communication section and updates the review activities to indicate the letter has been signed and forwarded. An email with the signed letter and an explanation of its contents is sent to the PI, appropriate study contacts, and any other designated recipients. The signed letter is removed from the Signed Folder on the G: Drive.

QA Coordinator

The QA Coordinator reviews the minutes and stipulations for the modification once he/she receives the finalized minutes from the IRB administrator. The QA Coordinator ensures that the minutes clearly and accurately convey the Board’s discussion and determination. Any necessary revisions to the minutes are conveyed to the IRB administrator.

3B. Procedures Employed to Implement this Policy for Paper Applications

IRB Front Desk Administrative Assistant
The convened modification submission is received in the IRB office once signed-off by the Principal Investigator. Upon receipt in the IRB queue, the IRB Front Desk Administrative Assistant date stamps and logs the submission in PennERA for tracking purposes. The IRB Front Desk Administrative Assistant pulls the protocol’s most current file and places both the modification submission and file together on the distribution shelf for assignment by the Senior Administrator.

The IRB Front Desk Administrative Assistant utilizes the “Add new” field in the Submissions page to create a new Amendment review record in PennERA. Once a new amendment record is created, the front desk assistant updates the review activities page to reflect and places the submission on the distribution shelf for the Senior Administrator to assign to the appropriate IRB Administrator for processing.

ORA Administrator
The ORA Administrator checks the distribution shelf and assigns the modification to the appropriate IRB Administrator for screening on the next available meeting agenda. Once the board determination is complete, the modification submission is placed on the convened board shelf for the appropriate IRB Administrator for processing. The ORA Administrator notifies the administrator of the new assignment via email, detailing the type of submission and any deadlines for review. The ORA Administrator may utilize the Modification Submission and the PennERA Protocol Status when assessing the appropriateness of full board review. The ORA Administrator also considers the volume of actions scheduled and the expertise of the Board when determining which Board should review the modification.

IRB Administrator
The IRB Administrator screens the convened modification action for completeness and determines if the submission is ready for scheduling on the next available meeting agenda.

To screen the modification submission, the administrator utilizes the Modification Submission and the Protocol File. The administrator should ensure the submission has sufficient information for the Board’s consideration including a summary of changes for the modification request, rationale for the proposed revisions, and tracked/clean version of the revised documents.

If the IRB Administrator determines the submission is incomplete or not yet ready to be scheduled on the next appropriate meeting agenda, the submitter is emailed in notification with the issues to be addressed. The review activities field for the submission in PennERA should be updated to document the issues raised with the study team. The email correspondence with the study team and any additional documents provided are incorporated into the paper submission.

The IRB Administrator verifies that the required human subjects’ training is present for all research personnel. If training is expired or not completed, the IRB Administrator will notify the study team and inform them that the affected research staff cannot conduct research related activity until the training has been completed.

If the submission is ready for scheduling on the next available meeting agenda, the IRB Administrator assigns the review action to the appropriate board and completes the agenda entry in PennERA.
The IRB Administrator completes the agenda entry in PennERA by locating the review action in the Submissions page. To complete the agenda entry, the IRB Administrator uses the edit field to update the agenda entry description field, review activities, and post review pages to reflect the review action has been completed.

IRB Administrative Assistant
The IRB Administrative Assistant may be asked to assist the administrator in completion of the agenda entry, as needed, upon which the modification submission and protocol file will be forwarded to the assistant to complete data entry.

Upon notification of the assignment, the assistant locates the review action in the Submissions page in PennERA and uses the edit field to update the agenda entry description field, review activities, and post review pages to reflect the review action has been completed.

If at any point in the above processes, the IRB Administrator, Senior Administrator, or Regulatory Representative determines that the study requires expedited IRB review, the study is then placed up for expedited review.

Board Members
When conducting modification review at a convened IRB, Penn uses a primary reviewer system for modification review. The primary reviewer presents their findings to the convened IRB based on their review of the modification request. The Board discusses any issues with the submission raised by the primary reviewer as well as any potential added issues or questions that may be raised by other members of the board. The convened IRB considers the findings presented and makes a determination for approval, withheld approval, tabling, or disapproval of the modification.

IRB Administrator and Administrative Assistant
For all voting actions, the IRB Administrator and Administrative Assistant present at the meeting ensure a quorum is present for the discussion and vote.

During the meeting, the IRB Administrator and Administrative Assistant take minutes during the discussion of the review, and generate final minutes and IRB decision letters collaboratively based on the convened meeting discussion. The minutes taken includes an overview of the review discussion by the Board, including a summary of the proposed modification request and rationale, any controverted issues and their resolutions, re-assessment of risk determination, considerations for subpart reviews and plan for re-consent (if applicable), final decision and vote counts.

IRB Administrative Assistant
After the meeting, the IRB Administrative Assistant uses the notes taken during the meeting and any additional comments provided by Board Members to compile a draft of the minutes and stipulations. This draft is then sent to the IRB Administrator as a single word document.

IRB Administrator
The IRB Administrator reviews the document and either approves the language or requests revisions, as needed. The Senior Administrator or Regulatory Representative may be consulted in order to clarify and controverted issues regarding the Board’s determination.

IRB Administrative Assistant
Once determined to be appropriate by the administrator, the assistant enters the final version of
the minutes and any stipulations in the post review page of PennERA and generates the letter
for the administrator to sign.

The IRB Administrative Assistant uses the Submissions page to locate the review action in
PennERA and enters the finalized minutes, review decision, and vote accounts in the post
review page, as well as updating the review activities page to reflect the completed action. The
overall summary page of PennERA and the submission is updated to reflect the changes from
the Board’s decision. The administrative Assistant reviews the PennERA protocol’s
management folders and updates any applicable fields to reflect the Board’s decision.

The IRB Administrative Assistant generates the decision letter by using the communications
folder for this review action. The IRB Administrative Assistant selects the appropriate letter
template and builds the letter. The IRB Administrative Assistant then transfers the letter into a
word document and makes revisions to ensure that the letter is appropriately formatted and
accurately documents the outcome of the IRB’s review. The letter is then converted into an
Adobe PDF and combines any applicable study documents with an appropriate stamp, if
needed. The letter is placed in the appropriate IRB Administrator Letters to be Signed folder on
the G: Drive. The modification submission and the protocol file are placed in the IRB
administrator’s designated area for letters for signature.

**IRB Administrator**

The IRB Administrator reviews the letter to ensure that the information contained is accurate
and appropriately formatted. The Administrator may refer to the modification submission to
verify the accuracy of the document listing and template language. The IRB Administrator also
ensures that the appropriate documents are attached to the letter and accurately stamped and
that PennERA has been correctly updated to reflect the Board’s decision. If revisions to the
letter are necessary the administrator informs the assistant of the required revisions and deletes
the PDF of the approval letter. If revisions to the letter are not required, the IRB administrator
electronically signs the PDF and saves the signed letter in the IRB Administrative Assistant
Letters Signed Folder on the G: Drive. The IRB Administrator updates the PennERA review
activities section for the submission to indicate that the letter has been signed. A copy of the
signed letter is printed and attached to the paper submission and protocol file. The submission
is then returned to the Administrative Assistant for forwarding.

**IRB Administrative Assistant**

The IRB Administrative Assistant locates the signed letter from the IRB Administrative Assistant
Signed Letters Folder on the G: Drive. The IRB Administrative Assistant uploads the signed
letter in the communications folder in the PennERA communication section and updates the
review activities to indicate the letter has been signed and forwarded. An email with the signed
letter and an explanation of its contents is sent to the PI, appropriate study contacts, and any
other designated recipients. The signed letter is removed from the Signed Folder on the G:
Drive. The approval letter and submission documents are placed in the paper protocol file. The
Assistant conducts a quality assurance review of the file to ensure that actions are organized
appropriately. The Assistant then returns the file to the file room.

**QA Coordinator**

The QA Coordinator reviews the minutes and stipulates for the modification once he/she
receives the finalized minutes from the IRB administrator. The QA Coordinator ensures that the
minutes clearly and accurately convey the Board’s discussion and determination. Any necessary revisions to the minutes are conveyed to the IRB administrator.
Research Review Processes – Modification Reviews

Review of Convened Responses to Convened Modifications and Continuing Reviews

1. PROCESS OVERVIEW
This procedure outlines the review processes for responses to stipulations raised during review of modifications and continuing reviews by the convened IRB. This section applies to responses that require convened review. This section details the procedures for Responses submitted through the paper and electronic submission processes.

2. RESPONSIBILITY

IRB Administrator/Administrative Assistant
The role of the IRB Administrator or Administrative Assistant is to screen the convened response assigned to them for processing, assess for completeness of the application, complete data entry, and assign the review action to the appropriate meeting agenda and reviewer. The IRB Administrator or Administrative Assistant is also responsible for completion of minutes and letters for the response review action.

ORA Administrator
The role of the ORA Administrator is to check for incoming convened responses and assign to the appropriate IRB Administrator for screening and scheduling for the next appropriate board. The ORA Administrator is also responsible for re-assignment of convened responses to the IRB Administrator for re-submitted protocols.

IRB Senior Administrator
The IRB Senior Administrator is responsible for supporting the IRB administrator as needed. The Senior Administrator may be consulted to ensure that the modification is appropriate to schedule for convened review.

IRB Board Members
The role of the IRB Board Member is to review the protocol submission to determine if the criteria for approval have been met, assess the protocol for any controverted issues and raise the issues for discussion during the meeting, along with their resolutions, and vote on the risk assessment and final review decision.

Regulatory Representative
The regulatory representative is a senior member of the IRB staff (typically the Director or Associate Director) who serves as an IRB Board Member. In addition to Board Member duties the Regulatory Representative also provides expertise on federal regulations and Penn policy and provides guidance in order to ensure that policies are applied consistently across all Penn Boards. The regulatory representative also provides assistance to the IRB administrator by discussing potential issues prior to the meeting and reviewing minutes and letters generated after the meeting.
3A. Procedures Employed to Implement this Policy For HS-ERA applications

ORA Administrator:
The ORA Administrator identifies incoming response that requires full board review and assigns to the appropriate IRB Administrator for screening. The ORA Administrator utilizes the Assign to IRB admin section of HS-ERA and sorts submissions by Status so that all submissions with an “accepted and submitted for review status” appear first. The ORA Administrator uses the assign field for the submission and adds a comment to the submission detailing the type of submission and any deadlines for review. The ORA Administrator conducts an initial pre-screen of the protocol and assess for appropriateness of level of review required.

IRB Administrator:
Upon receipt of the assignment, the IRB Administrator assigns the re-submission to the designated board per the ORA Administrator’s comment in HS-ERA using the HS-ERA assign field for the re-submission.

Responses to modifications that are tabled by the convened IRB at the time of review require Convened Board review. Responses to continuing reviews that are suspended or terminated also require Convened Board review. Responses to modifications that received Withheld Approval by the Convened IRB at the time of review require Convened Board review when the Board’s stipulations have not been addressed or an additional substantive modification has been submitted for concurrent review. The IRB Administrator should consult with the IRB Senior Administrator to verify that the Response to Withheld re-submission requires Convened Board review.

The IRB Administrator screens the response submission for completeness. The IRB Administrator creates a summary document that outlines the stipulations raised by the Board in the manner in which they appear in the initial withheld approval letter. Below each stipulation, the administrator should summarize the response provided by the study team and any comments that should be brought to the reviewer’s attention. The summary document should also include the minutes from the Board’s initial review of the submission.

To determine if the response submission is ready for convened review, the administrator reviews the online application and any attached documents under the HS-ERA Review field, verified that the required changes were made, as well as to check for tracked/clean copies of any revised documents.

If the IRB Administrator determines the submission is incomplete or not yet ready to be scheduled on the next appropriate meeting agenda, the submission is returned to the submitter for response without approval using the assign field following addition of a comment regarding the issues to be addressed.

ORA Administrator
By returning the submission, the application is opened to the research staff to address the concerns noted during review. When the research team returns the application to the IRB, the ORA Administrator assigns the application to the IRB administrator who completed the initial review per the process above.

**IRB Administrator**

If no issues were noted or if the issues raised by the IRB Administrator have been resolved, the IRB Administrator scheduled the submission for the next appropriate meeting agenda. The administrator assigns the review action to the appropriate board using the HS-ERA assign field for the submission and adds a comment detailing why the response requires convened review and which IRB meeting agenda the review has been scheduled for.

The IRB Administrator begins the agenda entry in PennERA by locating the review action in the Submissions page. The IRB Administrator uses the edit field to update the agenda entry description field, review activities, and post review pages to reflect the review action have been scheduled.

**ORA Administrator**

The IRB Administrative Assistant may be asked to assist the administrator in completion of the agenda entry, as needed, upon which an ORA Administrator is notified to re-assign the full board response in HS-ERA to the assistant to complete data entry.

**IRB Administrative Assistant**

Upon notification of the assignment, the assistant locates the review action in the Submissions page in PennERA and uses the edit field to update the agenda entry description field, review activities, and post review pages to reflect the review action has been completed.

**Board Members**

When conducting response review at a convened IRB, Penn uses a primary reviewer system for the review. The primary reviewer presents their findings to the convened IRB based on their review of the modification request. The Board discusses any issues with the submission raised by the primary reviewer as well as any potential issues or questions that may be raised by other members of the Board. The convened IRB considers the findings presented and makes a determination for approval, withheld approval, tabling, or disapproval of the modification.

**IRB Administrator and Administrative Assistant**

For all voting actions, the IRB Administrator and Assistant present at the meeting ensure a quorum is present for the discussion and vote.

The IRB Administrator and Administrative Assistant take minutes during the discussion of the review, and generate final minutes and IRB decision letters collaboratively based on the convened meeting discussion. The minutes taken includes an overview of the review discussion by the Board, including a summary of the proposed modification request and rationale, any controverted issues and their resolutions, re-assessment of risk determination, considerations
IRB Administrative Assistant
After the meeting, the IRB Administrative Assistant uses the notes taken during the meeting and any additional comments provided by Board Members to compile a draft of the minutes and stipulations. This draft is then sent to the IRB Administrator as a single word document.

IRB Administrator
The IRB Administrator reviews the document and either approves the language or requests revisions, as needed. The senior administrator or regulatory representative may be consulted in order to clarify any controverted issues regarding the Board’s determination.

IRB Administrative Assistant
Once determined to be appropriate by the administrator; the assistant enters the final version of the minutes and any stipulations in the post review page of PennERA and generates the letter for the administrator to sign.

The IRB Administrative Assistant uses the Submissions page to locate the review action in PennERA and enters the finalized minutes, review decision, and vote accounts in the post review page, as well as updating the review activities page to reflect the completed action. The overall summary page of PennERA and the submission is updated to reflect the changes from the Board’s decision. The Administrative Assistant reviews the PennERA protocol’s management folders and updates any applicable fields to reflect the Board’s decision.

The IRB Administrative Assistant generates the decision letter by using the communications folder for this review action. The administrative assistant selects the appropriate letter template and builds the letter. The assistant then transfers the letter into a word document and makes revisions to ensure that the letter is appropriately formatted and accurately documents the outcome of the IRB’s review. The letter is then converted into an Adobe PDF and combines any applicable study documents with an appropriate stamp, if needed. The letter is placed in the appropriate IRB Administrator Letters to be Signed folder on the G: Drive.

IRB Administrator
The IRB Administrator reviews the letter to ensure that the information contained is accurate and appropriately formatted. The Administrator may refer to the submission in HS-ERA to verify the accuracy of the document listing and template language. The IRB Administrator also ensures that the appropriate documents are attached to the letter and accurately stamped and that PennERA has been correctly updated to reflect the new approval. If revisions to the letter are necessary the administrator informs the assistant of the required revisions and deletes the PDF of the approval letter. If revisions to the letter are not required, the IRB Administrator electronically signs the PDF and saves the signed letter in the IRB Administrative Assistant Letters Signed Folder on the G: Drive. The IRB administrator updates the PennERA review activities section for the submission to indicate that the letter has been signed.
IRB Administrative Assistant

The IRB Administrative Assistant locates the signed letter from the IRB Administrator in the Letters Signed Folder on the G: Drive. The HS-ERA modification review submission is accessed to upload the signed letter in the add decision document page. After the review decision and signed letter are selected, the letter is uploaded.

The IRB Administrative Assistant uploads the signed letter in the communications folder in the PennERA communication section and updates the review activities to indicate the letter has been signed and forwarded. An email with the signed letter and an explanation of its contents is sent to the PI, appropriate study contacts, and any other designated recipients. The signed letter is removed from the Signed Folder on the G: Drive.

QA Coordinator

The QA Coordinator reviews the minutes and stipulations for the modification once he/she receives the finalized minutes from the IRB administrator. The QA Coordinator ensures that the minutes clearly and accurately convey the Board’s discussion and determination. Any necessary revisions to the minutes are conveyed to the IRB administrator.

3B. Procedures Employed to Implement this Policy for Paper Applications

IRB Front Desk Administrative Assistant

The convened modification response is received in the IRB office once signed-off by the Principal Investigator. Upon receipt in the IRB queue, the IRB Front Desk Administrative Assistant date stamps and logs the submission in PennERA for tracking purposes. The IRB Front Desk Administrative Assistant pulls the protocol’s most current file and places both the modification submission and file together on the distribution shelf for assignment by the Senior Administrator.

The IRB Front Desk Administrative Assistant utilizes the “Add new” field in the Submissions page to create a new Amendment review record in PennERA. Once a new amendment record is created, the front desk assistant updates the review activities page to reflect this and places the submission on the distribution shelf for the ORA Administrator to assign to the appropriate IRB Administrator for processing.

ORA Administrator

The ORA Administrator checks the distribution shelf and assigns the response to the appropriate IRB Administrator for screening on the next available meeting agenda. Once the board determination is complete, the submission is placed on the convened board shelf for the appropriate Administrator for processing. The ORA Administrator notifies the administrator of the new assignment via email, detailing the type of submission and any deadlines for review. The ORA Administrator may utilize the Submission and the PennERA Protocol Status when assessing the appropriateness of full board review.

IRB Administrator

Responses to modifications that are tabled by the convened IRB at the time of review require Convened Board review. Responses to continuing reviews that are suspended or terminated also required Convened Board review. Responses to modifications that received Withheld
Approval by the Convened IRB at the time of review require Convened Board review when the Board’s stipulations have not been addressed or an additional substantive modification has been submitted for concurrent review. The IRB Administrator should consult with the IRB Senior Administrator to verify that the Response to Withheld re-submission requires Convened Board review.

The IRB Administrator screens the response submission for completeness. The IRB Administrator creates a summary document that outlines the stipulations raised by the Board in the manner in which they appear in the initial withheld approval letter. Below each stipulation, the administrator should summarize the response provided by the study team and any comments that should be brought to the reviewer’s attention. The summary document should also include the minutes from the Board’s initial review of the submission.

To determine if the response submission is ready for convened review, the IRB Administrator reviews the documents submitted and the protocol file, verifies that the required changes were made, as well as checking for tracked/clean copies of any revised documents.

If the IRB Administrator determines the submission is incomplete or not yet ready to be scheduled on the next appropriate meeting agenda, the submitter is emailed in notification with the issues to be addressed. The review activities field for the submission in PennERA should be updated to document the issues raised with the study team. The email correspondence with the study team and any additional documents provided are incorporated into the paper submission.

If the submission is ready for scheduling on the next available meeting agenda, the IRB Administrator assigns the review action to the appropriate board and completes the agenda entry in PennERA.

The IRB Administrator completes the agenda entry in PennERA by locating the review action in the Submissions page. To complete the agenda entry, the IRB Administrator uses the edit field to update the agenda entry description field, review activities, and post review pages to reflect the review action has been completed.

**IRB Administrative Assistant**

The IRB Administrative Assistant may be asked to assist the administrator in completion of the agenda entry, as needed, upon which the modification submission and protocol file will be forwarded to the assistant to complete data entry.

Upon notification of the assignment, the assistant locates the review action in the Submissions page in PennERA and uses the edit field to update the agenda entry description field, review activities, and post review pages to reflect the review action has been completed.

**Board Members**

When conducting modification response reviews at a convened IRB, Penn uses a primary reviewer system for modification review. The primary reviewer presents his/her findings to the convened IRB based on his/her review of the modification request. The board discusses any issues with the submission raised by the primary reviewer as well as any potential added issues or questions that may be raised by other members of the board. The convened IRB considers
the findings presented and makes a determination for approval, withheld approval, tabling, or disapproval of the modification.

**IRB Administrator and Administrative Assistant**

For all voting actions, the IRB Administrator and Assistant present at the meeting ensures a quorum is present for the discussion and vote.

During the meeting, the IRB Administrator and Administrative Assistant take minutes during the discussion of the review, and generate final minutes and IRB decision letters collaboratively based on the convened meeting discussion. The minutes taken includes an overview of the review discussion by the Board, including a summary of the proposed modification request and rationale, any controverted issues and their resolutions, re-assessment of risk determination, considerations for subpart reviews and plan for re-consent (if applicable), final decision and vote counts.

**IRB Administrative Assistant**

After the meeting, the IRB Administrative Assistant uses the notes taken during the meeting and any additional comments provided by Board Members to compile a draft of the minutes and stipulations. This draft is then sent to the IRB Administrator as a single word document.

**IRB Administrator**

The administrator reviews the document and either approves the language or requests revisions, as needed. The senior administrator or regulatory representative/Chair may be consulted in order to clarify and controverted issues regarding the Board’s determination.

**IRB Administrative Assistant**

Once determined to be appropriate by the IRB Administrator, the IRB Administrative Assistant enters the final version of the minutes and any stipulations in the post review page of PennERA and generates the letter for the IRB Administrator to sign.

The IRB Administrative Assistant uses the Submissions page to locate the review action in PennERA and enters the finalized minutes, review decision, and vote accounts in the post review page, as well as updating the review activities page to reflect the completed action. The overall summary page of PennERA and the submission is updated to reflect the changes from the Board’s decision. The IRB Administrative Assistant reviews the PennERA protocol’s management folders and updates any applicable fields to reflect the Board’s decision.

The IRB Administrative Assistant generates the decision letter by using the communications folder for this review action. The IRB Administrative Assistant selects the appropriate letter template and builds the letter. The IRB Administrative Assistant then transfers the letter into a word document and makes revisions to ensure that the letter is appropriately formatted and accurately documents the outcome of the IRB’s review. The letter is then converted into an Adobe PDF and combines any applicable study documents with an appropriate stamp, if needed. The letter is placed in the appropriate IRB Administrator Letters to be Signed folder on the G: Drive. The modification submission and the protocol file are placed in the IRB administrator’s designated area for letters for signature.

**IRB Administrator**

The IRB Administrator reviews the letter to ensure that the information contained is accurate and appropriately formatted. The IRB Administrator may refer to the modification submission to verify the accuracy of the document listing and template language. The administrator also
ensures that the appropriate documents are attached to the letter and accurately stamped and that PennERA has been correctly updated to reflect the Board’s decision. If revisions to the letter are necessary the administrator informs the assistant of the required revisions and deletes the PDF of the approval letter. If revisions to the letter are not required, the IRB administrator electronically signs the PDF and saves the signed letter in the IRB Administrative Assistant Letters Signed Folder on the G: Drive. The IRB administrator updates the PennERA review activities section for the submission to indicate that the letter has been signed. A copy of the signed letter is printed and attached to the paper submission and protocol file. The submission is then returned to the Administrative Assistant for forwarding.

IRB Administrative Assistant
The IRB Administrative Assistant locates the signed letter from the IRB Administrative Assistant Signed Letters Folder on the G: Drive. The IRB Administrative Assistant uploads the signed letter in the communications folder in the PennERA communication section and updates the review activities to indicate the letter has been signed and forwarded. An email with the signed letter and an explanation of its contents is sent to the PI, appropriate study contacts, and any other designated recipients. The signed letter is removed from the Signed Folder on the G: Drive. The approval letter and submission documents are placed in the paper protocol file. The IRB Administrative Assistant conducts a quality assurance review of the file to ensure that actions are organized appropriately. The IRB Administrative Assistant then returns the file to the file room.

QA Coordinator
The QA Coordinator reviews the minutes and stipulates for the modification once he/she receives the finalized minutes from the IRB administrator. The QA Coordinator ensures that the minutes clearly and accurately convey the Board’s discussion and determination. Any necessary revisions to the minutes are conveyed to the IRB administrator.
Research Review Processes – Modification Reviews

Review of Expedited Responses to Convened Modifications and Continuing Reviews

1. PROCESS OVERVIEW
This procedure outlines the review processes for responses to stipulations raised during review by the convened IRB of modification and continuing review submissions. This section applies to responses that are eligible for expedited review. This section details the procedures for Responses submitted through the paper and electronic submission processes.

2. RESPONSIBILITY

ORA Administrator
The role of the ORA Administrator is to check for incoming response submissions and assign to the appropriate IRB Administrator for review.

IRB Administrator/Appropriate IRB Staff
The role of the IRB Administrator is to review the response, complete data entry, and assign the review action to the appropriate IRB board. IRB Administrative assistants can be designated as appropriate IRB staff after undergoing appropriate training.

IRB Administrative Assistant
The role of the IRB Administrative Assistant is to provide assistance to the IRB Administrator as needed for completion of data entry for the initial review action. The Administrative Assistant is also responsible for drafting the IRB approval letter for the action.

IRB Chair or Designee
The IRB Chair or other appropriate IRB member completes a secondary review of the action and approves the action.

3A. Procedures Employed to Implement this Policy – For HS-ERA Applications

ORA Administrator
The response submission to Modification withheld approval or Continuing Review conditional re-approval decisions is received in the HS-ERA IRB queue once accepted by the submitter for submission to the IRB. Once accepted for submission to the IRB, the status of the submission is updated from “draft” to “accepted and submitted for review”.

The ORA Administrator identifies incoming response submissions to IRB withheld approval or conditional re-approval decisions and assigns to the appropriate IRB Administrative Assistant for screening. The ORA Administrator utilizes the Assign to IRB admin section of HS-ERA and sorts submissions by Status so that all submissions with an “accepted and submitted for review status” appear first. The ORA Administrator uses the view icon next to the submission to identify who the response submission should be assigned to. The ORA Administrator uses the assign field for the submission and adds a comment to the submission detailing the type of submission and any deadlines for review.
IRB Administrator/Appropriate IRB Staff
The IRB Administrator or Appropriate IRB Staff (referred to as IRB administrator throughout this section) screens the response submission for completeness. The Administrator creates a summary document that outlines the stipulations raised by the Board in the manner in which they appear in the modification withheld approval letter or continuing review conditional re-approval letter. Below each stipulation, the Administrator should summarize the response provided by the study team and any comments that should be brought to the reviewer’s attention.

To determine if the response submission is ready for final review, the IRB Administrator looks over the online application and any attached documents under the HS-ERA Review field, ensuring a copy of the response cover letter is attached as well as tracked/clean copies of any revised documents.

The IRB Administrator verifies that the required human subjects' training is present for all research personnel. If training is expired or not completed, the IRB Administrator will notify the study team and inform them that the affected research staff cannot conduct research related activity until the training has been completed.

During the screening of the response submission, the IRB Administrator should verify the submission is eligible for expedited review. Consult may be sought from the Senior IRB Administrator in assessing whether the response requires review by the convened IRB.

If the IRB Administrator determines the submission is incomplete or not yet ready for final review, the submission is returned to the submitter for response without approval using the assign field following the addition of a comment regarding the issues to be addressed. If the issues were identified after the response submission has been assigned to the board, the IRB Administrator updates the decision of the review from “logged” to “issue identified” using the review field of the PennERA and ensures that the updated decision is reflected in HS-ERA before returning.

ORA Administrator
By returning the submission, the application is opened to the research staff to address the concerns noted during review. When the research team returns the application to the IRB, the ORA Administrator assigns the application to the IRB Administrator who completed the initial review of the response submission per the process above.

IRB Administrator
If no issues requiring returning of the submission were noted during the initial screen or if the issues raised by the IRB Administrator upon returning of the submission have been resolved, the IRB Administrator finalizes the assignment to the IRB Chair or designee by updating the PennERA Summary and Review page. The IRB Administrator completes the agenda entry in PennERA by locating the review action in the Submissions page. The IRB Administrator uses
the edit field to update the agenda entry description field, review activities, and post review pages to reflect the review action has been assigned to the IRB Chair or designee.

The IRB Administrator ensures the data entry is complete in PennERA and is reflective of the review notes as outlined in the HS-ERA pre-review notes and includes appropriate language for inclusion in the final approval letter.

The IRB Administrator adds a comment in HS-ERA detailing the submission is ready for final review and uploads a copy of the response summary document. The IRB Chair or Designee is then notified via email for final review.

**IRB Chair or Designee**
The IRB Chair or Designee is notified of the pending assignment upon receipt of email notification from the IRB Administrator. The reviewer locates the submission in HS-ERA by opening the My Submissions Approvals – view assigned section. The reviewer reviews the application to determine concurrence with the IRB Administrator’s assessment that all stipulations have been appropriately addressed. If any questions or concerns related to the response submission are identified, the approver communicates these issues to the IRB Administrator. If no concerns are raised and the issues raised by the IRB Administrator upon pre-review are appropriately addressed, the reviewer then approves the submission in My Submissions Approvals – view assigned section by submitting a decision for this protocol.

**IRB Administrator**
If issues are raised by the reviewer, the IRB Administrator relays those issues to the study team and may return the submission in HS-ERA for response without approval if appropriate.

If the response submission introduces a component of the research which warrants convened board review or if the study team refuses to address the Board’s stipulations, the IRB Administrator would then follow the procedures for processing convened responses to continuing reviews or modifications as described in the convened responses section. If at any point in the above processes, the IRB Administrator, or Chair/designee determines that the study requires convened IRB review, the Senior IRB Administrator is notified that the response submission will need to be scheduled for convened IRB review. The IRB Administrator (with consult from the Senior Administrator) should share his/her notes or comments about the submission with the appropriate IRB Administrator and IRB Administrative Assistant.

**ORA Administrator**
The approval will be reflected in the follow day’s letter generation report which is forwarded to the Director and designated ORA administrators.

The ORA Administrator assigns the submission to an IRB Administrative Assistant based on the previously completed letter generation report. The ORA administrator utilizes the Assign to IRB admin section of HS-ERA and locates submissions by filtering based on the protocol number or confirmation code provided in the letter generation report. The ORA Administrator uses the
assign field for the submission and adds a comment to the submission detailing the type of assignment and any deadlines for completion.

**IRB Administrative Assistant**
The IRB Administrative Assistant receives a notification email detailing the assignment and deadline for completion and locates the submission in assign to IRB section of HS-ERA and PennERA.

The IRB Administrative Assistant completes the data entry, as needed. The IRB Administrative Assistant uses the HS-ERA submission’s eyeglass and/or review view to identify all documents submitted for review and verifies the document listing in the review (general) page and Post-Review page in PennERA. The Administrative Assistant reviews the HS-ERA comments section to determine if any notes or supplemental language should be added to the approval letter and ensures those comments are listed on the Post-Review page. The overall summary page of PennERA and the submission is updated to reflect the changes from the new approval. The Administrative Assistant reviews the PennERA protocol’s management folders and updates any applicable fields to reflect the protocol approval.

The IRB Administrative Assistant generates the approval letter by using the communications folder for this review action. The IRB Administrative Assistant selects the appropriate letter template and builds the letter. The assistant then transfers the letter into a word document and makes revisions to ensure that the letter is appropriately formatted and accurately documents the outcome of the IRB’s review. The letter is then converted into an Adobe PDF and combines any applicable study documents with an appropriate stamp, if needed. The letter is placed in the appropriate IRB Administrator Letters to be Signed folder on the G: Drive.

**IRB Administrator**
The IRB Administrator reviews the letter to ensure that the information contained is accurate and appropriately formatted. The IRB Administrator may refer to the submission in HS-ERA to verify the accuracy of the document listing and template language. The IRB Administrator also ensures that the appropriate documents are attached to the letter and accurately stamped and that PennERA has been correctly updated to reflect the new approval. If revisions to the letter are necessary the Administrator informs the Assistant of the required revisions and deletes the PDF of the approval letter. If revisions to the letter are not required, the IRB Administrator electronically signs the PDF and saves the signed letter in the IRB Administrative Assistant Letters Signed Folder on the G: Drive. The IRB Administrator updates the PennERA review activities section for the submission to indicate that the letter has been signed.

**IRB Administrative Assistant**
The IRB Administrative Assistant locates the signed letter from the IRB Administrator in the Signed Folder on the G: Drive. The HS-ERA modification Submission is accessed to upload the signed letter in the add decision document page. After the review decision and signed letter are selected, the letter is uploaded.
The IRB Administrative Assistant uploads the signed letter in the communications folder in the PennERA communication section and indicates through the review activities as sent and uploaded. An email with the signed letter and an explanation of its contents is sent to the PI, appropriate study contacts, and any other designated recipients. The signed letter is removed from the Signed Folder on the G: Drive.

3B. Procedures Employed to Implement this Policy – For Paper Submissions

IRB Front Desk Administrative Assistant
The expedited response to Modification withheld approval or Continuing Review conditional re-approval is received in the IRB office once signed-off by the Principal Investigator. Upon receipt in the IRB queue, the IRB Front Desk Administrative Assistant date stamps and logs the submission in PennERA for tracking purposes. The IRB Front Desk Administrative Assistant utilizes the “Add new” field in the Submissions page to create a new Review record in PennERA. Once a new Review record is created, the front desk assistant updates the review activities page to reflect this task is complete. The IRB Front Desk Administrative Assistant pulls the protocol’s most current file and places both the response submission and file together on the distribution shelf for assignment by the ORA Administrator.

ORA Administrator
The ORA administrator checks the distribution shelf and assigns the response submission to IRB Staff for screening. The ORA administrator writes the type of assignment and deadlines for completion on the paper submission. The reviewer places the submission and protocol file in the IRB Staff’s designated area for response screening assignments.

IRB Administrator/Appropriate IRB Staff
The IRB Administrator or Appropriate IRB Staff (referred to as IRB Administrator throughout this section) screens the response submission for completeness. The IRB Administrator creates a summary document that outlines the stipulations raised by the Board in the manner in which they appear in the modification withheld approval letter or continuing review conditional re-approval letter. Below each stipulation, the IRB Administrator should summarize the response provided by the study team and any comments that should be brought to the reviewer’s attention.

To determine if the response submission is ready for final review, the IRB Administrator looks over the study documents and the file, ensuring a copy of the response cover letter is attached as well as tracked/clean copies of any revised documents.

The IRB Administrator verifies that the required human subjects’ training is present for all research personnel. If training is expired or not completed, the IRB Administrator will notify the study team and inform them that the affected research staff cannot conduct research related activity until the training has been completed.

During the screening of the response submission, the IRB Administrator should verify the
submit is eligible for expedited review. Consult may be sought from a Senior IRB Administrator in assessing whether the response requires review by the convened IRB.

If the IRB Administrator determines the submission is incomplete or not yet ready for final review, the IRB Administrator contacts the study team regarding the issues to be addressed. The IRB Administrator updates the review activities to “outgoing correspondence” to reflect the issues raised during the screening process. The email correspondence with the study team and any additional documents provided are incorporated into the paper submission.

If no concerns are raised or the issues raised by the IRB Administrator have been appropriately addressed, the IRB Administrator places the submission up for expedited review in PennERA by locating the review action in the Submissions page. The IRB Administrator updates the review activities section to indicate that the review has been assigned the administrator then navigates to the post-review page and assigns the review action to the Executive Chair (or authorized designee), who will be referred to moving forward as the “reviewer.” The submission and the file are then placed in the designated location for expedited paper reviews.

IRB Chair or Designee
The reviewer checks the location for expedited paper reviews and reviews the submission to determine concurrence with the IRB Administrator’s assessment that all stipulations have been appropriately addressed. If any questions or concerns related to the criteria for approval are identified, the approver communicates these issues to the IRB administrator and returns the submission and protocol file. If no concerns are raised or the issues raised by the reviewer are appropriately addressed, the reviewer affix his/her approval comments and signature.

IRB Administrator If issues are raised by the reviewer, the IRB Administrator relays those issues to the study team. The study team’s response and any additional documents are incorporated into the submission and the submission and file are returned to the designated location for expedited reviews.

If the response submission introduces a component of the research which warrants convened board review or if the study team refuses to address the Board’s stipulations, the IRB Administrator would then follow the procedures for processing convened responses to continuing reviews or modifications as outlined in convened responses section. If at any point in the above processes, the IRB Administrator, or Chair/designee determines that the study requires convened IRB review, the Senior IRB Administrator is notified that the response submission will need to be scheduled for convened IRB review. The IRB Administrator (with consult from the Senior Administrator) should share his/her notes or comments about the submission with the appropriate IRB Administrator and IRB Administrative Assistant (if not the same administrator/assistant who had processed the responses submission).

ORA Administrator/IRB Senior Staff
After the submission is approved, the reviewer assigns the submission to an IRB Administrative Assistant for letter generation. The reviewer writes the type of assignment and deadlines for
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completion on the paper submission. The reviewer places the submission and protocol file in the assistants designated area for letter generation assignments.

**IRB Administrative Assistant**
The IRB Administrative Assistant retrieves the response submission from his/her designated area and locates the submission in PennERA.

The IRB Administrative Assistant completes the data entry, as needed. The IRB Administrative Assistant reviews the paper documents and lists them into the review (general) page and Post-Review page in PennERA. The Administrative Assistant reviews the documents to determine if any notes or supplemental language should be added to the approval letter and lists those comments on the Post-review page. The overall summary page of PennERA and the submission is updated to reflect any changes from the response submission. The Administrative Assistant reviews the PennERA protocol’s management folders and updates any applicable fields to reflect the modification approval.

The IRB Administrative Assistant generates the approval letter by using the communications folder for this review action. The Assistant selects the appropriate letter template and builds the letter. The Assistant then transfers the letter into a word document and makes revisions to ensure that the letter is appropriately formatted and accurately documents the outcome of the IRB’s review. The letter is then converted into an Adobe PDF. Any applicable study documents are scanned into PDFs and affixed with an appropriate stamp, if needed. The letter and scanned documents are combined and placed in the appropriate IRB Administrator Letters to be Signed folder on the G: Drive. The paper submission and protocol are file are placed in the IRB Administrator’s designated area for letters to be signed.

**IRB Administrator**
The IRB Administrator reviews the letter to ensure that the information contained is accurate and appropriately formatted. The IRB Administrator may refer to the paper submission to verify the accuracy of the document listing and template language. The IRB Administrator also ensures that the appropriate documents are attached to the letter and accurately stamped and that PennERA has been correctly updated to reflect the new approval. If revisions to the letter are necessary the administrator informs the assistant of the required revisions, deletes the PDF of the approval letter, and returns the submission and protocol file to the IRB Administrative Assistant. If revisions to the letter are not required, the IRB administrator electronically signs the PDF and saves the signed letter in the IRB Administrative Assistant Letters Signed Folder on the G: Drive. The IRB administrator updates the PennERA review activities section for the submission to indicate that the letter has been signed. A copy of the signed letter is printed and attached to the paper submission and protocol file. The submission is then returned to the Administrative Assistant for forwarding.

**IRB Administrative Assistant**
The IRB Administrative Assistant locates the signed letter from the IRB Administrative Assistant Signed Letters Folder on the G: Drive. The IRB Administrative Assistant uploads the signed
letter in the communications folder in the PennERA communication section and updates the review activities to indicate the letter has been signed and forwarded. An email with the signed letter and an explanation of its contents is sent to the PI, appropriate study contacts, and any other designated recipients. The signed letter is removed from the Signed Folder on the G: Drive. The approval letter and submission documents are placed in the paper protocol file. The IRB Administrative Assistant conducts a quality assurance review of the file to ensure that actions are organized appropriately. The Assistant then returns the file to the file room.
Research Review Processes – Modification Reviews

Deviation Submissions

1. PROCESS OVERVIEW
This procedure outlines the review processes for reports of protocol deviations submitted to the IRB via the paper and electronic submission processes.

2. RESPONSIBILITY
ORA Administrator
The role of the ORA Administrator is to check for incoming submissions and assign to the appropriate IRB Administrator for review.

IRB Administrator
The role of the IRB Administrator is to review the submission, begin data entry, and assign the review action to the appropriate IRB board.

IRB Administrative Assistant
The role of the IRB Administrative Assistant is to provide assistance to the IRB Administrator as needed for completion of data entry for the initial review action. The Administrative Assistant is also responsible for drafting the IRB approval letter for the action.

IRB Director or Designee
The IRB Director or designee (“reviewer”) completes a secondary review of the action and acknowledges the action and may require further action, if appropriate.

Procedures Employed to Implement this Policy – For HS-ERA Applications
ORA Administrator
The deviation submission is received in the HS-ERA IRB queue once approved by the Principal Investigator. Upon receipt in the IRB queue, the status of the submission is changed from “Pending review by (Principal Investigator’s name)” to “Accepted and submitted for review”.

The ORA Administrator identifies incoming deviation requests that are labeled for expedited review and assigns to the appropriate IRB Administrator for screening. The ORA administrator considers the complexity of the deviation and whether a timely review is required when determining which staff member should screen the deviation. If the deviation has the potential to qualify as a reportable event, the process outlined in the reportable event section below should be followed. The administrator utilizes the Assign to IRB admin section of HS-ERA and sorts submissions by Status so that all submissions with an “accepted and submitted for review status” appear first. The ORA Administrator uses the assign field for the submission and adds a comment to the submission detailing the type of submission and any deadlines for review. The ORA Administrator may utilize the HS-ERA Modification-deviation Submission and the PennERA Protocol Status when assessing the appropriateness of expedited review.

IRB Administrator
The IRB Administrator screens the expedited deviation submission for completeness. PennERA, the HS-ERA modification-deviation submission, and previous HS-ERA submissions for the protocol may all be utilized to assist the administrator in his/her assessment. To
determine if the submission is ready for review, the administrator looks over the modification-deviation summary, any tracked changes to the online application (if the deviation request results in a permanent change to the protocol), and any attached documents under the Review field.

The IRB Administrator should verify the submission is eligible for expedited review and that the revised application (if applicable) continues to meet the criteria for acknowledgement and/or approval. The administrator should also make sure that there is sufficient detail to evaluate the deviation report, consider the study team’s corrective action plan, justify any changes to the study documents, and that the revisions are made consistently throughout the application. A consult review from the Director, Associate Director or Executive Chair may be necessary to determine what questions should be raised to the study team.

If the IRB Administrator determines the submission is incomplete or not yet ready to be reviewed, the submission is returned to the submitter for revision without approval using the assign field following the addition of a comment regarding the issues to be addressed.

ORA Administrator
By returning the submission, the application is opened to the research staff to address the concerns noted during review. When the research team returns the application to the IRB, the ORA Administrator assigns the application to the IRB Administrator who completed the initial review per the process above.

IRB Administrator
If no issues were noted during the initial review or if the issues raised by the administrator have been resolved, the IRB Administrator assigns the review action to the appropriate board using the HS-ERA assign field for the submission and adds a comment summarizing his/her findings. A modification worksheet may be uploaded in the comments section to detail the administrator’s screening and any issues raised with the study team.

The IRB Administrator places the modification-deviation submission up for expedited review in PennERA by locating the review action in the Submissions page. The IRB Administrator updates the review activities section to indicate that the review has been assigned. The Administrator then navigates to the post-review page and assigns the review action to the Executive Chair (or authorized designee), who will be referred to moving forward as the “reviewer.”

Director or Designee
The reviewer finds the submission in HS-ERA by opening the My Submissions Approvals – view assigned section. The reviewer reviews the application to determine if the criteria for expedited acknowledgement and/or approval have been met. If any questions or concerns related to the criteria for acknowledgement and/or approval are identified, the approver communicates these issues to the IRB administrator. If no concerns are raised or the issues raised by the reviewer are appropriately addressed, the reviewer then acknowledges and/or approves the submission in My Submissions Approvals – view assigned section by submitting a decision for this protocol.

IRB Administrator
If issues are raised by the reviewer, the IRB Administrator relays those issues to the study team and may return the submission in HS-ERA if appropriate.

If at any point in the above processes, it is determined that the deviation(s) requires convened
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IRB review, the appropriate IRB staff member is notified that he/she should schedule the study for convened IRB review. If the Staff member processing the deviation is not the Administrator for the Board in which the deviation is being scheduled, the IRB Staff member should share his/her notes or comments about the submission with appropriate IRB staff.

**ORA Administrator**
The acknowledgement and/or approval will be reflected in the following day’s letter generation report which is forwarded to the Director and designated ORA administrators.

The ORA Administrator assigns the submission to an IRB Administrative Assistant based on the previously completed letter generation report. The ORA Administrator utilizes the Assign to IRB admin section of HS-ERA and locates submissions by filtering based on the protocol number or confirmation code provided in the letter generation report. The ORA Administrator uses the assign field for the submission and adds a comment to the submission detailing the type of assignment and any deadlines for completion.

**IRB Administrative Assistant**
The IRB Administrative Assistant receives a notification email detailing the assignment and deadline for completion and locates the submission in assign to IRB section of HS-ERA and PennERA.

The IRB Administrative Assistant completes the data entry, as needed. The IRB Administrative Assistant uses the HS-ERA submission’s eyeglass and/or review view to identify all documents submitted for review and lists them into the review (general) page and Post-Review page in PennERA. The Administrative Assistant reviews the HS-ERA comments section to determine if any notes or supplemental language should be added to the acknowledgement and/or approval letter and lists those comments on the Post-Review page. The overall summary page of PennERA and the submission is updated to reflect the changes from the modification-deviation submission. The Administrative Assistant reviews the PennERA protocol’s management folders and updates any applicable fields to reflect the modification-deviation (and approval if appropriate).

The IRB Administrative Assistant generates the acknowledgement and/or approval letter by using the communications folder for this review action. The Assistant selects the appropriate letter template and builds the letter. The assistant then transfers the letter into a word document and makes revisions to ensure that the letter is appropriately formatted and accurately documents the outcome of the IRB’s review. The letter is then converted into an Adobe PDF and combines any applicable study documents with an appropriate stamp, if needed. The letter is placed in the appropriate IRB Administrator Letters to be Signed folder on the G: Drive.

**IRB Administrator**
The IRB Administrator reviews the letter to ensure that the information contained is accurate and appropriately formatted. The Administrator may refer to the submission in HS-ERA to verify the accuracy of the document listing and template language. The Administrator also ensures that the appropriate documents are attached to the letter and accurately stamped and that PennERA has been correctly updated to reflect the new acknowledgement and/or approval (if appropriate). If revisions to the letter are necessary the IRB Administrator informs the Assistant of the required revisions and deletes the PDF of the acknowledgement and/or approval letter. If revisions to the letter are not required, the IRB Administrator electronically signs the PDF and saves the signed letter in the IRB Administrative Assistant Letters Signed Folder on the G: Drive. The IRB administrator updates the PennERA review activities section for the submission.
The IRB Administrative Assistant locates the signed letter from the IRB Administrator in the Signed Folder on the G: Drive. The HS-ERA Modification-deviation Submission is accessed to upload the signed letter in the add decision document page. After the review decision and signed letter are selected, the letter is uploaded.

The IRB Administrative Assistant uploads the signed letter in the communications folder in the PennERA communication section and indicates through the review activities as sent and uploaded. An email with the signed letter and an explanation of its contents is sent to the PI, appropriate study contacts, and any other designated recipients. The signed letter is removed from the Signed Folder on the G: Drive.
Procedures Employed to Implement this Policy For Paper Applications

IRB Front Desk Administrative Assistant
The expedited modification-deviation submission is received in the IRB office once signed-off by the Principal Investigator. Upon receipt in the IRB queue, the IRB Front Desk Administrative Assistant date stamps and logs the submission in PennERA for tracking purposes. The IRB Front Desk Administrative Assistant utilizes the “Add new” field in the Submissions page to create a new Amendment review record in PennERA. Once a new amendment record is created, the front desk assistant updates the review activities page to reflect this task is complete. The IRB Front Desk Administrative Assistant pulls the protocol’s most current file and places both the modification-deviation submission and file together on the distribution shelf for assignment by the ORA Administrator.

ORA Administrator
The ORA administrator checks the distribution shelf and assigns the submission to an IRB Administrator for screening. The ORA administrator considers the complexity of the deviation and whether a timely review is required when determining which staff member should screen the deviation.

The ORA administrator writes the type of assignment and deadlines for completion on the paper submission. The reviewer places the submission and protocol file in the IRB administrators designated area for new expedited screening assignments.

IRB Administrator
The IRB Administrator screens the expedited modification-deviation submission for completeness. PennERA, the modification-deviation submission, and previous submissions in the protocol file may all be utilized to assist the administrator in his/her assessment. The administrator should verify the submission is eligible for expedited review and that the revised application continues to meet the criteria for acknowledgement and/or approval. The administrator should also make sure that there is sufficient detail to evaluate the deviation report, consider the study team’s corrective action plan, justify any changes to the study documents, and that the revisions are made consistently throughout the application. A consult review from the Director, Associate Director or Executive Chair may be necessary to determine what questions should be raised to the study team.

If the IRB Administrator determined the submission is incomplete or not yet ready to be reviewed, the submitter is emailed a notification with the issues to be addressed. The review activities field for the submission in PennERA should be updated to document the issues raised with the study team. The email correspondence with the study team and any additional documents provided are incorporated into the paper submission.

If no concerns are raised or the issues raised by the IRB Administrator have been appropriately addressed, the IRB Administrator places the submission up for expedited review in PennERA by locating the review action in the Submissions page. The administrator updates the review activities section to indicate that the review has been assigned the administrator then navigates to the post-review page and assigns the review action to the Director (or authorized designee), who will be referred to moving forward as the “reviewer.” The submission and the file are then placed in the designated location for expedited paper reviews.

Director or Designee
The reviewer checks the location for expedited paper reviews and determines if the criteria for expedited acknowledgement and/or approval have been met. If any questions or concerns related to the criteria for acknowledgement and/or approval are identified, the approver communicates these issues to the IRB Administrator and returns the submission and protocol file. If no concerns are raised or the issues raised by the reviewer are appropriately addressed, the reviewer affixes his/her acknowledgement and/or approval comments and signature.

**IRB Administrator**
If issues are raised by the reviewer, the administrator relays those issues to the study team. The study team’s response and any additional documents are incorporated into the submission and the submission and file are returned to the designated location for expedited reviews.

If at any point in the above processes, the administrator or reviewer determines that the submission requires convened IRB review, a Senior IRB Administrator is notified that he/she should schedule the study for convened IRB review. The IRB Administrator should share his/her notes or comments about the submission with appropriate IRB staff.

**ORA Administrator/IRB Senior Staff**
After the submission is acknowledged, the reviewer assigns the submission to an IRB Administrative Assistant for letter generation. The reviewer writes the type of assignment and deadlines for completion on the paper submission. The reviewer places the submission and protocol file in the assistant’s designated area for letter generation assignments.

**IRB Administrative Assistant**
The IRB Administrative Assistant retrieves the modification-deviation from his/her designated area and locates the submission in PennERA.

The IRB Administrative Assistant completes the data entry, as needed. The IRB Administrative Assistant reviews the paper documents and lists them into the review (general) page and Post-Review page in PennERA. The Administrative Assistant reviews the documents to determine if any notes or supplemental language should be added to the acknowledgement and/or approval letter and lists those comments on the Post-review page. The overall summary page of PennERA and the submission is updated to reflect the changes from the modification-deviation submission. The Administrative Assistant reviews the PennERA protocol’s management folders and updates any applicable fields to reflect the modification-deviation acknowledgement and/or approval.

The IRB Administrative Assistant generates the acknowledgement and/or approval letter by using the communications folder for this review action. The Assistant selects the appropriate letter template and builds the letter. The Assistant then transfers the letter into a word document and makes revisions to ensure that the letter is appropriately formatted and accurately documents the outcome of the IRB’s review. The letter is then converted into an Adobe PDF. Any applicable study documents are scanned into PDFs and affixed with an appropriate stamp, if needed. The letter and scanned documents are combined and placed in the appropriate IRB Administrator Letters to be Signed folder on the G: Drive. The paper submission and protocol file are placed in the IRB Administrator’s designated area for letters to be signed.

**IRB Administrator**
The IRB Administrator reviews the letter to ensure that the information contained is accurate and appropriately formatted. The IRB Administrator may refer to the paper submission to verify the accuracy of the document listing and template language. The administrator also ensures
that the appropriate documents are attached to the letter and accurately stamped and that PennERA has been correctly updated to reflect the new acknowledgement and/or approval. If revisions to the letter are necessary the administrator informs the assistant of the required revisions, deletes the PDF of the acknowledgement and/or approval letter, and returns the submission and protocol file to the IRB Administrative Assistant. If revisions to the letter are not required, the IRB administrator electronically signs the PDF and saves the signed letter in the IRB Administrative Assistant Letters Signed Folder on the G: Drive. The IRB Administrator updates the PennERA review activities section for the submission to indicate that the letter has been signed. A copy of the signed letter is printed and attached to the paper submission and protocol file. The submission is then returned to the IRB Administrative Assistant for forwarding.

**IRB Administrative Assistant**
The IRB Administrative Assistant locates the signed letter from the IRB Administrative Assistant Signed Letters Folder on the G: Drive. The IRB Administrative Assistant uploads the signed letter in the communications folder in the PennERA communication section and updates the review activities to indicate the letter has been signed and forwarded. An email with the signed letter and an explanation of its contents is sent to the PI, appropriate study contacts, and any other designated recipients. The signed letter is removed from the Signed Folder on the G: Drive. The acknowledgement and/or approval letter and submission documents are placed in the paper protocol file. The IRB Administrative Assistant conducts a quality assurance review of the file to ensure that actions are organized appropriately. The IRB Administrative Assistant then returns the file to the file room.
Research Review Processes – Modification Reviews

Exception Requests

1. PROCESS OVERVIEW
This procedure outlines the review processes for protocol exception requests submitted to the IRB via the paper and electronic submission processes.

2. RESPONSIBILITY
ORA Administrator
The role of the ORA Administrator is to check for incoming submissions and assign to the appropriate IRB Administrator for review.

IRB Administrator
The role of the IRB Administrator is to review the submission, begin data entry, and assign the review action to the appropriate IRB board.

IRB Administrative Assistant
The role of the IRB Administrative Assistant is to provide assistance to the IRB Administrator as needed for completion of data entry for the initial review action. The Administrative Assistant is also responsible for drafting the IRB approval letter for the action.

IRB Director or Designee
The IRB Director or designee ("reviewer") completes a secondary review of the action and approves the action.

3A. Procedures Employed to Implement this Policy – For HS-ERA Applications
ORA Administrator
The exception submission is received in the HS-ERA IRB queue once approved by the Principal Investigator. Upon receipt in the IRB queue, the status of the submission is changed from “Pending review by (Principal Investigator’s name)” to “Accepted and submitted for review”.

The ORA Administrator identifies incoming exception requests that are labeled for expedited review and assigns to the appropriate IRB Administrator for screening. The ORA administrator considers the complexity of the deviation and whether a timely review is required when determining which staff member should screen the deviation. The ORA Administrator utilizes the Assign to IRB admin section of HS-ERA and sorts submissions by Status so that all submissions with an “accepted and submitted for review status” appear first. The ORA Administrator uses the assign field for the submission and adds a comment to the submission detailing the type of submission and any deadlines for review. The ORA Administrator may utilize the HS-ERA Modification-exception Submission and the PennERA Protocol Status when assessing the appropriateness of expedited review.

IRB Administrator
The IRB Administrator screens the expedited exception submission for completeness. PennERA, the HS-ERA modification-exception submission, and previous HS-ERA submissions for the protocol may all be utilized to assist the administrator in his/her assessment. To
determine if the submission is ready for review, the administrator looks over the modification-
exception summary, any tracked changes to the online application (if the exception request
results in a permanent change to the protocol), and any attached documents under the Review
field.

The IRB Administrator should verify the submission is eligible for expedited review and that the
revised application (if applicable) continues to meet the criteria for approval. The administrator
should also make sure that there is sufficient rationale to justify the exception request and any
changes to the study documents, and that the revisions are made consistently throughout the
application. The administrator should determine whether other monitoring entities have
oversight of this protocol and request documentation of their approval if necessary. A consult
review from the Director, Associate Director or Executive Chair may be necessary to determine
what questions should be raised to the study team.

If the IRB Administrator determines the submission is incomplete or not yet ready to be
reviewed, the submission is returned to the submitter for revision without approval using the
assign field following the addition of a comment regarding the issues to be addressed.

ORA Administrator
By returning the submission, the application is opened to the research staff to address the
concerns noted during review. When the research team returns the application to the IRB, the
ORA Administrator assigns the application to the IRB Administrator who completed the initial
review per the process above.

IRB Administrator
If no issues were noted during the initial review or if the issues raised by the administrator have
been resolved, the IRB Administrator assigns the review action to the appropriate board using
the HS-ERA assign field for the submission and adds a comment summarizing his/her findings.
A modification worksheet may be uploaded in the comments section to detail the administrator’s
screening and any issues raised with the study team.

The IRB Administrator places the modification-exception submission up for expedited review in
PennERA by locating the review action in the Submissions page. The IRB Administrator
updates the review activities section to indicate that the review has been assigned. The IRB
Administrator then navigates to the post-review page and assigns the review action to the
Director (or authorized designee), who will be referred to moving forward as the “reviewer.”

Director or Designee
The reviewer finds the submission in HS-ERA by opening the My Submissions Approvals – view
assigned section. The reviewer reviews the application to determine if the criteria for expedited
approval have been met. If any questions or concerns related to the criteria for approval are
identified, the approver communicates these issues to the IRB Administrator. If no concerns are
raised or the issues raised by the reviewer are appropriately addressed, the reviewer then
approves the submission in My Submissions Approvals – view assigned section by submitting a
decision for this protocol.

IRB Administrator
If issues are raised by the reviewer, the administrator relays those issues to the study team and
may return the submission in HS-ERA if appropriate.

If at any point in the above processes, the administrator or reviewer determines that the study
requires convened IRB review, a Senior IRB Administrator is notified that he/she should schedule the study for convened IRB review. The IRB Administrator should share his/her notes or comments about the submission with appropriate IRB staff.

**ORA Administrator**
The approval will be reflected in the follow day letter generation report which is forwarded to the Director and designated ORA Administrators.

The ORA Administrator assigns the submission to an IRB Administrative Assistant based on the previously completed letter generation report. The ORA Administrator utilizes the Assign to IRB admin section of HS-ERA and locates submissions by filtering based on the protocol number or confirmation code provided in the letter generation report. The ORA Administrator uses the assign field for the submission and adds a comment to the submission detailing the type of assignment and any deadlines for completion.

**IRB Administrative Assistant**
The IRB Administrative Assistant receives a notification email detailing the assignment and deadline for completion and locates the submission in assign to IRB section of HS-ERA and PennERA.

The IRB Administrative Assistant completes the data entry, as needed. The IRB Administrative Assistant uses the HS-ERA submission’s eyeglass and/or review view to identify all documents submitted for review and lists them into the review (general) page and Post-Review page in PennERA. The Administrative Assistant reviews the HS-ERA comments section to determine if any notes or supplemental language should be added to the approval letter and lists those comments on the Post-Review page. The overall summary page of PennERA and the submission is updated to reflect the changes from the modification-exception submission. The Administrative Assistant reviews the PennERA protocol’s management folders and updates any applicable fields to reflect the modification-exception approval.

The IRB Administrative Assistant generates the approval letter by using the communications folder for this review action. The Assistant selects the appropriate letter template and builds the letter. The assistant then transfers the letter into a word document and makes revisions to ensure that the letter is appropriately formatted and accurately documents the outcome of the IRB’s review. The letter is then converted into an Adobe PDF and combines any applicable study documents with an appropriate stamp, if needed. The letter is placed in the appropriate IRB Administrator Letters to be Signed folder on the G: Drive.

**IRB Administrator**
The IRB Administrator reviews the letter to ensure that the information contained is accurate and appropriately formatted. The IRB Administrator may refer to the submission in HS-ERA to verify the accuracy of the document listing and template language. The IRB Administrator also ensures that the appropriate documents are attached to the letter and accurately stamped and that PennERA has been correctly updates to reflect the new approval. If revisions to the letter are necessary the IRB Administrator informs the IRB Administrative Assistant of the required revisions and deletes the PDF of the approval letter. If revisions to the letter are not required, the IRB administrator electronically signs the PDF and saves the signed letter in the IRB Administrative Assistant Letters Signed Folder on the G: Drive. The IRB Administrator updates the PennERA review activities section for the submission to indicate that the letter has been signed.
The IRB Administrative Assistant locates the signed letter from the IRB Administrator in the Signed Folder on the G: Drive. The HS-ERA modification-exception Submission is accessed to upload the signed letter in the add decision document page. After the review decision and signed letter are selected, the letter is uploaded.

The IRB Administrative Assistant uploads the signed letter in the communications folder in the PennERA communication section and indicates through the review activities as sent and uploaded. An email with the signed letter and an explanation of its contents is sent to the PI, appropriate study contacts, and any other designated recipients. The signed letter is removed from the Signed Folder on the G: Drive.

**NOTE:** The IRB accepts email exception requests under limited circumstances for HS-ERA protocols where timing or other special circumstances do not allow for study team to easily access or submit the request through HS-ERA. The IRB would allow for alternate revenue of receipt of submission provided the study team is advised of requirement to follow-up with an official submission for completion of the electronic file record in HS-ERA.
3B. Procedures Employed to Implement this Policy For Paper Applications

IRB Front Desk Administrative Assistant
The expedited modification-exception submission is received in the IRB office once signed-off by the Principal Investigator. Upon receipt in the IRB queue, the IRB Front Desk Administrative Assistant date stamps and logs the submission in PennERA for tracking purposes. The IRB Front Desk Administrative Assistant utilizes the “Add new” field in the Submissions page to create a new Amendment review record in PennERA. Once a new amendment record is created, the front desk assistant updates the review activities page to reflect this task is complete. The IRB Front Desk Administrative Assistant pulls the protocol’s most current file and places both the modification-exception submission and file together on the distribution shelf for assignment by the ORA Administrator.

ORA Administrator
The ORA Administrator checks the distribution shelf and assigns the submission to an IRB Administrator for screening. A consult review from the Director, Associate Director or Executive Chair may be necessary to determine what questions should be raised to the study team. The ORA Administrator writes the type of assignment and deadlines for completion on the paper submission. The reviewer places the submission and protocol file in the IRB Administrators designated area for new expedited screening assignments.

IRB Administrator
The IRB Administrator screens the expedited modification-exception submission for completeness. PennERA, the modification-exception submission, and previous submissions in the protocol file may all be utilized to assist the administrator in his/her assessment. The administrator should verify the submission is eligible for expedited review and that the revised application continues to meet the criteria for approval. The IRB Administrator should also make sure that there is sufficient rationale to justify the exception request and any changes to the study documents, and that the revisions are made consistently throughout the application. The administrator should determine whether other monitoring entities have oversight of this protocol and request documentation of their approval if necessary. A consult review from the Director, Associate Director or Executive Chair may be necessary to determine what questions should be raised to the study team.

If the IRB Administrator determined the submission is incomplete or not yet ready to be reviewed, the submitter is emailed a notification with the issues to be addressed. The review activities field for the submission in PennERA should be updated to document the issues raised with the study team. The email correspondence with the study team and any additional documents provided are incorporated into the paper submission.

If no concerns are raised or the issues raised by the administrator have been appropriately addressed, the IRB Administrator places the submission up for expedited review in PennERA by locating the review action in the Submissions page. The IRB Administrator updates the review activities section to indicate that the review has been assigned the administrator then navigates to the post-review page and assigns the review action to the Director (or authorized designee), who will be referred to moving forward as the “reviewer.” The submission and the file are then placed in the designated location for expedited paper reviews.

Director or Designee
The reviewer checks the location for expedited paper reviews and determines if the criteria for
expedited approval have been met. If any questions or concerns related to the criteria for
approval are identified, the approver communicates these issues to the IRB Administrator and
returns the submission and protocol file. If no concerns are raised or the issues raised by the
reviewer are appropriately addressed, the reviewer affix his/her approval comments and
signature.

**IRB Administrator**
If issues are raised by the reviewer, the IRB Administrator relays those issues to the study team.
The study team’s response and any additional documents are incorporated into the submission
and the submission and file are returned to the designated location for expedited reviews.

If at any point in the above processes, the IRB Administrator or reviewer determines that the
study requires convened IRB review, a Senior IRB Administrator is notified that he/she should
schedule the study for convened IRB review. The IRB Administrator should share his/her notes
or comments about the submission with appropriate IRB staff.

**ORA Administrator/IRB Senior Staff**
After the submission is approved, the reviewer assigns the submission to an IRB Administrative
Assistant for letter generation. The reviewer writes the type of assignment and deadlines for
completion on the paper submission. The reviewer places the submission and protocol file in the
assistants designated area for letter generation assignments.

**IRB Administrative Assistant**
The IRB Administrative Assistant retrieves the modification-exception request from his/her
designated area and locates the submission in PennERA.

The IRB Administrative Assistant completes the data entry, as needed. The IRB Administrative
Assistant reviews the paper documents and lists them into the review (general) page and Post-
Review page in PennERA. The Administrative Assistant reviews the documents to determine if
any notes or supplemental language should be added to the approval letter and lists those
comments on the Post-review page. The overall summary page of PennERA and the
submission is updated to reflect the changes from the modification-exception submission. The
Administrative Assistant reviews the PennERA protocol’s management folders and updates any
applicable fields to reflect the modification-exception approval.

The IRB Administrative Assistant generates the approval letter by using the communications
folder for this review action. The Assistant selects the appropriate letter template and builds the
letter. The Assistant then transfers the letter into a word document and makes revisions to
ensure that the letter is appropriately formatted and accurately documents the outcome of the
IRB’s review. The letter is then converted into an Adobe PDF. Any applicable study documents
are scanned into PDFs and affixed with an appropriate stamp, if needed. The letter and
scanned documents are combined and placed in the appropriate IRB Administrator Letters to be
Signed folder on the G: Drive. The paper submission and protocol file are placed in the IRB
Administrator’s designated area for letters to be signed.

**IRB Administrator**
The IRB Administrator reviews the letter to ensure that the information contained is accurate
and appropriately formatted. The IRB Administrator may refer to the paper submission to verify
the accuracy of the document listing and template language. The administrator also ensures
that the appropriate documents are attached to the letter and accurately stamped and that
PennERA has been correctly updated to reflect the new approval. If revisions to the letter are necessary the administrator informs the assistant of the required revisions, deletes the PDF of the approval letter, and returns the submission and protocol file to the IRB administrative assistant. If revisions to the letter are not required, the IRB Administrator electronically signs the PDF and saves the signed letter in the IRB Administrative Assistant Letters Signed Folder on the G: Drive. The IRB Administrator updates the PennERA review activities section for the submission to indicate that the letter has been signed. A copy of the signed letter is printed and attached to the paper submission and protocol file. The submission is then returned to the Administrative Assistant for forwarding.

**IRB Administrative Assistant**
The IRB Administrative Assistant locates the signed letter from the IRB Administrative Assistant Signed Letters Folder on the G: Drive. The IRB Administrative Assistant uploads the signed letter in the communications folder in the PennERA communication section and updates the review activities to indicate the letter has been signed and forwarded. An email with the signed letter and an explanation of its contents is sent to the PI, appropriate study contacts, and any other designated recipients. The signed letter is removed from the Signed Folder on the G: Drive. The approval letter and submission documents are placed in the paper protocol file. The Assistant conducts a quality assurance review of the file to ensure that actions are organized appropriately. The IRB Administrative Assistant then returns the file to the file room.
Reportable Event Submissions

1. PROCESS OVERVIEW
This procedure outlines the review of reportable events submitted to the IRB. Investigators are required to submit reports for events that qualify as reportable according to the definition provided in SOP RR404 Section 3.2. The IRB Staff should determine whether the submission contains enough information to determine if the event meets the IRB’s reporting criteria. The IRB will accept reports when the investigator is unsure whether the event should be reported and the IRB will review these reports to determine whether the event qualifies as a reportable event requiring convened review. Reportable event submissions for both Paper and Electronic Studies should be submitted through the HS-ERA electronic submission system. Paper documents may be accepted in certain circumstances in order to facilitate review.

2. RESPONSIBILITY

ORA Administrator
The role of the ORA Administrator is to check for incoming submissions and assign to the appropriate IRB Administrator for review.

Senior IRB Staff
The role of the Senior IRB Staff is to review the submission, begin data entry, and assign the review action to the appropriate IRB Chair or Designee or IRB board. The Senior IRB Staff member may also be responsible for drafting the minutes and letter that result from convened review of reportable events. This role is typically performed by the Assistant Director but may be performed by experienced Senior IRB Administrators and IRB Administrators.

IRB Administrative Assistant
The role of the IRB Administrative Assistant is to provide assistance to the Senior IRB Staff as needed for completion of data entry for the initial review action. The Administrative Assistant may also be responsible for drafting the IRB approval letter for the action.

IRB Director or Designee
The IRB Director or designee completes a secondary review of the action and acknowledges the action and may require additional action or refer the event to the convened board for review.

IRB Board Members
The role of the IRB Board Member is to review the protocol submission to determine whether to accept the report, whether additional action in response to the event is needed, raise issues for discussion during the meeting, along with their resolutions, and vote on the risk assessment and final review decision.

Regulatory Representative
The Regulatory Representative is a senior member of the IRB staff (typically the Director, Associate Director, or Assistant Director) who serves as an IRB Board Member. In addition to Board Member duties the Regulatory Representative also provides expertise on federal regulations and Penn policy and provides guidance in order to ensure that policies are applied consistently across all Penn Boards. The Regulatory Representative also provides assistance to
3A. Procedures Employed to Implement this Policy - If the event does not meet reporting criteria

ORA Administrator

The reportable event submission is received in the HS-ERA IRB queue once approved by the Principal Investigator. Upon receipt in the IRB queue, the status of the submission is changed from “Pending review by (Principal Investigator’s name)” to “Accepted and submitted for review”.

The ORA Administrator identifies incoming reportable event and assigns to the appropriate IRB Staff for screening. The ORA administrator considers the complexity of the event report and whether a timely review is required when determining which staff member should screen the submission. The administrator utilizes the Assign to IRB admin section of HS-ERA and sorts submissions by Status so that all submissions with an “accepted and submitted for review status” appear first. The ORA Administrator uses the assign field for the submission and adds a comment to the submission detailing the type of submission and any deadlines for review. The ORA Administrator may utilize the HS-ERA Reportable Event Submission and the PennERA Protocol Status when determining the appropriate staff for assignment.

Senior IRB Staff

The Senior IRB Staff screens the reportable event for completeness. PennERA, the HS-ERA submission, and previous HS-ERA submissions for the protocol may all be utilized to assist the staff in his/her assessment. To determine if the submission is ready for review, the staff reviews the reportable event form and any attached documents under the Review field.

The Senior IRB Staff should determine whether the submission contains enough information to determine if the event meets the IRB’s event reporting criteria. The event is considered reportable if it meets the reportable event definition provided in SOP RR404 Section 3.2. If inadequate information is provided to determine if the event meets the reporting criteria, the staff should request additional information from the investigator. The staff should not return the submission to the study team in HS-ERA. Comments should be solicited via email in order to facilitate timely consideration of the event. Comments and clarifications from the study team should be uploaded to the submission in the comments section in HS-ERA. The staff may consult with the IRB Director, Associate Director, Assistant Director, IRB Chair(s) in order to determine the appropriate course of action for reviewing the event.

In addition to verifying whether the submission meets the criteria of a reportable event, the staff should verify that the study team has detailed an appropriate corrective action plan, if necessary, and consider whether any study documents should be revised in response to the event.

If the Senior IRB staff determines that the submission does not meet the reporting criteria and that no other concerns are raised with the submission, the submission can be returned to the study team. The staff uses the assign field and adds a comment to the submission informing the study team that the event does not meet the reporting criteria. The comment also informs the study team that if additional information becomes available and the PI’s assessment of the event changes, the event should be resubmitted to the IRB with the additional information.
If the Senior IRB staff is unsure if the event is reportable or determines that the decision about whether the event is reportable should be made by the Executive Chair or designee, the staff assigns the review action to the appropriate board using the HS-ERA assign field for the submission and adds a comment summarizing his/her findings. A summary document may be uploaded in the comments section to detail the staff’s screening and any issues raised with the study team. These steps may also be taken if the Senior IRB staff determines that the event does not meet our reporting criteria but should be acknowledged by the IRB because of a Sponsor request or other appropriate need for documentation of the IRB’s decision related to the submission.

The staff places the reportable event submission up for expedited review in PennERA by locating the review action in the Submissions page. The staff updates the review activities section to indicate that the review has been assigned. The review type is also set as serious unanticipated adverse event, non-compliance, or potential unanticipated problem. The staff then navigates to the post-review page and assigns the review action to the Executive Chair (or authorized designee), who will be referred to moving forward as the “reviewer.”

**Director or Designee**
The reviewer finds the submission in HS-ERA by opening the My Submissions Approvals – view assigned section. The reviewer reviews the application to determine if the event does not meet the IRB reporting criteria and can be acknowledged or if additional information is required. If any questions or concerns are identified, the reviewer communicates these issues to the Senior IRB staff. If no concerns are raised or the issues raised by the reviewer are appropriately addressed, the reviewer then acknowledges the submission in My Submissions Approvals – view assigned section by submitting a decision for this protocol. (If the Director or Designee determined that the event does meet IRB reporting criteria, the event is referred to the convened IRB according to the procedure described in below in Section 3B.)

**Senior IRB Staff**
If issues are raised by the reviewer, the Senior IRB Staff relays those issues to the study team and will upload the study team’s responses to the comments field.

**ORA Administrator**
The acknowledgement will be reflected in the following day’s letter generation report which is forwarded to the Director and designated ORA administrators.

The ORA Administrator assigns the submission to an IRB Administrative Assistant based on the previously completed letter generation report. The ORA Administrator utilizes the Assign to IRB admin section of HS-ERA and locates submissions by filtering based on the protocol number or confirmation code provided in the letter generation report. The ORA Administrator uses the assign field for the submission and adds a comment to the submission detailing the type of assignment and any deadlines for completion.

**IRB Administrative Assistant**
The IRB Administrative Assistant receives a notification email detailing the assignment and deadline for completion and locates the submission in the assign to IRB section of HS-ERA and PennERA.

The IRB Administrative Assistant completes the data entry, as needed. The IRB Administrative Assistant uses the HS-ERA submission’s eyeglass and/or review view to identify all documents submitted for review and lists them into the review (general) page and Post-Review page in
PennERA. The IRB Administrative Assistant reviews the HS-ERA comments section to determine if any notes or supplemental language should be added to the acknowledgment letter and lists those comments on the Post-Review page. The overall summary page of PennERA and the submission is updated to reflect the changes from the reportable event submission. The Administrative Assistant reviews the PennERA protocol's management folders and updates any applicable fields to reflect the acknowledgment.

The IRB Administrative Assistant generates the acknowledgment letter by using the communications folder for this review action. The Administrative Assistant selects the appropriate letter template and builds the letter. The assistant then transfers the letter into a word document and makes revisions to ensure that the letter is appropriately formatted and accurately documents the outcome of the IRB's review. The letter is then converted into an Adobe PDF. The letter is placed in the appropriate IRB Administrator Letters to be Signed folder on the G: Drive.

IRB Administrator
The IRB Administrator reviews the letter to ensure that the information contained is accurate and appropriately formatted. The Administrator may refer to the submission in HS-ERA to verify the accuracy of the document listing and template language. The IRB Administrator also ensures that the appropriate comments have been added and that PennERA has been correctly updated to reflect the review. If revisions to the letter are necessary the IRB Administrator informs the IRB Administrative Assistant of the required revisions and deletes the PDF of the approval letter. If revisions to the letter are not required, the IRB Administrator electronically signs the PDF and saves the signed letter in the IRB Administrative Assistant Letters Signed Folder on the G: Drive. The IRB administrator updates the PennERA review activities section for the submission to indicate that the letter has been signed.

IRB Administrative Assistant
The IRB Administrative Assistant locates the signed letter from the IRB Administrator in the Signed Folder on the G: Drive. The HS-ERA Submission is accessed to upload the signed letter in the add decision document page. After the review decision and signed letter are selected, the letter is uploaded.

The IRB Administrative Assistant uploads the signed letter in the communications folder in the PennERA communication section and indicates through the review activities as sent and uploaded. An email with the signed letter and an explanation of its contents is sent to the PI, appropriate study contacts, and any other designated recipients. The signed letter is removed from the Signed Folder on the G: Drive.

If the reportable event submission was submitted and reviewed for a paper file, the administrative assistant prints out the submission. The approval letter and submission documents are placed in the paper protocol file. The IRB Administrative Assistant conducts a quality assurance review of the file to ensure that actions are organized appropriately. The Assistant then returns the file to the file room.

3B. Procedures Employed to Implement this Policy - If the event does meet reporting criteria
ORA Administrator
The reportable event submission is received in the HS-ERA IRB queue once approved by the Principal Investigator. Upon receipt in the IRB queue, the status of the submission is changed from "Pending review by (Principal Investigator's name)" to “Accepted and submitted for review".
The ORA Administrator identifies incoming reportable event and assigns to the appropriate IRB Staff for screening. The ORA administrator considers the complexity of the event report and whether a timely review is required when determining which staff member should screen the submission. The administrator utilizes the Assign to IRB admin section of HS-ERA and sorts submissions by Status so that all submissions with an “accepted and submitted for review status” appear first. The ORA Administrator uses the assign field for the submission and adds a comment to the submission detailing the type of submission and any deadlines for review. The ORA Administrator may utilize the HS-ERA Reportable Event Submission and the PennERA Protocol Status when determining the appropriate staff for assignment.

**Senior IRB Staff**

The Senior IRB Staff screens the reportable event for completeness. PennERA, the HS-ERA submission, and previous HS-ERA submissions for the protocol may all be utilized to assist the staff in his/her assessment. To determine if the submission is ready for review, the staff reviews the reportable event form and any attached documents under the Review field.

The Senior IRB Staff should determine whether the submission contains enough information to determine if the event meets the IRB’s event reporting criteria. The event is considered reportable if it meets the reportable event definition provided in SOP RR404 Section 3.2. If inadequate information is provided to determine if the event meets the reporting criteria, the staff should request additional information from the investigator. The staff should not return the submission to the study team in HS-ERA. Comments should be solicited via email in order to facilitate timely consideration of the event. Comments and clarifications from the study team should be uploaded to the submission in the comments section in HS-ERA. The staff may consult with the IRB Director, Associate Director, Assistant Director, or IRB Chair(s) in order to determine the appropriate course of action for reviewing the event.

In addition to verifying whether the submission meets the criteria of a reportable event, the staff should verify that the study team has detailed an appropriate corrective action plan, if necessary, and consider whether any study documents should be revised in response to the event.

If the Senior IRB Staff determines that the submission does meet the reporting criteria, the staff processes the submission for acknowledgement of timely reporting. The staff assigns the review action to the appropriate board using the HS-ERA assign field for the submission and adds a comment summarizing his/her findings. A summary document may be uploaded in the comments section to detail the staff’s screening and any issues raised with the study team.

The staff places the reportable event submission up for expedited review in PennERA by locating the review action in the Submissions page. The IRB Administrator updates the review activities section to indicate that the review has been assigned. The review type is also set as serious unanticipated adverse event, non-compliance, or potential unanticipated problem. The IRB Administrator then navigates to the post-review page and assigns the review action to the Director (or authorized designee), who will be referred to moving forward as the “reviewer.”

**Director or Designee**

The reviewer finds the submission in HS-ERA by opening the My Submissions Approvals – view assigned section. The reviewer reviews the application to determine that the event meets the reporting criteria and requires convened IRB review. If the reviewer identifies any additional information that the Board requires before consideration of the event, the reviewer
communicates these issues to the IRB administrator by adding a comment to the HS-ERA submission. The reviewer then acknowledges the submission in My Submissions Approvals – view assigned section by submitting a decision for this protocol. This acknowledgement is made in order to acknowledge the timeliness of the report.

**ORA Administrator, IRB Administrator, and Administrative Assistant**

After the event is acknowledged, the IRB generates an acknowledgement letter in the same manner described in section 3A. The acknowledgement letter includes a comment informing the study team that the event will be scheduled for convened Board review once they have responded to any issues raised in the acknowledgement letter. If no issues are identified and the submission is ready for convened review, the Senior Staff will determine which Board should review the action and inform the study team of the date of that meeting. The Senior Staff informs the ORA Administrator about the event and the need for convened review. Staff provide the ORA Administrator with guidance regarding the appropriate review assignment in order to ensure that the submission is assigned to the appropriate convened board meeting.

**ORA Administrator**

The follow up report is received in the HS-ERA IRB queue once approved by the Principal Investigator. Upon receipt in the IRB queue, the status of the submission is changed from “Pending review by (Principal Investigator’s name) “to “Accepted and submitted for review”.

The ORA Administrator identifies the report and assigns to the appropriate IRB Administrator for screening on the next available meeting agenda. The ORA Administrator utilizes the Assign to IRB admin section of HS-ERA and sorts submissions by Status so that all submissions with an “accepted and submitted for review status” appear first. The ORA Administrator uses the assign field for the submission and adds a comment to the submission detailing the type of submission and any deadlines for review. The ORA Administrator may utilize the HS-ERA Submission, the PennERA Protocol Status, and the information previously provided by Senior IRB Staff when assigning to the appropriate meeting agenda.

**IRB Administrator**

The IRB Administrator screens the follow up report for completeness and determines if the submission is ready for scheduling on the next available meeting agenda.

To screen the submission, the administrator utilizes the Assign to IRB section of HS-ERA and sorts submissions by Status so that all submissions with an “assign to (IRB Administrator name)” appear first or via a search of the submission using the confirmation code and/or protocol number from the email notification provided at receipt of the assignment. The administrator uses the Review field for the submission and completes the screening.

To determine if the submission is ready for review, the IRB Administrator looks over the report and any attached documents under the Review field. The IRB Administrator should ensure the follow up submission addresses the issues raised by the acknowledgement review and has sufficient information for the Board’s consideration. The administrator consults with the Director, Assistant Director, or Associate Director as needed, to ensure the completeness of the response.

If the IRB Administrator determines the submission is incomplete or not yet ready to be scheduled on the next appropriate meeting agenda, the submission is returned to the submitter for revision without approval using the assign field following addition of a comment regarding the
issues to be addressed.

**ORA Administrator**
By returning the submission, the application is opened to the research staff to address the concerns noted during review. When the research team returns the application to the IRB, the ORA Administrator assigns the application to the IRB Administrator who completed the initial review per the process above.

**IRB Administrator**
If no issues were noted or if the issues raised by the administrator have been resolved, the IRB Administrator schedules the submission for the next available meeting agenda. The administrator assigns the review action to the appropriate board using the HS-ERA assign field for the submission and adds a comment detailing why the reportable event requires convened review, which IRB meeting agenda the review has been scheduled for, and any other specific determinations the Board will be asked to make.

The IRB Administrator begins the agenda entry in PennERA by locating the review action in the Submissions page. The IRB Administrator uses the edit field to update the agenda entry description field, review activities, and post review pages to reflect the review action have been scheduled.

**ORA Administrator**
The IRB Administrative Assistant may be asked to assist the administrator in completion of the agenda entry, as needed, upon which an ORA Administrator is notified to re-assign the full board modification in HS-ERA to the assistant to complete data entry.

**IRB Administrative Assistant**
Upon notification of the assignment, the assistant locates the review action in the Submissions page in PennERA and uses the edit field to update the agenda entry description field, review activities, and post review pages to reflect the review action has been completed.

**Board Members**
When conducting reportable event review at a convened IRB, Penn uses a primary reviewer system for review. The primary reviewer presents their findings to the convened IRB based on their review of the modification request. The board discusses any issues with the submission raised by the primary reviewer as well as any potential issues or questions that may be raised by other members of the board. The convened IRB may need to make multiple determinations related to the reportable event. These determinations include but are not limited to: 1) whether the event meets the definition of an unanticipated problem posing risks to subjects or others; and 2) whether the event meets the definition of serious or continuing non-compliance. The convened IRB will also determine whether additional steps need to be taken to resolve the event, including but not limited to changes to the study documents, placing an administrative hold on the study, requiring additional information be provided to the subjects, requiring additional training of the investigator, termination of the research etc.

**IRB Administrator and Administrative Assistant**
For all voting actions, the IRB Administrator and Administrative Assistant present at the meeting ensure a quorum is present for the discussion and vote.

The IRB Administrator and Administrative Assistant take minutes during the discussion of the review, and generate final minutes and IRB decision letters collaboratively based on the
convened meeting discussion. The minutes taken includes an overview of the review discussion by the Board, including a summary of the proposed event, any controverted issues and their resolutions, re-assessment of risk determination, plan for re-consent (if applicable), final decision and vote counts.

**IRB Administrator:**
After the meeting, the IRB Administrator uses the notes taken during the meeting and any additional comments provided by Board Members to compile a draft of the minutes and stipulations. The information that is captured in the minutes should mirror the Board’s discussion and concerns. The minutes should not be a transcript of the Board’s discussion but rather a summary of the discussion including descriptions of controverted issues raised by members and the resolution of those issues. The stipulations and recommendations should be directive statements written to the study team informing them how to respond to the Board’s requirements.

Once the first draft of the minutes have been written in a word document, the Administrator emails the word document containing the minutes to the Regulatory Representative who attended the meeting.

**Regulatory Representative**
The Regulatory Representative reviews the document and either approves the language or requests revisions, as needed. The Regulatory Representative reviews the document to ensure that it is complete and accurately reflects the Board’s review of the event.

**IRB Administrator**
The IRB Administrator makes the appropriate revisions to the minute’s document based on the Regulatory Representative’s comments. The Regulatory Representative will communicate to the Administrator whether the second draft of the minutes will be required to be reviewed again by the Regulatory Representative. If so, the second draft of the minute word document will be required to be sent to the Regulatory Representative for a second review once completed.

Once determined to be appropriate by the Regulatory Representative, the Administrator enters the final version of the minutes and any stipulations in the post review page of PennERA and generates the letter for the administrator to sign.

The IRB Administrator uses the Submissions page to locate the review action in PennERA and enters the finalized minutes, review decision, and vote count in the post review page, as well as updating the review activities page to reflect the completed action. The overall summary page of PennERA and the submission is updated to reflect the changes from the Board’s decision. The Administrator reviews the PennERA protocol’s management folders and updates any applicable fields to reflect the Board’s decision.

The IRB Administrator generates the decision letter by using the communications folder for this review action. The administrator selects the appropriate letter template and builds the letter. The administrator then transfers the letter into a word document and makes revisions to ensure that the letter is appropriately formatted and accurately documents the outcome of the IRB’s review. The letter is then converted into an Adobe PDF.

The IRB Administrator electronically signs the PDF and saves the signed letter. The IRB Administrator updates the PennERA review activities section for the submission to indicate that
The IRB Administrator accesses the HS-ERA reportable event submission to upload the signed letter in the add decision document page. After the review decision and signed letter are selected, the letter is uploaded. The IRB Administrator uploads the signed letter in the communications folder in the PennERA communication section and updates the review activities to indicate the letter has been signed and forwarded. An email with the signed letter and an explanation of its contents is sent to the PI, appropriate study contacts, and any other designated recipients. If necessary, the HS-ERA submission is returned for response using the assign to IRB field in HS-ERA.

**IRB Administrative Assistant**

If the reportable event submission was submitted and reviewed for a paper file, the administrative assistant prints out the submission. The approval letter and submission documents are placed in the paper protocol file. The IRB Administrative Assistant conducts a quality assurance review of the file to ensure that actions are organized appropriately. The IRB Administrative Assistant then returns the file to the file room.

**Regulatory Representative**

If the Board’s determination requires additional reporting, the Regulatory Representative or appropriate IRB Staff member who attended the meeting drafts a letter detailing the event, the Board’s review, and the IRB’s plan of action. The draft of the letter is reviewed by a Regulatory Representative not present at the meeting and if needed, the IRB Chair, any edits/comments are incorporated into the final version. The final version of the letter is sent out to the PI/study team, the Institutional Official, Relevant Outside Agencies, and/or Relevant Internal offices.
Research Review Processes – Closure Requests

Closure Requests and Reports of Study Completion

1. PROCESS OVERVIEW
This procedure outlines the completion of expedited or convened applications submitted via the HS-ERA electronic submission system and the paper submission process.

2. RESPONSIBILITY

IRB Front Desk Administrative Assistant
The role of the IRB Front Desk Administrative Assistant is to receive incoming paper actions, complete initial data entry into PennERA and is to place the action in the designated distribution area.

ORA Administrator
The role of the ORA Administrator is to check for incoming closures and assign to the appropriate IRB Administrator/IRB Staff for review.

IRB Administrator/Appropriate IRB Staff
The role of the IRB Administrator is to review the closure action, complete data entry, and assign the review action to the appropriate IRB board. IRB Administrative Assistants can be designated as appropriate IRB staff after undergoing appropriate training.

IRB Administrative Assistant
The role of the IRB Administrative Assistant is to provide assistance to the IRB Administrator as needed for completion of data entry for the initial review action.

IRB Administrative Staff
The IRB Staff is responsible for drafting the IRB closure letter for the action.

Director or Designee
The Executive Chair or designee ("reviewer") completes a secondary review of the action and approves the action.

3A. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY - For HS-ERA Applications

ORA Administrator
The closure submission is received in the HS-ERA IRB queue once approved by the Principal Investigator. The preferred closure submission is the HSERA continuing review application but the IRB can process a modification application to close a project. Upon receipt in the IRB queue, the status of the submission is changed from “Pending review by (Principal Investigator’s name)” to “Accepted and submitted for review”.

The ORA Administrator identifies incoming requests for closure and assigns to the appropriate IRB Administrator/Staff member for screening. The ORA Administrator utilizes the Assign to IRB admin section of HS-ERA and sorts submissions by Status so that all submissions with an “accepted and submitted for review status” appear first. The ORA Administrator uses the assign
field for the submission and adds a comment to the submission detailing the type of submission and any deadlines for review. The ORA Administrator may utilize the HS-ERA Continuing Review Submission and the PennERA Protocol Status when assessing the appropriateness of expedited review.

**IRB Administrator/Appropriate IRB Staff**

The IRB Administrator or Appropriate IRB Staff (referred to as IRB Administrator throughout this section) reviews the closure request. PennERA, the HS-ERA closure submission, and previous HS-ERA submissions for the protocol may all be utilized to assist the administrator in his/her assessment. The administrator should verify that the enrollment numbers are consistent with previous protocol submissions, that the request to close the study is appropriate, and that any issues raised within the closure submission are appropriately addressed.

If the IRB Administrator determines the submission is incomplete or not yet ready to be reviewed, the submission is returned to the submitter for revision without PI approval using the assign field following the addition of a comment regarding the issues to be addressed.

The IRB Administrator may determine that the project should not be closed. The IRB Administrator notifies the research via email to confirm that continuing the project is appropriate and determines whether the submission should be withdrawn or processed according to the procedures outlined in the expedited continuing review section.

**ORA Administrator**

By returning the submission, the application is opened to the research staff to address the concerns noted during review. When the research team returns the application to the IRB, the ORA Administrator assigns the application to the IRB Administrator who completed the initial closure review per the process above.

**IRB Administrator**

If no issues were noted during the closure review or if the issues raised by the administrator have been resolved, the IRB Administrator assigns the review action to the appropriate board using the HS-ERA assign field for the submission and adds a comment summarizing their findings. A note recommending the closure of the project should be uploaded in the comments section.

The IRB Administrator places the submission up for expedited review in PennERA by locating the review action in the Submissions page. The administrator updates the review activities section to indicate that the review has been assigned. The IRB Administrator then navigates to the post-review page and assigns the review action to the Executive Chair (or authorized designee), who will be referred to moving forward as the “reviewer.”

**Director or Designee**

The reviewer finds the submission in HS-ERA by opening the My Submissions Approvals – view assigned section. The reviewer reviews the application to determine if the closing the application is appropriate. If any questions or concerns are identified, the approver
communicates these issues to the IRB Administrator. If no concerns are raised or the issues raised by the reviewer are appropriately addressed, the reviewer then approves the closure of the submission in My Submissions Approvals – view assigned section by submitting a decision for this protocol.

**IRB Administrator**
If issues are raised by the reviewer, the administrator relays those issues to the study team and may return the submission in HS-ERA if appropriate.

**ORA Administrator**
The approval will be reflected in the following day’s letter generation report which is forwarded to the Director and designated ORA Administrators.

The ORA Administrator assigns the submission to an IRB Record Specialists based on the previously completed letter generation report. The ORA Administrator utilizes the Assign to IRB admin section of HS-ERA and locates submissions by filtering based on the protocol number or confirmation code provided in the letter generation report. The ORA Administrator uses the assign field for the submission and adds a comment to the submission detailing the type of assignment and any deadlines for completion.

**IRB Administrative Staff**
The IRB Administrative Staff receives a notification email detailing the assignment and deadline for completion and locates the submission in assign to IRB section of HS-ERA and PennERA.

The IRB Administrative Staff completes the data entry, as needed. The IRB Administrative Staff uses the HS-ERA submission’s eyeglass and/or review views to identify all documents submitted for review and list them into the review (general) page and Post-Review page in PennERA. The Administrative Staff reviews the HS-ERA comments section to determine if any notes should be added to the approval letter and lists those comments on the Post-Review page. The overall summary page of PennERA and the submission is updated to reflect that the project is complete. The Administrative Staff reviews the PennERA protocol’s management folders and updates sections, when appropriate, to ensure the protocol and status accurately to reflect the closure.

The Administrative Staff generates the closure letter by using the communications folder for this review action. The Administrative Staff selects the appropriate letter template and builds the letter. The assistant then transfers the letter into a word document and makes revisions to ensure that the letter is appropriately formatted and accurately documents the outcome of the IRB’s review. The letter is then converted into an Adobe PDF. The letter is placed in the appropriate IRB Administrator Letters to be Signed folder on the G: Drive.

**IRB Administrator**
The IRB Administrator reviews the letter to ensure that the information contained is accurate and appropriately formatted. The Administrator may refer to the submission in HS-ERA to verify the accuracy of the document listing and template language. The IRB Administrator also that PennERA has been correctly updated to reflect the closure. If revisions to the letter are necessary the administrator informs the assistant of the required revisions and deletes the PDF.
of the approval letter. If revisions to the letter are not required, the IRB administrator electronically signs the PDF and saves the signed letter in the Administrative Staff Letters Signed Folder on the G: Drive. The IRB Administrator updates the PennERA review activities section for the submission to indicate that the letter has been signed.

**IRB Administrative Staff**
The Administrative Staff locates the signed letter from the IRB Administrator in the Signed Folder on the G: Drive. The HS-ERA continuing review submission is accessed to upload the signed letter in the add decision document page. After the review decision and signed letter are selected, the letter is uploaded.

The Administrative Staff uploads the signed letter in the communications folder in the PennERA communication section and updates the review activities to indicate the letter has been signed and forwarded. An email with the signed letter and an explanation of its contents is sent to the PI, appropriate study contacts, and any other designated recipients. The signed letter is removed from the Signed Folder on the G: Drive.

**Note:** The preferred closure submission is the continuing review application but the IRB can process a modification application to close a project or an email. A paper continuing review, modification, or email submission can be used to create an HSERA closure. However, there will not be a corresponding action in HSERA.
3B. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY For Paper Applications

IRB Front Desk Administrative Assistant
The expedited continuing review submission is received in the IRB office once signed-off by the Principal Investigator. Upon receipt in the IRB queue, the IRB Front Desk Administrative Assistant date stamps and logs the submission in PennERA for tracking purposes. The IRB Front Desk Administrative Assistant utilizes the “Add new” field in the Submissions page to create a new Review record in PennERA. Once a new Review record is created, the front desk assistant updates the review activities page to reflect that this task is complete. The IRB Front Desk Administrative Assistant pulls the protocol’s most current file and places both the continuing review submission and file together on the distribution shelf for assignment by the ORA Administrator.

ORA Administrator
The ORA Administrator checks the distribution shelf and assigns the submission to an IRB Administrator/Staff member for screening. The ORA administrator writes the type of assignment and deadlines for completion on the paper submission. The reviewer places the submission and protocol file in the IRB administrator’s/IRB Staff’s designated area for new expedited screening assignments.

IRB Administrator/Appropriate IRB Staff
The IRB Administrator or Appropriate IRB Staff (referred to as IRB Administrator Throughout this section) screens the closure review submission. PennERA, the continuing review submission, and previous submissions in the protocol file may be utilized to assist the administrator in his/her assessment. The IRB Administrator should verify that the enrollment numbers are consistent with previous protocol submissions, that the request to close the study is appropriate, and that any issues raised within the closure submission are appropriately addressed.

If the IRB Administrator determines the submission is incomplete, the submitter is emailed a notification with the issues to be addressed. The review activities field for the submission in PennERA should be updated to document the issues raised with the study team. The email correspondence with the study team and any additional documents provided are incorporated into the paper submission.

The IRB Administrator may determine that the project should not be closed. The IRB Administrator notifies the research via email to confirm that continuing the project is appropriate and determines whether the submission should be withdrawn or processed according to the procedures outlined in the expedited continuing review section.

If the submission is ready for review or the issues raised by the administrator have been appropriately addressed, the IRB Administrator places the submission up for expedited review in PennERA by locating the review action in the Submissions page. The IRB Administrator updates the review activities section to indicate that the review has been assigned. The administrator then navigates to the post-review page and assigns the review action to the
Director (or authorized designee), who will be referred to moving forward as the “reviewer.” The submission and the file are then placed in the designated location for expedited paper reviews.

**Director or Designee**

The reviewer checks the location for expedited paper reviews and determines if closing the application is appropriate. If any questions or concerns are identified, the approver communicates these issues to the IRB Administrator and returns the submission and protocol file. If no concerns are raised or the issues raised by the reviewer are appropriately addressed, the reviewer affixes his/her approval comments and signature.

**IRB Administrator**

If issues are raised by the reviewer, the administrator relays those issues to the study team. The study team’s response and any additional documents are incorporated into the submission and the submission and file are returned to the designated location for expedited reviews.

**ORA Administrator/IRB Senior Staff**

After the submission is approved, the reviewer assigns the submission to an IRB Administrative Assistant for letter generation. The reviewer writes the type of assignment and deadlines for completion on the paper submission. The reviewer places the submission and protocol file in the IRB Administrative Staff’s designated area for letter generation assignments.

**IRB Administrative Staff**

The Administrative Staff retrieve the continuing review from his/her designated area and locates the submission in PennERA.

The Administrative Staff completes the data entry, as needed. The Administrative Staff reviews the paper documents and lists them into the review (general) page and Post-Review page in PennERA. The Administrative Staff reviews the documents to determine if any notes should be added to the closure letter and lists those comments on the Post- review page. The overall summary page of PennERA and the submission is updated to reflect the project is complete. The Administrative Staff reviews the PennERA protocol’s management folders and updates sections, when appropriate, to ensure the protocol and status accurately to reflect the closure.

The IRB Administrative Staff generates the closure letter by using the communications folder for this review action. The Administrative Staff selects the appropriate letter template and builds the letter. The specialist then transfers the letter into a word document and makes revisions to ensure that the letter is appropriately formatted and accurately documents the outcome of the IRB’s review. The letter is then converted into an Adobe PDF. The letter is placed in the appropriate IRB Administrator Letters to be Signed folder on the G: Drive. The paper submission and protocol file are placed in the IRB Administrator’s designated area for letters to be signed.

**IRB Administrator**

The IRB Administrator reviews the letter to ensure that the information contained is accurate and appropriately formatted. If revisions to the letter are necessary the administrator informs the assistant of the required revisions, deletes the PDF of the approval letter, and returns the submission and protocol file to the IRB Administrative Assistant. If revisions to the letter are not required, the IRB Administrator electronically signs the PDF and saves the signed letter in the
IRB Administrative Assistant Letters Signed Folder on the G: Drive. The IRB Administrator updates the PennERA review activities section for the submission to indicate that the letter has been signed. A copy of the signed letter is printed and attached to the paper submission and protocol file. The submission is then returned to the record specialist for forwarding.

IRB Administrative Staff
The IRB Administrative Staff locates the signed letter from the IRB Administrative Assistant Signed Letters Folder on the G: Drive. The IRB Administrative Assistant uploads the signed letter in the communications folder in the PennERA communication section and updates the review activities to indicate the letter has been signed and forwarded. An email with the signed letter and an explanation of its contents is sent to the PI, appropriate study contacts, and any other designated recipients. The signed letter is removed from the Signed Folder on the G: Drive. The closure letter and submission documents are placed in the paper protocol file. The assistant conducts a quality assurance review of the file to ensure that actions are organized appropriately. The IRB Administrative Staff then log the file and send the file to archives.
Reviews involving Subpart Considerations

1. Process Overview
The federal regulations place additional requirements on human subjects’ research that involves pregnant women, neonates, or fetuses; prisoners; and children. The IRB has processes in place to conduct this subpart reviews at the exempt, expedited, and convened board reviews. Those processes are described below.

2. RESPONSIBILITY

IRB Administrator
The role of the IRB Administrator is to screen the application to determine if any vulnerable population will be included. The IRB Administrator also confirms that the letter generated includes the appropriate supplemental language.

IRB Administrative Assistant
The role of the IRB Administrative Assistant is to provide assistance to the IRB Administrator as needed for completion of data entry.

Director or Designee
The role of Director or designee is to complete a secondary review of the initial action and approve the subpart determination if appropriate.

IRB Board Members
The role of the IRB Board Member is to review the vulnerable population form, assess the protocol for any controverted issues relating to the inclusion of vulnerable populations and raise the issues for discussion during the meeting, along with their resolutions, and complete the supplemental determination.

3a. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY – EXEMPT REVIEW

IRB Administrator
The IRB Administrator will determine if a vulnerable population is being recruited and enrolled in the project during the initial screening process. If a subpart review is necessary, the IRB Administrator reviews the vulnerable populations’ supplemental form submitted by the researcher or may request that a form be completed and submitted for review, if required to complete the vulnerable population determination. The IRB administrator may utilize the appropriate vulnerable populations’ worksheet to determine criteria for approval under the subpart are met.

Please note that enrollment of pregnant women is not prohibited per any of the exempt categories. The enrollment of children is permitted for all exempt categories except for category 2. Protocols that enroll children and meet the criteria for exempt category 2 will be reviewed at the expedited level. Prisoners cannot participate in any exempt research. If prisoners are identified as participants, an expedited or a convened application is required.
Director or Designee
The Director or designee completes a secondary review of the initial action and may approve a subpart determination as part of her review of the entire protocol.

Note: If an exempt review protocol is modified to include a vulnerable population, and a previously established exemption would be affected by this review, a subpart review may be completed as part of that modification review process. A subpart determination may also be made if the study is modified in a way that impacts any previously made vulnerable population determinations.

3b. Procedures Employed to Implement this Policy – Expedited

IRB Administrator
The IRB Administrator will determine if a vulnerable population is being recruited and enrolled in the project during the initial screening process. If a subpart review is necessary, the IRB Administrator reviews the vulnerable populations’ supplemental form submitted by the researcher or may request that a form be completed and submitted for review, if required to complete the vulnerable population determination. The IRB Administrator utilizes the appropriate vulnerable populations’ worksheet to determine if the study meets the criteria for approval under the subpart. The completed worksheet is uploaded to the comments section of HS-ERA and forwarded to the Director or designee for final approval at the same time the study is forwarded for approval.

The IRB Administrator verifies that the required human subjects’ training is present for all research personnel. If training is expired or not completed, the IRB Administrator will notify the study team and inform them that the affected research staff cannot conduct research related activity until the training has been completed.

Please note that enrollment of pregnant women and children are not prohibited per any of the expedited categories, provided the criteria for approval under that subpart have been met. The enrollment of prisoners is permitted only under expedited category 5, for research that involves the secondary review of data. If prisoners are directly interacted with, a convened board review is required.

If a study involving prisoners undergoes expedited review, a prisoner representative may be consulted during the review process. The IRB Administrator should consult with the Director to determine if review by a prisoner representative is required. The IRB Administrator will forward the protocol to the prisoner representative for review at the same time the study is sent to the Director.

Prisoner representative
The prisoner representative reviews the application and any secondary document to confirm that the inclusion of the prisoners is appropriate. The representative assists the IRB Administrator by indicating the appropriate subpart category and outlines the questions detailed in the subpart determination form. The IRB Administrator completes the subpart C determination worksheet.

Director or Designee
The Director or designee completes a secondary review of the initial action and approves the subpart determination except for prisoner research.
IRB Administrative Assistant
The IRB Administrative Assistant generates the expedited letter per usual practice but does add the appropriate Subpart determination language to the approval letter. The Administrative Assistant uses the subpart determination worksheet uploaded by the IRB Administrator as a guide for drafting the correct subpart review language.
Note: If an expedited review protocol is modified to include a vulnerable population, a subpart review should be completed as part of that modification review process. A subpart determination should be also be made if the study is modified in a way that impacts any previously made vulnerable population determinations. At the time of continuing review, the IRB Administrator and Director should consider whether the study continues to meet the criteria for approval under the subpart.

3c. Procedures Employed to Implement this Policy – Convened

IRB Administrator
During the pre-review of the application, the IRB Administrator determines if a vulnerable population is being recruited and enrolled in the project. If a vulnerable population is being enrolled, the IRB administrator reviews the vulnerable population supplemental form submitted by the researcher or may request that a form be completed and submitted for review, if required to complete the vulnerable populations’ determination.

The IRB Administrator verifies that the required human subjects’ training is present for all research personnel. If training is expired or not completed, the IRB Administrator will notify the study team and inform them that the affected research staff cannot conduct research related activity until the training has been completed.

Please note: If the convened submission includes collection of data from incidental pregnancy, of either the subject or the female partner of a male subject, the subpart review for the collection of data during the pregnancy and any outcome data is reviewed by the Regulatory Representative or Chair attending the meeting and the forms are signed and uploaded to document the outcome of the determination for the subpart B and D determinations for data collection during pregnancy and outcome data.

If prisoner subjects are enrolled, the IRB Administrator schedules the study for convened Board review on IRB 7 or 8. The IRB Administrator also confirms that a prisoner representative can attend the IRB meeting. The prisoner representative is assigned to consult on the review of the protocol.

The IRB Administrator notifies the Board that a subpart determination will be required by adding a note to the agenda notes section of PennERA. In addition, the Board members are emailed a copy of the subpart determination worksheet for use as a reference during their review. The IRB Administrator also ensures that copies of the determination worksheet are available to the Board members during the discussion of the protocol.

Prisoner representative
The prisoner representative reviews the application and any secondary document to confirm that the inclusion of the prisoners is appropriate. The representative leads the discussion of the subpart determination during the Board’s discussion of the protocol.

IRB Board Members
During the discussion of the protocol, the Board members will discuss whether the study meets the criteria for approval under the appropriate subpart. The Board Members use the subpart determination worksheet as a guide. Each criterion for approval under the subpart is discussed and the rationale for why the study meets or does not meet that specific criteria is provided. The IRB Board Members assess the protocol for any controverted issues relating to the inclusion of
vulnerable populations and raise the issues for discussion during the meeting along with their resolutions. The Chair will summarize the subpart determination and include it in the final vote motion for the protocol.

**IRB Administrator and Administrative Assistant**

Either the IRB Administrator or Administrative Assistant documents the subpart decision as part of the overall minutes for that specific review. The minutes include a description of the subpart criteria and the rationale for why the Board determined the criteria to be met. The IRB Administrator generating the decision letter includes language detailing the appropriate Subpart determination made during the meeting.

Note: If a convened review protocol is modified to include a vulnerable population, a subpart review should be completed as part of that modification review process. A subpart determination should be also be made if the study is modified in a way that impacts any previously made vulnerable population determinations. At the time of continuing review, the Board should consider whether the study continues to meet the criteria for approval under the subpart.

Note: If a convened review protocol is modified and the changes do not affect the vulnerable population determination, then a prisoner representative review is not required. At the time of continuing review, if a convened review protocol is in its data analysis stages then a prisoner representative review is not required.
Research Review Processes – Research Involving Other Sites

Determining Engagement in Research

1. PROCESS OVERVIEW
Penn investigators often participate in research studies that involve sites and groups outside of Penn. For multi-site studies where Penn is not serving as the central IRB of record for participating sites, each site is responsible for obtaining their own IRB approval.

When the Penn investigator is the lead investigator for a study or Penn is the lead site for a study, the Penn IRB may assist in determining which sites and outside groups involved are engaged in the research. The term engaged in research is defined according to the federal regulations and guidance provided by the Office of Human Research Protections and the FDA. All sites that are engaged in human subject research must obtain IRB approval of their activities. This section will outline the procedure for an administrator to determine if a site or individual is engaged in human subjects’ research.

2. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY

IRB Administrator
While screening a submission, the IRB Administrator should make note of the entities outside of Penn that are participating in the research. The IRB Administrator should also note whether the Penn site and/or investigators are taking a lead role in the research. If Penn is taking a lead role in the project and there are other sites involved, the IRB Administrator should confirm whether the other sites are obtaining their own IRB approval for their engagement in the research. If this confirmation cannot be provided, the IRB Administrator should verify the roles of the other sites in the project and the specific activities the other sites will conduct. The IRB Administrator should request information to determine if the site’s personnel will consent subjects, collect data, or analyze identifiable information.

If the researchers indicate that personnel at the external site will do this, then the IRB Administrator should confirm that the site is engaged and that the site’s activity will need to be reviewed and approved by an IRB. The IRB Administrator should confirm that the site does or does not have an IRB that will review its role in the research. If the site does not have an IRB, the IRB Administrator considers whether the Penn IRB can enter into an Individual Investigator agreement with the associated research personnel can be executed. If the site does have an IRB, the IRB Administrator will discuss with the Director, or appropriate Senior Staff, if an Institutional Authorization Agreement with the site can be executed. The IRB Administrator will assist the study team in moving through either process, if necessary. The study can be approved prior to receipt of IRB approval of finalized agreements with the other sites. However the study team must confirm that no research will be conducted at those sites before IRB approval of any applicable agreement(s) is in place.

If the site is determined to not be engaged in research, then the IRB Administrator can relay this information to the researchers and note that no further action is necessary.

Note: This process often occurs during initial review of a protocol. However, it can also be completed as part of a modification review if the modification adds additional sites to the protocol.
Research Review Processes – Research Involving Other Sites

Individual Investigator and IRB Authorization Agreements

1. PROCESS OVERVIEW

When the IRB is asked to serve as an IRB for investigators or institutions outside of Penn, the IRB enters into either Individual Investigator Agreements or IRB Authorization Agreements. This section details how the IRB reviews and approves these agreements when conducting a review.

PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY

Individual Investigator Agreements

IRB Administrator
Within an initial review or within a modification application, the IRB Administrator may receive a request for Penn to extend its purview over an unaffiliated individual. A collaborating independent investigator is defined as a person who is not otherwise an employee or agent of an institution with an IRB; conducting collaborative research activities outside the facilities of the institution; and not acting as an employee of any institution with respect to his or her involvement in the research being conducted by the institution. The IRB Administrator should identify that the investigator(s) is unaffiliated with another IRB. The IRB Administrator should also obtain details of the individual’s role in the research and documentation that the individual has completed human subjects’ research training. If the preliminary review of the request is found to be appropriate, the IRB Administrator requests a copy Individual Investigator Agreement document signed by the unaffiliated investigator. The signed agreement is then forwarded to the Director for review and approval. The IRB Director/Associate Director/Assistant Director will also serve as the Executive Chair’s authorized designee for review of the Individual Investigator Agreements.

IRB Director
The IRB Director reviews the submission and determines if the agreement is appropriate. If the Director approves the request, the Director signs the agreement and forwards this letter to the Assistant or Administrator processing the request.

IRB Administrator
The IRB Administrator is responsible for conveying the Director’s decision to the study team. If the request is not approved by the Director, the administrator notifies the study team detailing the rationale for rejection of the agreement. Penn ERA is updated to reflect the decision. If the study team wishes to respond to the rejection of the agreement, their response will be processed as a new request.

IRB Administrative Assistant
If the request is approved by the Director, the individual agreement form is signed and is incorporated into the letter of approval. If the request is processed in an initial review, the initial letter processing instructions should be followed. If the request is part of a modification, then the letter processing for a modification should be followed. This letter is forwarded to the study team and uploaded into PennERA. Penn ERA should be updated to reflect that an agreement is in place.
Institutional Authorization Agreements – Penn as IRB of Record

IRB Administrator
Within an initial review or within a modification application, the IRB administrator may receive a request for Penn to extend its purview over an unaffiliated institution. This institution may not have its own IRB or its IRB may be willing to allow Penn to serve as the IRB of Record for both sites. The IRB Administrator should request completion of the Institutional Authorization Agreement. The research team should complete the document with information given by the Penn’s IRB. The form will require FWA numbers, Institutional Numbers, Protocol Numbers, the Title of the project, and the appropriate contact information of the Institutional Officials for both institutions. This document should then be forwarded to the deferring Institution to sign.

If Penn is accepting responsibility for the project, the IRB Administrator requests a description of the study personnel at the deferring site and their roles in the research. The IRB authorization agreement will specify the roles and responsibilities of each IRB. The agreement will also detail any other local context reviews that will be performed by the deferring site.

Once signed by the deferring institution, the agreement is forwarded to the Director for review and approval. The IRB Director will also serve as the Executive Chair’s authorized designee for review of the Institutional Authorization Agreement.

IRB Director
The IRB Director reviews the submission and determines if the agreement is appropriate. If approved, the Director signs the form to indicate Penn’s agreement to accept responsibility over the project. The completed document is forward to the deferring institution again so that they receive a copy of the agreement signed by both institutions.

IRB Administrator
The IRB Administrator is responsible for conveying the Director’s decision to the study team. If the request is not approved by the Director, the IRB Administrator notifies the study team detailing the rationale for rejection of the agreement. Penn ERA is updated to reflect the decision. If the study team wishes to respond to the rejection of the agreement, there response will be processed as a new modification.

IRB Administrative Assistant
If the request is approved by the Director, the Institutional agreement form is signed and is incorporated into the letter of approval. If the request is processed in an initial review, the initial letter processing instructions should be followed. If the request is part of a modification, then the letter processing for a modification should be followed. This letter is forwarded to the study team. Penn ERA should be updated to reflect that an agreement is in place.

Note: When Penn is agreeing to serve as the IRB of Record for another institution, it is the IRB’s preference for the deferring institution to sign the Authorization agreement first. However, if the deferring institution requires that the Penn IRB sign the agreement first, the IRB Administrator should consult the Director to consider whether the request can be accommodated.

Institutional Authorization Agreements – Penn Is Not the IRB of Record

IRB Administrator
Within an initial review, the IRB Administrator may receive a request for Penn to allow another IRB to serve as the IRB of Record. The IRB Administrator should request an IRB authorization agreement from the other institution or receive confirmation that the Penn authorization agreement would be acceptable. The research team should complete the document with information provided by the IRB of Record. The form will require FWA numbers, Institutional Numbers, Protocol Numbers, the Title of the project, and the appropriate contact information of the Institutional Officials for both institutions. In addition, the research team should provide a completed Principal Investigator Responsibilities form.

If Penn is deferring responsibility for the project, the IRB Administrator requests information on the role Penn personnel will play in the study and the role of the IRB of Record. If Penn will be acting as an enrollment site, the IRB administrator will conduct review of the consent form to address local context concerns. The IRB administrator will also conduct reviews as based on parameters set in the IRB authorization agreement.

Once the form is complete and ready for signature, the agreement is forwarded to the Director for review and approval.

**IRB Director**
The IRB Director reviews the submission and determines if agreement is appropriate. If approved, the Director signs the form to indicate Penn's agreement to defer responsibility over the project. The completed document is forward to the IRB of Record for signature. The agreement is not considered finalized and approved until a copy of the agreement signed by both institutions has been received by the Penn IRB.

**IRB Administrator**
The IRB Administrator is responsible for conveying the Director's decision to the study team. If the request is not approved by the Director, the IRB Administrator notifies the study team detailing the rationale for rejection of the agreement. Penn ERA is updated to reflect the decision. If the study team wishes to respond to the rejection of the agreement, there response will be processed as a new modification.

**IRB Administrative Assistant**
If the request is approved by the Director, the Institutional Agreement form is signed and is incorporated into an acknowledgement letter. This letter is forwarded to the study team. Penn ERA should be updated to reflect that an agreement is in place and the authorization agreement will be uploaded as an attachment to PennERA.
Research Review Processes – Research Involving Other Sites

Penn/CHOP Cooperative Agreements

1. PROCESS OVERVIEW
The Penn and CHOP IRB have entered into a cooperative agreement that establishes a streamlined process for studies where both institutions are engaged in the research. The process allows for one IRB to serve as the IRB of Record for both institutions. This section details how the IRB reviews protocols that request a Penn/CHOP cooperative agreement. An application to both Penn and CHOP will be required but this process does lessen the burden for continuing reviews and most modification submissions. Both Penn and CHOP both retain the ability to review certain modifications even after an agreement is place, if review by the home institution is necessary.

2. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY
   **IRB Administrator**
   Within an initial review or within a modification application, the IRB Administrator may receive a request for either Penn or CHOP to be the IRB of record over a project where both and Penn and CHOP are engaged. The Penn/CHOP agreement form should be completed by the Principal Investigator indicating which Institution will be the IRB of record. The PI should sign this document. Once the PI has indicated the IRB they want to be the IRB of record, the PI forwards the Penn/CHOP agreement to the institution who will be the IRB of record. Once that institution has signed the agreement, the agreement form is forwarded to the deferring institution.

   If Penn is accepting responsibility for the project, the IRB administrator requests a list of all study personnel at CHOP.

   **IRB Director**
   The IRB Director reviews the submission and determines if the agreement is appropriate. If the Director approves the request, the Director signs the agreement and forwards this letter to the Assistant or Administrator processing the request.

   **IRB Administrative Assistant**
   If the request is approved by the Director, the Penn/CHOP agreement form is signed and is incorporated into the letter of approval. If the request is processed in an initial review, the initial letter processing instructions should be followed. If the request is part of a modification, then the letter processing for a modification should be followed. This letter is forwarded to the study team. Penn ERA should be updated to reflect that an agreement is in place.

   After the agreement has been put in place, future continuing review and modification approval letters are shared between the two sites through designated email accounts. IRB staff should copy the CHOP designated email address on all approval letters for protocols where Penn is the IRB of Record. When the Penn IRB received correspondence from the CHOP IRB, that correspondence is filed in the attachments section of PennERA for the protocol.
Research Review Processes – Research Involving Other Sites

Research Conducted at Monell Chemical Senses Center

1. PROCESS OVERVIEW

Appendix Overview
Monell Chemical Senses Center is an independent institution that has entered into an agreement to rely on the Penn IRB to complete human subjects’ research reviews for Monell researchers. This appendix reviews the process for completing Monell Chemical Senses Center reviews.

2. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY

IRB Administrator
Please note that Monell researchers should submit their applications similar to the Initial, Continuing Review, and Modification procedures outlined within these policies. Please refer to the appropriate actions above to process the current submission submitted by Monell.

There are some specific considerations for Monell applications. Not all Monell personnel are selectable within the Penn IRB review system. If those individuals are selectable, then the IRB Administrator should request that they be added to the HSERA application for any initial review. If the Monell personnel are not selectable within the Penn submission system, the Administrator should request a list of all Monell personnel that are not selectable and request their CITI human subjects training information.

Monell applications typically contain a template consent form addendum for employees and family members that enroll in Monell research studies. This document has already been reviewed and approved by the IRB and so no further review other than documenting its inclusion is required. In addition, this consent form addendum does not require an IRB approval stamp.

The Penn IRB and Monell have agreed upon template language regarding research related injury and the inclusion of research information in the medial record. The IRB Administrator should review the consent form to ensure that this template language is appropriately incorporated.

Monell is not a HIPAA covered entity. Therefore medically based studies conducted solely at Monell are not required to include a research HIPAA authorization. However, if Monell is interacting with the University Health System, the IRB Administrator should determine if a HIPAA authorization is required.
Research Review Processes – Appendices

Document Listing for IRB Review Letters

IRB agenda notes and decision letters for all expedited and convened reviews include a complete listing of the documents submitted for review. IRB Administrators and Administrative Assistants are required to complete document listing for these reviews. This appendix details the best practices for document listing.

Procedures for Document Listing:

The following is an example of a document list:
- HS-ERA Continuing Review (Confirmation code: abcdefg) submitted 05/25/12
- UPCC #12345 Study Protocol version 9.0 dated 03/14/12
- Informed Consent and HIPAA Authorization Form version 2 dated 03/14/12
- ABC-123 Injection Investigator's Brochure Edition 2.1 dated 10/17/11
- IRB Self-Assessment Form uploaded 05/14/12

All HS-ERA submission document lists should note the type of submission (Continuing Review, Modification, Exception, etc), the confirmation code, and the date the submission was approved by the PI/Department Head (submission date).

Example: - HS-ERA Continuing Review (Confirmation code: jbegcfa) submitted 05/25/12
For paper submissions, the name of the IRB form including the date the form was signed should be listed.

Example: - IRB Continuing Review Form signed on 05/25/12

When listing protocol documents, staff should adhere to the naming conventions utilized by the study team whenever possible. In this case, staff should use (whenever possible) the protocol #, version #, and version date included on the document.

Example: - UPCC #12345 Study Protocol version 9.0 dated 03/14/12

When listing informed consent forms and HIPAA authorization forms, staff should include the version # and version date (when available).

Example: - Informed Consent Form version 2 dated 03/14/12

Whenever an informed consent form and a HIPAA authorization form are combined, the document naming convention should reflect this.

Example: - Informed Consent and HIPAA Authorization Form version 2 dated 03/14/12

When listing investigational brochures or package inserts, staff should provide as much information as possible including the edition #, edition date, and the name of the product.

Examples:
- ABC-123 Injection Investigator's Brochure Edition 2.1 dated 10/17/11
- Kryptonex Package Insert revised 02/2010
In some cases, documents are submitted to the IRB without version or signature dates. When this occurs, staff should defer to the date it was either received at the front desk or uploaded in HS-ERA.

**Examples:**
- IRB Self-Assessment Form uploaded 05/14/12 (HS-ERA)
- IRB Self-Assessment Form received 05/14/12 (Paper)

**Responses**
When creating a document list for a response submission (response to withheld or tabled modification, continuing review, or initial), the document lists should include more than one section. The first section should include a list of documents submitted with the response. The second section should include any documents submitted previously that were unchanged by the response.

The following example is a document list for a modification that was reviewed by the convened IRB and given withheld approval pending revisions to the informed consent form. The study team provided a response and was subsequently given an approval letter.

The following documents were included with the response submission:
- HS-ERA Modification (Confirmation #abcdef) submitted 05/04/12
- Response Letter dated 05/04/12
- Combined Informed Consent and HIPAA Authorization Form Version 05/04/12

The following documents were reviewed by the convened IRB on 30-Apr-2012, and are now approved:
- HS-ERA Modification (Confirmation #abcdeg) submitted 04/20/12
- Cover Letter dated 04/20/12
- Combined Informed Consent and HIPAA Authorization Form Version 04/20/12
- Sponsor X Full Clinical Protocol Version 2 revised 04/12/12
- Recruitment Brochure uploaded 04/20/12

Please note that the informed consent form above was stricken from the document list because further revisions were required by the convened IRB. If a document was revised by request of the reviewer or the convened IRB, it should not be included in the final approval list of documents. In this case, no revisions were required for the recruitment brochure or clinical protocol; therefore, they are included in the second section.

**Other examples of common documents listings:**

**HIPAA Forms**
- HIPAA Authorization Form Version 1.0 dated 06/08/12
- IRB Request for Waiver of HIPAA Authorization Form uploaded 06/08/12

**Human Subjects Training**
For documentation of human subjects training, please note that the “human research” course was completed, the name of the student, and the date the course was passed on.

**Example:** - CITI Human Research Curriculum Completion Report for John Smith passed on 06/08/12
Questionnaires
Whenever possible, the IRB Administrative Assistant should utilize the naming convention used by the study team.
Example: - Community Health Demographics Survey Version 1.0 dated 03/01/12

In some cases, the document will not have a clear name, version #, or version date. When this happens, the IRB Administrative Assistant should use his/her best judgment to determine what the document should be named.
Examples:
- Survey uploaded 06/08/12
- Questionnaire uploaded 06/08/12

Vulnerable Populations (Supplemental Forms)
- IRB Supplemental Form, Vulnerable Populations: Research Involving Prisoners uploaded 06/08/12

Miscellaneous
In general, staff should name the document in a way that best describes the form itself. The IRB often receives correspondence pertinent to the review decision. The purpose of these documents should be reflected in the naming convention. This description should provide a summary of the submission and its content.
Example: - Email Correspondence dated 06/01/12 re: Medical Monitor Review

The naming convention should attempt to capture the content of this document.
Example: - Letter of Approval from Miscellaneous University dated 06/01/12
Stamping Informed Consent Forms

All informed consent forms for expedited and convened protocols require an IRB approval stamp. Standalone HIPAA authorization forms and Information Sheets that contain the elements of consent but do not obtain documented consent from subjects do not require an approval stamp. This appendix details the process for stamping informed consent forms.

Procedures for Determining Stamp

When stamping an informed consent form, the IRB Administrative Assistant should determine if the following applies:

- the informed consent form has designated signatory line for the participant/subject and/or legally authorized representative
- the protocol is currently enrolling, the protocol requires for subject(s) to be re-consented, or the protocol requires for subject(s) to be enrolled despite the enrollment status
- the informed consent form is the most up-to-date version
- the protocol is currently approved

If an IRB Administrative Assistant determines all four of the criteria listed above are met, then the informed consent form is given a digital stamp. The only exception to this process is when the IRB staff indicates a consent form should not be provided through a comment in HS-ERA or within the paper submission. This often occurs if a protocol receives an administratively finalized or approved, contract pending determination.

The IRB only provides a digital stamp on an informed consent form. In no other case may a digital stamp be provided on any other protocol documents. Protocols conditionally re-approved or withheld do not receive stamped informed consent form(s) with the IRB decision letter.

Combined Informed Consent and HIPAA Authorization Forms

Informed consent forms combined with HIPAA authorizations are to be included in the procedures for digital stamping (such documents are usually titled “Informed Consent and HIPAA Authorization Form”). All references to informed consent forms may include those combined with HIPAA authorization forms. However, standalone HIPAA authorization forms do not get stamped in any case.

Procedures for Digital Stamping

The informed consent form may be submitted as a Microsoft Word document, paper document, or an Adobe PDF. In addition, any previously affixed approval stamps should be removed. This is commonly referenced as a “clean consent.” If the informed consent form has approval stamp from another IRB and the consent form requires a stamp form the Penn IRB, the consent form is stamped.

Informed consent forms in a Microsoft Word format are converted into a PDF. Informed consent forms as a paper documents are scanned into a PDF.
A PDF version of the informed consent form accompanies a PDF version of an IRB decision letter. The PDF informed consent form is attached below the PDF IRB decision letter by using Adobe Acrobat.

A protocol may have multiple informed consent forms. All informed consent forms receive the same stamp unless directed otherwise by IRB.

The informed consent form(s) are given a digital stamp by using the Adobe Acrobat Add Watermark function.

Procedures for Formatting, Determining Approval Period, and Special Conditions

Determining the Approval Period for Stamping
The IRB Administrative Assistant uses the Adobe “Watermark” tool for inserting the digital stamp. The primary function of the stamp is to state informed consent form’s approval period and may also indicate if there are any conditions on the usage of the form. The text of stamp should state the approval period from the initial date of the submission’s approval to the date of the protocol’s expiration. The approval period is dependent on the submission type and level of review. The approval period will fall into three of the following conditions:

1. If the informed consent form is approved with an expedited continuing review, the approval period will start the date of the expedited protocol’s approval and end 364 days later. The expiration date is the last date that the protocol is approved through.
2. If the informed consent form is approved with an expedited/full modification, the approval period will start the date of the protocol’s approval and ends the day protocol is set to expire.
3. If the informed consent form is approved with a response an initial withheld review, the approval period will start the date of the protocol’s approval and end 364 days later from the initial withheld date.
4. If the IRB approves research with conditions, date of approval is the date that the conditions were determined to be met.

The stamp font should be Monotype Corsiva Italic and no larger than 12 point. The stamp should be placed on every page of the consent form and not cover any of the documents text. Typically the stamp is placed in the corner of the form. Below is an example of a digital stamp:

IRB Approved From: 06-01-2012 To: 05-31-2013

If sufficient space for a three line consent form is not available, the consent form may be condensed into one or two lines. Below is an example of a one line consent form:

IRB Approved From: 06-01-2012 To: 05-31-2013

Special Conditions
The IRB Administrative Assistant may be instructed to stamp an informed consent form when (1) the consent form is intended for re-consent purposes only or (2) the consent form is intended for a one-time use by the protocol site. The Administrative Assistant may consult the appropriate IRB Administrator for assistance when one of these conditions may apply.
(1) Special Condition: One-time use only
If an informed consent form will be used for only a single subject, the stamp should reflect the consent form’s one-time use as shown below.

```
ONE-TIME USE ONLY
IRB Approved
From: 06-01-2012
To: 05-31-2013
```

(2) Special Condition: Re-consenting
If an informed consent form is intended for only the re-consenting of subjects, the stamp should reflect the consent form’s one-time use as shown below.

```
FOR RE-CONSENT ONLY
IRB Approved
From: 06-01-2012
To: 05-31-2013
```

The following list references the different type of informed consent documents that typically require a digital stamp on the PDF converted protocol document:

- Informed Consent Form
- Combined Informed Consent and HIPAA Authorization Form
- Parental Permission Form
- Parental Permission and HIPAA Authorization Form
- Assent Form
- Consent Form – Short Form
- Addendum to Informed Consent Form

Scenarios for Determining Dates of Approval and Expiration
Scenario 1: The IRB reviews and approves a study for one year, without any conditions, at a convened meeting on October 1, 2013. The date of IRB approval is October 1, 2013 and the date of IRB expiration is September 30, 2014.

Scenario 2: The IRB reviews a study at a convened meeting on October 1, 2013, and approves the study for one year, contingent on specific minor conditions the IRB chair or his or her designee can verify. On October 31, 2013, the IRB chair or designee confirms that the required minor changes were made. The date of approval is October 31, 2013 and the date of expiration is September 30, 2014. Continuing review must occur within one year of the date of the convened IRB meeting at which the IRB reviewed and approved the study, that is, by September 30, 2014.

Scenario 3: The IRB reviews a study at a convened meeting on October 1, 2013, and has serious concerns or lacks significant information that requires IRB review of the study at subsequent convened meetings on November 3, 2013 and December 5, 2013. On December 5, 2013, the IRB completes its review and approves the study for one year. The date of IRB approval is December 5, 2014 and the date of expiration is December 4, 2013.
Scenario 4: The IRB reviews and approves a study via expedited continuing review on October 1, 2013. The informed consent form is approved with an approval period that starts October 1, 2013 and ends September 30, 2014.

Scenario 5: The IRB reviews and approves a modification to a protocol on October 1, 2013. The most recent continuing review was conducted on February 1, 2013. The informed consent form is approved with an approval period that starts on October 1, 2013 and ends January 31, 2014.
Waivers of HIPAA Authorization and Data Use Agreements

This section outlines how the IRB reviews Waivers of HIPAA Authorization or a Data Use Agreement. It also describes the specific steps that need to be taken to document the IRB’s review and determination.

Waivers of HIPAA Authorization:

Unless there is a noted exception provided by the Director or Associate Director, all requests for HIPAA waivers must include a completed HIPAA waiver request form. If a HIPAA waiver is needed for a study and this form is not provided, the IRB Administrator must request that the form be completed and attached to the submission.

Consideration of a New Request for Waiver of HIPAA authorization:

IRB Administrator

A new request for a waiver of HIPAA authorization may be attached to an initial or modification submission. When a request is received, the IRB Administrator should review the request to ensure that it is appropriately documented in the study documents and that the criteria for waiver of HIPAA authorization are met. Any questions related to this determination should be sent to the study team for clarification and/or revision. If any information provided in the HIPAA waiver request form is found to be inaccurate, the administrator should request that the form be revised.

The IRB Administrator’s determination and recommendation regarding the acceptability of the waiver request should be documented on either the initial expedited review worksheet or modification worksheet.

If the waiver request includes the disclosure of protected health information (PHI) outside the covered entity that does not qualify for a data use agreement, the Administrator should determine whether convened IRB review of the request is necessary. If convened IRB review is necessary, the submission should be referred to Senior Administrator so submission can be assigned to appropriate Board for review.

Once the waiver request and any other outstanding issues are addressed, the submission may be reviewed at the appropriate level for the submission.

IRB Administrative Assistant

Once the submission and HIPAA waiver request are approved, the submission will be returned to an IRB Administrative Assistant for letter generation. During the letter generation process, the Post-Review page in PennERA entry will need to include the list of used/collected and disclosed as determined appropriate with the waiver request. The list of indirect and direct PHI for which use or access has been determined appropriate with the waiver request can be located on the waiver of HIPAA authorization form. This information should be inputted into the comments box found in the post review section in addition to the list of documents included with the review.

Once all appropriate fields in PennERA have been updated to reflect the new approval, the IRB Administrative Assistant should generate the approval letter in the communications section by using the “HS – Initial Apprvl – Expd w/HIPAA” letter template.
Consideration of a Modification to Existing HIPAA Waiver:

**IRB Administrator**
A change to an existing HIPAA waiver may be attached to a modification or continuing review submission. If a change is included in the continuing review, the administrator should inform the study team that they will need to submit a separate modification request for this review. The continuing review can then be processed and the approval letter should note that the revised HIPAA waiver was not considered at the time of continuing review. It is not always the case that a revision to the HIPAA waiver attached to a continuing review is readily apparent. The administrator is responsible for reviewing any continuing review submission for studies with approved HIPAA waivers to ensure that the study is being conducted in accordance with the initial HIPAA waiver.

Once a modification to the existing HIPAA waiver request has been received, the IRB Administrator should review the submission to determine if the criteria for waiver of HIPAA authorization are met. Any questions related to this determination should be sent to the study team for clarification and/or revision. The IRB Administrator should review the existing HIPAA waiver request form and determine if revisions are necessary to appropriately incorporate the revised waiver request. If any information provided in the revised HIPAA waiver request form is found to be inaccurate, the IRB Administrator should request that the form be revised.

The IRB Administrator’s determination and recommendation regarding the acceptability of this HIPAA waiver should be documented on the modification worksheet.

If the waiver request includes the disclosure of PHI outside the covered entity that does not qualify for a data use agreement, the Administrator should determine whether convened IRB review of the request is necessary. If convened Privacy Board review is necessary, submission should be referred to Senior Administrator so submission can be assigned to appropriate committee for review.

Once the waiver request and any other outstanding issues are addressed, the submission may be reviewed at the appropriate level for the submission.

**IRB Administrative Assistant**
Once the submission and HIPAA waiver request are approved, the submission will be returned to an IRB Assistant for letter generation. During the letter generation process, the Post-Review page in PennERA entry will need to include the list of used/collected and disclosed as determined appropriate with the waiver request. The list of indirect and direct PHI for which use or access has been determined appropriate with the waiver request can be located on the waiver of HIPAA authorization form. This information should be inputted into the comments box found in the post review section in addition to the list of documents included with the review. Please note that additional waiver language as found in the initial expedited w/HIPAA letter template will also need to be added to the comments section. Once all appropriate fields in PennERA have been updated to reflect the new approval, the assistant should generate the approval letter in the communications section by using the “HS Amendment-Expedited” letter template.
Consideration of Data Use Agreements:

IRB Administrator

The IRB Administrator should consider when a data use agreement is necessary for a particular study. Data use agreements are required when a limited dataset is being disclosed to an individual or organization outside of one of Penn’s covered entities and authorization from subjects for the disclosure will not be obtained.

These disclosures may be identified during initial and modification submissions. When these disclosures are identified, the administrator should confirm with the study team that the following criteria are met:

a. Disclosed dataset qualifies as a limited dataset per HIPAA regulations
b. The study team will work with the appropriate office to enter into a data use agreement with the site receiving the dataset or if the data use agreement is attached to the application it may be signed by the Director.
Research Review Processes – Appendices

IND Exemption and Non-Significant Risk Device Determinations

1. PROCESS OVERVIEW
Research involving investigational uses of drugs and devices may involve FDA approval of the use via an Investigational New Drug or Investigational Device Exemption application. However, in certain circumstances, application to the FDA for approval of the investigational use is not required. This is the case for planned research activities that qualify for an IND exemption and studies that involve the use of non-significant risk devices (NSR) or the use of the device is determined to be exempt from the IDE regulations. For non-significant risk device determinations, the IRB may act as a surrogate of the FDA to confirm that the criteria are met.

2. RESPONSIBILITY

IRB Administrator
The role of the IRB Administrator is to screen the application to determine if either an IND exemption or NSR determination is required. The IRB Administrator also determines if sufficient information is present in the application for the Board’s consideration.

Director and IRB Chair
The role of the Director, IRB Chair, or appropriate Senior IRB Staff, is to consider whether consideration of the determination is appropriate and if the IRB has sufficient expertise present at the meeting to complete the review.

IRB Board Members
The role of the IRB Board Member is to review the application, consider whether the study meets the criteria for either an IND exemption or NSR determination, and raise issues for discussion during the meeting, along with their resolutions, and complete the supplemental determination. The Board will also be informed when the research involves use of a device or drug “on-label” that the regulations don’t apply for investigational use of the device or drug.

3. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY

IRB Administrator
During the pre-review of the application, the IRB Administrator determines if an IND exemption or NSR determination is being requested. If determination is being requested, the IRB administrator reviews the application to determine if the study team provides enough information for the Board to consider whether the application meets the criteria for either an IND exemption or an NSR determination.

An IND exemption is required when the research uses an FDA approved drug in a manner that is not in accordance with its approved labeling (off label use). The IRB Administrator should first identify if the drug is FDA approved and being used in a manner that is not in accordance with its labeling. If this is the case, the IRB Administrator should verify whether the study team is seeking an IND or IND exemption from the FDA. If the study team is not seeking an IND or IND exemption from the FDA, the study will require an IND exemption determination by an appropriate internal office. In cases where a determination is not sought from the FDA, confirmation that a research activity qualifies for IND exemption may be provided by the Office
of Clinical Research (OCR), the Clinical Trials Safety and Monitoring Committee (CTSRMC), Department of Radiology IND Office or the IRB. The IRB Administrator should first confirm if the study team is seeking an IND exemption from either OCR or the CTSRMC. If an IND exemption is not being sought from these entities and the study team is requesting an IND exemption be granted by the IRB, the IRB Administrator should consult with the Director and Executive Chair about whether it is appropriate for the convened Board to consider making the IND exemption determination for this research.

An NSR determination is required when the research uses an investigational device that does not qualify as a significant risk device according to FDA regulations. The IRB Administrator should first identify if the device is FDA approved or if it is considered a significant risk device. If the drug is investigational and qualifies as a significant risk device, application to the FDA for an IDE is required if the study team asserts that the device qualifies as a non-significant risk device the study will require an NSR determination. The administrator should confirm if the study team is requesting an NSR determination be granted by the IRB. If an NSR determination is required the IRB administrator should consult with the Director and Executive Chair about whether it is appropriate for the convened Board to consider making the NSR determination for this research.

**Director and Executive Chair**

The Executive Chair and Senior IRB Staff may discuss the protocol or Senior Staff will determine an appropriate course of action for review, if Executive Chair consult is not required. The complexity of the protocol, the available convened Board meetings and the expertise of the Board attendees will be considered when assigning a determination to the convened board. The convened Board will be informed that the submission requires an IND exemption, non-significant risk device determination or confirmation that a device is exempt from IDE regulation. The Board will be reminded that consult may be sought from the FDA regarding these determinations if necessary.

**IRB Administrator**

The IRB Administrator informs the study team of the IRB’s plans for review of the protocol. If the Board will consider the IND exemption or NSR determination, the IRB Administrator should confirm that the application contains sufficient information for the Board’s consideration of the request. The application should contain rationale for why all the criteria for the exemption/determination are met. If sufficient rationale is not provided, the IRB administrator should request additional information from the study team. Once the application is determined to be ready for scheduling, the IRB administrator includes a note in the agenda indicating that the Board is asked to consider the IND exemption or NSR determination for the protocol.

**IRB Board Members**

During the discussion of the protocol, the Board members will discuss whether the study meets the criteria for IND exemption or NSR determination. The Board Members are provided with reference documents detailing the criteria for each decision. Each criterion for approval is discussed and the rationale for why the study meets or does not meet that specific criterion is provided. The IRB Board Members assess the protocol for any controverted issues and raise the issues for discussion during the meeting along with their resolutions. The Chair will summarize the determination and include it in the final vote motion for the protocol. If the Board is unable to determine that the criteria are met, the study team will be informed that they should either provide additional rationale or consult with the FDA or other review entity that may make the determination.
IRB Administrator
The IRB Administrator documents the decision as part of the overall minutes for that specific review. The minutes include a description of the criteria and the rationale for why the Board determined the criteria to be met. The IRB Administrator generating the decision letter includes language detailing the appropriate determination made during the meeting.

Note: If a convened review protocol is modified to request an IND exemption or NSR determination, a review should be completed as part of that modification review process. A determination may also be made if the study is modified in a way that impacts any previously made determinations.
Research Review Processes – Appendices

Requests for Permission to Use Data

1. PROCESS OVERVIEW
The IRB has processes in place for reviewing submissions where human subjects research is conducted without IRB approval. When this occurs, the IRB does not grant retrospective approval of the research but can consider whether or not to grant permission to use the data in research publications. The process for considering these requests is described below.

2. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY

IRB Administrator
If a researcher has contacted the IRB to discuss a project that has been completed without IRB approval, the IRB should direct the researcher to submit an application for initial review. A research project may be submitted to the IRB without prior discussion. If the IRB Administrator identifies a submission that has conducted human subjects research prior to receiving IRB approval, the IRB should discuss the project with the research team.

If the project is found to qualify for exemption from IRB review, the IRB Administrator should review the study according to standard exempt review practices. If the IRB determines that the study was conducted in agreement with the IRB’s criteria for approval of exempt research, then the project can be reviewed by the Director or designee and permission to use the data may be granted.

If the project would have required expedited review, the project cannot follow the standard initial expedited procedures. Permission to use the data for these projects can only be granted by the convened board. The protocol should be screened and scheduled for convened IRB review according to standard practices. The IRB Administrator should ensure the application details how the study was conducted, whether consent from subjects was obtained, and the reasons why prior IRB approval had not been obtained. The IRB Administrator should add language to the agenda notes to inform the Board that the request is for a study that has been completed and the IRB is asked to consider granting permission to use the data.

After the review of the project, the IRB Administrator should generate a decision letter according to standard practices. This letter should be revised to remove language pertaining to approval. Only language related to “permission to use the data generated” language should be used.
Research Review Processes – Appendices

Short Form Consent Process

1. PROCESS OVERVIEW

If a protocol seeks to enroll a subject who does not speak the language the consent form is written in, the study team may request to use an Informed Consent Short Form. These requests are typically only granted for a specific subject. If multiple subjects who speak a different language are expected to be enrolled, the study team should submit translated consent forms for review and approval. The process for reviewing the short form consent request is detailed in this section.

2. RESPONSIBILITY

Director or Designee
The Director or Designee reviews the submission that includes the short informed consent form.

ORA Administrator
The ORA Administrator assigns the HS-ERA or paper submission including the short informed consent form to the IRB Administrator.

IRB Administrator
The IRB Administrator screens the request and places the request up for final review. After approval has been granted, the IRB Administrator will work with the administrative assistant to generate an approval letter and stamped consent form as quickly as possible.

IRB Administrative Assistant
The IRB Administrative Assistant provides a digital stamp on the short informed consent form as instructed.

3. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY

IRB Administrator
If the IRB Administrator determines the submission consists of a request to allow for use a short form for a non-English speaking subject, the IRB Administrator reviews the submission for completeness to make sure the appropriate information is present in the submission received. This includes a summary of the modification request, details regarding who the request is for and the circumstances which prompted the need for the short form use, a copy of the relevant short form, and information on who will serve as a translator when the study team discusses the study with the subject. The IRB Administrator verifies a copy of the relevant short form written in IRB Penn template language is attached to the submission. The IRB Administrator verifies that an appropriate plan is in place for ensuring a translator will be available to go over the full study consent form with the non-English speaking subject at the time of the initial consent process, as well as ongoing subject participation throughout the remaining duration of the subject’s participation in the study.
The IRB Administrator should exercise caution in assuring the submission does not include any changes to the protocol inclusion/exclusion criteria. The short form is designated for one-time single subject use only in the event a non-English speaking subject is identified as being eligible for the study when the study does not anticipate targeting non-English speaking subjects. In the event that non-English speaking subjects will now be targeted, a fully translated consent form in the language of that non-English speaking demographic would be warranted. The IRB Administrator should exercise caution in assuring the study file history does not communicate a trend in short form requests for the same non-English speaking population to the level such that it implicates a need for consideration of a permanent revision to the protocol inclusion/exclusion criteria.

Once the submission is determined to be appropriate, the IRB Administrator places the submission up for expedited review according to standard practices.

The IRB Administrator inputs a comment in HS-ERA or leaves a note within the paper submission that notifies the IRB Administrative Assistant to stamp the short informed consent form for one-time use only.

After the submission has been approved, the IRB Administrator contacts an ORA administrator and assigns the submission to an IRB Administrative Assistant for a letter generation.

**ORA Administrator**

The ORA Administrator assigns the HS-ERA or paper submission including the short informed consent form to the IRB Administrative Assistant.

**IRB Administrative Assistant**

During the letter generation process, the IRB Administrator Assistant should exercise caution when stamping the relevant short form for approval (given that this is a one-time single subject use request). The IRB Administrator Assistant should ensure the approval stamp reflects the one-time use nature of the request. The IRB Administrative Assistant notes any comments in the HS-ERA or paper submission indicating that short informed consent form should be stamped for one time use. The Administrative Assistant then follows the appropriate procedures for generating the letter for the submission.

After the IRB decision letter is converted into a PDF, the IRB Administrative Assistant attaches a PDF copy of the short informed consent form below the PDF version of the IRB decision letter in Adobe Acrobat. Next, the IRB Administrative Assistant stamps the short informed consent form with a digital stamp that indicates the short form’s one-time and the protocol’s current approval range (refer to Stamping Consent Form Appendix for determining approval range).

A short informed consent form the stamp should reflect the consent form’s one-time use as shown below.

```
ONE-TIME USE ONLY
IRB Approved
From: 06-01-2012
To: 05-31-2013
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Research Review Processes – Appendices

NIH Certificates of Confidentiality

Appendix Overview
Certificates of Confidentiality (CoC) are issued by the National Institutes of Health (NIH) to protect identifiable research information from forced disclosure. Research studies at Penn that seek Certificates of Confidentiality are required to inform the IRB. When this occurs, the IRB application and informed consent form must indicate that the study team has sought or obtained the Certificate of Confidentiality. This section outlines the considerations and determinations the IRB may make when protocols require, seek, and/or obtain a Certificate of Confidentiality.

Considerations for Certificates of Confidentiality:
The IRB Administrator should determine if the study team is seeking or has obtained a Certificate of Confidentiality when screening the protocol submission. Typically, the data confidentiality section of the online application will indicate that a CoC has been obtained. The Consent form may also discuss a CoC. The IRB Administrator should contact the study team and confirm if they have obtained or are seeking a CoC.

The IRB Administrator reviews the informed consent form to see if it discusses the CoC. The consent form should include a description of the protections and limitations of the CoC, including the circumstances in which the investigators plan to disclose voluntarily identifying information about research participants.

If the study team indicates that they have not yet received a CoC but they are planning to apply for one, the consent form should state that the study team is seeking a CoC. If the consent form incorrectly states that they have obtained a CoC for the study, the IRB will require that the form be revised or the study team will be prohibited from enrolling subjects until documentation of the CoC has been submitted to the IRB.

If the study team indicates that they have received a CoC, the IRB Administrator should request documentation of the Certificate. Once documentation has been provided the consent form may state that the study team has obtained a CoC.

If a study includes sensitive information (such as drug use, illegal conduct, etc.) that may affect a participant’s financial standing, employability or reputation, the Board may require that the study team seek a CoC. Only the convened board can stipulate that a CoC be sought. IRB staff may recommend that the study team apply for a certificate.

Once the study team obtains a CoC from the NIH, they are required to submit a separate modification to the IRB to update the consent form and other protocol documents to indicate that the Certificate has been obtained or if these changes were already implemented at the request of the NIH, the IRB will be notified of the receipt of the CoC.
Research Review Processes – Appendices

Contract Review for Industry Sponsored Studies

1. PROCESS OVERVIEW
The IRB regularly grants approval of industry-sponsored protocols prior to the finalization of the contract for that protocol. The negotiated contract impacts the consent form for the study because the contract describes the circumstances where coverage for research related injury will be provided by the sponsor. The IRB has put in place processes to ensure that the consent form appropriately details what will occur if a subject is injured. This section details those processes.

2. RESPONSIBILITY

IRB Administrator
The IRB Administrator reviews the contract and the consent form and informs the study team of any required changes to the consent form.

IRB Administrative Assistant
IRB Administrative Assistant generates an IRB approved consent form once the contract review has been completed and the consent form has been determined to be appropriate.

3. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY

See separate document detailing the step by step process for reconciliation of the subject injury language in the contract and consent form. This guide is available on the G: Drive
Research Review Processes – Appendices

IRB/CTRC Joint Review Procedures

1. PROCESS OVERVIEW

The IRB and the Clinical and Translational Research Center (CTRC) have entered into an agreement to conduct a joint review of research studies that utilize CTRC resources. These joint reviews are performed at IRB 3 meetings. The IRB has processes in place to ensure that protocols are appropriately moved through this joint review process.

2. RESPONSIBILITY

ORA Administrator
The ORA Administrator assigns initial protocols and modifications for convened review. The administrator is responsible for conducting an initial screen to determine if IRB/CTRC Joint Review is required.

IRB Administrator
IRB Administrator determines if IRB/CTRC Joint Review is required during screening and ensures that the study is scheduled for appropriate review.

3. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY

ORA Administrator
When assigning initial protocols for convened review, the ORA Administrator should review the HS-ERA application to determine if IRB/CTRC Joint Review is required. If the study answers yes to the CTRC resources questions, then the study should be referred to IRB 3 for review. The submission should be assigned to the IRB 3 administrator for screening.

When assigning modifications for convened review, the ORA Administrator should also verify whether the study uses CTRC resources. If yes, the ORA Administrator should also assign the protocol to the IRB 3 administrator for screening. If it is determined that the modification does not impact CTRC resources, then the modification may be referred to another Board for review if necessary.

IRB Administrator
When screening the protocol, the IRB Administrator should confirm that the study does use CTRC resources and that the online application was not completed in error. Once CTRC resources have been confirmed, the IRB Administrator completes the screening according to standard practice. Once screening is complete, the agenda notes should be updated to indicate that joint review is required. In addition, one of the CTRC members who serve on the IRB should be assigned the primary or secondary review.
On occasion, the IRB may need to review a CTRC protocol at another Board besides IRB 3. If this occurs, the IRA administrator should consult with the Director to confirm that scheduling the protocol at a non-CTRC board is appropriate. Once this is confirmed, the IRB Administrator should contact the CTRC to confirm that they are willing to permit the protocol to be reviewed outside of the IRB/CTRC Joint Review process. After this review is complete, the study should be referred back to IRB 3 for future reviews.
Research Review Processes – Appendices

IBC Review Procedures

1. PROCESS OVERVIEW

The IBC is responsible for providing review and oversight to ensure that all forms of research involving recombinant DNA, infectious agents, human and non-human primate materials (including established cell lines), select agents, and human gene transfer studies conducted at the University of Pennsylvania and within the University of Pennsylvania Health System are in compliance with the NIH Guidelines and all of the University's policies. IRB approval of protocols requiring IBC review cannot occur until IBC approval has been granted. This section details the processes in place to ensure that the IRB accounts for IBC review during the review process.

2. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY

IRB Administrator
When screening the protocol, the IRB Administrator should confirm that IBC review is required. The online application's question should be answered yes to indicate when IBC review is requested. If the IRB Administrator believes that the question is answered incorrectly, the IRB Administrator should obtain confirmation from the study team regarding whether the study requires IBC review. Once IBC review has been confirmed, the IRB Administrator completes the screening according to standard practice. Once screening is complete, the agenda notes should be updated to indicate that IBC review is required before IRB approval can be granted. An administrative stipulation detailing the requirements for IBC review should be added to the determination letter. Once notification of approval is received by IBC, the submission can be placed for approval, assuming all other IRB stipulations are met.
Research Review Processes – Appendices

CTSRMC Review Procedures

1. PROCESS OVERVIEW

The Cancer Center's Clinical Trials Scientific Review and Monitoring Committee (CTSRMC) are tasked with reviewing most cancer related research. IRB approval of cancer related research protocols can occur prior to CTSRMC review, but subjects are not permitted to be enrolled until CTSRMC review has occurred or been determined to be not applicable. This section details the processes in place to ensure that the IRB accounts for CTSRMC review during the review process.

2. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY

IRB Administrator and Director

When screening a protocol, the IRB Administrator should confirm that the study is considered cancer related research. The online application’s cancer related research question should be answered yes to indicate that cancer-related studies are involved only if the research is not being conducted by an NCI cooperative group. If the IRB Administrator believes that the question is answered incorrectly, the administrator should obtain confirmation from the study team regarding whether is considered cancer related research. Once confirmed, the IRB Administrator should continue to screen and schedule the protocol according to standard practice. Once screening is complete, the agenda notes should be updated to indicate that CTSRMC review is required. An administrative stipulation detailing the requirements for CTSRMC review should be added to the determination letter if the study has not yet been reviewed by the CTSRMC.

If CTSRMC review occurs before IRB review, the IRB Administrator and Director may be forwarded a copy of the CTSRMC decision letter for review of any stipulations that may impact the IRB’s approval criteria. Prior to the convened meeting the IRB Administrator will contact the study team to request for a response to any stipulation that could impact the IRB’s approval criteria and upload the CTSRMC decision letter to the HSERA application in order to allow IRB Members access to this letter. The IRB Administrator will share any responses from the study team with the IRB Members to be considered during the convened meeting. If a stipulation impacts the IRB’s approval criteria and is not addressed prior to IRB review, the IRB decision letter will include a stipulation similar to the CTSRMC’s stipulation.

If the study is approved by the IRB prior to approval by the CTSRMC, the approval letter should include a note indicated that enrollment cannot commence until CTRSMC review has been obtained. The stamped informed consent form should be provided.
Research Review Processes – Appendices

Ancillary Review Procedures

1. PROCESS OVERVIEW

Penn has a number of entities that review human subjects’ research protocols. These Ancillary Entities have jurisdiction over research protocols that involve certain procedures. For example, studies that involve MRI procedures for research purposes must be reviewed by the Center for Advanced Magnetic Resonance Imaging and Spectroscopy (CAMRIS). The IRB can grant approval of research protocols before they are reviewed by the ancillary entity but subjects are not permitted to be enrolled until review has occurred. This section details the processes in place to ensure that the IRB accounts for Ancillary Entity review during the review process.

2. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY

IRB Administrator and Director
When screening a protocol, the IRB Administrator should confirm whether the study is subject to review by any specific ancillary committees. The online application contains multiple questions related to the ancillary committees’ review requirements and each question should be answered yes when committee review is required. If the IRB Administrator believes that the question is answered incorrectly, the IRB Administrator should obtain confirmation from the study team regarding whether a specific committee review is necessary. Once confirmed, the IRB Administrator should continue to screen and schedule the protocol according to standard practice. Once screening is complete, the agenda notes may be updated to indicate which committees are reviewing the protocol. If the study is approved by the IRB prior to approval by the ancillary committee, the approval letter template language confirms that the study team cannot enroll subjects until all relevant approvals have been obtained. The stamped informed consent form should be provided.
1. PROCESS OVERVIEW

The mission of the HRAC is to advise the Vice Provost for Research on the potential institutional impact of issues related individual research protocols (specifically use of gene transfer), and research programs when appropriate. HRAC may also advise on issues related to overall institutional approach to the execution of human research.

2. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY

IRB Administrator and Director
When screening the protocol, the IRB Administrator should confirm if the study involves gene transfer or any other elements of institutional risk or heightened risk to an Investigator. The online application’s gene transfer question should be answered yes to indicate that gene transfer is involved. If the IRB Administrator believes that the question is answered incorrectly, the IRB Administrator should obtain confirmation from the study team regarding whether the study involves gene transfer. Once confirmed, the IRB Administrator should inform the IRB Director that the protocol is being scheduled for review. The Director will contact the Vice Provost for Research to determine if HRAC review is warranted. The Director may also identify research that requires HRAC review because it may require special considerations regarding research subject or institutional risk. Once the determination is made, the Director informs the IRB Administrator. Either the Director or the IRB Administrator will contact the study team to inform them of the requirement for HRAC review. The details of the HRAC review process will also be sent to the study team by the IRB. Once screening is complete, the agenda notes should be updated to indicate that HRAC review is required before IRB approval can be granted. An administrative stipulation detailing the requirements for HRAC review should be added to the determination letter.
HSRAC Review Procedures

1. PROCESS OVERVIEW

The Human Stem Cell Research Advisory Committee (HSRAC) is charged with review of certain research protocols that involve human embryonic and human induced pluripotent stem cells. This section details the processes in place to ensure that the IRB accounts for HSRAC review during the review process.

2. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY

When screening the protocol, the IRB Administrator should confirm whether the study involves human embryonic or human induced pluripotent stem cells. If the IRB Administrator is unsure about the source of the cells, the IRB Administrator should obtain confirmation from the study team regarding whether the study involves the use of either human embryonic stem cells or human induced pluripotent stem cells. Once this has been confirmed, the Administrator informs the IRB Associate Director. The Associate Director notifies the HSRAC Administrator about the protocol. The Associate Director serves as a liaison for the HSRAC and will work with the Committee to ensure that they have the information needed to determine an appropriate course of action.

Often, stem cell research protocols submitted to the IRB will not meet the definition of human subjects’ research. The IRB Administrator should determine if the study requires review by the IRB. If the study does not meet the definition of human subjects’ research, the IRB Administrator should discuss whether the IRB’s determination letter should be held pending the results of the HSRAC committee review. HSRAC committee approval may not be required prior to issuance of an IRB determination letter. However, HSRAC must be notified of the protocol and given sufficient time and information to consider their review before the IRB determination letter is sent to the study team.

If the study is determined to meet the definition of human subjects’ research, IRB approval cannot be granted until HSRAC committee review and approval has been granted or the HSRAC Administrator has confirmed that HSRAC review is not required. The IRB Administrator and Associate Director will work with the HSRAC Administrator to make sure that issues related to IRB approval and HSRAC approval are resolved with the study team. The protocol will be reviewed according to standard practice but PennERA will be updated to indicate that HSRAC review is required.
Management of Conflicts of Interest: Investigators and Research Staff

1. PROCESS OVERVIEW

Conflicts of interest are defined by institutional policies and the federal regulations. Research protocols involving investigators with a significant financial interest must be reviewed to determine if the interest represents a financial conflict of interest that requires further action or management. The management of conflicts of interest is the responsibility of the Vice Provost for Research as Advised through the Conflicts of Interest Standing Committee (CISC). This section details the steps taken to ensure the IRB accounts for this review process.

2. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY

IRB Administrator
Principal Investigators are required to certify that they have reviewed the institutional policy on conflicts of interest related to research and as part of the IRB protocol application, all study team members with significant financial interests to report must be identified. If a significant financial interest requiring reporting is identified, the individual must submit a financial disclosure through the applicable electronic reporting systems. When screening the protocol, the IRB Administrator should determine whether the study team has identified a potential conflict. The online application’s question regarding significant financial interests should be answered yes in the event that a significant financial interest requiring reporting has been identified. If the study does have significant financial interest requiring reporting identified, the IRB Administrator should notify the Associate Director.

IRB Associate Director
The Associate Director will correspond with the Office of the Vice Provost for Research as applicable to facilitate their review. The IRB Associate Director and the Associate Vice Provost for Human Research participate in the CISC discussions and inform the development of management strategies needed to ensure human subjects protections issues are addressed.

IRB Administrator
The IRB Administrator completes the screening according to standard practice. Once screening is complete, the agenda notes should be updated to indicate that CISC review is required before IRB approval can be granted. An administrative stipulation detailing the requirements for CISC review should be added to the determination letter.

Regulatory Representative
During the convened meeting, the Regulatory Representative will provide an update on the conflict of interest review including a summary of any management plans implemented by the time of the convened IRB review.
Once review by the Office of the Vice Provost for Research has been completed, the review determination will be sent to the IRB. When the review determination is received by the IRB, the Associate Director will then review the determination and the study protocol and determine if any further revisions to the documents submitted to the IRB for review, including the consent form are necessary based on the final management plan. In the event that additional protections are required to ensure human subjects protections that extend beyond those which have been incorporated in the management plan required by the Vice Provost for Research, a convened IRB will be required to review the plans for management and institute any required changes necessary to ensure that human subjects protections have been appropriately addressed and the study meets the criteria for IRB approval. This could include any changes needed to the management strategies in response to an investigator appeal.

The results of this review will be forwarded to the administrator.

**IRB Administrator**

The IRB Administrator will then continue to process the response submission according to standard practice. If additional changes are required, the administrator will either forward these changes to the study team or when applicable, schedule a convened IRB review. The IRB Administrator and Associate Director will summarize the management plan and the review. This summary will be documented in the response submission and the IRB meeting minutes.

When continuing reviews are received for studies where an interest requiring reporting is identified, the administrator will contact the Associate Director to determine if any further action is required. The Associate Director will correspond with the Office of the Vice Provost for research to determine if follow-up action related to the reported interest is required before continuing re-approval can be granted.
Requests to Certify Submissions of Data to the NIH GWAS Data Repository

Appendix Overview
This section details how the IRB reviews Requests for Certification of Data Submission for Sharing of Data in NIH Supported or Conducted Genome-Wide Association Studies.

PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY

IRB Front Desk Administrative Assistance or ORA Administrator
GWAS certification request are received as either paper modification submissions or HS-ERA Modification Submissions. The submission is received and assigned to an IRB Administrator in the same manner as an expedited modification and should be logged in PennERA as an Amendment.

IRB Administrator
The IRB Administrator reviews the submission to determine if certification of the request is appropriate. The submission should be reviewed for completeness. The submission should include a cover letter, a copy of the informed consent form, and the HIPAA authorization form and protocol summary if appropriate. If documents are missing they can be obtained from existing file or via email to study team.

Documents are reviewed to determine if NIH criteria for certification have been met. If questions or concerns are raised, the administrator should contact the study team via email. PennERA and HS-ERA should be continuously updated in a manner similar to pending modification submissions. GWAS requests should not be returned to the study team via HS-ERA unless multiple significant concerns are raised. The IRB Administrator should seek approval from senior staff before returning these submissions.

Once all questions have been addressed by the study team, the submission is placed up for review by the IRB Director. A summary of the request, the issues raised, and a final recommendation regarding whether certification is or is not appropriate should be attached to the submission.

The IRB Administrator should draft a certification letter using the existing GWAS templates. This letter should be provided to the director. GWAS template letters are not available in PennERA but will be provided to the administrator by a senior administrator upon request. The Administrator should update the PennERA Summary Page to reflect that GWAS certification has been obtained.

IRB Director
The IRB Director reviews the submission and determines if certification is appropriate. If the Director approves the request, the certification letter is requested from the IRB Administrator. The Director forwards that letter to the Institutional Official for signature.

Once the letter is signed by the Institutional Official, the Director forwards that letter to the administrator for processing

IRB Administrator
The IRB Administrator is responsible for conveying the Director’s decision to the study team.

If the request is not approved by the Director, the IRB Administrator drafts a miscellaneous template letter to the study team detailing the rationale for the decision not to certify the submission of data. PennERA is updated to reflect the decision and include the letter. The process is similar to expedited modifications except that the submission should not be reported on IRB agendas. The letter is signed and forwarded by an assistant in a similar manner to expedited modifications. If the study team wishes to respond to the submission, that response will be processed as a new request for certification.

If the request is approved by the Director, the signed letter is forwarded to the study team. PennERA should be updated in a similar manner to expedited modifications except that the submission should not be reported on IRB agendas. The letter should be included in paper or HS_ERA file and PennERA.
OHRP Certification Letters

1. PROCESS OVERVIEW
This appendix details the process of obtaining an OHRP certification letter. This certification letter is required for any NIH/federally funded project that enrolls prisoner subjects.

2. RESPONSIBILITY

IRB Front Desk Administrative Assistant
The role of the FD IRB associate is to receive and forward the OHRP letter and materials.

IRB Administrator
The role of the IRB Administrator is to draft the letter and provide it to the Executive Chair or designee for review.

Director or Designee
The role of Director or designee is to review the OHRP letter and sign the letter.

3. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY

IRB Administrator
The IRB Administrator will need to generate an OHRP letter when an HHS funded project will directly interact with prisoner participants. A subpart C determination will need to be completed and IRB approval of the project must be granted before a certification letter can be generated. The IRB Administrator should inform the research team that prisoner subjects should not be enrolled in a project before the certification is completed.

The IRB Administrator should use the OHRP certification template when drafting the letter. The IRB Administrator should also gather paper versions of the application, consent forms which will be used with prisoners, necessary secondary documents that will be used with prisoners, the HHS grant, and vulnerable populations supplemental form provided by the research team.

The IRB Administrator ensures that contact information for Penn and for the OHRP sis included at the beginning of the letter. The contact information for OHRP should note the grant number, grant coordinator, OHRP Assurance number, and the IRB number. The grant information should be provided by the research team. The OHRP certification contact information can be found on the OHRP website pertaining to OHRP certification letters.

The minutes from the IRB Board meeting corresponding to the subpart determination can be used to complete the body of the letter. Each of the 7 criteria for approval for subpart C determination should be incorporated into the letter, each as a separate paragraph. The rationale and the final determination for each of the 7 criteria by the board should be detailed in the body of the letter. The date of the initial IRB review and date of the Subpart C should be included in the letter.

The Director of the IRB should be used in the salutation and a list of the documents is included as an enclosure. The IRB Administrator places the letter up for final review.
The Director of the IRB reviews the OHRP letter and signs the letter if completed. If the Director notes issues with the letter, this letter is returned to the IRB Administrator for correction.

**IRB Administrator**

The IRB Administrator correct any issues noted by the Director. After receiving the signed letter, the IRB Administrator compiles the OHRP certification packet and places the certificate request letter on top.

**IRB Administrator**

OHRP will review the certification packet and determine if the project meets its own criteria. Once certified, OHRP will send the IRB a certification approval letter. This letter should be copied and the copy placed into the IRB folder in the action approving the Subpart C. The original letter should be forwarded to the research team.
Research Conducted by Penn Investigators in Foreign Countries

Appendix Overview
When Penn Investigators plan to conduct human subjects' research in foreign countries, there are some additional considerations and requirements involved in the IRB review process. This section outlines the considerations and determinations the IRB may make when protocols involve Penn Investigators conducting human subjects' research in foreign countries.

Considerations for International Research:
The IRB Administrator should determine if any member of the study team is planning on conducting the research in a foreign country. The online application should detail where the study will be conducted and the personnel who will be traveling. If it is unclear where the study will be conducted and who will be involved at the study site, the IRB Administrator should contact the study team and confirm this information.

In order to insure that the protocol is reviewed by individuals with expertise and knowledge of the country, local laws, and cultural context, all studies that are conducted in foreign countries must be approved by the local country's appropriate regulatory bodies, when applicable. This typically involves approval from an IRB or ethics committee that oversees research at the study site. Additional approvals may be required from government agencies (e.g. Ministries of Health, Education, Labor, etc). The IRB should verify the regulations governing research in that country and contact the study team to confirm that appropriate approvals have been sought. IRB staff are encouraged to refer to the International Compilation of Human Research Standards document compiled by the Office of Human Research Protections to identify appropriate regulations. The Compilation is stored on the IRB shared drive for staff's reference. When appropriate, IRB staff may consult with local review entities directly to obtain information regarding the submission.

In the event that the country does not have a local IRB or Ethics Committee that can review the protocol and assess local considerations, the study team must provide the IRB with a review of the research by a local expert which could include a researcher, or representative from a local institution or community organization that has appropriate expertise to review and comment on the appropriateness of the research and the plans for human subjects protections with consideration for any issues related to the local context.
For all studies that are conducted in foreign countries, the study team must obtain approval from that country's appropriate regulatory bodies. This typically involves approval from an IRB or ethics committee that oversees research at the study site. Additional approvals may be required from government agencies (e.g. Ministries of Health, Education, Labor, etc). The IRB should verify the regulations governing research in that country and contact the study team to confirm that appropriate approvals have been sought. IRB staff are encouraged to refer to the International Compilation of Human Research Standards document compiled by the Office of Human Research Protections to identify appropriate regulations. The Compilation is stored on the IRB shared drive for staff’s reference.

The Penn IRB cannot approve research conducted in a foreign country until documentation of local IRB or ethics committee approval has been obtained. If there are no regulations governing research in a country and the study site does not have a local IRB or Ethics Committee, the study team must identify a local entity or community organization with appropriate expertise to
review and comment on the research. The study team should provide the IRB with information about this review entity.

If the study is being conducted with non-English speaking subjects, the study team must provide translated copies of the consent form(s). English and translated versions of the consent form(s) should be included in the IRB application.

There are circumstances where Penn IRB approval is needed before consent forms can be translated and local approval can be obtained. In these circumstances, the Penn IRB can review the study to determine if it meets the criteria for approval. However, the Penn IRB will not approve the study. Instead, the IRB will classify the study as administratively finalized. The IRB will issue a letter to the study team indicating that the IRB has determined the criteria for approval have been met but final approval will not be granted until documentation of local approval and/or translated copies of the consent(s) have been provided. The IRB Administrator is responsible for ensuring that the administratively finalized letter includes the appropriate issues that need to be addressed.

When reviewing continuing review and modification applications for research conducting in foreign countries, the IRB staff considers whether any information in the submission warrants input from the local review entity. If consult is needed, IRB staff may request documentation of local IRB or Ethics Committee approval of the action or request confirmation that their approval will be sought before changes are implemented. When appropriate, IRB staff may consult with local review entities directly to obtain information regarding the submission.

Penn investigators are required to submit reports of potential non-compliance, subject complaints, and unanticipated problems to the IRB according to applicable regulations and Penn policies. This includes reports regarding the actions of Penn study personnel in research conducted in foreign countries and reports for protocols where Penn has a lead site oversight role in research conducted in foreign counties. The IRB will review these reports according to standard operating practices. If consult is needed, IRB staff may request documentation of local IRB or Ethics Committee review of the report and any corrective actions required by local review. When appropriate, IRB staff may consult with local review entities directly to obtain information regarding the submission.
Research Review Processes – Appendices

Quality Control and Improvement Program

1. PROCESS OVERVIEW
This section details how IRB staff act to ensure that work is completed in a timely and accurate manner. The section also details how staff typically works to correct errors and omissions in processes and procedures.

2. RESPONSIBILITY

**Director**
The Director tasks the members of the quality improvement team with specific projects and processes that need review. The Director also reviews and comments on the findings and recommendations made by the QI team.

**QI Team Leader**
The QI Team Leader serves as the supervisor of QI Coordinators and other team members with regard to Quality Improvement activities. The Team Leader designates individual responsibilities when completing specific tasks and provides guidance on how processes should be implemented.

**QI Coordinators and Team Members**
QI Team Members primarily review IRB minutes in order to ensure complete and accurate documentation of decisions. They also participate in other QI activities at the discretion of the Director and Team Leader.

3. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY

**Quality Control of Daily Operations**

The IRB’s day to day review procedures were designed with multiple layers or review in order to ensure that work is completed in a timely and accurate fashion. Processes involve IRB Administrative Assistants, IRB Administrators, and senior members of IRB staff. All staff members are charged with reviewing the work presented to them and identifying errors and omissions. Corrections are made as they are identified in order to ensure an accurate record of the IRB’s reviews.

**Quality Improvement Review of IRB Minutes**

All convened, expedited, and exempt review determinations are documented in the monthly IRB minutes. This minutes document is sent to the Board members for review per the federal
regulations. Because of its near comprehensive documentation of IRB review activities, the minutes are a central document in the quality control review processes.

**QI Team**
After the minutes have been generated and reviewed according to IRB policies, they are sent to a QI Coordinator for review. The QI Coordinator reviews the minutes to ensure that they contain complete and accurate documentation of that months’ convened, expedited, and exempt reviews. If errors or omissions are identified, the coordinator determines which member of the IRB staff is in the best position to resolve the error. After the QI Coordinator’s review is complete, the QI Coordinator notifies the staff of errors and omissions for prompt corrections.

**QI Team Leader**
The QI Team Leader is responsible for ensuring that the minutes review occurs promptly and that identified errors are resolved. The QI Team Leader will also resolve any disputes related to the review of the minutes and will report any unresolved findings for the Director, if necessary.

**QC/QI Process Development**

If new quality control needs are identified, new quality improvement and quality control processes may be developed in order to better ensure accurate and timely completion of IRB activities. While needs may be identified by any member of the IRB staff, the QC development processes may not move forward without approval from the Director. The Director will charge the QI team leader and other members of IRB staff to develop new processes. These processes will then be presented to the IRB staff before implementation. Processes will be piloted and revised as needed. If the process is determined to be effective and appropriate, the Director will determine if it should be made permanent. Once the process is made permanent, IRB policy documents will be reviewed to determine if any revisions are required in response to the new process.
Research Review Processes – Appendices

Federalwide Assurance and OHRP Roster Updates

1. PROCESS OVERVIEW

The IRB is required to keep its Federalwide Assurance and its rosters registered and up to date with the Office of Human Research Protections. The processes for completing these tasks are described below.

2. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY

Director
The IRB Director works with the Institutional Official to ensure that the University’s Federalwide Assurance (FWA) remains current. The FWA must be renewed every 5 years. However if changes are made to the legal name of the Institution, the Human Protections Administrator/IRB Director, or the Signatory Official at any time during the 5 year approval period, the FWA must be updated within 90 days. The Director will complete the steps necessary for submitting timely FWA renewal requests. The Director may designate support staff to assist in this process.

The Director is also responsible for updating the membership rosters filed with the Office of Human Research Protections (OHRP). The Director will regularly review the OHRP rosters and update them according to the rosters stored on PennERA and the G: Drive. The Director may designate support staff to assist in this process.
Responding to Subject Questions and Complaints

1. PROCESS OVERVIEW

Research subjects are encouraged to contact the IRB if they would like to speak to someone who is not a member of the study team, have questions about their rights as a research subject, or would like to register a complaint about a research study. This section describes how the IRB receives and responds to these communications with subjects.

2. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY

The Informed Consent Form template includes a telephone number subjects can use to call the IRB if they have questions, concerns or complaints regarding their participation in a research study. The template language informs subjects that it is recommended that they first speak with the principal investigator for the study but if a member of the study team cannot be reached or subjects want to speak to someone who is not working on the study, then they should contact the IRB.

IRB Front Desk Assistant

The phone number provided is staffed by the IRB Front Desk Assistant during normal office hours. The Front Desk Assistant will first receive the call and identify that it is a subject complaint. The Assistant should then identify which IRB staff member is available to take the call. Subject complaints should be forwarded to the IRB Assistant Director. If the Assistant Director is unavailable, the Associate Director or Director should take the call. If they are not available, an experienced member of the IRB staff may take a message and forward it on to the Assistant Director.

IRB Assistant Director

The IRB Assistant Director receives the complaint or questions from the subject. The Assistant Director takes informal notes during the conversation. The Assistant Director focuses on obtaining information about the question or complaint, information about the study the subject was enrolled on (name of principal investigator, study title, etc.), and the name of the member of the study team with whom the subject has been interacting.

The Assistant Director should take down the name and contact information for the subject who is raising the concern. The Assistant Director should also confirm whether or not the subject is lodging the complaint anonymously or if the subjects’ name can be used when inquiring with the study team or others. Finally, the Assistant Director should give the subject a time frame for when the subject should expect to receive a resolution or update on the status of the complaint.

The Assistant Director then drafts a summary of the notes taken during the conversation. The complaint is also logged on the Subject Complaint tracking spreadsheet stored on the G: Drive. This spreadsheet only contains identifiable information and the name of the IRB staff member handling the complaint. The nature of the complaint is not stored on the spreadsheet.
Assistant Director should take care to securely handle the information obtained from the subject. Discussions and email correspondence about the complaint should refrain from using identifiable information unless absolutely necessary and the subject has given the IRB permission to use identifiable information.

The Assistant Director contacts the study team to obtain any additional necessary information from them about the study. The Assistant Director then discusses the concern with the study team and together they attempt to resolve the issue. The Assistant Director provides recommendations for the resolution of this complaint and for taking steps to ensure similar complaints are not raised in the future. If additional entities at Penn or at other institutions need to be contacted, either the Assistant Director or the study team should contact the appropriate entities. At any point during this time, the Assistant Director may consult with the Associate Director and Director to determine the most appropriate course of action.

Once a plan for resolving the issue has been put in place, either the Assistant Director or the study team should contact the subject and inform them of the outcome. If the subject is unsatisfied with the result, additional steps can be taken to address the complaint.

In the event, the study team is unwilling to take the steps needed to resolve the complaint and the subject is unwilling to accept the study team’s response, the Assistant Director may refer to the complaint to the convened IRB for review. This complaint would be considered a reportable event and reviewed according to the Reportable Event Procedure.

The Assistant Director takes notes throughout this entire process. Once the complaint has been resolved, the notes and any supporting documentation are provided to the Director for filing. The Director maintains a subject complaint file for the IRB. The tracking spreadsheet is updated to indicate that the complaint has been resolved and no further action is required.
Research Review Processes – Appendices

Expedited Review Assignments

1. PROCESS OVERVIEW

In order to ensure actions submitted to the IRB for expedited review are assigned to reviewers with the appropriate and applicable expertise, IRB staff will utilize the review assignment plan outlined below.

2. PROCEDURES EMPLOYED TO IMPLEMENT THIS PROGRAM

Expedited submissions that are assessed to either have a potential impact on subject safety or require a scientific assessment to determine that continuing approval should be granted will be reviewed either by a scientific IRB member or physician scientist member, when necessary. If a submission has both a scientific IRB member reviewer and a physician scientist as consult, this will be documented by selecting two reviewers for the expedited action.

Examples of types of actions and appropriate reviewers include:

- Deviations with a potential impact on subject safety
  - Require review by an IRB Chair or appropriate IRB physician scientist member
- Exceptions with potential safety implications
  - Require review by an IRB Chair or appropriate IRB physician scientist member
- Potential Unanticipated Problems that meet IRB reporting criteria (unexpected and related events)
  - Require review by an IRB Chair or appropriate IRB physician scientist member
- Modifications to convened protocols that have a potential implication for subject safety (i.e. new safety data)
  - Require review by an IRB Chair or appropriate IRB physician scientist member

Expedited submissions that do not meet the criteria listed above will be assigned to scientific and non-scientific IRB members. Member assignments are based on the content of the submission and the expertise of the IRB members.

IRB Director, Associate Director and Assistant Director

The IRB Director, Associate Director and Assistant Director are responsible for ensuring that all actions assigned for expedited review are assigned to an expedited reviewer with appropriate and applicable expertise. This is monitored at the time of review assignment and final review based on the content of the specific submissions.
Research Review Processes – Appendices

Single Patient Treatment Use Requests/Compassionate Use Requests

This appendix describes the submission requirements associated with treatment use of an investigational product regulated by the FDA for clinical purposes with a single patient or group of patients.

Investigational drugs and devices that have not yet been approved by the FDA for marketing may be appropriate to use in the treatment of serious or life-threatening conditions either for a single subject or for a group of subjects who are not in clinical trials. The FDA allows such use of an investigational drug or device in these circumstances through expanded access mechanisms.

The following FDA mechanisms expand access to investigational drugs:
- Open label protocol or open protocol IND (investigational new drug)
- Treatment IND
- Group C treatment IND
- Parallel track
- Emergency use IND

The following FDA mechanisms expand access to investigational devices:
- Emergency use
- Compassionate use or single patient/small group access
- Treatment IDE (investigational device exemption)
- Continued access

The treatment use protocols commonly conducted at Penn are open label, treatment IND, and emergency use IND protocols.

In an emergency situation, the request to use an investigational drug may proceed without prospective IRB approval. If this occurs without prospective IRB approval, the IRB requires a follow-up report within 5 days of the event. The follow-up report needs to include affirmation that the treating physician and an independent physician, who was not otherwise participating in the treatment adequately certified the following in writing prior to use of the test-article:

- The human subject was confronted by a life-threatening situation necessitating the use of the test article.
- Informed consent could not be obtained from the subject because of an inability to communicate with, or obtain legally effective consent from, the subject.
- Time was not sufficient to obtain consent from the subject's legal representative.
- There was available no alternative method of approved or generally recognized therapy that provided an equal or greater likelihood of saving the life of the subject.
If immediate use of the test article is, in the investigator’s opinion, required to preserve the life of the subject, and time is not sufficient, prior to administering the test-article, to obtain an independent physician’s opinion, the determinations of the investigator must be reviewed in writing within 5 days after the use of the test article by a physician not otherwise participating in the clinical investigation. In this event, a copy of the independent review must be submitted to IRB within 5 days after the use of the test article.

Emergency use is not the same as “off label” use of approved drugs, devices, or biologics.

**Initial Submission Guidelines:**

At the time of considering a treatment use request, the IRB should be made aware of the request to provide expanded access of investigational product to a patient(s) even if the FDA has not yet authorized the treatment IND, single patient IND, compassionate use IDE or treatment IDE in order to begin the review process. However, the IRB requires approval documentation from the FDA of the expanded access request prior to issuing approval.

**Submission requirements for use of investigational products under expanded access:**

Prior to approving treatment use of an investigational product the IRB must review the following:
- A single patient treatment use cover letter (template provided on the IRB’s forms webpage)
- Assurance document for a patient receiving access to an investigational drug/biologic/other therapy via a single patient treatment use request (form provided on the IRB’s forms webpage)
- For an investigational drug:
  - Single patient IND application or treatment IND application
  - Documentation of single patient IND or treatment IND granted by the FDA
- For an investigational device:
  - Documentation of IDE supplement for compassionate use or treatment IDE
- A sponsor, manufacturer or investigator protocol
- Informed consent and HIPAA authorization form modified according the IRB’s consent template for treatment use protocols
- Investigator’s brochure, instructions for use, user’s manual or supporting documentation related to safety
- Documentation from the manufacturer approving the plan to supply the drug
- Other documents as requested by the IRB (e.g. FDA Form 1571)

**Consent Form Template:**

The template consent form for treatment use protocols is located on the IRB’s forms webpage. The single patient treatment use consent form template should be used when developing a consent form for a treatment use protocol.
Research Review Processes – Appendices

Application of International Conference on Harmonization (ICH) Good Clinical Practice (GCP) (E6) Guidance

PROCESS OVERVIEW/DEFINITION OF GUIDANCE:

Good clinical practice (GCP) is an international ethical and scientific quality standard for designing, conducting, recording, and reporting trials that involve the participation of human subjects. Compliance with this standard provides public assurance that the rights, safety, and wellbeing of trial subjects are protected; consistent with the principles that have their origin in the Declaration of Helsinki, and that the clinical trial data are credible.

The objective of this ICH GCP guidance is to provide a unified standard for the European Union (EU), Japan, and the United States to facilitate the mutual acceptance of clinical data by the regulatory authorities in these jurisdictions.

The guidance was developed with consideration of the current good clinical practices of the European Union, Japan, and the United States, as well as those of Australia, Canada, the Nordic countries, and the World Health Organization (WHO).

This guidance should be followed when generating clinical trial data that are intended to be submitted to regulatory authorities.

The principles established in this guidance may also be applied to other clinical investigations that may have an impact on the safety and well-being of human subjects.

APPLICATION OF ICH-GCP (E6):

As ICH-GCP (E6) provides supplemental guidance in addition to the FDA and DHHS regulations, ICH-GCP (E6) will not be followed to completion for most research conducted at the institution. For a complete overview of which parts of ICH-GCP (E6) the University of Penn IRB is not compliant with, the ICH-GCP compliance letter, available on the IRB website, should be referenced.

For research submissions that require alignment with ICH-GCP (E6), the IRB will work the Principal Investigator (PI)/Research Team to meet the additional elements outlined in ICH-GCP (E6).

IRB Administrator
When screening an initial submission, if it is requested in the submission that the study be aligned with ICH-GCP (E6), the IRB Administrator will bring this request to the attention of a member of the senior team.

Senior IRB Administrator/Assistant Director/Associate Director/Director
The request to align the submission with ICH-GCP (E6) will be considered and if appropriate for the particular submission, the IRB Senior Staff will work the IRB Administrator and the research team to employ any revisions needed to align the submission with ICH-GCP (E6) guidance.
Management of Conflicts of Interest: Organizational/Institutional

1. PROCESS OVERVIEW

Conflicts of interest are defined by institutional policies and the federal regulations. In addition to individual investigator interests, interests of the institution that could potentially impact the conduct of any specific human subjects' research protocol or the integrity of the Human Research Protections Program (HRPP) must also be addressed. When institutional interests of this nature are identified, review is required to determine appropriate strategies for mitigating or managing the interests. The review of organizational/institutional conflicts of interest is the responsibility of the Human Research Advisory Committee (HRAC).

2. PROCEDURES EMPLOYED TO IDENTIFY POTENTIAL ORGANIZATIONAL/INSTITUTIONAL CONFLICTS OF INTEREST

Potential organizational/institutional conflicts of interest that may require review/management by HRAC may be reported to the IRB by a variety of mechanisms including but not limited to:

1. Directly through the IRB application through identification of intellectual property interests or interests of a senior departmental leader
2. Through the review of individual financial interests reported to the Office of the Vice Provost for Research
3. Via the Penn Center for Innovation

Director/Associate Director

The Director/Associate Director will receive notification of a potential organizational/institutional conflict of interest either by the IRB Administrator screening the submission for completeness or via an external office as noted above. Any potential ICOIs identified directly to the IRB will be referred by the Director/Associate Director to the Vice Provost for Research for consideration of the requirement for HRAC review. The Director/Associate Director will attend the HRAC meeting and subsequent to the meeting will ensure that any required management strategies that may impact the IRB submission for a given protocol are implemented before the IRB grants approval.

IRB Administrator

The IRB Administrator, as part of the completeness check process for initial submissions, modifications or requests for continuing review, may identify through the screening of the HSERA application that a new institutional interest (e.g. interest of a senior leader or intellectual property interest) has been identified. In these instances, the IRB Administrator will notify the IRB Director/Associate Director. The IRB Administrator will also note in Penn ERA and HSERA that the submission may not be approved until HRAC review has occurred or a determination that HRAC review is not required has been made.
Research Review Processes – Appendices

Community Outreach Activities and Periodic Evaluations

1. PROCESS OVERVIEW

Community outreach should occur in an ongoing fashion and feedback provided from the research community in the surrounding area should be incorporated into research practices in order to improve subject understanding of what research entails and what participation in research means. The IRB website contains information for subjects about participation in research and some links to information pertaining to the role of a research subject.

On an annual basis, the community outreach efforts and information provided for the research community are assessed and any improvements/additions that can be made are incorporated. These assessments and any revisions/improvements made in response shall be announced via a memo on the IRB website for the research community and the Philadelphia area to view.

2. PROCEDURES EMPLOYED TO IMPLEMENT THIS PROGRAM

Assessments of ongoing community activities will occur to verify opportunities to reach out to the general public in the Philadelphia area and provide information/education about available research studies and the role of the research subject.

Annually, the IRB will solicit a report of all community outreach efforts conducted by members of the Penn research community. This will include reporting from investigators conducting community engagement and outreach to specific communities as a part of IRB approved protocols. Examples would include results of community consultations for protocols requesting exception from informed consent, targeted recruitment initiatives and field work in specific communities conducted to obtain input on study design and execution. These reports shall include any results of evaluations performed for these activities.

Annually the IRB will collate these efforts into one report for analysis. This annual report compiled by the IRB, which will also include additional community outreach specifically conducted by the HRPP, will be reviewed at the IRB Chairs meeting and will be assessed for determining what revisions/additions/deletions should be made to community outreach practices. The findings of the IRB Chairs will be reported back to all entities engaging in community outreach. Best practices will be developed in partnership with the research community and will then be shared with the community. These assessments and any revisions/improvements made in response shall be announced via a memo on the IRB website for the research community and the Philadelphia area to view.

The progress of these efforts will continually be monitored through the annual reporting and evaluation described above.

Associate Director and other designated personnel:

The Associate Director oversees the team of IRB staff participating in community outreach activities led by the IRB and is responsible for securing information about the community outreach activities of the research community and compiling them into the annual report for
evaluation. Staff members may be selected to participate, based on their background or particular role at the IRB, or Staff members may volunteer to work on these efforts. The Associate Director considers proposals from the IRB staff, or the research community, and identifies which proposals may produce the most advantageous opportunities to reach the potential research community in the Philadelphia area based on the annual evaluations.
Research Review Processes – Appendices

Community Based Research and Exception from Informed Consent (EFIC)

1. PROCESS OVERVIEW

The IRB supports the conduct of research that involves community involvement and will generally be aligned with a request for exception from informed consent (EFIC). The IRB provides guidance to the researcher and their team related to these types of submissions by providing a timeline for best practices to have this research reviewed and providing support to the community consultation process.

2. PROCEDURES EMPLOYED TO IMPLEMENT THIS PROGRAM

The initial review of research of this nature is focused solely on the plan for community consultation and outreach.

One of the IRBs at Penn has received specific training in EFIC research and community consultation and outreach. This IRB will review all requests for EFIC research and will attempt to maintain a membership that has at least one member who has an invested effort in the Philadelphia community or prior experience with research of this nature. Each IRB will always have a community member on the roster, but the community member may not be present at all meetings.

The specific training received by the IRB was led by the Program Manager for a researcher who has conducted EFIC research in the past. The Committee was informed of the expectations for their review of the community consultation and outreach plan and was encouraged to attend the scheduled sessions themselves.

If the pre-determined date of the meeting for the Committee did not allow for appropriate representation available for the meeting, the IRB may seek consult related to the community consultation plan or any other outreach procedures. The consultant would either attend the meeting for the review of the particular protocol or would provide commentary that would be provided to the members in advance of the meeting.

To date, there have been only a small number of requests for EFIC research; therefore, the application materials do not distinctly speak to the criteria necessary for exception from informed consent and the corresponding community outreach process. IRB staff will assist the researcher and their team with these types of submissions and will verify that enough information is present to determine that the community outreach plan is sufficient and will target the appropriate potential subjects. If any revisions are required to the community outreach plan, the IRB will raise these in the stipulations letter to the research and their team.
Once the community consultation plan is complete, the IRB will receive a report of the outcome and any revisions proposed to the initial research idea and/or design as warranted. The IRB will also be informed of approval, if required, or status of review, from any local offices or officials (i.e. City of Philadelphia representatives).

**Assistant Director**

The Assistant Director provides initial support to the researcher and their team regarding creation of the IRB application and providing of the necessary components to consider the exception from informed consent and the corresponding community outreach plan.

**IRB Administrator**

The IRB Administrator schedules the submission for convened review and works with the members in advance of the meeting to address any substantial concerns. The IRB Administrator reports to the Assistant Director the attendance for the meeting that is reviewing the submission and verifies that the appropriate representation of the community will be present. If not, the IRB Administrator works with the Assistant Director to obtain a consult from an appropriate member/research community representative in advance of the meeting.

The IRB Administrator drafts the correspondence back to the researcher and their team outlining any stipulations and/or recommendations related to the community consultation plan. The IRB Administrator also receives the final report from the research and their team related to the outcome of community consultation and schedules this for review when complete.

**IRB Members**

Once the community consultation plan is accepted and the local reviews are completed as required, the remainder of the IRB review aligns with the standard practices for initial reviews (establishing the approval criteria are met and verifying that the research qualifies for exception from informed consent).