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 and Associate Director**
The Director and the Associate 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 or Associate 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 draft to determine if it is satisfactory. Once revised policies are determined to be appropriate, the Director will determine if further review by the Executive Chair or 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 and Associate Director**
The Director and the Associate 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 or Associate 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 fourth 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 year.
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 Designees
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 Designees
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. Feedback from the Director is often solicited.

Individual Trainings

Associate Director and Designees
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 Executive Chair and Senior 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 Associate 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 members are required to sign a statement detailing that they are aware of and agree to University Policy.

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.
IRB Membership Administrative Processes

Membership Recruitment and Selection

1. PROCESS OVERVIEW

The Board Member recruitment process is flexible and Senior Staff and the Executive Chair 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.

Executive Chair
Reviews membership requests and approves new Board members.

3. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY

The overall Board Membership recruitment strategy is set by the Director in consultation with the Executive Chair. 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 Executive Chair.

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 discussion the staff member forwards the information to the Executive Chair for review.

**Executive Chair**
The Executive Chair receives a copy of the potential members CV and a description of the Boards and membership slots that are available at this time. The Executive Chair considers the expertise of the member and the needs of the IRB when deciding whether to approve a term for the Member. The Chair informs the senior staff of the decision.

**Senior IRB Staff**
If the member is accepted, the Senior Staff member begins the process of adding the member to a roster and training the new member.

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

Executive Chair
The Executive Chair reviews IRB membership letters for IRB Members and will provide a signed IRB membership to a designated IRB Administrator.

IRB Roster Administrator
The IRB Roster Administrator is responsible for the maintenance of all IRB rosters for each individual Board and corresponds with the Executive Chair, the Board Members, and the IRB Administrative Assistant to ensure the most current Board membership information is captured in the appropriate record databases.

IRB Roster Assistant
The role of the IRB Roster Assistant is to draft and convert IRB membership letters for new and renewing Members.

IRB Administrators
The IRB Administrator is responsible for updating Member information in PennERA and corresponding with the Roster Administrator to ensure that membership letters are sent to Board 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 Roster Administrator. 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.

**IRB Roster Administrator**
The IRB Roster Administrator tracks all new membership additions and processes them as part of the monthly membership letter generation process.

### Renewing Existing Membership Terms

**IRB Roster Administrator**
On a monthly basis, IRB members with terms that are set to expire in the near future are identified. The IRB Roster Administrator compiles a list of the current Board Members who are set to expire and sends a monthly email notification to the IRB administrator. The Roster administrator also includes any previously identified new members in this email in order to remind administrators to update their rosters accordingly.

**IRB Administrator**
After receiving the email from the Roster Administrator, the IRB Administrator contacts both the Board Chair and the Executive Chair and requests their determination on whether the member's term should be renewed or expired. If the Chairs 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 Roster Administrator 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.

**IRB Roster Administrator**
The IRB Roster Administrator tracks all membership renewals and expirations and processes them as part of the monthly membership letter generation process.

### 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, Executive Chair, 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 Roster Administrator that a thank you for your service letter should be drafted for the member.

**IRB Roster Administrator**
The IRB Roster Administrator tracks all terminations and processes them as part of the monthly membership letter generation process.
Membership Letter Generation

**IRB Roster Administrator**
On a monthly basis, the IRB Roster Administrator compiles all membership letter requests received for the IRB Members into a single email. That email contains sufficient information for the IRB Roster Assistant for creating draft membership letters for each request. The email is sent to the Roster Assistant.

**IRB Roster Assistant**
After receiving an email from the Roster 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 Roster Administrator.

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

**Executive Chair**
The Executive Chair reviews and signs the IRB membership letters. Signed letters are then returned to the Roster Administrator.

**Roster Administrator and Assistant**
The Roster Administrator and 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, 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 required 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 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 conducts a mentorship program for new IRB members. This program pairs new members with seasoned IRB members on the same Board. 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 are 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

Executive Chair, 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. The Executive Chair often participates in this meeting. However if the Chair is unable to participate the results of the discussion will be reported by an attendee.

Expiration Review

**Executive Chair, IRB Chair, and IRB Administrator**

When a Board members term is set to expire, the IRB administrator asks the Chair and Executive Chair to consider whether the member should be asked to return for another term. The Chairs review the members’ expertise and contributions to the Board over the previous term. The Chairs 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.
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 gives it to the Roster Administrator or Assistant for filing.

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 ensure that the items scheduled for the meeting agenda have been screened and scheduled appropriately. The Senior Administrator also reviews 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 assigns primary reviewers for all continuing review submissions. The IRB Administrator assigns Primary and Secondary reviewers for all submissions for initial review. The IRB Administrator also assigns primary reviewers for all modification submissions and reportable events. The IRB Administrator also reviews the IRB Administrative Assistant’s continuing review assignments and makes any revisions as necessary.

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

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. Once the agenda has been finalized, the IRB Administrator forwards it to the Senior Administrator for review.
Senior Administrator

The Senior Administrator reviews each item scheduled for the convened Board’s consideration. The Senior Administrator ensures that convened review is appropriate and that no submissions are eligible for expedited review. The Senior IRB Administrator checks to ensure that the items were screened correctly and that any notes for the Board’s consideration are included.

Revisions to the agenda document and/or individual submissions are forwarded to the IRB Administrator. If items are determined to be eligible for expedited review, the Senior Administrator ensures that they are removed from the agenda and re-assigned to appropriate staff.

IRB Administrator

The IRB Administrator makes the revisions requested by the Senior Administrator. Once the agenda is finalized, the IRB Administrator forwards it to the IRB Administrative Assistant for packet distribution. The IRB Administrator sends the agenda to the Board members in an email along with the minutes from the previous months meeting. The email should also include 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.

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 packets of 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 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 members or the study team prior to the meeting.

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.

Primary and Backup IRB Administrators, Administrative Assistant, and Senior Administrator

Prior to the convened meeting, the IRB Staff attending the meeting and the appropriate Senior Administrator 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 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 backup IRB Administrator(s), 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” 15 minutes. 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 anytime 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 Modification 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 shared between the primary and backup administrators. The primary administrator determines which initial protocols will be assigned to the primary and backup administrators. The assistant is responsible for drafting letters and minutes for continuing reviews and modifications. The primary 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 month’s 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 Senior Administrator for review.

IRB Senior Administrator:

The IRB Senior Administrator reviews the finalized meeting minutes of the Continuing Reviews and Modifications to identify any potential errors and omissions. The IRB Senior Administrator provides comments and questions to the Administrator so that revisions can be made.

IRB Administrator:

After all issues raised by the Senior Administrator have been resolved, the IRB administrator will forward the minutes document to the QA coordinator for review. 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.
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 Subject Complaints
Senior members of the IRB staff receive and process any complaints from research participants. Staff record the information received from the participants and work with the study team and other relevant Penn Offices to resolve the complaint. The IRB staff member keeps a record of his or her work to resolve the complaint. If the IRB staff member is able to reach an acceptable resolution, the complaint is logged and stored by that staff. If the staff member is unable to resolve the complaint, the issue will be processed as a reportable event that requires convened IRB review. All documents created by the staff member will then be incorporated into the protocol file.

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 resumes are stored on the G: Drive in designated folders. The IRB Roster 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 for 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

IRB Administrator

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 Office of the Vice Provost for Research. This list of protocols also contains information related to the industry sponsor that will be billed.

The IRB Administrator also receives a copy of a finalized contract for any human subjects’ research protocol. The Billing Administrator reviews the contract to determine if it contains language related to IRB fees. The administrator 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 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. Experienced IRB member reviewers designated in writing by the Executive Chair review submissions to determine if they meet the HHS and FDA definitions of human subjects research. Reviewers may request revisions to the submitted documents and review the revisions prior to forwarding the submission to the Executive Chair 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.

Executive Chair or Designee
The Executive Chair 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.

**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 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 there of) 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.

Executive Chair 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 word document and makes revisions to ensure that the letter is appropriately formatted and accurately indicates if the project fails to meet the definition of research or the definition of human-subjects research. 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

Exempt Research Reviews

1. PROCESS OVERVIEW
Experienced IRB member reviewers designated in writing by the Executive Chair 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 Executive Chair 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.

Executive Chair or Designee
The Executive Chair 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.
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 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 convened IRB review is required, the submission should be returned to the study team so they can complete an application for full board review.

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.

Executive Chair 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 designated in writing by the Executive Chair 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 Executive Chair or Designee for approval of the concept in principal.

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.

Executive Chair or Designee
The Executive Chair 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, the documents will be forwarded directly to the IRB Administrator for review by whoever received the paper submission.

**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 Executive Chair/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.
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 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.

Executive Chair 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 approval, 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 overall summary page of PennERA and the submission is updated to reflect the approval and expiration dates. The Administrative Assistant reviews the PennERA protocol's management folders and updates sections, when appropriate, to ensure the protocol and status accurately 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 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 the Executive Chair or Designee for approval. The Executive 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.

Executive Chair or Designee
The Executive Chair 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 with the application or study documents (or lack thereof) affecting the criteria for approval should be noted within a problems/Issues document. 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.

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 or request additional information via email. 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.

**Executive Chair 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
If 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 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 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 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 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 designated in writing by the Executive Chair conducts expedited initial review. Expedited reviewers may request revisions to the submitted documents and review the revisions prior to forwarding the submission to the Executive Chair or Designee for approval. The Executive 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 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.

Executive Chair or Designee
The Executive Chair 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.

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.

Executive Chair 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 approval, 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 completion of initial review of minutes and letters for the convened initial protocol review action to assess for appropriateness and accuracy of content.

IRB Senior Administrator
The role of the Senior 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 Senior Administrator is also responsible for re-assignment of convened initial protocols to the IRB Administrator for re-submitted protocols.

After assignments are made, the IRB Senior Administrator is responsible for assessing initial protocols scheduled on the meeting agenda for IRB boards which they have oversight. The Senior Administrator is also responsible for assessing the protocols on the agenda to determine that it was 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

**Senior 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 Senior 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 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 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 protocol to the designated board per the Senior 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. The IRB Administrator’s findings and checklists are forwarded to the Senior Administrator once the IRB Administrator’s screening is complete.

**Senior Administrator**

The Senior Administrator provides consult to the IRB Administrator upon receipt of the pre-review document. The Senior Administrator reviews 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 also provides 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 (with consult from the Senior 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.

Senior 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 Senior 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 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 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 why the protocol requires convened review and which IRB meeting agenda the review has been scheduled for. The completeness check tool is then uploaded to the HS-ERA comments section to detail the administrator’s screening and any issues for consideration by the convened board. The separate word document documenting the review finding that was created by the IRB Administrator in concurrence with the completeness check is then forwarded to the Senior Administrator via email for checking.

Senior Administrator
Prior to the distribution of the agenda, the Senior Administrator will review the submission to determine that it was appropriately scheduled and that the submission is not eligible for expedited review.

If at any point in the above processes, the IRB Administrator or Senior Administrator 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 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 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
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.
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 applicable study documents, if needed. The letter is then forwarded to a regulatory representative who did not attend the meeting.

The Regulatory Representative reviews the letter to ensure that the information contained is clear and able to be understood by an individual who did not attend the Board meeting. The Regulatory Representative reviews the letter and either approves the language or requests revisions.

Once determined to be appropriate by the Regulatory Representative, 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 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 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 administrator utilizes 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.

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 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. The IRB administrator should share his/her notes or comments about the submission with the appropriate IRB Administrator.

**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 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.

**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 IRB Administrator informs the 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 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 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

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.

IRB Senior Administrator
The role of the Senior 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 Senior Administrator is also responsible for re-assignment of convened responses to the IRB Administrator for re-submitted protocols.

After assignments are made, the IRB Senior Administrator is responsible for assessing responses scheduled on the meeting agenda for IRB boards which they have oversight. The Senior Administrator is also responsible for assessing the protocols on the agenda to determine that it was 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

Senior Administrator:
The Senior Administrator identifies incoming response submission that is labeled for full board review and assigns to the appropriate IRB Administrator for screening. 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.

IRB Administrator:
Upon receipt of the assignment, the IRB Administrator assigns the re-submission to the designated board per the Senior 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 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 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’s findings and summary are forwarded to the Senior Administrator once the IRB Administrator’s screening is complete.

Senior Administrator
The Senior Administrator provides consult to the IRB Administrator upon receipt of the pre-review document. The Senior Administrator reviews 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 administrators should 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 meeting discussion.

**IRB Administrator**
If the IRB Administrator (with consult from the Senior 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.

**Senior 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 Senior 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.

**Senior Administrator**
Prior to the distribution of the agenda, the Senior Administrator will review the submission to determine that it was appropriately scheduled and that the submission is not eligible for expedited review.

If at any point in the above processes, the IRB Administrator or Senior Administrator 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 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.

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. 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
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 applicable study documents with an approval stamp, if needed. The letter is then forwarded to a regulatory representative who did not attend the meeting.

Regulatory Representative
The IRB Administrator reviews the letter to ensure that the information contained is clear and able to be understood by an individual who did not attend the Board meeting. The Regulatory Representative reviews the letter and either approves the language or requests revisions, as needed.

IRB Administrator
Once determined to be appropriate by the Regulatory Representative, 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 to receive incoming paper actions, log the submission in PennERA, and to give the action to the appropriate IRB Senior Administrator or IRB Administrative Assistant.

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

IRB Administrator
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 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.

Executive Chair 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 - 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 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 may utilize the HS-ERA Continuing Review Submission and the PennERA Protocol Status when assessing the appropriateness of expedited review.

**IRB Administrator**
The IRB Administrator 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.

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 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.”

**Executive Chair 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. 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 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 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 continuing review submission and file together on the distribution shelf for assignment by the ORA Administrator.
The ORA administrator checks the distribution shelf and assigns the submission to an IRB Administrator 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.

The IRB Administrator 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.

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.

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.

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.

**Executive Chair or Designee**

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.
Research Review Processes – Continuing Reviews

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 to give the action to the appropriate IRB Senior Administrator or IRB Administrative Assistant.

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.

Senior Administrator
The role of the Senior Administrator is to distribute the action to the appropriate IRB Administrator, review the pre-review from that administrator, and confirm that the action is appropriate schedule for the convened IRB 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 - HS-ERA Applications

Senior 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 Senior Administrator identifies incoming continuing reviews that are labeled for full board review and assigns to the appropriate IRB Administrative Assistant for screening on the next available meeting agenda. Assignments are made based on 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 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.

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.
Senior 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 Senior 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.

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.

Senior Administrator
Prior to the distribution of the agenda, the Senior Administrator will review the submission to determine that it was appropriately scheduled and that the submission is not eligible for expedited review.

If at any point in the above processes, the IRB Administrator or Senior Administrator 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 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 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.

**Senior Administrator**

The Senior Administrator reviews the minutes and stipulations for the continuing review once he/she receives the finalized minutes from the IRB Administrator. The Senior Administrator 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
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 Review 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 and places the submission on the distribution shelf for the Senior Administrator to assign to the appropriate IRB Administrative Assistant for screening.

**Senior Administrator**
The Senior 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 Senior Administrator notifies the assistant and IRB administrator of the new assignment via email, detailing the type of submission and any deadlines for review. The Senior 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 printed and stored with the continuing review submission.

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 screens the IRB Administrative Assistant's convened continuing review checklist and verifies if the submission and agenda entry in the PennERA is appropriate for scheduling on the next available meeting agenda. If issues are raised from the convened review submission and/or checklist, the IRB Administrator coordinates with the IRB Administrative Assistant to address any issues that may need to be resolved.

If substantive issues are documented in the continuing review checklist, the IRB Administrator confirms whether the submission is incomplete or not yet ready to be scheduled on the next appropriate meeting agenda. If incomplete or not ready, the IRB Administrator may provide the IRB Administrative Assistant consultation for drafting an email to the study team requesting further information and/or study documents.

When the IRB Administrator determines the IRB Administrative Assistant's convened review checklist and agenda entry are complete, the IRB Administrator signs the checklist and returns the submission, signed checklist, and file to the IRB Administrative Assistant.

**Senior Administrator**

Prior to the distribution of the agenda, the Senior Administrator will review the submission to determine that it was appropriately scheduled and the submission is not eligible for expedited review.

If at any point in the above processes, the IRB Administrator or Senior Administrator 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 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.

**Senior Administrator**
The IRB Senior Administrator reviews the minutes and stipulates for the modification once he/she receives the finalized minutes from the IRB administrator. The IRB Senior Administrator 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 increases 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 give the action to the appropriate IRB Administrator.

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

IRB Administrator
The role of the IRB Administrator is to screen the exempt changes to determine if the application exempt criteria still apply to the application.

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.

Executive Chair or Designee
The Executive Chair 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
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
The IRB Administrator screens the expedited modification submission for completeness to the noted changed 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.”

**Executive Chair 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 Administrator reviews the letter to ensure that the information contained is accurate and appropriately formatted. New approval dates limiting the approval to annual review should be included in the modification letter. 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 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 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 contacts the appropriate IRB administrator notifying him or her that a modification for an exempt protocol. The Front Desk Assistant then gives the modification to that IRB administrator.

**IRB Administrator**
The IRB administrator review 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 give the action to the appropriate IRB senior administrator or IRB assistant.

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.

Executive Chair or Designee
The Executive Chair or designee completes a secondary review of the initial 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
The ORA Administrator identifies incoming modifications that are labeled for expedited 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 ORA Administrator may utilize the HS-ERA Modification Submission and the PennERA Protocol Status when assessing the appropriateness of expedited review.

IRB Administrator
The IRB Administrator 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.

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
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 IRB Administrator’s screening and any issues identified 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. The 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
Executive Chair 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 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 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 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.
The ORA administrator checks the distribution shelf and assigns the submission to an IRB Administrator 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**

The IRB Administrator 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.

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.

**Executive Chair 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 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.

**Executive Chair or Designee**
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 file 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.
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 give the action to the appropriate IRB senior administrator or IRB assistant.

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 role of the Senior Administrator is to distribute the action to the appropriate IRB administrator, review the pre-review from that administrator, and confirm that the action is appropriate schedule for the convened IRB 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
3A. Procedures Employed to Implement this Policy For HS-ERA applications

Senior 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 Senior 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 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 Modification Submission and the PennERA Protocol Status when assessing the appropriateness of full board review.

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.

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.
Senior 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 Senior 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.

Senior Administrator
Prior to the distribution of the agenda, the Senior Administrator will review the submission to determine that it was appropriately scheduled and that the submission is not eligible for expedited review.

If at any point in the above processes, the IRB Administrator or Senior Administrator 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 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 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 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.

**Senior Administrator**
The senior administrator reviews the minutes and stipulations for the modification once he/she receives the finalized minutes from the IRB administrator. The senior administrator 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 the action is complete and places the submission on the distribution shelf for the Senior Administrator to assign to the appropriate IRB Administrator for processing.

**Senior Administrator**

The Senior 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 Senior Administrator notifies the administrator of the new assignment via email, detailing the type of submission and any deadlines for review. The Senior Administrator may utilize the Modification Submission and the PennERA Protocol Status when assessing the appropriateness of full board review.

**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.

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.
Senior Administrator
Prior to the distribution of the agenda, the Senior Administrator will review the submission to
determine that it was appropriately scheduled and the submission is not eligible for expedited
review.

If at any point in the above processes, the IRB Administrator or Senior Administrator determines
that the study require expedited IRB review, the study is then placed up for expedited review
according to the procedures described in Section 404B.

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.

Senior Administrator
The senior administrator reviews the minutes and stipulates for the modification once he/she receives the finalized minutes from the IRB administrator. The senior administrator 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

Convened Responses to Convened Modification Review

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. This section details the procedures for Responses submitted through the paper and electronic submission processes.

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.

IRB Senior Administrator
The role of the Senior 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 Senior Administrator is also responsible for re-assignment of convened responses to the IRB Administrator for re-submitted protocols.

After assignments are made, the IRB Senior Administrator is responsible for assessing responses scheduled on the meeting agenda for IRB boards which they have oversight. The Senior Administrator is also responsible for assessing the protocols on the agenda to determine that it was 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.
3A. Procedures Employed to Implement this Policy For HS-ERA applications

Senior Administrator:
The Senior Administrator identifies incoming response modification that is labeled for full board review and assigns to the appropriate IRB Administrator for screening. 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 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 Senior 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 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, ensuring a copy of the response cover letter is attached as well as tracked/clean copies of any revised documents. The administrator’s findings and checklists are forwarded to the Senior Administrator once the IRB Administrator’s screening is complete.

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.
University of Pennsylvania IRB  
Guide to Daily Operations  
Version Date: 2/4/2013  

Research Review Processes  
Modification Reviews  
Convened Responses to Mods – HS-ERA

Senior 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 Senior 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 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.

Senior Administrator
Prior to the distribution of the agenda, the Senior Administrator will review the submission to determine that it was appropriately scheduled and that the submission is not eligible for expedited review.

Board Members
When conducting response to tabled modification 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 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 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.

**Senior Administrator**
The Senior Administrator reviews the minutes and stipulations for the modification once he/she receives the finalized minutes from the IRB administrator. The Senior Administrator 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 the action is complete and places the submission on the distribution shelf for the Senior Administrator to assign to the appropriate IRB Administrator for processing.

**Senior Administrator**
The Senior Administrator checks the distribution shelf and assigns the modification response 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 Administrator for processing. The Senior Administrator notifies
the administrator of the new assignment via email, detailing the type of submission and any deadlines for review. The Senior Administrator may utilize the Modification 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 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, ensuring a copy of the response cover letter is attached as well as 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.
Senior Administrator
Prior to the distribution of the agenda, the Senior Administrator will review the submission to determine that it was appropriately scheduled and the submission is not eligible for expedited review.

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 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.

Senior Administrator
The senior administrator reviews the minutes and stipulates for the modification once he/she receives the finalized minutes from the IRB administrator. The senior administrator 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

Expedited Responses to Convened Modification Review

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 to 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
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.

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 Administrative Assistant
The IRB Administrative Assistant screens the response submission for completeness. The Administrative Assistant 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 Administrative Assistant 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 Administrative Assistant 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.

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

If the IRB Administrative Assistant (with consult from the IRB Administrator and the Senior 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 Administrative Assistant 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 Administrative Assistant who completed the initial review of the response submission per the process above.

IRB Administrative Assistant
If no issues requiring returning of the submission were noted during the initial screen or if the issues raised by the IRB Administrative Assistant upon returning of the submission have been resolved, the IRB Administrative Assistant finalizes the assignment to the IRB Chair or designee by updating the PennERA Summary and Review page. The IRB Administrative Assistant completes the agenda entry in PennERA by locating the review action in the Submissions page. The IRB Administrative Assistant 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 Administrative Assistant 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 Administrative Assistant 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 Administrative Assistant. 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 Administrative Assistant’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 Administrative Assistant. If no concerns are raised and the issues raised by the IRB Administrative Assistant 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 Administrative Assistant**
If issues are raised by the reviewer, the IRB Administrative Assistant 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 Administrative Assistant 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 Administrative Assistant, 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 Administrative Assistant (with consult from the IRB Administrator or 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.
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.

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 the action 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 an IRB Administrative Assistant 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 Administrative Assistant's designated area for response screening assignments.

**IRB Administrative Assistant**
The IRB Administrative Assistant screens the response submission for completeness. The Administrative Assistant 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 Administrative Assistant 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 Administrative Assistant 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.

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

If the IRB Administrative Assistant (with consult from the IRB Administrator and the Senior Administrator) determines the submission is incomplete or not yet ready for final review, the IRB Administrative Assistant contacts the study team regarding the issues to be addressed. The IRB Administrative Assistant 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 Administrative Assistant have been appropriately addressed, the IRB Administrative Assistant places the submission up for expedited 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 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 Administrative Assistant’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 Administrative Assistant**

If issues are raised by the reviewer, the IRB Administrative Assistant 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 Administrative Assistant 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 Administrative Assistant, 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 Administrative Assistant (with consult from the IRB Administrator or 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).

**IRB Chair or Designee**

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 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 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 Chair or Designee
The IRB Chair or designee (“reviewer”) completes a secondary review of the action and approves the action.

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 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 utilizes 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
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.

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.”

Executive Chair 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, 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.
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.

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.

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 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 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-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 the action 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 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.

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 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.

**Executive Chair 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.

**Executive Chair or Designee**

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 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.
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 Chair or Designee
The IRB 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 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 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
University of Pennsylvania IRB Research Review Processes
Guide to Daily Operations Modification Reviews
Version Date: 2/4/2013 Exception Requests – HS-ERA

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.

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 Executive Chair (or authorized designee), who will be referred to moving forward as the “reviewer.”

Executive Chair 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 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 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 the action 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. 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.

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 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.

**Executive Chair 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 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.

**Executive Chair or Designee**
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.
Research Review Processes – Reportable Events

Reportable Event Submissions

1. PROCESS OVERVIEW
This procedure outlines the review of reportable events submitted to the IRB. Investigators are required to submit reports within 10 working days of events that meet the definition of an unanticipated problem involving risks to subjects or others. If the adverse event involved a death and indicates that participants or others are at increased risk of harm, investigators are required to submit a report to the RIB within 3 days. 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 meets the definition of an unanticipated problem. 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.

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

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 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

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 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 ORA Administrator may utilize the HS-ERA Reportable Event Submission and the PennERA Protocol Status when determining the appropriate administrator for assignment.

IRB Administrator
The IRB Administrator screens the reportable for completeness. PennERA, the HS-ERA 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 reviews the reportable event form and any attached documents under the Review field.

The IRB Administrator 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 was unexpected, expected but happening with greater severity or frequency than expected, and if the event is more likely than not related to participation in the research. Other events that meet the IRB’s reporting criteria are: 1) violations or deviations from the protocol that place one or more participants at an increased risk of harm or that represent serious or continuing non-compliance; 2) possible breaches of confidentiality; 3) subject complaints that indicate unexpected risks or that cannot be resolved by the research team; and 4) incarceration of a participant when the research was not previously approved under subpart C and the investigator wishes to allow the subject to continue to serve on the study.

If inadequate information is provided to determine if the event meets the reporting criteria, the administrator should request additional information from the investigator. The IRB Administrator 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 administrator may consult with Senior IRB Staff (including the Executive Chair) 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 administrator should verify that the study team has detailed an appropriate corrective action plan and considered whether any study documents should be revised in response to the event.

If the event does not require acknowledgement from the IRB
If the IRB Administrator determines that the submission does not meet the reporting criteria and that no other concerns are raised with the submission, the submission is returned to the study team. The IRB Administrator uses the assign field and adds a comment to the submission informing the study team that the event does not meet the reporting criteria and that the event will not be acknowledged. 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 event does not meet reporting criteria but requires acknowledgement from the IRB
In some cases, the event will need to be acknowledged by the IRB even if it does not meet our reporting criteria. If the IRB Administrator determines that the submission does not meet the reporting criteria but should be acknowledged and that no other concerns are raised with the submission, 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 summary document 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 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 Executive Chair (or authorized designee), who will be referred to moving forward as the “reviewer.”

Executive Chair 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 can be acknowledged or if additional information is required. 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 acknowledges 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 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.

If the event does meet reporting criteria and requires review by the convened IRB
If the IRB administrator determines that the submission does meet the reporting criteria and that sufficient information is provided for the Board’s consideration, 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 summary document 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 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 Executive Chair (or authorized designee), who will be referred to moving forward as the “reviewer.”

Executive Chair 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 above. 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 appropriate, the submission is returned for response with approval using the assign page in HS-ERA.

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 and the PennERA Protocol Status when assessing the appropriateness of full board review.

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.

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.

Senior Administrator
Prior to the distribution of the agenda, the Senior Administrator will review the submission to determine that it was appropriately scheduled.

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; 2)
whether the event meets the definition of serious or continuing non-compliance; and 3) whether reporting to the Institutional Official and other outside Agencies is required. 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 letter is then forwarded to a regulatory representative who did not attend the meeting.

Regulatory Representative
The IRB Administrator reviews the letter to ensure that the information contained is clear and able to be understood by an individual who did not attend the Board meeting. The Regulatory Representative reviews the letter and either approves the language or requests revisions, as needed.

IRB Administrator
Once determined to be appropriate by the Regulatory Representative, 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 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 who attended the meeting drafts a letter detailing the event, the Board’s review, and the IRB’s plan of action. The letter is sent out to the study team, the Institutional Official, Relevant Outside Agencies, and/or Relevant Internal Agencies. The letter is then attached to PennERA, the HS-ERA submission, and/or the paper file.
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 give the action to the appropriate IRB senior administrator or IRB assistant.

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

IRB Administrator
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 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.

Record Specialist
The record specialist is responsible for drafting the IRB closure letter for the action.

Executive Chair 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 continuing reviews that are labeled for expedited 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 may utilize the HS-ERA Continuing Review Submission and the PennERA Protocol Status when assessing the appropriateness of expedited review.

**IRB Administrator**

The IRB Administrator 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.”

**Executive Chair 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 related to the criteria for re-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 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 Record Specialists**
The IRB Record Specialists 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 Record Specialists 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 Record Specialists 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 Record Specialists reviews the PennERA protocol’s management
folders and updates sections, when appropriate, to ensure the protocol and status accurately to
reflect the closure.

The Record Specialists generates the closure letter by using the communications folder for this
review action. The Record Specialists 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 Record Specialists 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 Record Specialists**

The Record Specialists 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 Record Specialists 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 the action 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 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**

The IRB Administrator 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 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.

**Executive Chair or Designee**
The reviewer checks the location for expedited paper reviews and determines if closing the application is appropriate. 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.

**Executive Chair or Designee**
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 Record Specialists designated area for letter generation assignments.

**IRB Record Specialists**
The Record Specialists retrieve the continuing review from his/her designated area and locates the submission in PennERA.

The c completes the data entry, as needed. The Record Specialists reviews the paper
documents and lists them into the review (general) page and Post-Review page in PennERA. The Record Specialists 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 Record Specialists 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 Record Specialists generates the closure letter by using the communications folder for this review action. The Record Specialists 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 Record Specialists**
The IRB Record Specialists 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 Record Specialists then log the file and send the file to archives.
Research Review Processes – Vulnerable Populations

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.

Executive Chair or Designee
The role of Executive Chair 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.

3. 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 requests that a form be completed and submitted for review. 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 Executive Chair or designee for final approval at the same time the study is forwarded for exempt review and approval.

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, more likely, a convened application is required.
Executive Chair or Designee
The Executive Chair or designee completes a secondary review of the initial action and approves the subpart determination as part of her review of the entire protocol.

Note: If an exempt 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 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 requests that a form be completed and submitted for review. 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 Executive Chair or designee for final approval at the same time the study is forwarded for exempt review and approval.

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 must take part in that review process. The IRB Administrator will forward the protocol to the prisoner representative for review at the same time the study is sent to the Executive Chair.

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.

Executive Chair or Designee
The Executive Chair 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 Executive Chair 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 to make sure it is complete or requests one should one not be submitted.

If prisoner subjects are enrolled, the IRB Administrator schedules the study for convened Board review on IRB 7 or 8. The administrator also confirms that a prisoner representative can attend the IRB meeting. The prisoner representative is assigned the secondary 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.
Determining Engagement in Research

1. PROCESS OVERVIEW
Penn investigators often participate in research studies that involve sites and groups outside of Penn. When the Penn investigator is the lead investigator for a study or Penn is the lead site for a study, the Penn IRB is responsible for 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. 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 can be considered engaged in the research. 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 or that IRB wishes to allow Penn to be the IRB of Record for both sites, the IRB Administrator considers whether the Penn IRB can enter into an Individual Investigator agreement or Institutional Authorization Agreement with the site. 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 a finalized authorization agreement with the other sites. However the study team must confirm that no research will be conducted at those sites before IRB approval of an authorization agreement is put 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.
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 will also serve as the Executive Chair’s authorized designee for review of the Individual Investigator Agreement.

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. 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 list of all study personnel at the deferring site, a description of their roles in the research, and documentation of their human subjects’ research training.

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.

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.

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.
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. An application to both Penn and CHOP will be required but this process does lessen the burden for modification and continuing reviews. 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.

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.
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 medical 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.
2. If the informed consent form is approved with an expedited/full modification, the approval period will start the date of the expedited 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 expedited protocol’s approval and end 364 days later from the initial withheld date.

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
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**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 patient, 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
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 another organization 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 Office of Research Services to enter into a data use agreement with the site receiving the dataset.

The IRB is not charged with reviewing the data use agreement. Once these items have been confirmed and any other outstanding issues are addressed, the submission may be reviewed at the appropriate level for the submission.
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). In these circumstances, the IRB may act as a surrogate of the FDA to confirm that the criteria for these determinations have been met. This section details how the IRB makes these determinations.

2. RESPONSIBILITY

IRB Administrator
The role of the IRB Administrator is to screen the application to determine if 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 Executive Chair
The role of Director and Executive Chair 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 IND exemption or NSR determination, and raise issues for discussion during the meeting, along with their resolutions, and complete the supplemental determination.

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 Human Research (OHR), the Clinical Trials Safety and Monitoring Committee (CTSRMC) or the IRB. The IRB Administrator should first confirm if the study team is seeking an IND
exemption from either OHR 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 Director and Executive Chair discuss the protocol and determine an appropriate course of action for review. The complexity of the protocol, the available convened Board meetings and the expertise of the Board attendees are considered. The Director and Executive Chair inform the IRB Administrator of their decision. That decision may include a determination of the appropriate Board to review the determination and in the case of IND exemption determinations, may include deferral to another internal reviewing entity or the FDA.

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 should be also be made if the study is modified in a way that impacts any previously made determinations.
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 Executive chair 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.
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

Executive Chair or Designee
The Executive Chair 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 (i.e. no more than 2 prior requests for the same non-English speaking population).

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 rush 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
```
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 to indicate that the Certificate has been obtained.
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
 IRB Administrator
 For industry sponsored studies, a stamped informed consent form is not provided to the research team until after the contract for that protocol has been finalized. When reviewing industry sponsored studies, the IRB Administrator is responsible for ensuring that a stamped consent form is not provided to the study team prior to contract review. Notes should be added to the agenda notes section of PennERA at the time of initial convened review. Notes should also be added to the comments section of HS-ERA when responses are reviewed in order to ensure that the IRB Administrative Assistant does not stamp the consent form once the response is approved. The IRB Administrator should also make sure the study team is aware of why a consent form is not provided. Template language detailing the contract review procedures should be inserted into the review letters.

Once the contract is finalized, the IRB Administrator will receive an email notification indicating that the contract has been approved. The email will also contain a copy of the contract. The IRB Administrator reviews the contract language regarding research related injuries. The administrator should also review any Master Clinical Trial Agreements between Penn and the sponsor. If the master agreement discusses research related injury, both documents should be considered as part of the review. The IRB Administrator then reviews the informed consent form. The consent form language should be in agreement with the language included in the contract and/or master agreement.

If revisions to the consent form are necessary, the IRB Administrator contacts the study team and informs them of the changes required. If the study has already been approved by the IRB,
the study team is told to submit a modification to revise the consent form. If the study has not yet been approved by the IRB, the study team is told to revise the consent form when they submit their response submission for review. The IRB Administrator updates PennERA and HS-ERA to indicate that the contract was reviewed and changes were requested.

If revisions to the consent form are not required, the IRB Administrator updates PennERA and HS-ERA to indicate that the contract was reviewed and no changes were requested. If the study has not yet been approved by the IRB, no further action is required. If the study has been approved, the IRB Administrator emails an IRB Administrative Assistant and requests that an updated letter including a stamped consent form be sent to the study team.

IRB Administrative Assistant
The IRB Administrative Assistant generates a revised letter and stamped consent form in PennERA. The most recent approved submission is revised to indicate that the contract review was completed. A new letter is generated and the consent form is stamped according to standard practice. The approval date is the date the contract review occurred. The revised letter and stamped consent form are sent to the administrator for signature. The letter is signed and forwarded according to standard practice.
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 at 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 gene transfer protocols 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 gene transfer 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.
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. 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 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.
Ancillary Committee Review Procedures

1. PROCESS OVERVIEW

Penn has a number of Committees that review human subjects’ research protocols. These Ancillary Committees 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 review by the ancillary committees 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 Committee 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. Administrative stipulations detailing the requirements for ancillary committee review should be added to the determination letter. 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.
Research Review Processes – Appendices

HRAC Review Procedures

1. PROCESS OVERVIEW

The Senior Vice Provost for Research’s Human Research Advisory Committee (HRAC) is tasked with reviewing certain research protocols that involve gene transfer or other areas of research that may require special considerations regarding research subject or institutional risk. In the event HRAC review is determined to be necessary, IRB approval may not be granted until HRAC review has occurred. This section details the processes in place to ensure that the IRB accounts for HRAC review during the review process.

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. 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 determine if HRAC review is necessary. 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 conflict of interest must be managed or eliminated so that the results of research are free from bias. The management of conflicts of interest is the responsibility of the Senior 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 the CISC review process.

2. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY

IRB Administrator

Principal Investigators are required to certify that they have reviewed the policies on conflict of interest and as part of the current protocol application, all study team members engaged in the research must indicate if conflicts of interest exist. If a conflict exists, 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 potential financial interest question should be answered yes in the event that a conflict has been identified. If the study does have a conflict identified, the IRB Administrator should notify the Associate Director. The Associate Director will correspond with CISC and ensure that CISC has IRB application materials for review. 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.

Once CISC review has been completed, the conflict of interest management plan or correspondence confirming no conflict will be sent to the IRB. When the CISC correspondence is received by the IRB, the Associate Director will then review the management plan and the study protocol and determine if any further revisions to the study monitoring plan or the consent form are necessary. The results of this review will be forwarded to the administrator. The IRB Administrator will then continue to process the response submission according to standard practice. If additional changes are required, the administrator will forward these changes to the study team.

When continuing reviews are received for studies that have undergone CISC review, the administrator will contact the Associate Director to determine if any further action is required. The Associate Director will correspond with the CISC to determine if annual certification or other procedures are required before continuing re-approval can be granted.
Requests to Certify Submission 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 requests 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.

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.
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.

Executive Chair or Designee
The role of Executive Chair 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.
Executive Chair or Designee
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 Front Desk Administrative Assistant
The Front Desk IRB associate forwards the packet to OHRP.

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.

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.

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.
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
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.
IRB Membership Administrative Processes

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.