In alignment with the NIH mandate for single IRB review that goes into effect in January 2018, HSERA is being updated to include a new reliance agreement specific application. This abbreviated online form is intended for study teams submitting new research protocols being conducted at Penn where another IRB will be the IRB of record instead of the Penn IRB. This application should not be used if another research site wants to rely on the Penn IRB. The IRB website has detailed instructions and guidance regarding this type of application on the How to Submit: Reliance Agreement page. Please note that revisions to the existing guidance documents related to submitting reliance agreements are also being revised to reflect the new application.

Please see below for screen shots and specific information about this new application.

To create the new application log into HSERA as usual and click Create and choose Initial Review:

After clicking Initial Review, choose Reliance agreement request:

Note: All references to the IRB website are for the following web address: www.upenn.edu/IRB
The Reliance Agreement application has fewer pages compared to the traditional application and it does not require selection of a level of review by choosing exempt or expedited categories.

After choosing the Reliance Agreement application from the create page, the first page will be the Basic Info page. The only difference to this page in the Reliance application compared to other applications is the application type is already chosen as “Reliance Agreement”:

Note: All references to the IRB website are for the following web address: www.upenn.edu/IRB
IRB News – 7.25.17: Addition of a new application type for submitting reliance agreements

After completing the Basic Info page and clicking “Next” the Personnel page will appear. There have been no changes to this page in the reliance agreement application. The screen shot below does not reflect the entire page. It should be completed the same way the personnel page is completed for any other application type:

Protocol Form - Study Personnel

Page must be error free before you can use ‘Save Draft’

Principal Investigator*

Complete if different from PI - Up to Three Allowed.
The contacts listed here will have viewing and editing capabilities to the submission after initial approval is granted.

Other Investigator

Note: All references to the IRB website are for the following web address: www.upenn.edu/IRB
IRB News – 7.25.17: Addition of a new application type for submitting reliance agreements

After completing the personnel page and clicking Next, the HRPP page will appear. This is the equivalent of the Bio page in other applications where information about biomedical interventions and procedures is provided. The entire HRPP page is not shown here but the questions are identical to the current Bio page in other applications. The selection of certain radial buttons will generate “pings” to other review entities at Penn (Radiation safety, Biosafety, etc...)

**Protocol Form - HRPP**

*Previous  Next  Save Draft*

Page must be error free before you can use ‘Save Draft’

**Investigator Initiated Trial**

Is this an investigator-initiated trial? PLEASE NOTE: An investigator initiated trial is one in which the individual PI both initiates (plans and designs) and conducts an investigation and under whose immediate direction the study drug is administered or dispensed, usually with an Investigator IND. The individual investigator has absolute responsibility and accountability and designs, conducts, monitors, manages the data, prepares reports and oversees all regulatory and ethical matters. See 21 CFR 312.3.

If Yes, upon approval the investigator is required to create a record in clinicaltrials.gov.

- Yes
- No

**Drugs or Devices**

- No
- Yes: Under an IND (Investigational New Drug Application), IDE (Investigational Device Exemption) or 510K
- Yes: Drugs or products administered to subjects not indicated in the FDA-approved drug labeling
- Yes: Drugs or products administered to subjects in combination with other drugs that is not considered standard of care
- Yes: Drugs, products or devices are used in accordance with FDA approval.
- Yes: Drugs, products or devices prepared or used in a manner not in the FDA-approved labeling.
- Yes: Investigational devices that may qualify as Non-Significant Risk.

For studies including IND or IDE’s, please provide the number(s) below

**IDE Review**

NOTE: For research involving investigational devices, you are required to review the guidance on Managing Research Device Inventory.

Consult the Penn Manual for Clinical Research:

https://somapps.med.upenn.edu/pennmanual/secure/pm/investigational-product-management-sites-not-using-investigational-drug-services-ids

Please check the box Yes if you have reviewed the guidance.

- Yes
- No

Note: All references to the IRB website are for the following web address: www.upenn.edu/IRB
After completing the HRPP page and clicking Next, the sponsors page will appear. The entire Sponsors page is not shown here but the questions are identical to the current Sponsors page in other application types.

**Protocol Form - Sponsor**

**Business Administrator***

***The Department of Medicine requires the inclusion of a Business Administrator (BA) for all regulatory submissions.

Name
Department/School/Division
Phone
Fax
Pager
Email

**Department budget code**

If your research is funded/will be funded, please provide an appropriate 26-digit account number for IRB billing purposes. For current IRB fees and for which studies are billable, please see the IRB website: [http://www.upenn.edu/IRB/mission-institutional-review-board-irb/irb-fees](http://www.upenn.edu/IRB/mission-institutional-review-board-irb/irb-fees).

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**Funding Sponsors**

Identify the agency, organization, company or person providing funds for the research study. The IRB charges fees to cover the costs associated with the review of industry sponsored investigational drug and device trials.

**Regulatory Sponsor**

This is the agency, organization, company or person primarily responsible for initiating and overseeing the research and ensuring the study complies with research standards and federal regulations. For clinical trials (studies involving drugs or devices) this is typically the FDA IND holder, for device studies, this is the FDA IDE holder.

- For industry-sponsored trials, typically the pharmaceutical/device/biotechnology company is the regulatory sponsor.
- For non-industry sponsored trials, the regulatory sponsor is typically the NIH or an NIH-designated entity (e.g. for the NCI, CTEP can be the regulatory sponsor if that entity holds the FDA IND or IDE).

For more information about regulatory sponsor status, INDs and IDEs, see the [Penn Manual for Clinical Research, section on Research Involving Drugs or Devices](http://www.upenn.edu/IRB).

Note: All references to the IRB website are for the following web address: [www.upenn.edu/IRB](http://www.upenn.edu/IRB)
IRB News – 7.25.17: Addition of a new application type for submitting reliance agreements

After completing the Sponsor page you will upload your associated documents on the Confirmation page. This is the final page of the reliance agreement application. The documents necessary for a reliance agreement are different than a typical application. The authorization, assurance and agreement documents are available on the IRB website Forms and Templates page. Instructions for their use are available on the IRB website How to Submit: Reliance Agreements page.

### Protocol Form - Submitter's assurance

**Documents already attached on previous pages**

**Supporting documents**

Check all that apply

- [ ] Cover Letter (with additional information that may help in the review)
- [ ] IRB Authorization Agreement (This is the form that the Penn IRB will sign to document the reliance agreement with the IRB of Record. It may also be referred to as a Reliance Agreement or Jurisdictional Waiver Form)

There are no documents attached for this item.

**Upload form**

- [ ] Principal Investigator Assurance (This is a Penn specific document available on the IRB website. A copy of the document signed by the PI is required for all reliance agreement requests)
- [ ] Full sponsor’s protocol
  
  Please note: If you do not have a full/clinical protocol for upload, please upload a copy of the application or protocol summary submitted to the central IRB for their review.
- [ ] Protocol Supplement for Reliance Agreements (This is a Penn specific document available on the IRB website)
- [ ] Informed consent form (and parental permission/assent form for research involving children)
- [ ] Investigator’s brochure/product labeling (for research involving investigational drugs or devices)
- [ ] If you have additional forms or documents to attach to the protocol, please upload them here.

By clicking 'I accept' below, you are **electronically** signing the following statements and **submitting** your application to the Institutional Review Board (IRB) for review.

I have read and understood the University of Pennsylvania guidelines concerning human subjects projects and protocols.

I certify that the information provided in this submission is complete and correct to the best of my knowledge.

[Back] [I accept]

Once all the documents have been completed and attached, the submitter will click the “I accept” button at the bottom of the page. The standard submission routing path will be followed:

- If the person identified as the PI on the personnel page is not the person who created and completed the application, the submission will be routed to the person identified as the PI for approval.
- Once the PI approves the application it will be routed to the Department head associated with the Org. code chosen on the Personnel page
- Once the Department head approves the application it will be received by the IRB for review

Note: All references to the IRB website are for the following web address: [www.upenn.edu/IRB](http://www.upenn.edu/IRB)
IRB News – 7.25.17: Addition of a new application type for submitting reliance agreements

The Manage Drafts page of HSERA is also being updated to include a new column which shows the review category of each submission in draft mode. For most submission types (like modifications and continuing reviews), the review category will show the level of review the submitter has chosen while drafting. For any submissions created related to a reliance application, the category will default to “Reliance”. Some submission types, such as Reportable Events will have an unknown review category since the IRB will need to make that determination upon receipt.

The reliance agreement application type will not allow for creation of Continuing Review or Exception Request submissions in the future since those should be submitted to the IRB of record. The system will allow for creation of Modifications, Deviations and Reportable Events. The Penn IRB requires that continuing approval letters from the IRB of record be submitted via a modification in HSERA for administrative acknowledgement so that we may update our records with the appropriate approval dates.

Note: All references to the IRB website are for the following web address: www.upenn.edu/IRB