Guidance on Submitting Research Conducted at Princeton Health (PH) to the Penn IRB

The Penn IRB will serve as the IRB for Princeton Health **as of April 2021.**

Please review the following information prior to submitting a Princeton Health study to the Penn IRB.

Instructions for Submitting Existing Studies

1. Please submit the existing study to the Penn IRB in the HS-ERA e-application system. Instructions are located here:

   a. ***If you are requesting to rely on an external IRB***, follow the Guidance on How to Submit a Request to Rely on an External IRB is online here: https://irb.upenn.edu/reliance-agreements. Questions about this process should be directed to Patrick Stanko at pstanko@upenn.edu.

   b. ***If Penn IRB is serving as the single IRB of Record for external sites***:
      i. Review the guidance online here: https://irb.upenn.edu/reliance-agreements under Asking Penn to serve as the IRB of Record for Multi-site studies.
      ii. Consult with Patrick Stanko at pstanko@upenn.edu prior to submission. Do not submit your study until you have consulted with Patrick.
      iii. Follow the Guidance on How to Submit for Penn IRB review: https://irb.upenn.edu/initial.

   c. ***If the study involves an HUD***, please follow guidance online here: https://irb.upenn.edu/how-submit-penn-irb/HUDs.

2. Please ensure that the following elements are addressed in the HSERA electronic submission:

   a. **Basic Info Page, Hospital Sites**: Please answer Yes and check off Princeton Health.

   b. **Personnel Page**: The Responsible Org should auto-populate for any Princeton Health researchers. However, please follow the steps below to ensure accuracy and appropriate routing.

      o Within the e-submission system, HSERA, ensure the Personnel Page, Responsible Org (Department/School/Division) is accurate. This section must list 10755 - Princeton HealthCare Holdings Inc. This is important to determining appropriate department chair routing.

Responsible Org (Department/School/Division) [Change] [Remove]

Pick the University unit that is supporting this research if different from the PI's department.

If your Org is not available for selection, please contact **hsera_help@lists.upenn.edu** and identify the approver (Dept Chair) for your Org so that it can be updated for you.

10755 - Princeton HealthCare Holdings Inc

- o If this does not auto-populate OR the PI is Health System/ UPHS staff under Responsible Org 2100 (Health System), change the Responsible Org by clicking the green Change button. Select Princeton HealthCare Holdings Inc.

c. Princeton Health investigators do not currently have access to the Penn FIDES Financial Interest Disclosure system. Princeton Health and any other non-Penn investigators must complete a paper version of the Financial Interest Disclosure Forms until the new e-COI system goes live. This form can be found online here: https://irb.upenn.edu/forms. Questions should be directed to Kim Craig at kcraig@upenn.edu.

  i. Please ensure all forms are completed and signed. To facilitate review, please combine all the forms into 1 PDF binder or portfolio, and upload the document into HSERA. Upload the forms on the Confirmation Page in HSERA under Additional Documents.

d. The remaining sections of the application should be completed to reflect the protocol as faithfully as possible. If a standalone protocol exists, references may be made to relevant sections of the approved protocol (e.g., Section 5.1). References should **not** be made to protocol page numbers because they change more frequently with protocol amendments. ***The following sections of HSERA may NOT refer to the protocol:***

  a. Basic Info Page, Brief Description of the Protocol

  b. Protocol Page, Abstract

  c. Populations Page, Target population

  d. Populations Page, Subject Recruitment: A local recruitment plan is required if recruitment is occurring locally, and the protocol is written by an industry sponsor or another site.

  e. Procedures Page, Subject Confidentiality: A local confidentiality plan is required if the protocol is written by an industry sponsor or another site.

  f. Risk Benefit Page, Potential Study Risks: Study risks must be outlined in this section. It is recommended that this be copied and pasted from the consent form. It should be kept updated with subsequent modifications.

e. Please upload the study documents (e.g. protocol, consent/assent/parental permission forms in Word format, product labeling / investigational brochure, recruitment materials, recruitment / consent scripts, survey materials, etc.).

f. Please draft and upload a cover letter explaining that this study is occurring at Princeton Health.

   i. ***For all greater than minimal risk research***, please include a listing of all of uploaded documents within the cover letter. The document listing should include the document name, version number (if applicable), and version date.

ONLINE RESOURCES

How to Submit

- Guidance on How to Submit for Penn IRB review for **exempt, expedited, or convened research**: https://irb.upenn.edu/initial.

- Guidance on How to Submit a **Request to Rely** on an External IRB is online here: https://irb.upenn.edu/reliance-agreements. All questions should be posed to Patrick Stanko, Penn IRB Reliance Manager.

- Guidance on How to Submit a Request for Penn to Serve as the **single IRB of Record (sIRB)** for multiple sites is online here: https://irb.upenn.edu/reliance-agreements. All questions should be posed to Patrick Stanko, Penn IRB Reliance Manager.

- Guidance on How to Submit a **Single Patient Treatment with an Investigational Agent** Request: https://irb.upenn.edu/how-submit-penn-irb/expandedaccess.

- Guidance on How to Submit a Use of an **HUD**: https://irb.upenn.edu/how-submit-penn-irb/HUDs.

- **Quality Improvement** Determinations: https://irb.upenn.edu/mission-institutional-review-board-irb/guidance/quality-performance-improvement-project-guidance

- **Not Human Subjects Research** Determinations: https://irb.upenn.edu/mission-institutional-review-board-irb/guidance/types-research, see Human Research - Is IRB Review Required?

HSERA E-Application Resources

- A full walkthrough of HSERA e-application system: https://irb.upenn.edu/sites/default/files/How%20to%20Submit-%20Initial-11.13.17.pdf

- FAQs about the HSERA e-application system: https://irb.upenn.edu/mission-institutional-review-board-irb/guidance/hsera-help

- If you have reviewed the walkthrough and FAQs and need *technical support*, email hsera_help@lists.upenn.edu

- If you have reviewed the walkthrough and FAQs and have *general submission related questions*, email PROVOST-IRB@pobox.upenn.edu

General Resources

- Training Requirements: https://irb.upenn.edu/mission-institutional-review-board-irb/guidance/citi-human-research-protections-training.

  - If training completion is pending, you may still submit in HSERA. However, staff will not be approved for research engagement until this training is complete. Likewise, a study will not be approved until the PI has completed CITI training.

- Forms and Templates: https://irb.upenn.edu/forms

- HIPAA Guidance: https://irb.upenn.edu/mission-institutional-review-board-irb/guidance/other-elements-research

- All Guidance: https://irb.upenn.edu/mission-institutional-review-board-irb/guidance

- How to Submit other types of submissions: https://irb.upenn.edu/how-submit-penn-irb

- IRB Policies: https://irb.upenn.edu/mission-institutional-review-board-irb/irb-policies

- IRB Staff Directory: https://irb.upenn.edu/directory.

- Other Penn Reviewing Entities & Committees: https://irb.upenn.edu/mission-institutional-review-board-irb/guidance/other-penn-reviewing-entities-committees