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

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

Instructions for Submitting Existing Studies
1. Please ensure that any items (e.g. modifications, reportable events, etc.) pending Princeton Health IRB review are resolved prior to submitting to the Penn IRB.
2. Please submit the existing study to the Penn IRB in the HS-ERA e-application system. Detailed instructions are located here:
   a. If Princeton Health IRB is currently the IRB of record, follow the Guidance on How to Submit for Penn IRB review: https://irb.upenn.edu/initial.
   b. If Princeton Health IRB was relying 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.
3. Please ensure that the following elements are addressed in the HSERA electronic submission:
   a. Basic Info Page: Please add the Princeton Health IRB number at the beginning of the Protocol Title and Short Title. Please refer to the example screenshot below.

   Protocol Information

<table>
<thead>
<tr>
<th>Protocol title*</th>
<th>PHIRB 1234 - Full Study Title matches protocol</th>
</tr>
</thead>
<tbody>
<tr>
<td>Short Title*</td>
<td>PHIRB 1234 - Short Title</td>
</tr>
<tr>
<td>Brief description of the protocol*</td>
<td>Add abstract description here.</td>
</tr>
<tr>
<td>Submission type*</td>
<td>• Biomedical Research</td>
</tr>
<tr>
<td></td>
<td>• Social and Behavioral Sciences</td>
</tr>
</tbody>
</table>

   b. Personnel Page: Health System/UPHS employees engaging in research at Princeton Health should change their Responsible Org on the Personnel Page in HSERA to 10755 - Princeton HealthCare Holdings Inc. This Responsible Org will auto populate for any Princeton Health researchers.
c. The remaining sections of the application should be completed to reflect the approved Princeton Health IRB protocol as faithfully as possible. If a standalone protocol exists, references may be made to relevant sections of the approved protocol. References should not be made to protocol page numbers.

d. Please upload the most recently approved versions of all study documents currently in use (e.g. protocol, unstamped consent/assent/parental permission forms in Word version, product labeling, recruitment materials, survey materials, etc.).

e. Please draft and upload a cover letter explaining that this submission is transferring approval from Princeton Health IRB to the Penn IRB.
   i. Please include within your cover letter, the date the study was initially approved by the Princeton Health IRB. As applicable, please also include your studies expiration date.
   ii. 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.

f. If you need to submit any new or revised documents, it is preferred that these be submitted after the Penn IRB does the initial review. However, if an amendment is time sensitive, please include a summary of the new or revised documents within your attached cover letter. A guidance on expectations surrounding modification summaries is online here: https://irb.upenn.edu/sites/default/files/How%20to%20Draft%20a%20Modification%20Summary%20of%20Changes_0.pdf.

NOTE: If your study will expire any time before June 1st, please email jessyoos@upenn.edu the 8-digit confirmation code of your HSERA submission to ensure that we review and approve it prior to the expiration date.

After Submitting the Existing Study
The transfer will be executed upon approval by the Penn IRB. Please note the following regarding ongoing Penn IRB review:

1. The electronic HS-ERA application will be assigned a new 6-digit protocol number which should be referenced in correspondence with the Penn IRB going forward. You
may continue to also reference the Princeton Health IRB number within the study title. However, the 6-digit protocol number must also be provided.

2. Following receipt of a letter documenting Penn IRB approval, please submit a formal closure request to the Princeton Health IRB. This request should include a copy of the Penn IRB approval letter.

3. Please submit all subsequent continuing reviews, modifications and reportable events to through the HS-ERA e-application going forward. Resources for these submissions are linked below.

**Resources**

**How to Submit**

- Guidance on How to Submit for Penn IRB review: [https://irb.upenn.edu/initial](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](https://irb.upenn.edu/reliance-agreements).
- Not Human Subjects Research Determinations: [https://irb.upenn.edu/mission-institutional-review-board-irb/guidance/types-research](https://irb.upenn.edu/mission-institutional-review-board-irb/guidance/types-research), see Human Research - Is IRB Review Required?

**HSERA Resources**

- FAQs about the HSERA e-application system: [https://irb.upenn.edu/mission-institutional-review-board-irb/guidance/hsera-help](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](mailto: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](mailto:PROVOST-IRB@pobox.upenn.edu)

**General Resources**

  - 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](https://irb.upenn.edu/forms)
• 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.