Penn University of Pennsylvania | Human Research Protections Program

Migrated Study Completeness Submission Walkthrough

Table of Contents

Introduction

The IRB is requesting that teams ensure completeness of their eIRB applications for migrated protocols with their first planned amendment submission in the new system. IRB staff will screen for completeness.

If you are unable to ensure completeness with this first planned amendment, please include rationale as to why you are unable to execute this task at this time, and when you plan to complete this requirement.

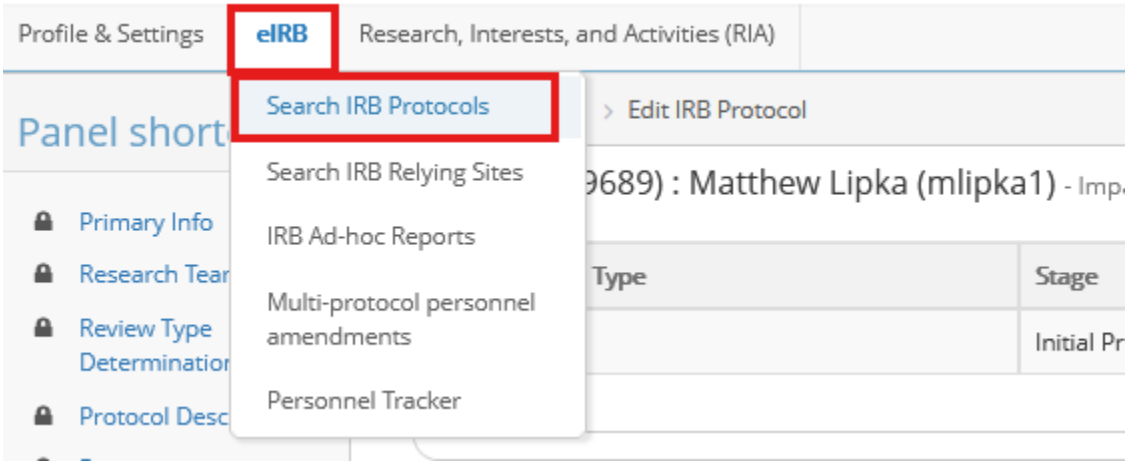
If there are no planned submissions, the IRB is asking for completeness within 1 year of eIRB launch (by February 2027).

This task must be completed via an amendment or continuing review + amendment submission. It may be combined with a planned amendment.

This task cannot be completed with a continuing review (CR), adverse event, deviation, or exception request, as the protocol application is locked. If you need to submit an AE, deviation, or exception – you may submit them.

1. Go to: https://apps.research.upenn.edu/login.
    a. Log in with your PennKey and password

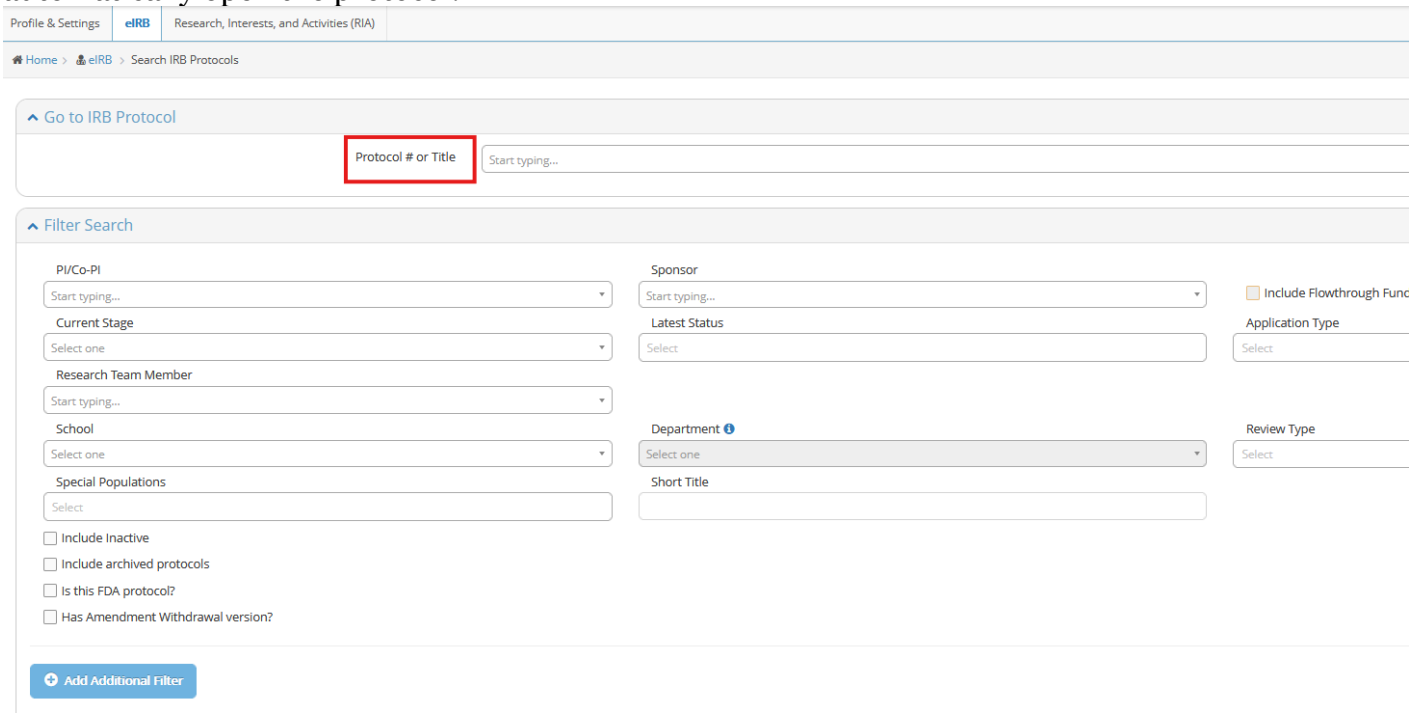
2. The system should take you to your Tasks menu automatically. Navigate to the Search menu by going to the menu at the top, hovering over eIRB, and then select Search IRB protocols.



A list of protocols on which you are listed as key personnel will be listed below. You can use the filters to find protocols that meet specific criteria.

Alternatively, you can search for a specific protocol with the protocol number in the Protocol # or Title field. You may search by your currently assigned IRB number (in

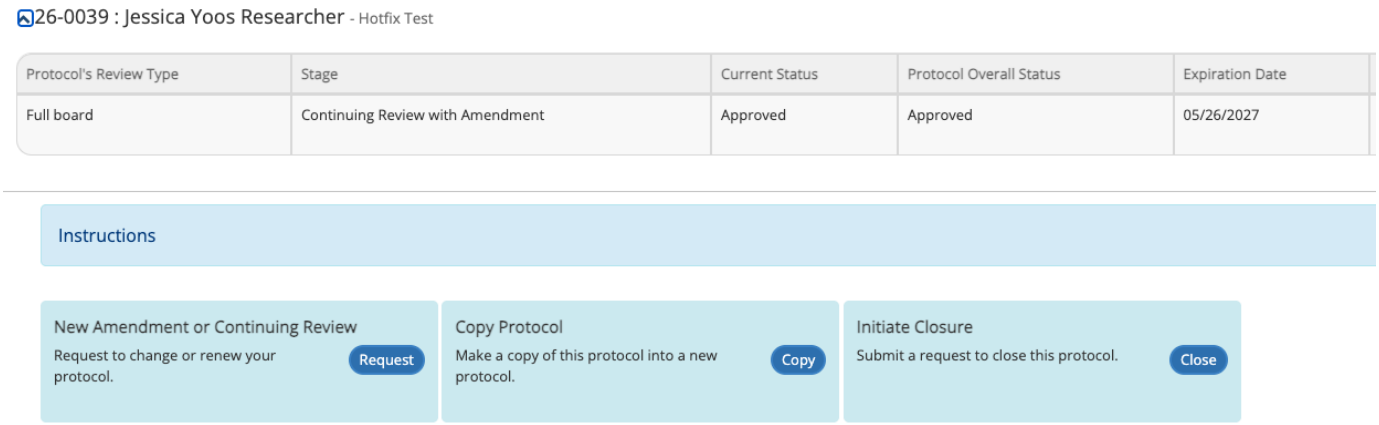
eIRB this is labeled the legacy IRB number). When it pops up, select it and it will automatically open the protocol.



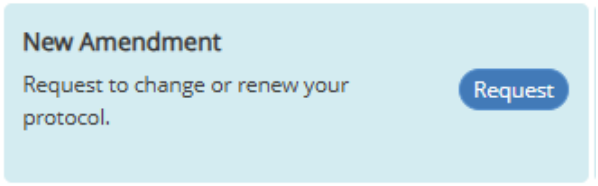
3. Once you are within the protocol application, review the information at the top.

   Note that if the protocol's current status is not listed as Approved, you will not see the options to submit an amendment or continuing review. You will need to wait until the IRB processes whatever submission may be pending.

   In the example below, the protocol is approved, and we can request an amendment or an amendment + CR.



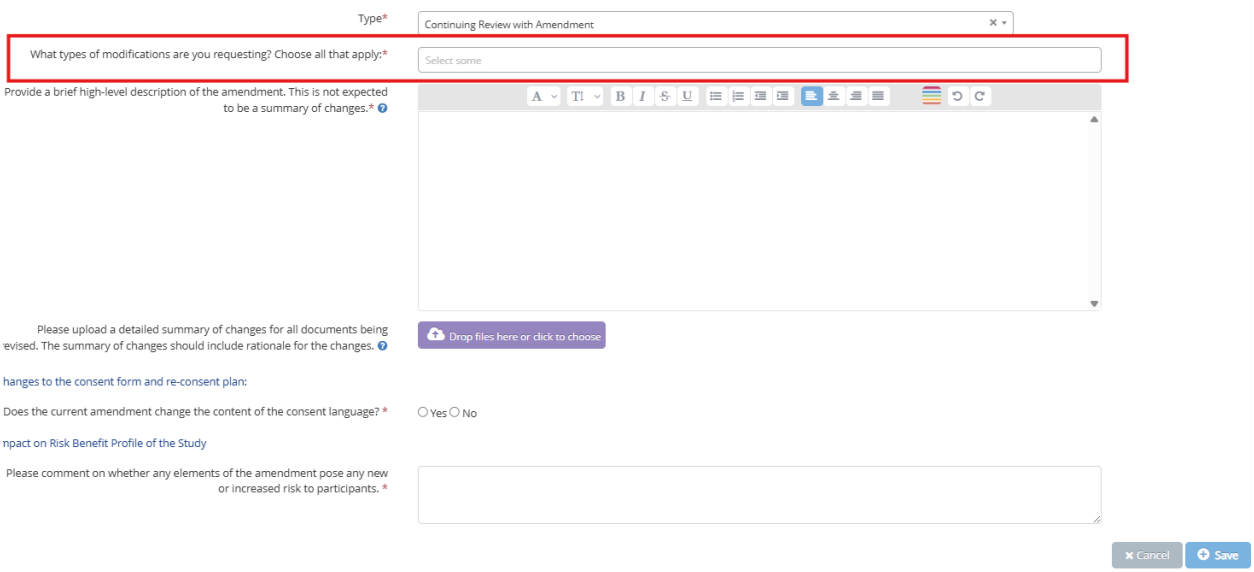
Protocols that have no annual continuing review requirement (e.g., minimal risk protocols that have undergone exempt or expedited review and are not FDA regulated) will not see an option for continuing review like so:



Click Request in the blue box. In the pop-up modal form, select whether you are submitting an amendment or a continuing review + amendment.

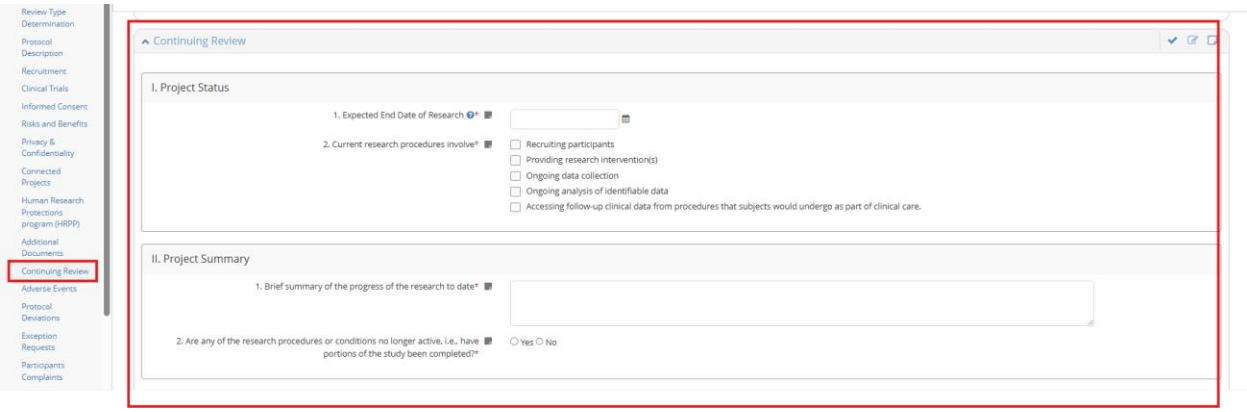
Complete the electronic amendment form (see screenshot below).
Click save.

NOTE: In eIRB certain types of amendments require an uploaded summary of changes document, based on what is selected.



Once you click Save, this opens up the protocol application for edits. Following the instructions on the subsequent pages complete the required fields and attach your supplementary documents within the protocol application.

If requesting a combined CR + Amendment, use the left-hand menu to navigate to the Continuing Review Panel and complete that form.



Required Fields for Paper Migrated Protocols

The full eIRB application must be completed, including the attachment of all study documents.

If you are submitting an amendment, upload your clean and tracked versions of revised documents in their designated panels. Upload any other documents under Additional Documents.

Please upload a cover letter that outlines the purpose of the submission. Be sure to indicate whether you are submitting for completeness only or whether you are submitting an amendment or amendment + CR. Please see a template cover letter on page 11.

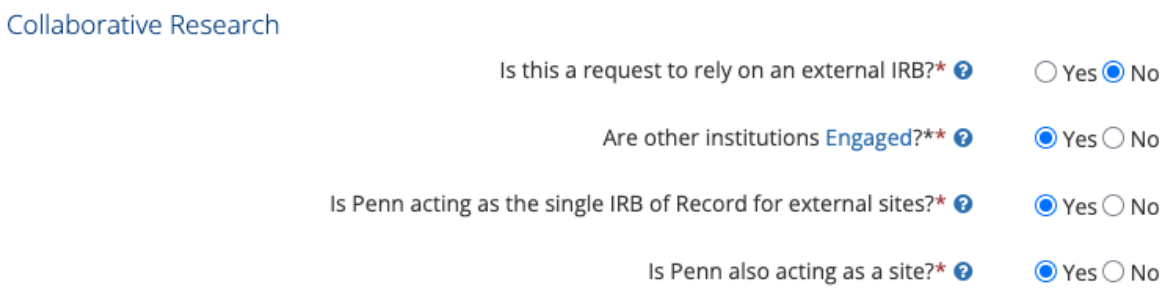
Required Fields for HSERA Migrated Protocols

Review Type Determination Panel

If your protocol relies on another IRB:

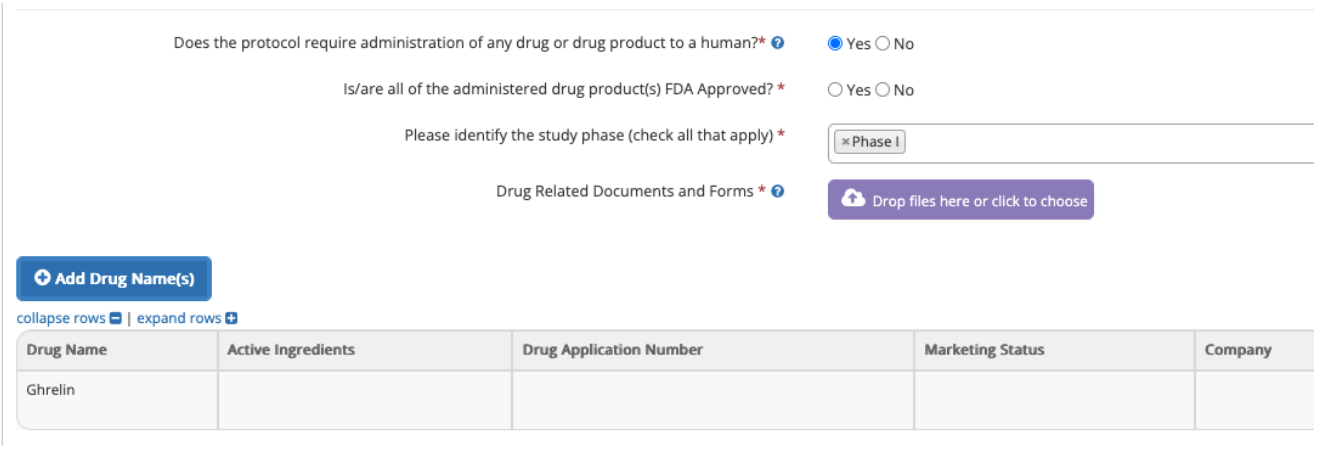
1. Ensure that the question "*Is this a request to rely on an external IRB?*" is answered Yes.

If your protocol involves relying sites where Penn is the single IRB of Record:
NOTE: The IRB is assisting Penn teams to ensure that the questions below are answered correctly, Penn sIRB Contact is identified on the Research teams panel, and that relying sites are added in the Relying Sites Panel.



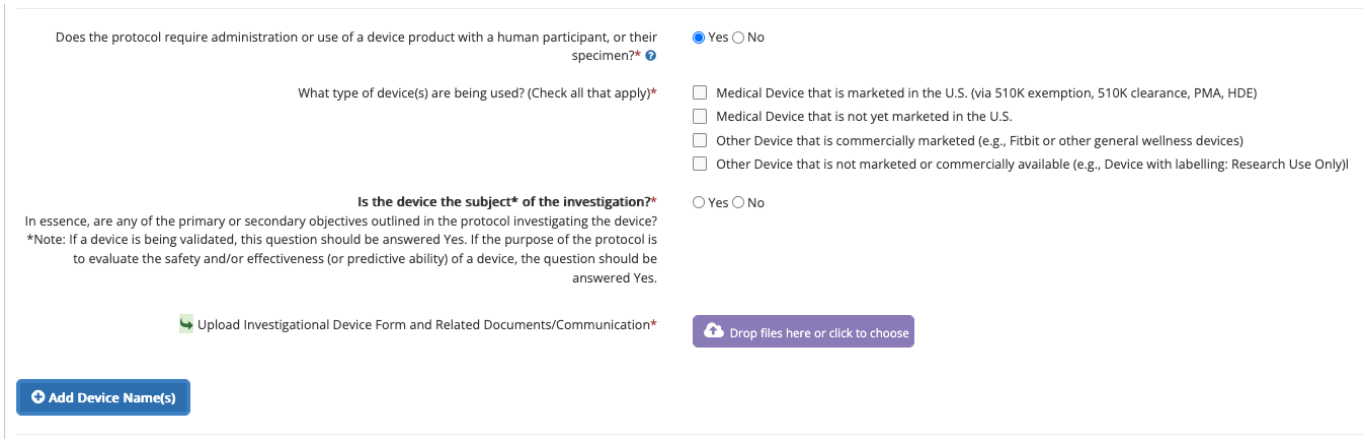
If your protocol involves the administration of a drug(s):

2. Review the Drug questions for accuracy.
3. Answer any unanswered questions related to the drug(s).



If your protocol involves the administration of a device(s):

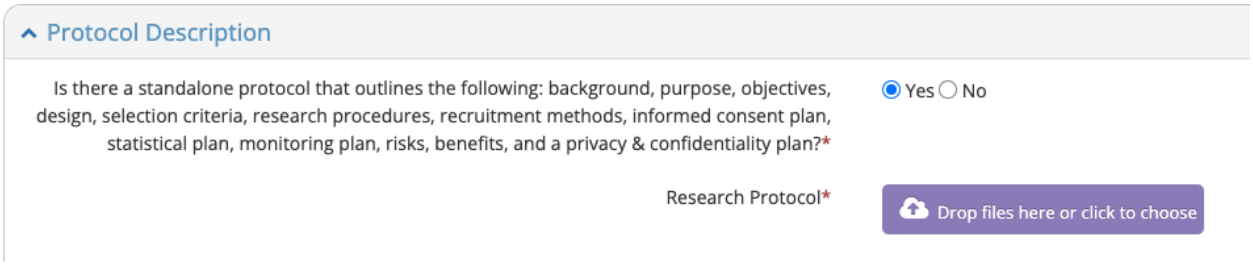
4. Review the Device questions for accuracy.
5. Answer any unanswered questions related to the device(s).



Protocol Description Panel

If you have a standalone protocol that you are amending with the submission:

6. Answer yes to the question "*Is there a standalone protocol that outlines the following: background, purpose, objectives, design, selection criteria, research procedures, recruitment methods, informed consent plan, statistical plan, monitoring plan, risks, benefits, and a privacy & confidentiality plan*?"
7. Upload your clean and tracked versions of your protocol in the purple research protocol upload box.

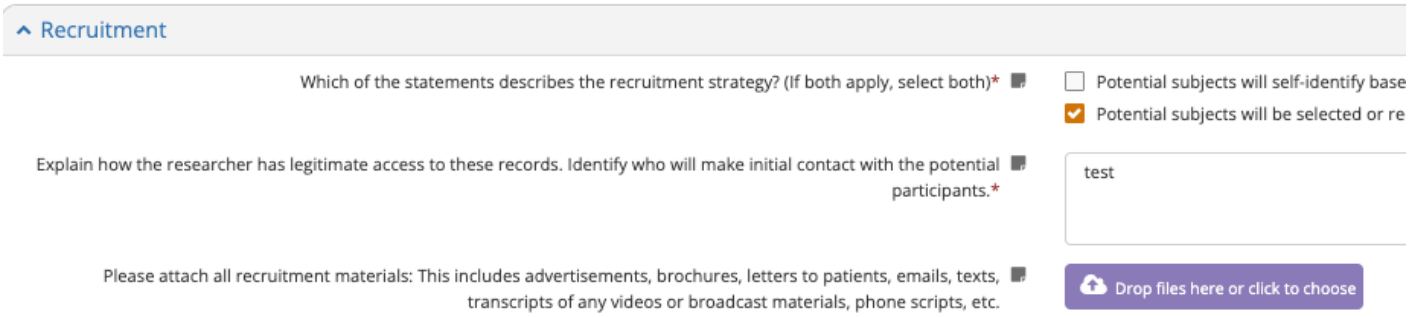


NOTE: If you are also requesting continuing review, please also upload your currently approved protocol under the Additional Documents panel for reference.

Recruitment Panel

If you have recruitment materials that you are amending with the submission:

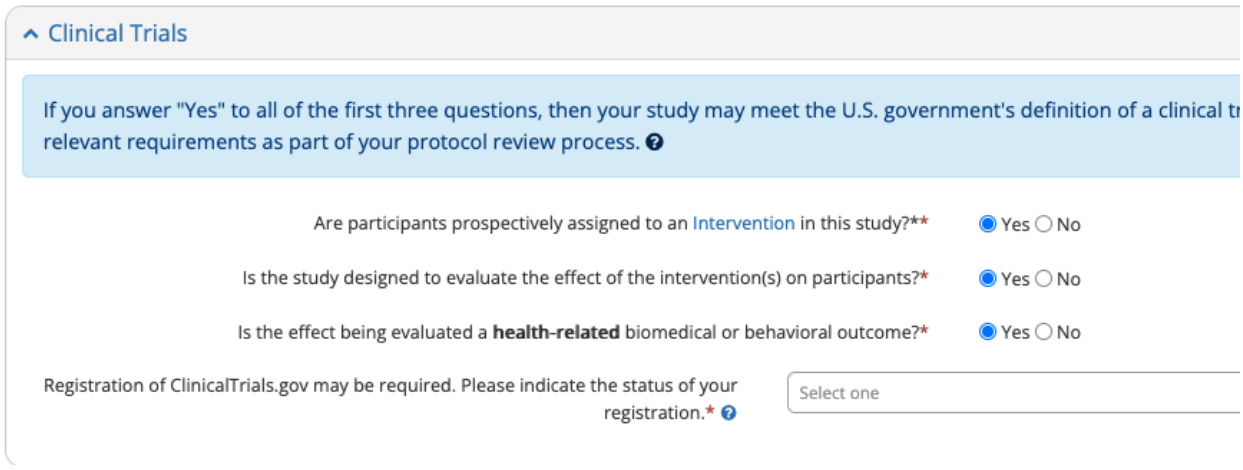
8. Upload your clean and tracked versions of your recruitment materials in the purple upload box.



Clinical Trials Panel

If your protocol meets the NIH definition of a clinical trial:

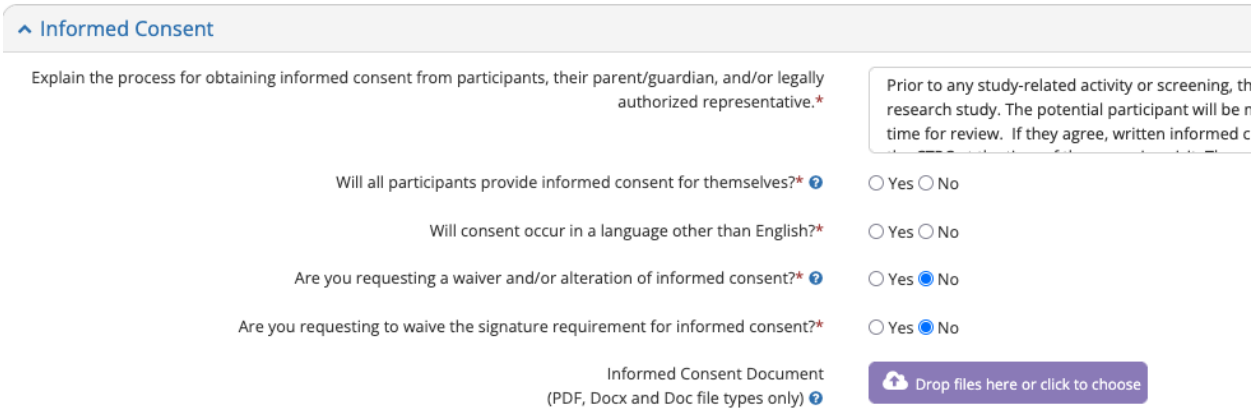
9. Please review the migrated data in this panel
10. Answer the question "Registration of ClinicalTrials.gov may be required. Please indicate the status of your registration."
    a. If the registration number is available, please add it.



Informed Consent Panel

If you have a consent form that you are amending with the submission:

11. Answer any unanswered questions
12. Upload your clean and tracked versions of your informed consent in the purple Informed Consent Document upload box.

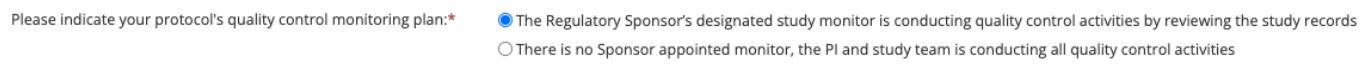


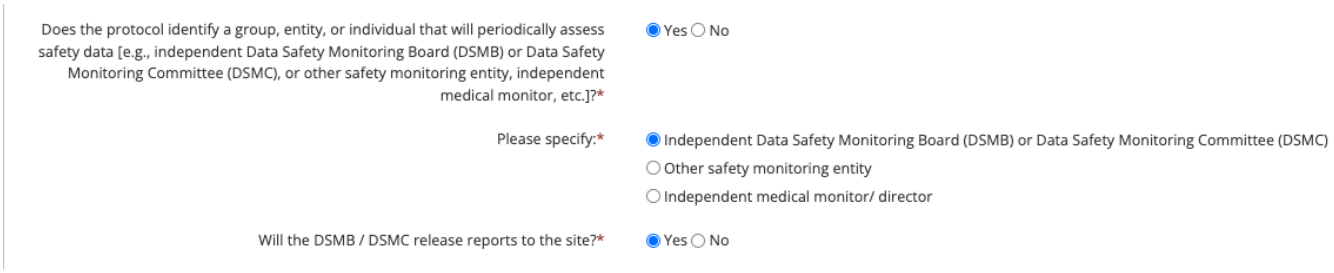
NOTE: If you are also requesting continuing review, please also upload your currently approved informed consent forms under the Additional Documents panel for reference.

Risks and Benefits

If your research has been determined to be greater than minimal risk:

13. Please answer the questions about quality control monitoring and safety monitoring.

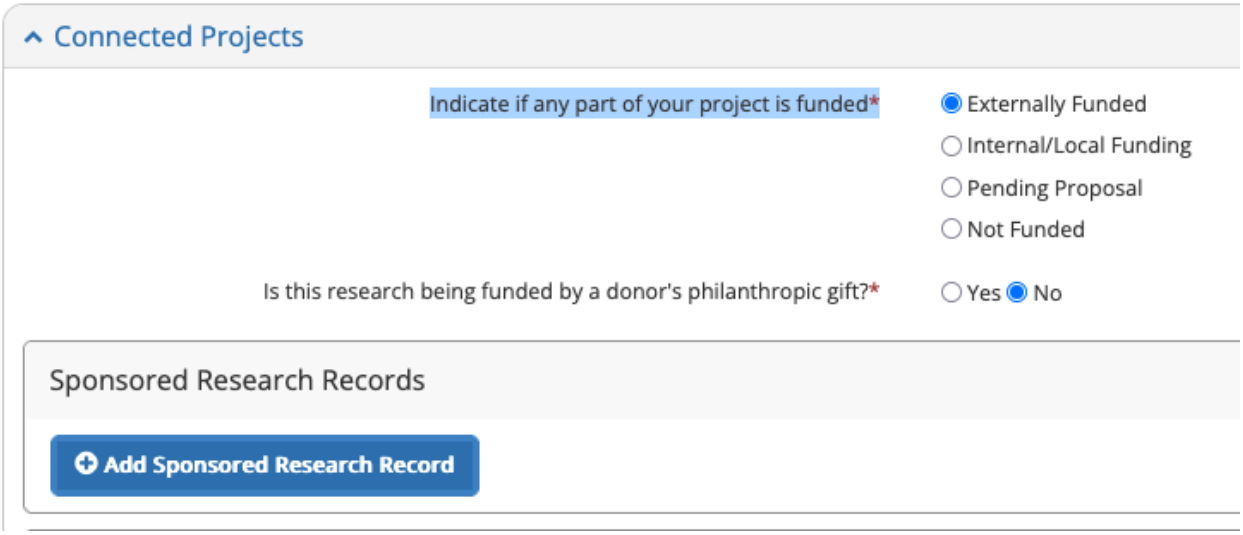




Connected Projects

All protocols:

14. Please review funding information. If there is an executed grant or contract, ensure externally funded is selected.
15. Connect the grant proposal or executed contract associated with the protocol by clicking Add Sponsored Research Record.



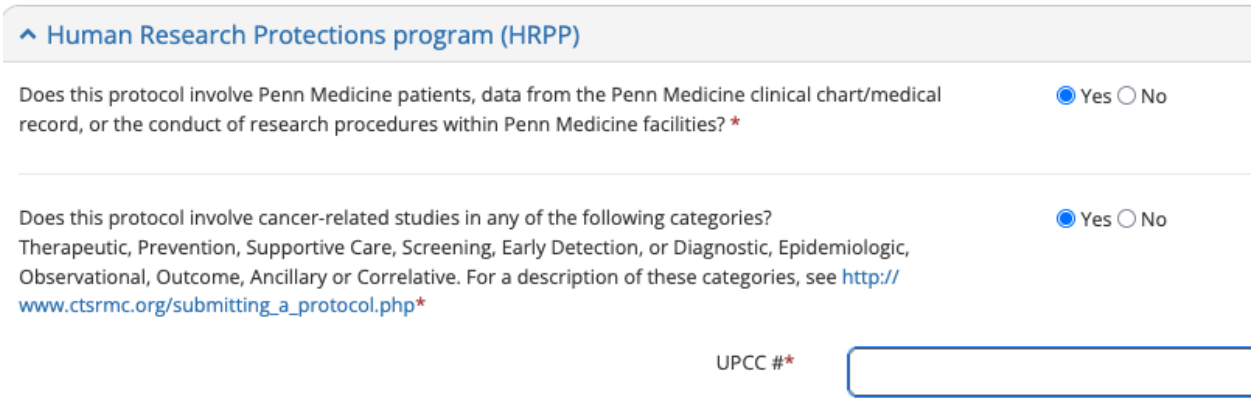
16. Under Connect an Agreement, if you have an RIS number(s) associated with this protocol, it is *recommended* but not required that they be added.

Human Research Protections Program (HRPP) Panel

17. All protocols: Please answer the following question: *Does this protocol involve Penn Medicine patients, data from the Penn Medicine clinical chart/medical record, or the conduct of research procedures within Penn Medicine facilities?*

If your protocol is cancer-related:

18. Please enter your UPCC number in the designated field.



Penn Medicine protocols only:

19. Please answer the question: *Please identify the primary type of clinical research this protocol falls under:*

Additional Documents

20. Please upload a cover letter that outlines the purpose of the submission. Be sure to indicate whether you are submitting for completeness only or whether you are submitting an amendment or amendment + CR. Please see a template cover letter on page 11.
21. Please upload any additional documents here as needed.

Continuing Review Panel

If you are submitting an amendment + continuing review submission type, please complete the continuing review panel.

Penn University of Pennsylvania | Human Research Protections Program

Template Cover Letter for Studies Migrated to eIRB

Below is an example cover letter for the first submission of a migrated study within the eIRB system.

PI:	[PI Name]
Date:	[Date]
Title:	[Study Title]
Legacy IRB#:	[Legacy IRB Protocol #]
Re:	Completeness Submission for Migrated Protocol

To Whom it May Concern,

The purpose of this submission is to:

- [Indicate whether you are submitting for completeness;
- Indicate whether you are submitting another type of submission, if applicable. E.g., continuing review, amendment, deviation, etc.]

[**If you are only submitting for completeness and there are no changes to any study documents include the statement below**. NOTE: There is no need for a document list in this case. eIRB will auto generate document lists, based on the documents uploaded in eIRB.]
Enclosed are the IRB approved study documents for eIRB completeness. Additionally, required fields have been completed.

[**If submitting an amendment or an amendment plus continuing review**; delete if not applicable. NOTE: Please include a document list in order to differentiate between approved and new documents.]

[If required by the amendment form based on the type of amendment, include summary of changes or note where it can be found if in a separate document.]

Enclosed are the IRB approved study documents for eIRB completeness.

- [Document] [version], dated [version date]
- [Document] [version], dated [version date]
- [Document] [version], dated [version date]

The following documents are revised and included for review:

- [Document] [version], dated [version date]
- [Document] [version], dated [version date]
- [Document] [version], dated [version date]