BROWN

Human Research Protection Program
PI Guidance

Non-reliance Collaborative Research

This SOP describes the procedures for review of a protocol that includes collaborative research that is ineligible for a reliance agreement, such as Exempt research or research with an institution/organization unwilling or unable to enter into a reliance agreement (i.e., Providence VAMC; certain international sites). It may also be used to document a study in which the local site has contracted an independent IRB for single-site research.

Non-reliance Collaborative Research

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- All questions marked with a red asterisk require a response.
- If a response is changed on any question, and there is a '**clear**' option, '**clear' needs to be selected before changing to a different response** (this applies to ALL pages of the submission).
- When uploading a document, please disregard the **Show Advanced Option**.
- At the end of every page:
  - Click **Continue** to move to the next page.
  - To exit the submission, click **Save** and then **Exit**.
  - *Note: these actions are on every page throughout the submission.*

How to Access the System

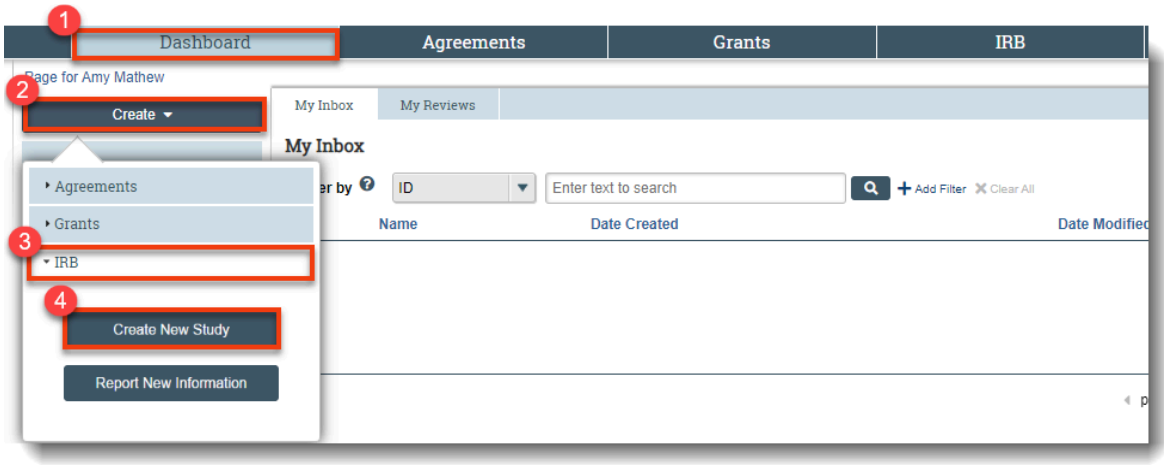
1. The Huron submission system can be accessed via the URL: https://irb-era.brown.edu/

2. When applicable, log in using the DUO Mobile two-factor authentication.

3. Huron can be accessed using Windows and Macintosh - Mozilla Firefox and Google Chrome. It cannot be accessed using Microsoft Internet Explorer or Microsoft Edge.

How to Create a Study

1. From the **Dashboard**,



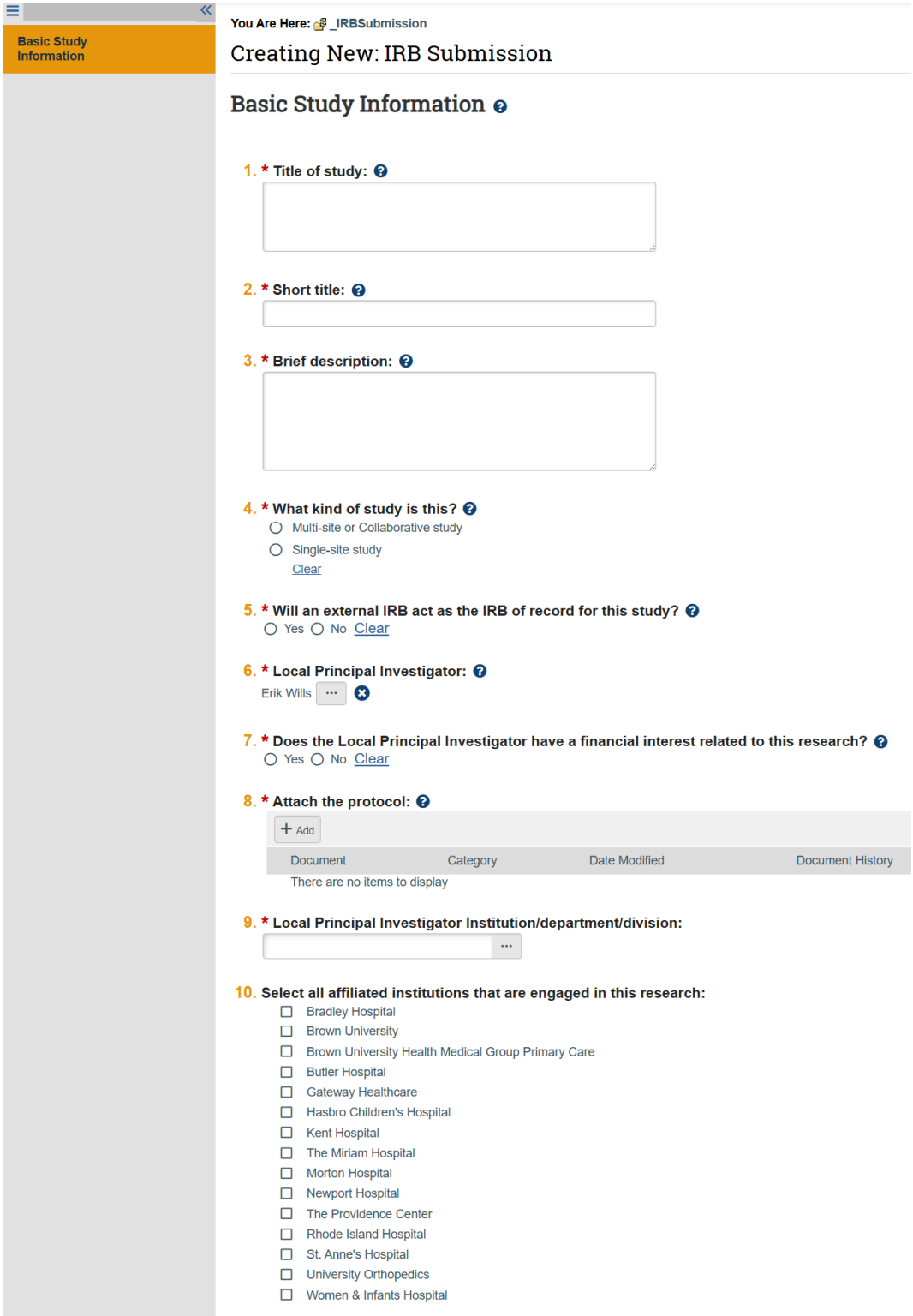
2. Click the **Create** menu,

3. Click **IRB**,

4. Select **Create New Study**.

5. The Basic Information page must be completed and saved to create the study record.

Basic Study Information Page



Basic Study Information

You Are Here: _IRBSubmission

Creating New: IRB Submission

Basic Study Information

1. * **Title of study:**

2. * **Short title:**

3. * **Brief description:**

4. * **What kind of study is this?**
   - Multi-site or Collaborative study
   - Single-site study

   Clear

5. * **Will an external IRB act as the IRB of record for this study?** Yes No Clear

6. * **Local Principal Investigator:** Erik Wills ···

7. * **Does the Local Principal Investigator have a financial interest related to this research?** Yes No Clear

8. * **Attach the protocol:**

   + Add

Document	Category	Date Modified	Document History

   There are no items to display

9. * **Local Principal Investigator Institution/department/division:** ···

10. **Select all affiliated institutions that are engaged in this research:**
    - Bradley Hospital
    - Brown University
    - Brown University Health Medical Group Primary Care
    - Butler Hospital
    - Gateway Healthcare
    - Hasbro Children's Hospital
    - Kent Hospital
    - The Miriam Hospital
    - Morton Hospital
    - Newport Hospital
    - The Providence Center
    - Rhode Island Hospital
    - St. Anne's Hospital
    - University Orthopedics
    - Women & Infants Hospital

1. **Title of the Study:** Add the title of the study. This title should match any official titles used for study (e.g. funding titles)

2. **Short Title:** Select a short title (50 characters max) that will be used to identify your study throughout the Huron system. For example, the study name used on recruitment materials or consent documents.

3. **Brief description:** In lay language, briefly summarize the study aims, objectives, and methods used (100 words max). For example, This is a <drug study, vaccine study, chart review, bio-specimen analysis, survey, or questionnaire study> that will examine…by <using interviews, surveys, tasks, intervention>. Include a brief description of the roles of each site and why the study is not eligible for a reliance agreement.

4. **What kind of study is this?:** Select Multi-site or Collaborative study
   A multi-site or collaborative research study means that the research is being conducted at one or more sites and that each site is under the control of a local Participating Investigator. Each site will be operating on the same overall study aims and hypothesis under a single protocol but do not need to be conducting the same specific research activities at each site. A site is considered a collaborating site (Multi-site study) if they are conducting research activities that include participant interaction, access to identifiable data or if they are the prime awardee of federal funding to conduct the research.

5. **Will an external IRB act as the IRB of record for this study?:** Select No.

6. **Will your IRB act as the single IRB of record for other participating sites?:** Select No.

7. **Local Principal Investigator:** Select the name of the PI responsible for the research. HRPP recognizes one Principal Investigator per study. Additional co-investigators may be listed on the Study Team Members page.

8. **Does the Local Principal Investigator have a financial interest related to this research?:** Review the help text for specific guidance on what constitutes a financial interest.

9. **Attach the protocol:** Upload the word version of the protocol. Documents permitted in this location are the: 503, 503a, 503b, 508p, 508r, IRB of Record Protocol, and sponsor's protocol. Please use the document most applicable.

a. The application should include a full overview of the study including all study procedures but with a clear delineation of what is occurring at by the local research team and under Brown IRB oversight, and what is occurring at the collaborating site and under their oversight in each applicable section. For clarity, include a brief statement in each appropriate section outlining roles. The HRPP will review the study as a whole but focus on those elements that are applicable to the Brown Innovation and Research Collaborative for Health's (BIRCH) role in the research.

   For example: Institution A will be conducting chart review for recruitment purposes, consenting and conducting all interviews. Local: Brown will be sending compensation for completed interviews and conducting data analysis. Identifiable data, including PHI, will be stored at Brown using Stronghold. For the overall project, we will be conducting interviews with disabled veterans presenting issues with substance use disorders. Initial eligibility will be determined by reviewing electronic health records.

b. Research involving secondary data must be evaluated for identifiability and sensitivity of the data collected. The study must also be evaluated for the risk level of the data to determine if it can be granted an Exempt Determination or should be elevated to an Expedited review, which could trigger the single IRB mandate and require a reliance agreement for review of the research.
   i. De-identified or anonymous secondary data does not meet the definition of human subjects. However, if the affiliated PI conducting the research has access to the identifiers through a role in the research study responsible for collecting the primary data, the study cannot be classified as de-identified or anonymous, regardless of the intent to access or record identifiers at an affiliated site.
   ii. The study application must reflect that the data is identifiable through the PI's affiliations with the primary data but that the data will be recorded at the local site without identifiers and that there will be no attempts to re-identify the data or contact participants (45 CFR 46.104(d)(4)(ii)).
   iii. Investigators should confirm that participants in the original data collection have agreed to share identifiable data outside of the original study.

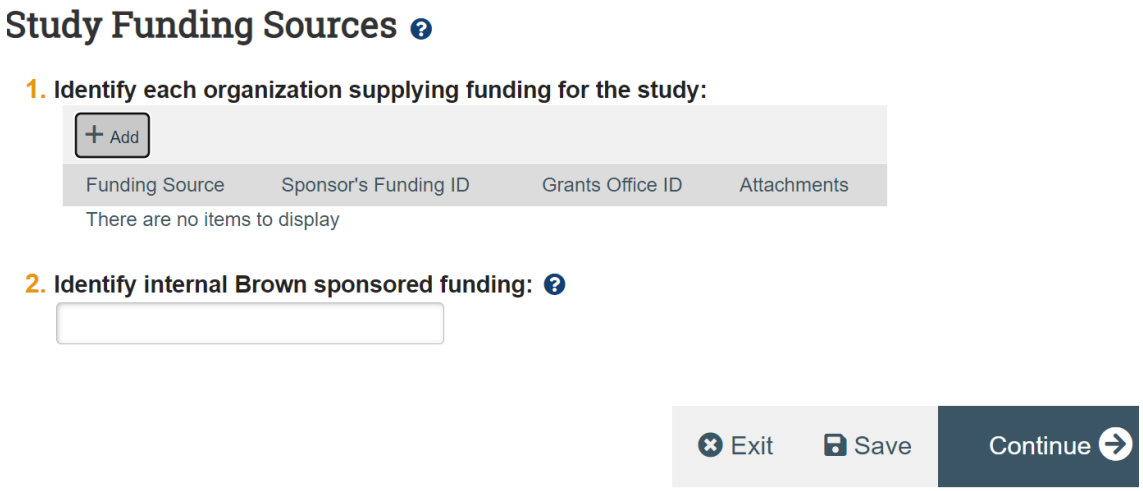
10. **Local Principal Investigator department:** Select the department of the Local Principal Investigator. If the PI is affiliated with more than one department, select the department the study is being conducted from.

11. **Select all affiliated institutions that are engaged in this research.** Select all applicable institutions for your study. This is specific to locations under Brown University Health, Care New England, and Brown University.

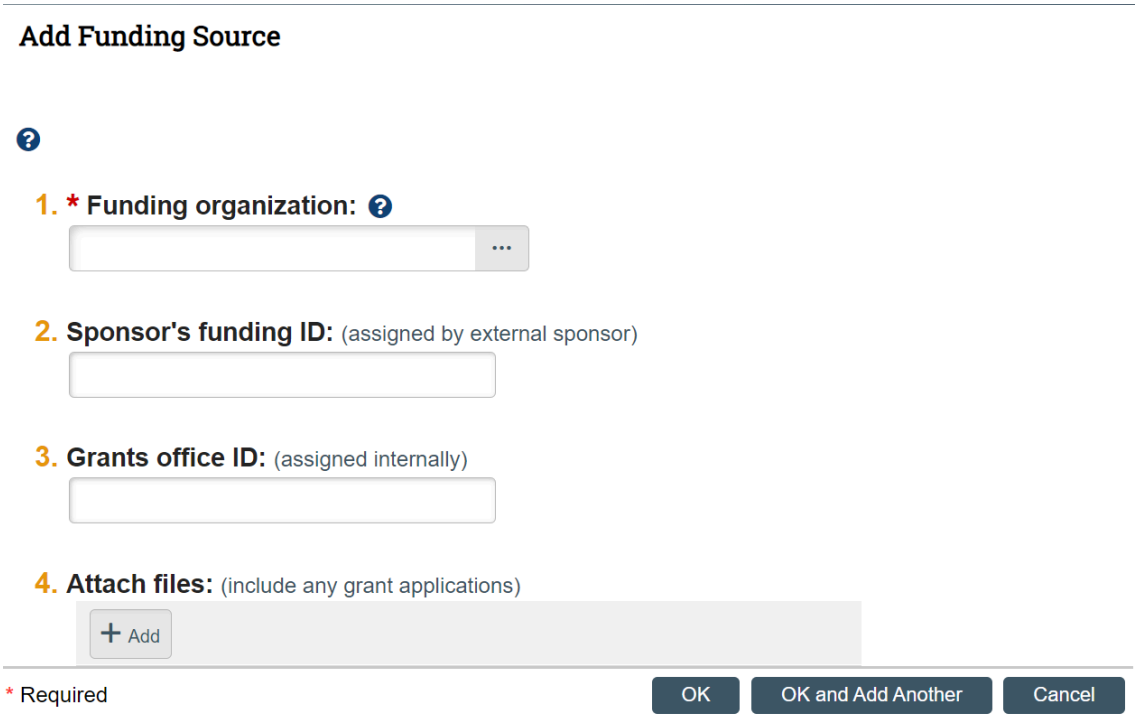
    Note: At minimum, PIs should select their own institution as being engaged in the research.

Click **Save**. Click **Continue** to move to the next page. To exit the submission, click **Exit**. These 3 actions are on every page.

Study Funding Sources Page



1. **Identify each organization supplying funding for the study**: If there is external funding for the study, select the +Add button to access the details.



1. **Funding Organization:** You can start typing the name of the organization (e.g. NIH) or select the three ellipses to access the full list of organizations. If your funding source is new and does not appear on the list, contact the Brown HRPP.

2. **Sponsor's funding ID:** If there is a funding ID, include this information. Identify all external funding sources, including the applicable proposal or award number (e.g., R01HD12345 or CNS-1234567).

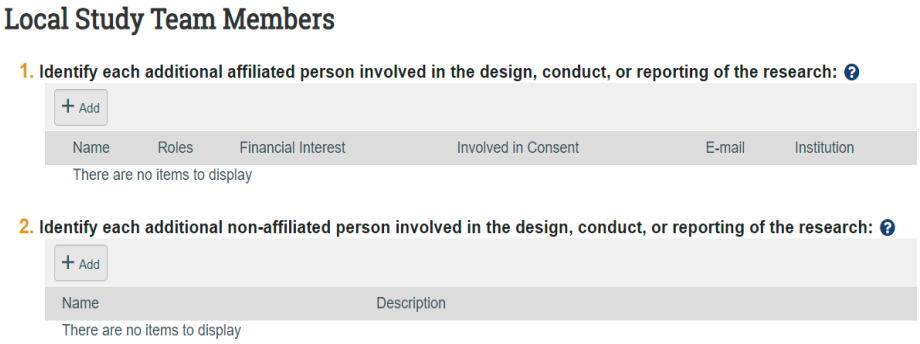
3. **Grant's office ID:** If there is a grant office ID, include this information. Identify all external funding sources, including the applicable proposal or award number (e.g., R01HD12345 or CNS-1234567).

4. **Attach files:** No documentation is required to be uploaded to this space.

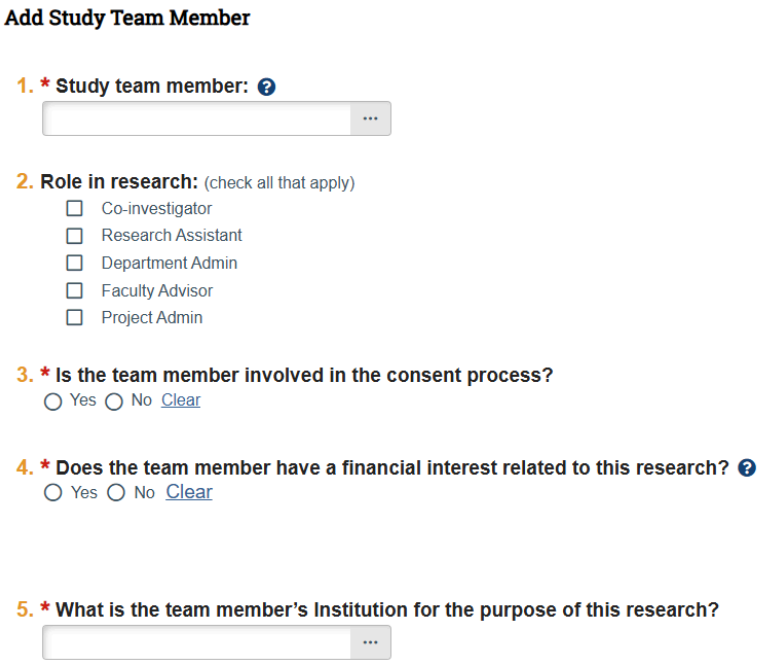
2. **Identify internal sponsored funding:** Identify all internal funding sources from your institution (e.g., Global Health Scholarship, Research Seed Funding, Salomon Faculty Research Awards, Research Achievement Awards).

Click **Save**. Click **Continue** to move to the next page. To exit the submission, click **Exit**. These 3 actions are on every page.

Local Study Team Members Page



1. **Identify each additional affiliated person involved in the design, conduct, or reporting of the research:** If there are additional study team members, select the +Add button to add each person. **Add information about all affiliated persons involved in the design, conduct, or reporting of the research.** The main principal investigator is listed on the Basic Information page and does not need to be included here. All other principal investigators for the sites listed within the application need to be listed below.



2.

    1. **Study team member:** Add information about affiliated persons involved in the design, conduct, or reporting of the research. The principal investigator is listed on the Basic Information page and does not need to be included here.

       Do not add the study's primary contact person for IRB communications here unless the person is also engaged in the research. The person who creates the study in the IRB system is assigned as the primary contact by default, and can be changed later as described in "Changing the Primary Contact" in the Study Submission Guide.

       If you have difficulty finding the person in the list, try typing the beginning of the first or last name. Contact the HRPP for assistance if a person is not listed in the system.

    2. **Role in research:** Select all that apply.

3. **Is the team member involved in the consent process?:** If the team member is involved in the process of consenting participants, select yes. If the team member is not involved in the process of consenting or for example, is only involved in the drafting of consent materials, select no.

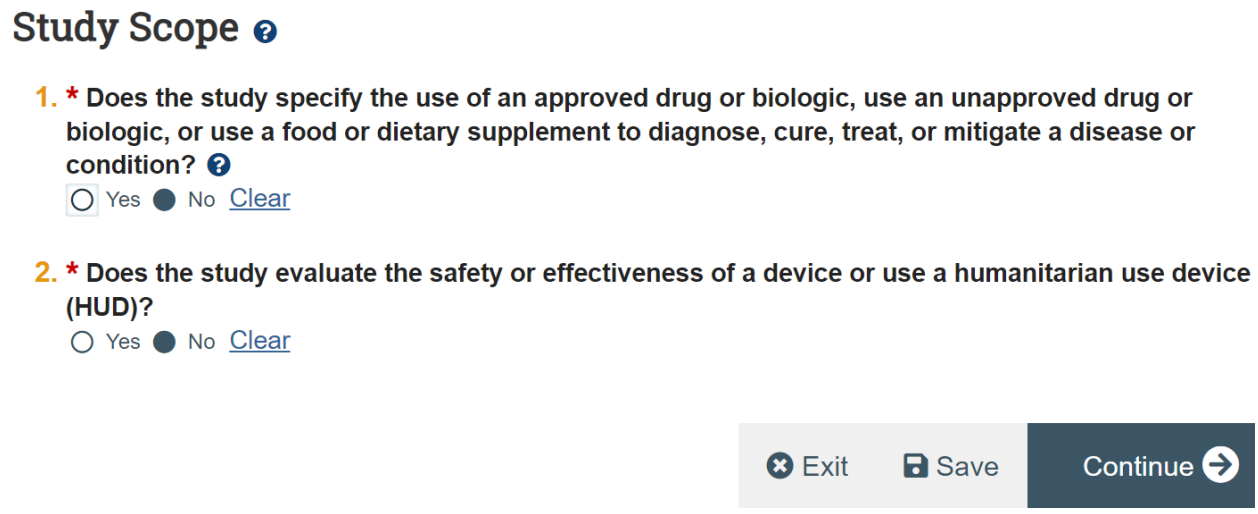
4. **Does the team member have a financial interest related to this research?:** Review the help text for specific guidance on what constitutes a financial interest.

5. **What is the team member's Institution for the purpose of this research?** Select the applicable institution for each study team member. If a team member is affiliated with more than one institution, select the institution where the study is being conducted from.

2. **Identify each additional non-affiliated person involved in the design, conduct, or reporting of the research:** Attach information about members of the research team who were not listed for selection in the previous question. Individual investigators are 1) not affiliated with any institution with respect to this project or 2) acting as an employee or agent of an institution that **is not engaged** in the research. This requires an Individual Investigator Authorization. Contact the HRPP prior to proceeding.

Click **Save**. Click **Continue** to move to the next page. To exit the submission, click **Exit**. These 3 actions are on every page.

Study Scope Page



1. **Does the study specify the use of an approved drug or biologic, use an unapproved drug or biologic, or use a food or dietary supplement to diagnose, cure, treat, or mitigate a disease or condition?:** Select yes if an approved drug or biologic, an unapproved drug or biologic, or a food or dietary supplement is under investigation per the study design. Selecting yes will open a follow on Drug page for additional information. "Specify the use of" means the protocol requires one or more subjects to use the drug, biologic, dietary supplement, or food as part of study participation, regardless of whether its use is considered standard of care.

2. **Does the study evaluate the safety or effectiveness of a device or use a humanitarian use device (HUD)?:** Select yes if the study is designed to evaluate the safety or effectiveness of a device or use a humanitarian use device (HUD). Selecting yes will open a follow on Device page for additional information. Per FDA regulations a medical device is "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:

   (A) recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,

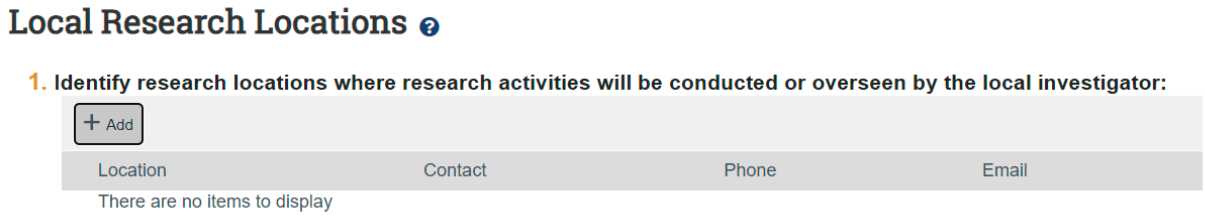
   (B) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or

   (C) intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes. The term "device" does not include software functions excluded pursuant to section 520(o)."

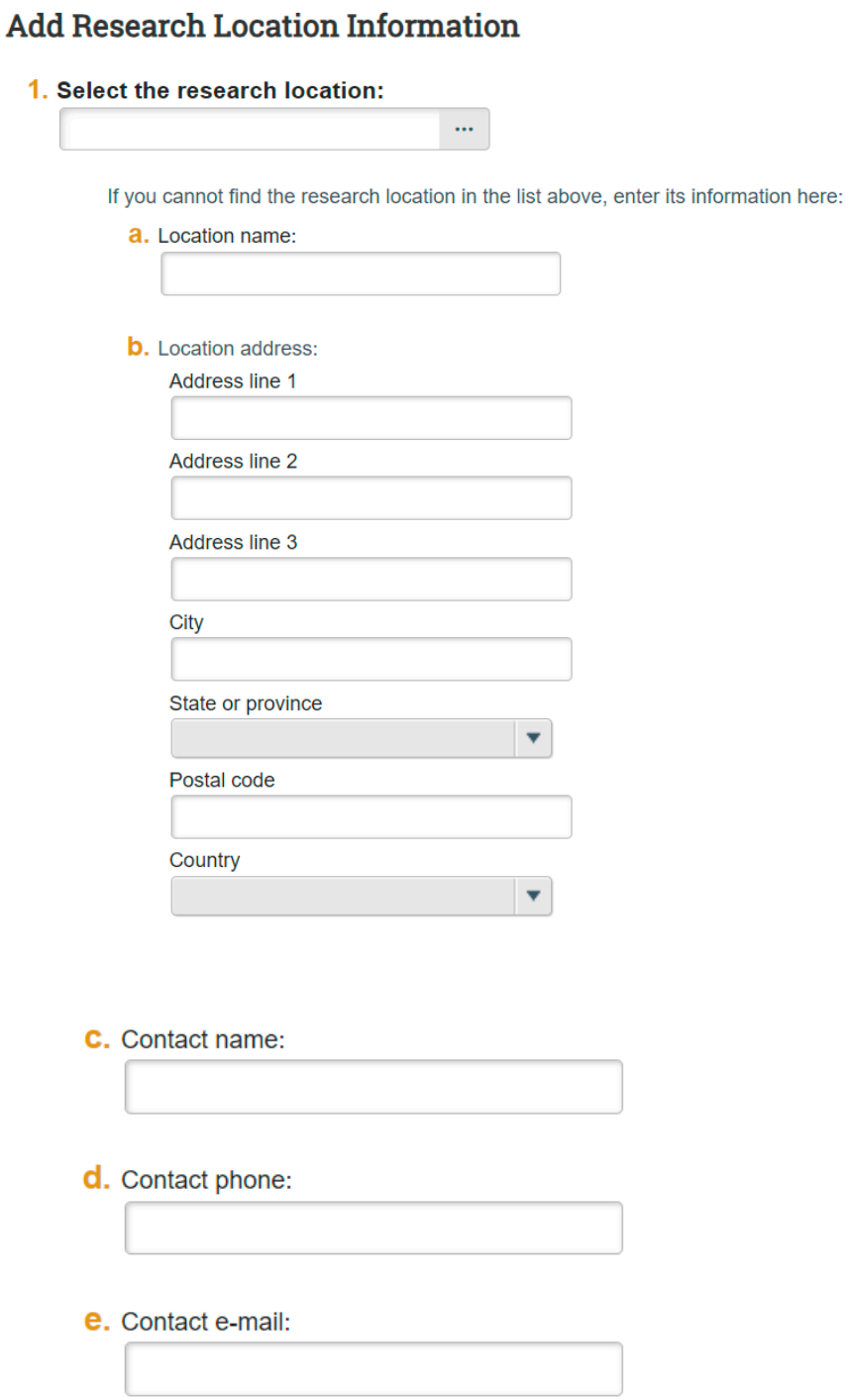
   Per FDA regulations an HUD is a "medical device intended to benefit patients in the treatment or diagnosis of a disease or condition that affects or is manifested in not more than 8,000 individuals in the United States per year."

Click **Save**. Click **Continue** to move to the next page. To exit the submission, click **Exit**. These 3 actions are on every page.

Local Research Locations Page



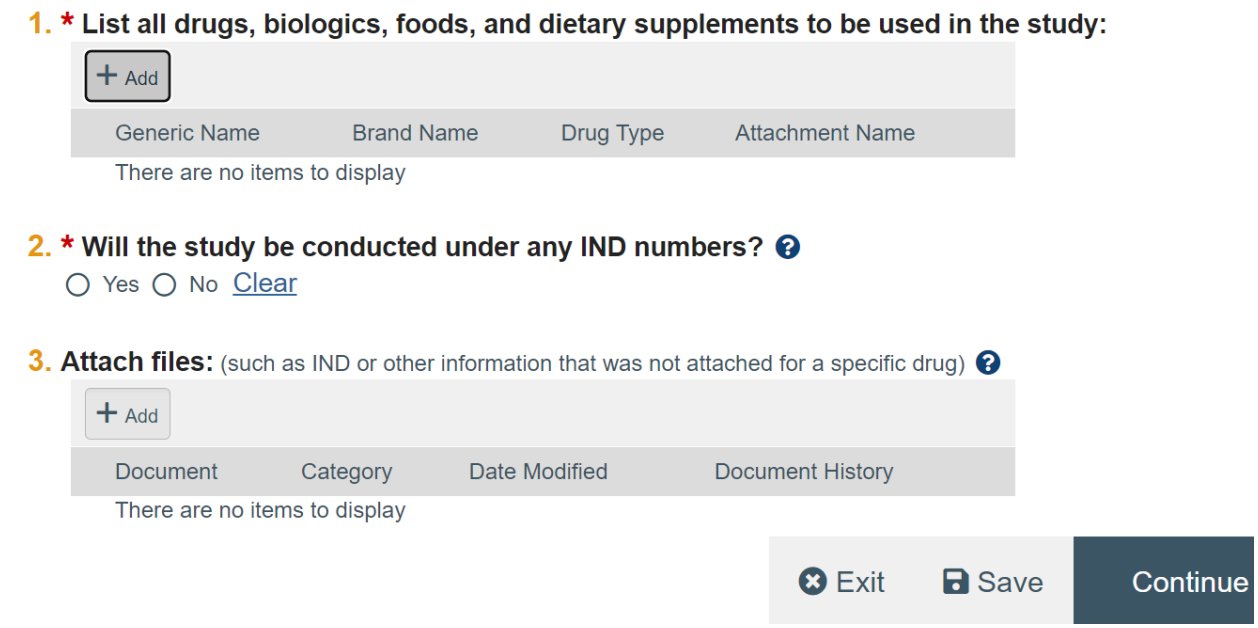
1. **Identify research locations where research activities will be conducted or overseen by the local investigator:** Identify research locations where research activities will be conducted. These research locations have been included because they are locations within your institution where institutional leadership would like to track human research activities, or because they are locations outside of the institution where your institution's principal investigators conduct human research.
    a. Research locations are not participating sites in multi-site or collaborative research with separate principal investigators. If your research location is not included for selection, you may enter information manually about that location. Please contact your HRPP if you are unsure whether your research location should actually be a participating site.



1. **Select the research location.** Select the research location from the drop down menu. If you cannot find the research location in the list above, enter its location information.

Click **Save**. Click **Continue** to move to the next page. To exit the submission, click **Exit**. These 3 actions are on every page.

Drugs Page *Only available if "yes" is selected to Question 1 on the Study Scope page.*



1. **List all drugs, biologics, foods, and dietary supplements to be used in the study:** This page will open if "yes" is selected for the Drug question on the Study Scope page. If there are drugs, biologics, foods, and dietary supplements under investigation in the study, select the +Add button to access the details.

Add Drug Information

1. Select the drug:

If you cannot find the drug in the list above, enter its information here:

Generic name:

Brand name:

2. * Specify the type:

- ○ Drug
- ○ Biologic
- ○ Food Product
- ○ Dietary Supplement
- ○ Other

Clear

3. Attach files related to this drug. Attachments may include a copy of the package insert, investigator brochure, product labeling, or verification of any IND number:

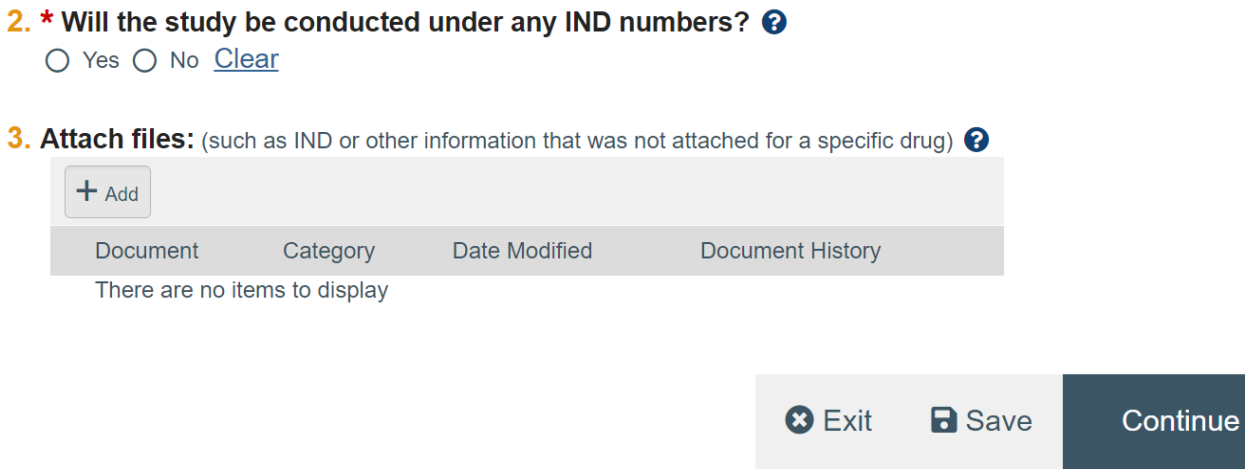
+ Add

Document	Category	Date Modified	Document History

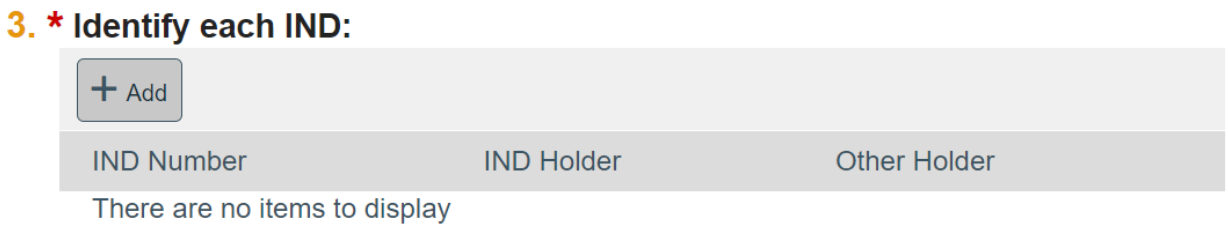
There are no items to display

Alt Text: Screenshot of Huron e-form section showing "Add Drug Information" questions.

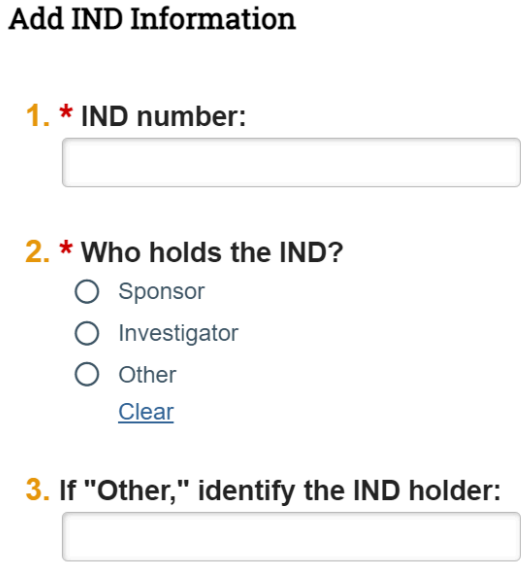
1. **Select the drug:** You can either start typing the name of the drug or select the three ellipses to access the list of drugs within the system. If you cannot locate the drug, enter the information under the Generic Name / Brand Name fields.
2. **Specify the type:** Select from the available options. If the type is not included, you will be prompted to complete "Other Drug Type description" if you select "Other."
3. **Attach files related to this drug. Attachments may include a copy of the package insert, investigator brochure, product labeling, or verification of any IND number:** Attach a copy of the related materials including but not limited to the package insert, labeling and verification of an IND number.



2. **Will the study be conducted under any IND numbers?:** If you select "Yes" a pop up will request additional information. If you select "No," proceed to question 3. See Guidance here.



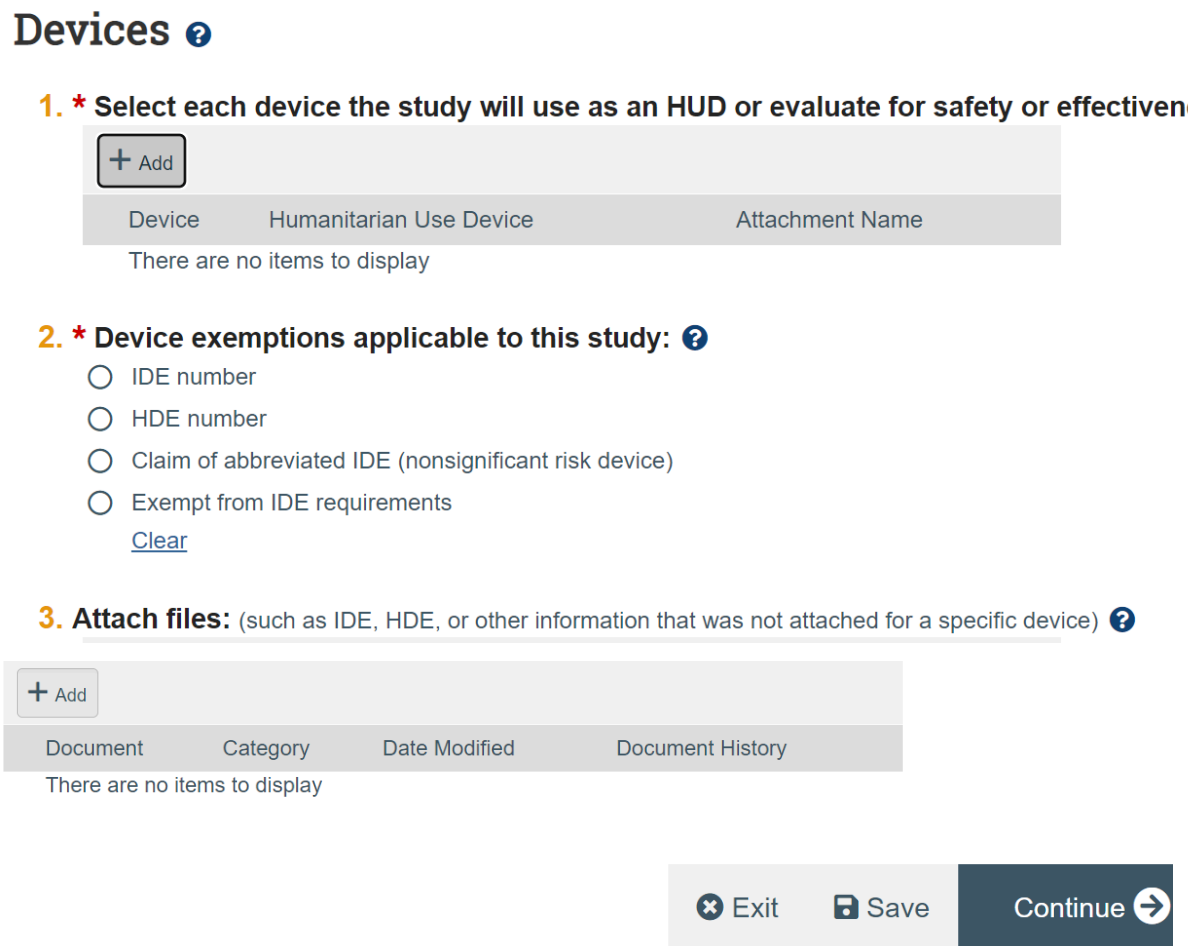
Select the +Add button to access the details.



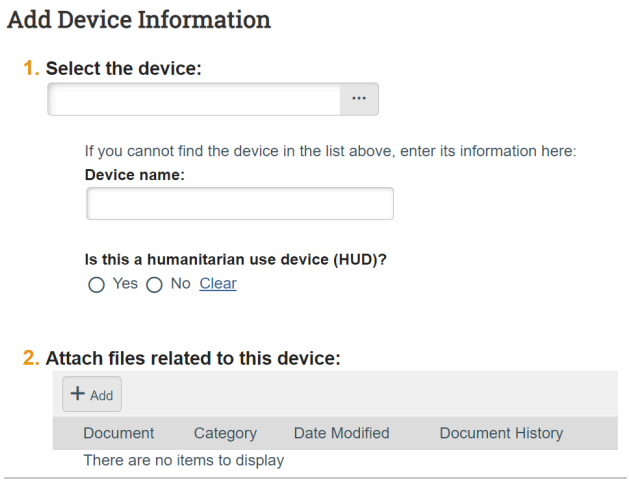
1. **IND number:** Add the IND number.
2. **Who holds the IND?:** Select from the available options.
3. **If "Other," identify the IND holder:** Identify the IND holder if they are not the Sponsor or the Investigator.

Click **Save**. Click **Continue** to move to the next page. To exit the submission, click **Exit**. These 3 actions are on every page.

Device Page *Only available if “yes” is selected to Question 2 on the Study Scope page.*



1. **Select each device the study will use as an HUD or evaluate for safety or effectiveness:** This page will open if “yes” is selected for the Device question on the Study Scope page. Select the +Add button to access the details to add each device the study will use as an HUD or evaluate for safety or effectiveness.



1. **Select the device:** You can either start typing the name of the device or select the three ellipses to access the list of drugs within the system. If you cannot locate the drug, enter the information under the Device Name field.

2. **Is this a humanitarian use device (HUD)?**: A HUD is defined as a medical device intended to benefit patients in the treatment or diagnosis of a disease or condition that affects or is manifested in not more than 8,000 individuals in the United States per year.

3. **Attach files related to this device:** Attach a copy of the investigator brochure and the product labeling/device instructions.

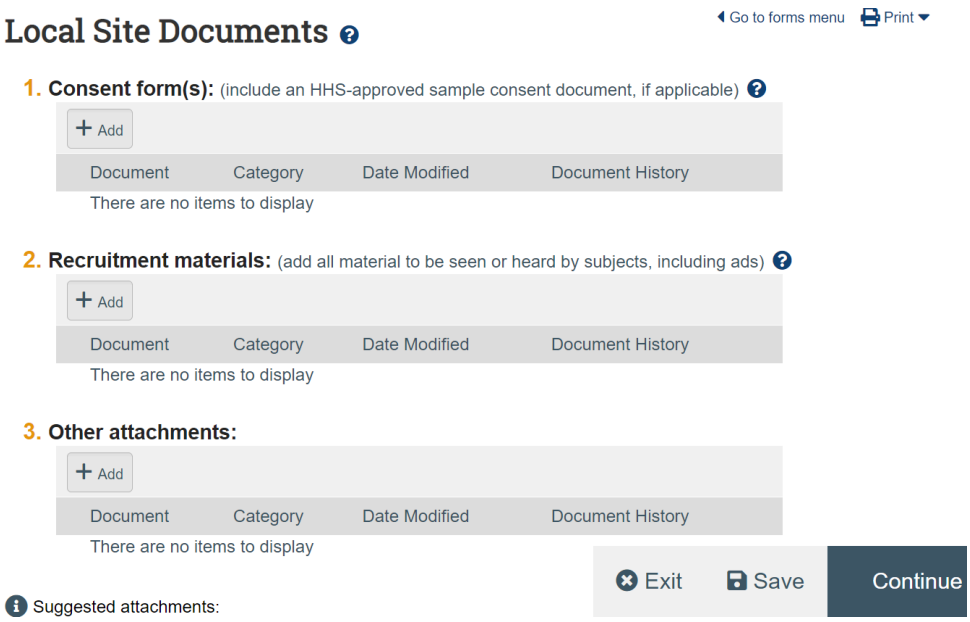
2. **Device exemptions applicable to this study:** Select the applicable device exemptions. See Guidance here.

3. **Attach files:** For each IDE / HDE number, attach one of the following, (1) a Sponsor protocol with the IDE / HDE number or (2) communication from the FDA or sponsor with the IDE / HDE number.

Click **Save**. Click **Continue** to move to the next page. To exit the submission, click **Exit**. These 3 actions are on every page.

Local Site Documents Page

If there are documents specific to the Local Site that have been approved by the collaborating organization, we will ensure that they meet the approval requirements and adhere to Institutional Policy, as applicable.



1. **Consent form(s):** Attach copies of the applicable materials used in the consenting process. See the HRPP Toolkit Template. If there are multiple forms, use Name to identify each document with the subject group/activity (e.g. Provider Interview Consent Form). Zip files are not accepted.
    a. If the document(s) was approved at the collaborating institution, it may not need to be on the Toolkit template.
    b. The document(s) should include affiliated investigators and research activities. At minimum, it should notify participants that the affiliated site(s) is engaged in the study and will have access to research data.
        - If the affiliated site's engagement is through funding only, the HRPP can make an exception to this requirement in certain situations on a case-by-case review.
    c. If consent will not be documented in writing, attach a script of information to be provided orally to subjects. Be sure to include foreign language versions of all documents if applicable.
    d. Make sure the consent documents, the protocol document, and the contract all use consistent language.

2. **Recruitment materials:** Attach copies of the applicable materials and tools used in recruitment. If you have multiple versions of the same type of recruitment, you can batch recruitment materials as Word uploads. For example, if you have multiple social media posts, upload one Word document "Social Media Posts" with all social media post

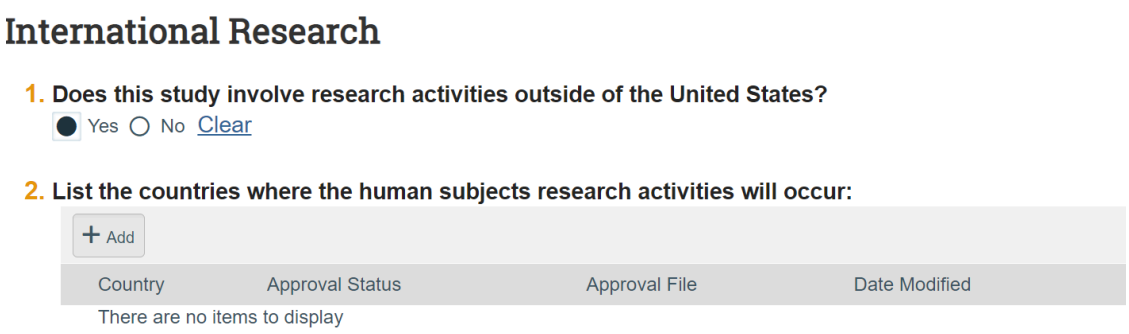
variations. If you have multiple flyers, upload one Word document "Flyers" with all flyer variations. Zip files are not accepted.

   a. If the materials were approved at the collaborating institution and the study does not recruit on the local site, approval requirements specific to local institutional policy may not apply.
   b. Important documents include: advertisements (printed, audio scripts, and video scripts), recruitment materials and verbal scripts.
   c. Be sure to include foreign language versions of all documents if possible.

3. **Other attachments:** Attach individual Word documents of all other study materials. This includes but is not limited to study measures such as interview guides and surveys, measures, letters of support, mental health safety plans, appendices, etc.
   Use Name to identify each document. Zip files are not accepted.
   a. Upload the approval memo and approved protocol as separate documents from the collaborating institution as reference and support that the study is receiving ethical oversight, at least in part, from another IRB.

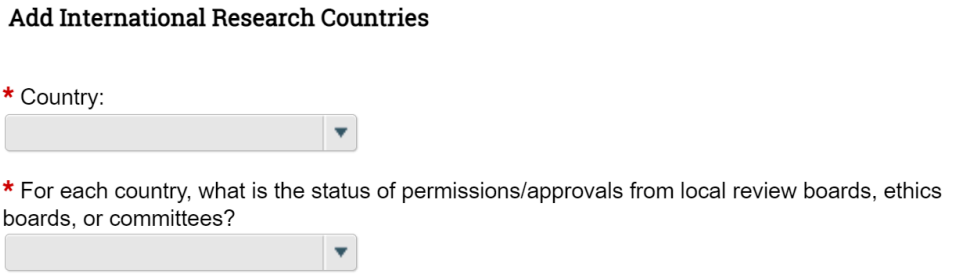
Click **Save**. Click **Continue** to move to the next page. To exit the submission, click **Exit**. These 3 actions are on every page.

International Research Page



1. **Does this study involve research activities outside of the United States?:** If the study does not involve research activities outside of the United States, select "No" and proceed to submitting the study record. If "Yes," questions 2 and 3 will open.

2. **List the countries where the human subjects research activities will occur:** To list the countries where the human subjects research activities will occur, select the +Add button to access the details.



Country: Select from the dropdown list.

For each country, what is the status of permissions/approvals from local review boards, ethics boards, or committees?:

Pending: If the review is pending, indicate in the protocol when approval is anticipated, where review is being received, and confirm the research will not begin until both this IRB review and local review are received.

Received: If the research received local approval, upload the approval memo in the Study Related Documents or Local Site Documents page (whichever is relevant).

N/A: If the submission is marked as N/A for receiving local review, indicate why this is the case in the protocol.

3. **Assurances:** Read and attest to each assurance checkbox. For additional information on each assurance:
    a. I have reviewed the current version of the International Compilation of Human Research Standards and agree to abide by relevant local laws, regulations, and guidelines.
    b. I have reviewed the General Data Protection Regulations guidance and will abide by any requirements.

Click **Save**. Click **Continue** to move to the next page. To exit the submission, click **Exit**. These 3 actions are on every page.

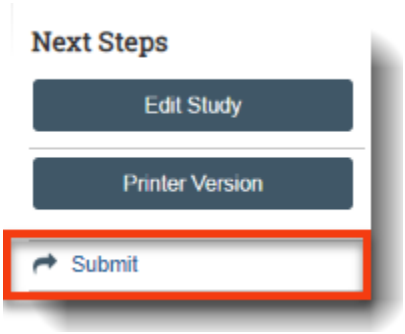
Important! Clicking Finish does not send the submission to the HRPP. When the study is ready for HRPP review, the PI or a PI Proxy must submit from the study record workspace.

Once the user clicks **Finish**, the user is brought back to the IRB workspace within the record. The study record is editable until it is submitted.

To Submit the Study

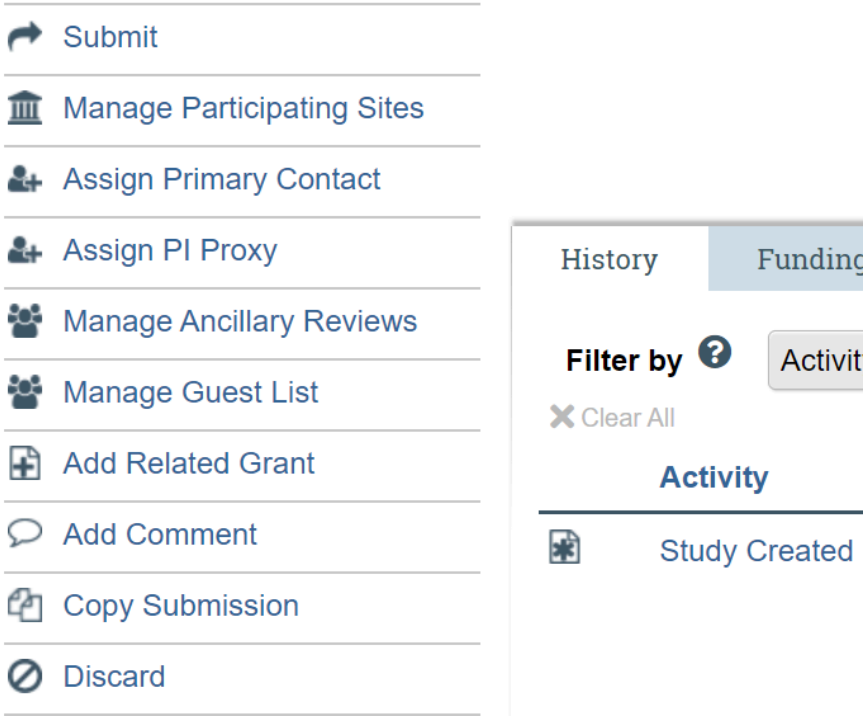
To submit a study for review, within the study record workspace:

1. Click **Submit**.
2. Click **OK** to agree to the terms.
3. Type in your login credentials and click **Submit**.



Once you select **Submit**, the study has been submitted to HRPP and is now in the Pre-Review state.

Study Record Menu Navigation



The left hand menu is available to the Principal Investigator, Primary Contact, PI Proxy and other study team members.

Submit: Will be removed as a menu option once the study record progresses to Pre-Review in the study timeline.

Manage Participating Sites: Manage Participating Sites should be completed post-approval. More information can be found in the Collaborating Research guidance.

Assign Primary Contact: The primary contact will receive all email notifications related to the submission and be able to create new Modifications, Continuing Reviews and Reportable New Information. The Principal Investigator will need to review and "Submit" the Modifications and Continuing Reviews before they are moved to Pre-Review.

Assign PI Proxy: PI Proxy is able to submit a study record on behalf of the PI. The PI Proxy must be a Study Team Member listed in the study record. Only the study's PI or an assigned PI

proxy can submit a record for review. PI Proxy is on a study by study basis. If you are serving as a PI's proxy for their research portfolio, this must be done in each of their study records.

Manage Ancillary Reviews: The study team can initiate any Ancillary Reviews needed prior to Pre-Review. See Guidance on Ancillary Reviews here and within the Investigator Manual (HRP-103).

Manage Guest List: Guest list can be used to give view-only access to other relevant parties such as grant or department administrators. Individuals on the guest list cannot modify the study record.

Add Related Grant: Do not use.

Add Comment: Add comment allows you to add information for the PI, study team or HRPP staff. Note, your comment is visible to anyone with access to this submission and will remain in the submission History. Use the **Who should receive an e-mail notification?** to send a notification to recipients. If a checkbox is not selected, no individual will be notified of the comment.

Copy Submission: Copy submission is a tool that is best suited for studies with multiple phases that have been split into different study records. For example, if a study has Phase I and Phase II that are submitted at different times but the Phase I record has been completed, you can use Copy Submission to create a new record with the same study team, funding, international locations, etc. pages. You would then go into the study record to update the new documents and submit for review.

Discard: This activity will permanently remove the submission. Discard will close the study record. The record will remain in Huron but you will not be able to take any further action such as submitting a modification, continuing review, etc.