AUBURN UNIVERSITY
Institutional Review Board

Creating a New Study Submission in Endeavor

ENDEAVOR
/// AUBURN UNIVERSITY

Version Date: 10/29/24

Table of Contents

How to Access the System

1. Endeavor can be accessed through the Auburn University IRB website, through AU Access, by navigating to https://endeavor.auburn.edu, or scan the QR code at the bottom of this page.

2. You will need to log in using the DUO mobile two-factor authentication.

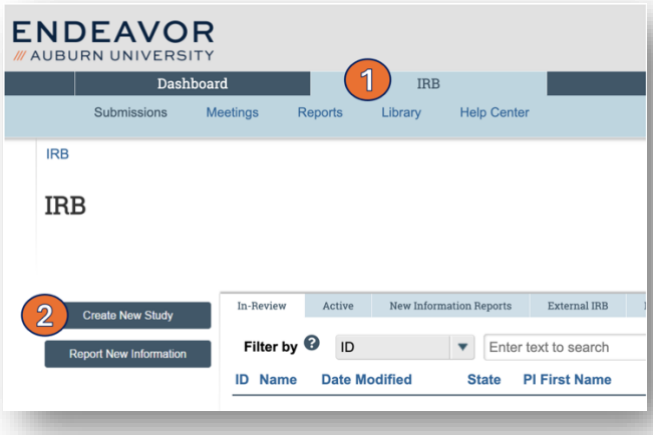
3. Endeavor can be accessed using Windows and Macintosh platforms. The preferred browsers are Google Chrome and Mozilla Firefox.

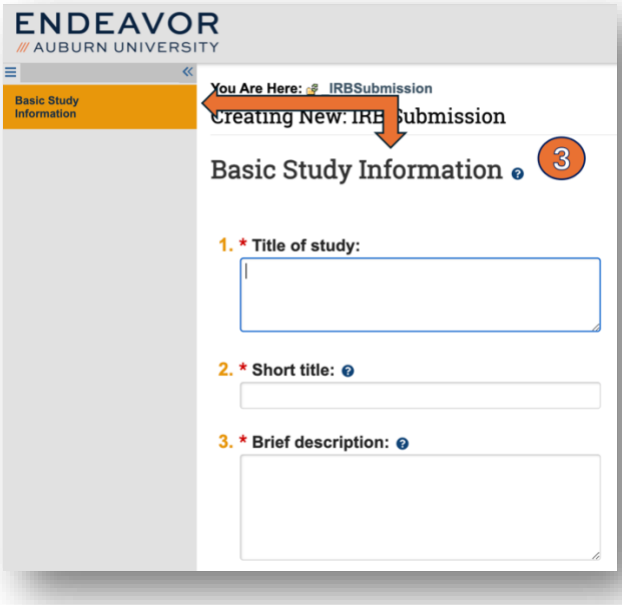
How to Create a Study

1. Once logged into Endeavor, click **IRB**,

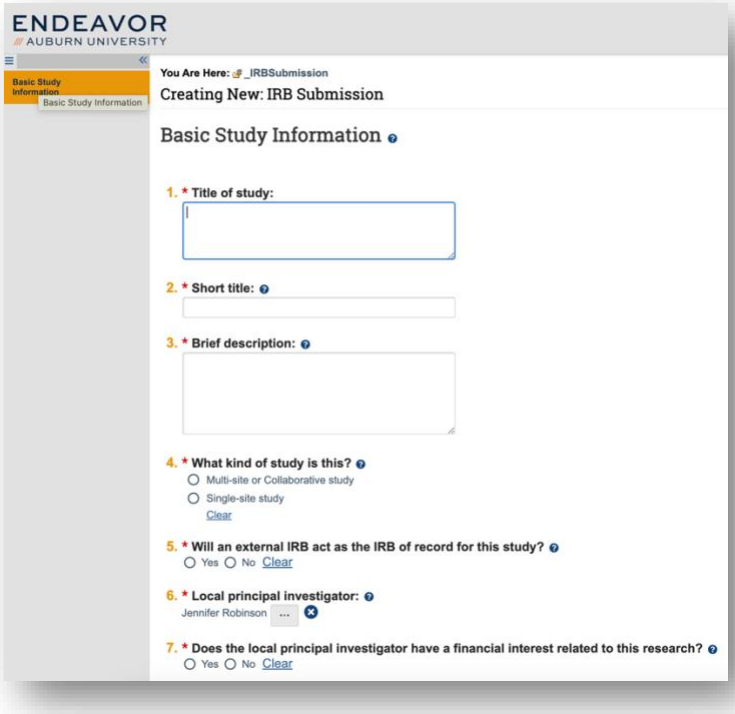
2. Select **Create New Study**.

3. The Basic Study Information SmartForm must be completed and saved to create the study record. All questions with a red asterisk (*) are required.





Basic Study Information Page



1. **Title of the Study:** Add the title of the study.

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

3. **Brief description:** In lay language, briefly describe the study and summarize the specific aims of the study (100 words max). For example, “This is a (drug study, vaccine study, chart review, bio-specimen analysis, survey, or questionnaire study) that will examine (insert condition, process, etc.) by (using interviews, surveys, tasks, intervention).”

4. **What kind of study is this?:** A single-site study is one where all research activities occur at one institution. 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 investigator. Each site will be

operating on the same overall study aims and hypothesis under a single protocol, but the sites 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 Yes if an IRB outside of AU will review this study. If AU is a participating site in a multi-site study, select **Yes**. If you are contracting an independent IRB to review the study, select **Yes**. If you are the single IRB of record for a multi-site or collaborative study, select **No**. If you select **Yes**, you will need to complete HRP-503b – TEMPLATE – Ceded Review. For additional guidance, please see HRP-103 or consult the Endeavor IRB Resource Center Canvas page.

6. **Local Principal Investigator:** This will default to the individual creating the record. Revise the Local Principal Investigator to the AU PI if you are creating the record on behalf of another study team member.

7. **Attach the IRB protocol:** Upload your submission using HRP-503 (for expedited and full board studies), HRP-503a (for exempt studies), HRP-503b (for ceded reviews), HRP-503c (for non-human subjects research determinations), or HRP-503d (for developmental approvals). Keep the submission form as a Word document. All forms can be found on the AU IRB website.

8. **Indicate the proposed review category:** Select the level of review or type of review. To determine if your research falls under an exemption category, please consult **HRP-312** (Worksheet - Exemption Determination) and/or the HHS decision chart for exemption determination. Please note that the IRB has final determination over whether your research falls into an exemption category and may require you to complete an expedited form.

9. **Does this research include a purchase, or purchases, that involve technology hardware, software, or online services?** Answer yes or no. If 'yes', you will need to contact the AU IT Vendor Vetting team at vetting@auburn.edu to ensure compliance with AU's Electronic and Information Technology Accessibility Policy and to ensure proper vendor

registration prior to completing the purchase. Please include a copy of the documentation of the approval from AU Vendor Vetting with your submission under Local Site Documents → Other Attachments. Your protocol will not be approved, and no stamped documents will be issued until proper documentation is uploaded with the protocol.

10. **Does the study expose participants to radiation?** Answer yes or no. If yes, please select what methodology will be used. The IRB will notify Risk Management and Safety to obtain ADPH approval.

11. **Is IBC (Institutional Biosafety Committee) approval required for this study?** Answer yes or no. If yes, you will be asked to provide the BUA # as well as the expiration date. Your protocol will be reviewed by the IBC as an ancillary review.

12. **Is IACUC (Institutional Animal Care and Use Committee) approval required for this study?** Answer yes or no. If yes, you will be asked to provide the protocol # as well as the expiration date. Your protocol will be reviewed by IACUC as an ancillary review.

13. **Does this study involve the Auburn University MRI Center?** Answer yes or no. If yes, indicate whether you will be using the 3T or 7T. Indicate whether any portion of the project requires review by the MRI Safety Advisory Council. Projects that would need review by the MRI Safety Advisory Council would be studies that involve new sequences or procedures that have not been previously used in research at AU. All MRI protocols will require an ancillary review. Please note that all studies involving the MRI center must include Julie Rodiek (rodieja) in the **Local Study Team Members** SmartForm.

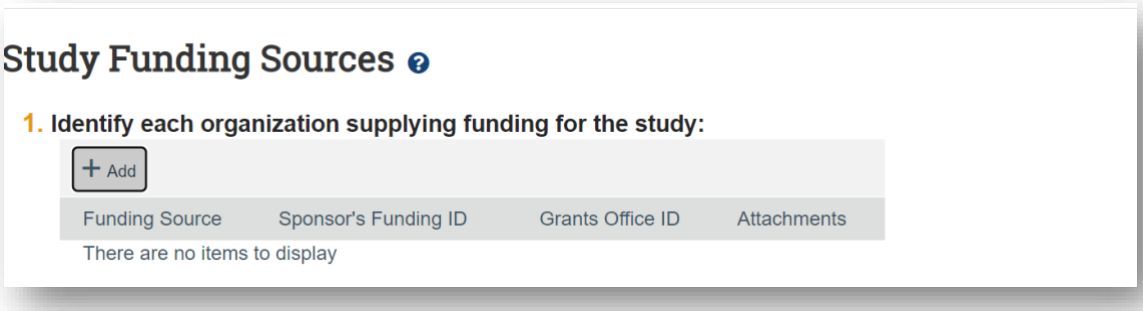
14. **Does this study involve vulnerable populations, or persons with disabilities or disadvantages?** Asner yes or no. If yes, select which populations you will be studying. Consult toolkit resources if you will be studying a vulnerable population:
    - Pregnant Women
        - HRP-412 (Checklist – Pregnant Women)
    - Prisoners
        - HRP-415 (Checklist Prisoners)
    - Children

  - HRP-013 (SOP – LARs, Children, & Guardians)
  - HRP-416 (Checklist – Children)
- Cognitively Impaired Adults
  - HRP-417 (Checklist – Cognitively Impaired Adults)

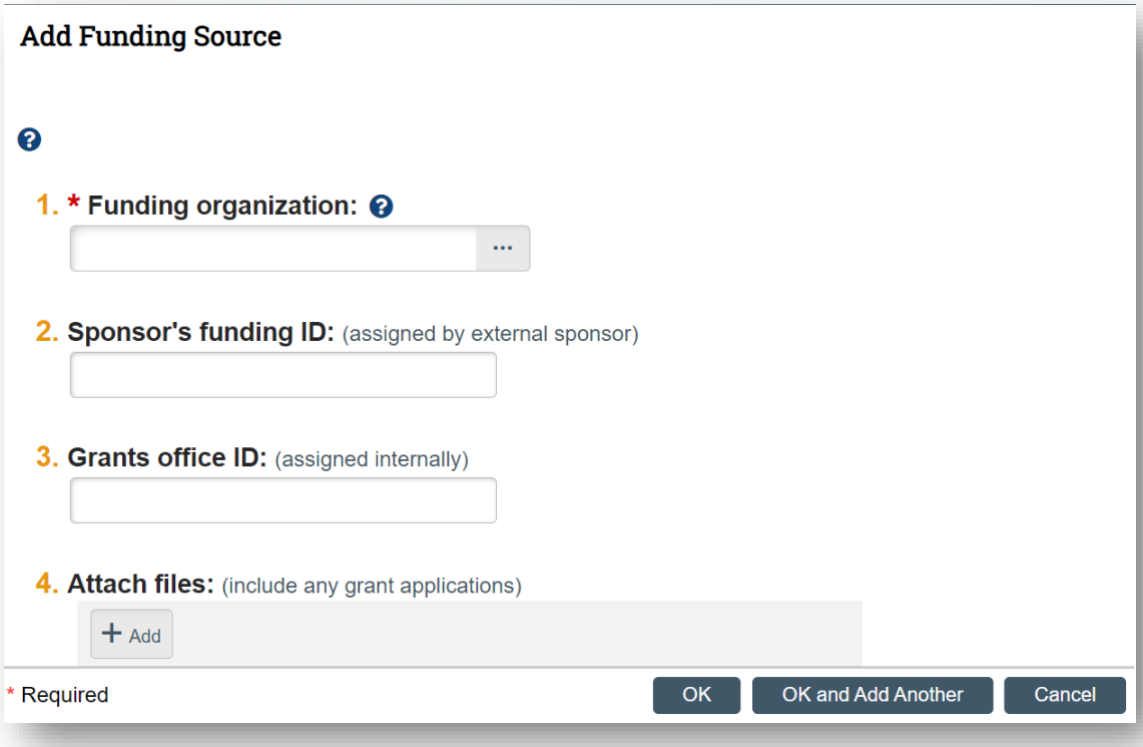
15. **Are you using Auburn University faculty, staff, or students in your research?** This question refers to whether you are targeting faculty, staff, or students in your research. Answer yes or no.

Click **Save**. Click **Continue** to move to the next page. To exit the submission, click **Exit**.

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.



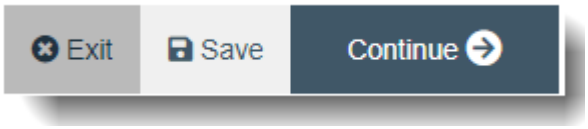
1. **Funding Organization:** You can start typing the name of the organization (e.g. NIH) or select the three ellipses to access the full list of organizations. If you cannot locate the funding organization, try adding % before and after your search term (i.e., %nih%). If you still have trouble locating your funding organization, please complete a support ticket at https://aub.ie/endeavorsupport.

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).

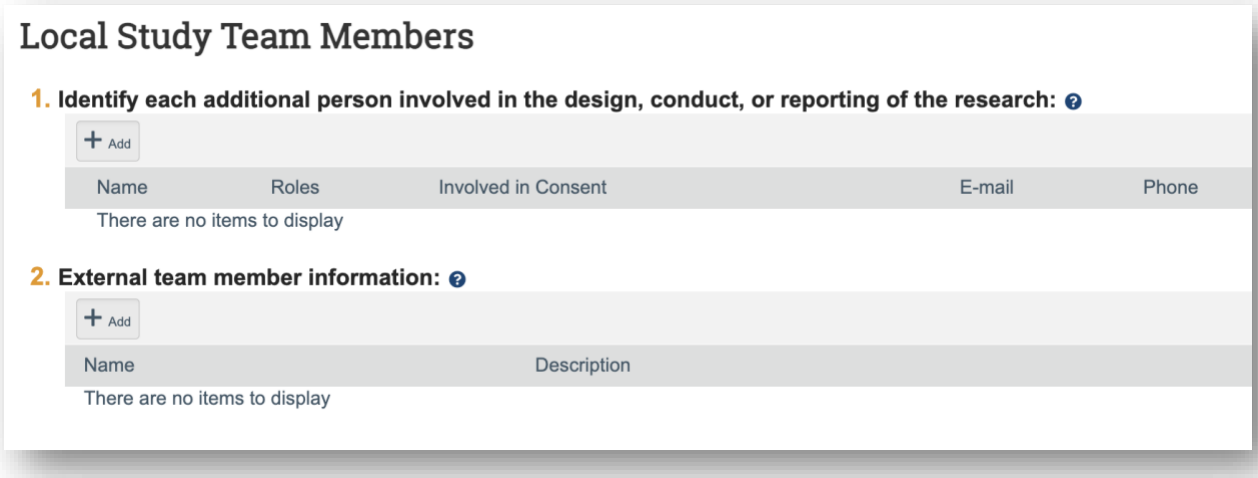
3. **Grant's office ID:** If there is an AU OSP number, include this information. Identify all external funding sources, including the applicable proposal or award number (e.g., R01HD12345 or CNS-1234567).

4. **Attach files:** Attach your grant or contract.

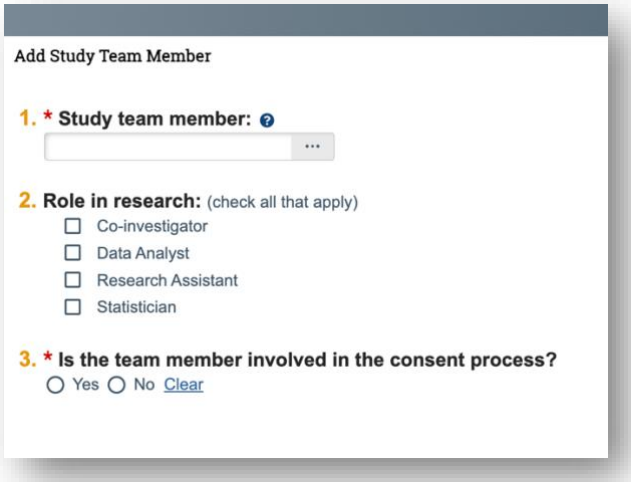
Click **Save**. Click **Continue** to move to the next page. To exit the submission, click **Exit**.



Local Study Team Members Page



1. **Identify each AU 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. The principal investigator is listed on the Basic Information page and does not need to be included here. Each person who is listed on this page will be required to have active CITI training that is affiliated with AU under their original email address, and not an alias. Training requirements can be found in HRP-103 – INVESTIGATOR MANUAL.



- **Study team member:** You can start typing the first or last name of the individual or select the three ellipses to access the list of affiliates. If you cannot locate the individual, please complete a support ticket at https://aub.ie/endeavorsupport. NOTE: This list is populated by an HR feed and will only include individuals who are employed at AU. You will need to request access for undergraduate research assistants and other research team members who are not a part of the feed. Please be sure to include their name and original AU email (not an alias) when requesting access.

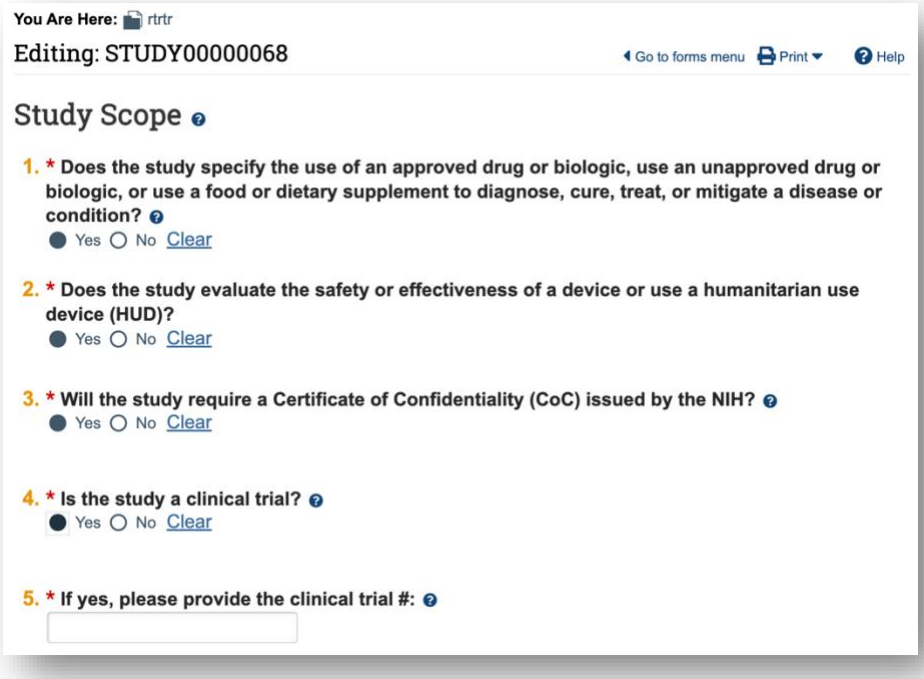
- **Role in research:** Select all that apply.

- **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.

2. **Identify each additional non-AU affiliated person involved in the design, conduct, or reporting of the research.** Attach information about members of your research team who are not affiliated with AU and were not listed for selection in the previous question. Your attachment should include training documents for the external team member, as well as their degree(s), role in the research, and affiliation. This would include individuals who are not covered by another institution's IRB review and may require an Individual Investigator Authorization. Individual investigators are 1) not affiliated with AU or 2) acting as an employee or agent of an institution that is not engaged in the research. Contact the irbadmin@auburn.edu or leave a comment in the main study workspace if there are questions about who to include here.

Click **Save**. Click **Continue** to move to the next page. To exit the submission, click **Exit**.

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.

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.

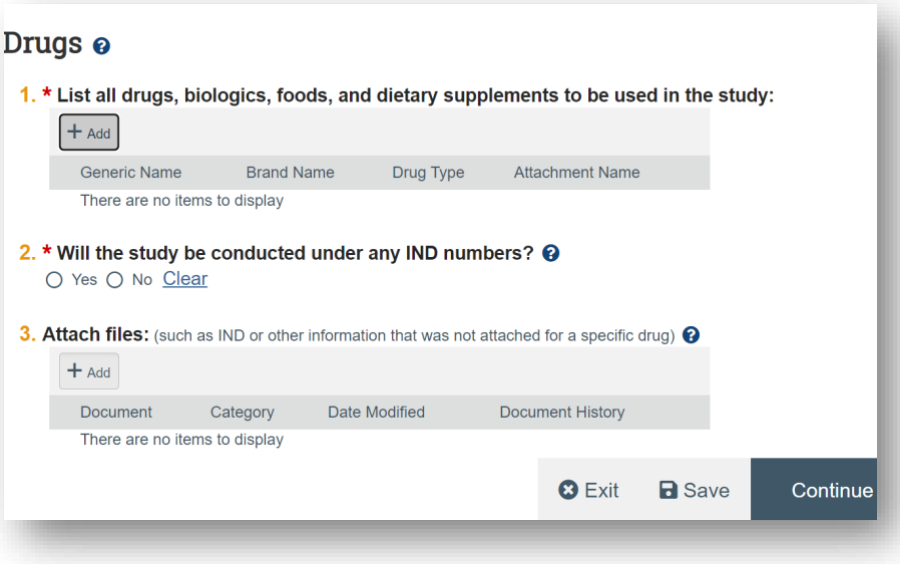
3. **Will the study require a Certificate of Confidentiality (CoC) issued by the NIH?** Select yes or no. If yes, be sure to include the standard CoC language in your consent form. You may also wish to consult HRP-333 (Worksheet – Certificate of Confidentiality).

4. **Is this study a clinical trial?** Select yes or no. If yes, you will be required to provide the clinical trial registration #. Keep in mind that if your study is a clinical trial, there is standard language that must be included in your consent form.

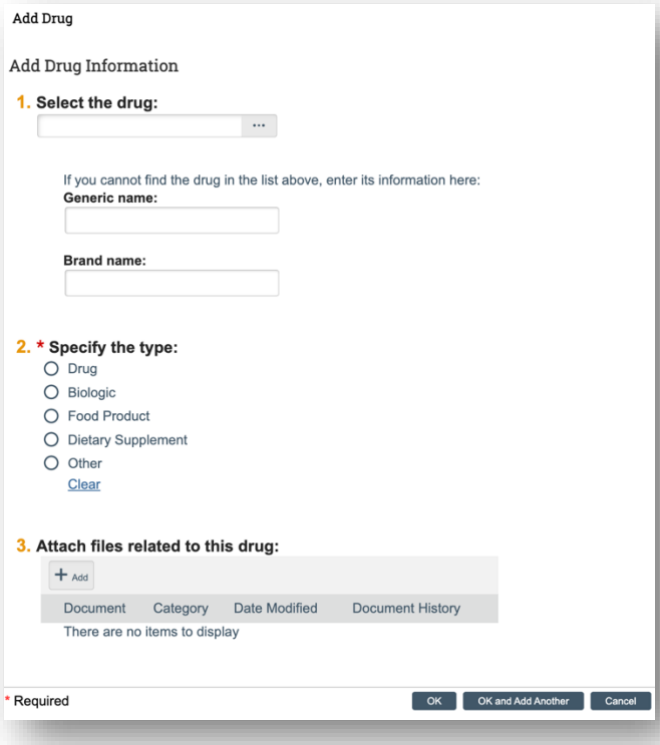
Click **Save**. Click **Continue** to move to the next page.

Drugs

Only available if “yes” is selected to Question 1 on the Study Scope page.

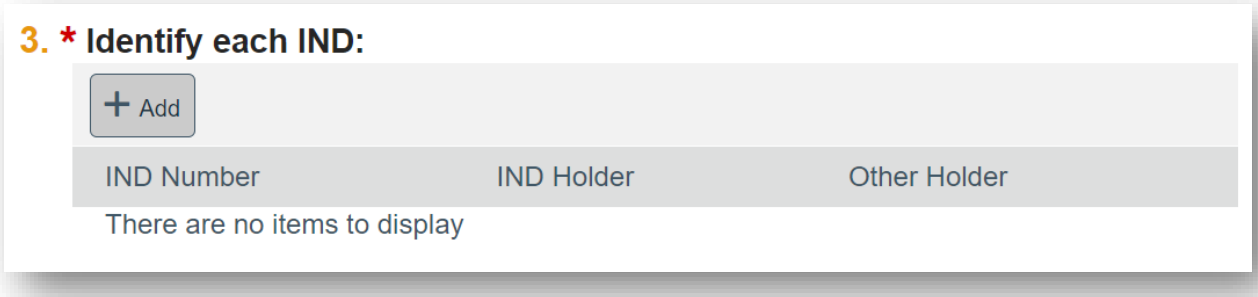


1. **List all drugs, biologics, foods, and dietary supplements to be used in the study.** This page will open if “yes” is selected for the Drug question on the Study Scope page. If there are drugs, biologics, foods, and dietary supplements under investigation in the study, select the +Add button to access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

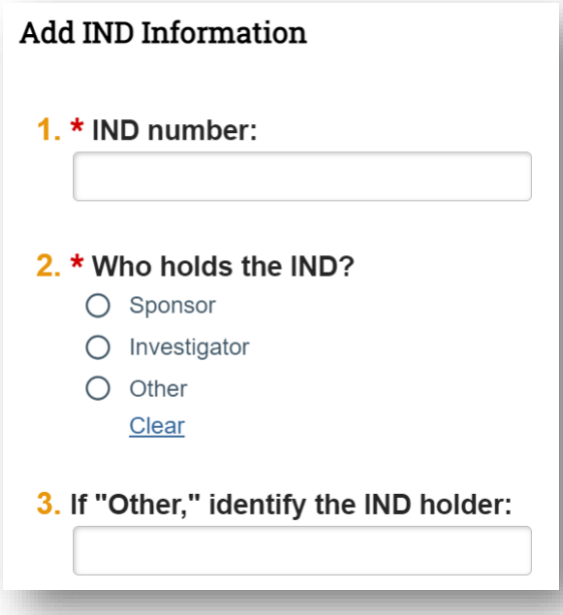


1. **Select the drug:** You can either start typing the name of the drug or select the three ellipses to access the list of drugs within the system. If you cannot locate the drug, try adding % before and after your search term. If you still cannot find it, enter the information under the Generic Name / Brand Name fields.
2. **Specify the type.** Select from the available options.
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.
4. **Who provides the study drug?:** Add the name of the Pharmacy Name and Manufacturer Name.

2. **Will the study be conducted under any IND numbers?** If you select yes, the system will request additional information.



Select the +Add button to access the details.

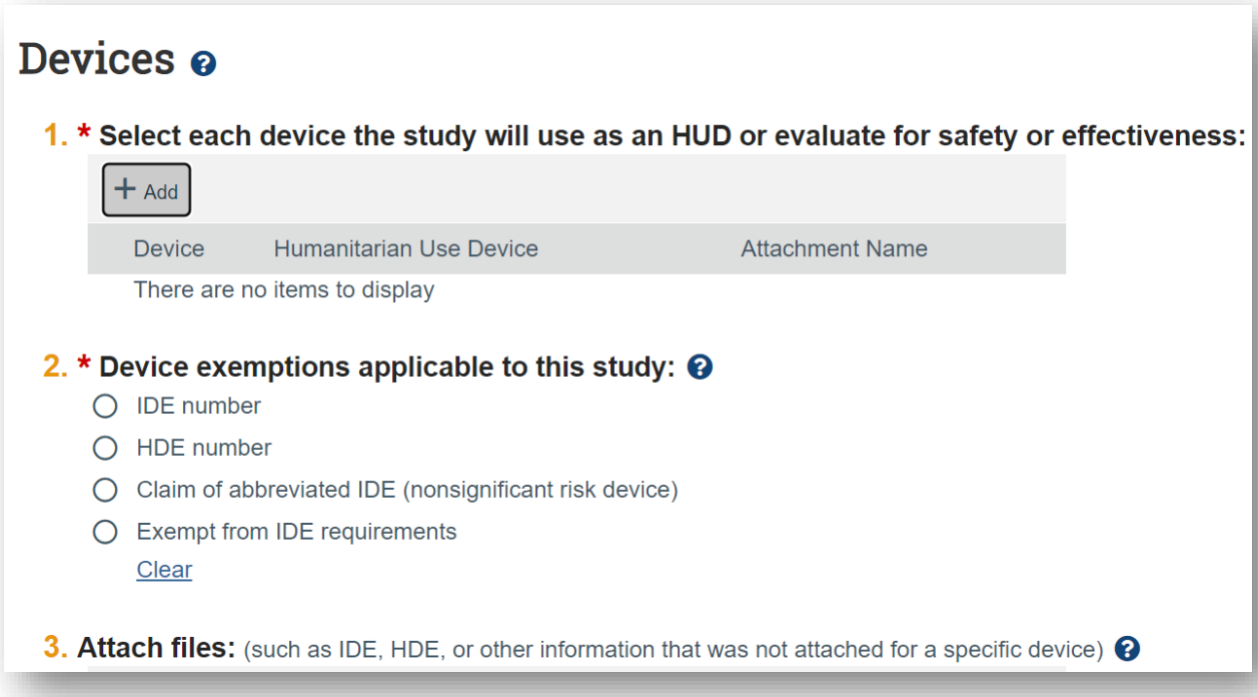


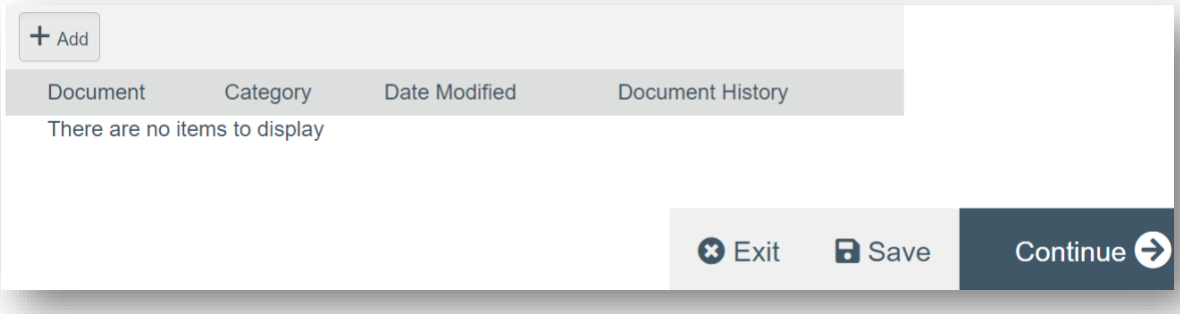
1. **IND number:** Add the IND number.
2. **Who holds the IND?** Select from the available options.
3. **If "Other," identify the IND holder.**

Click **Save**. Click **Continue** to move to the next page. To exit the submission, click **Exit**.

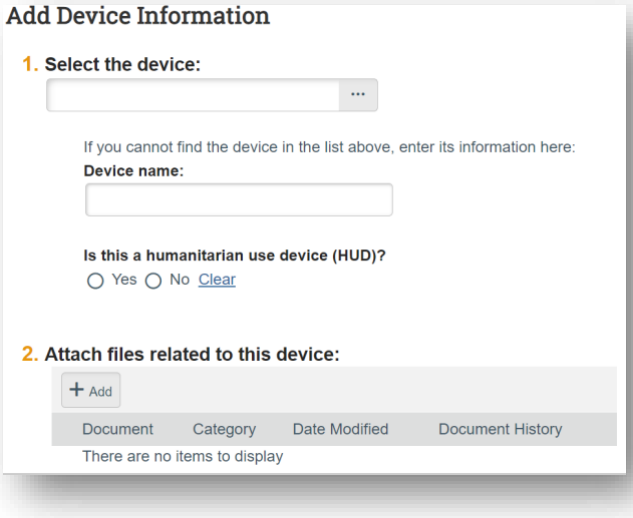
Device

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 devices within the system. If you cannot locate the device, try adding % before and after your search term. If you still cannot locate the device, 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.

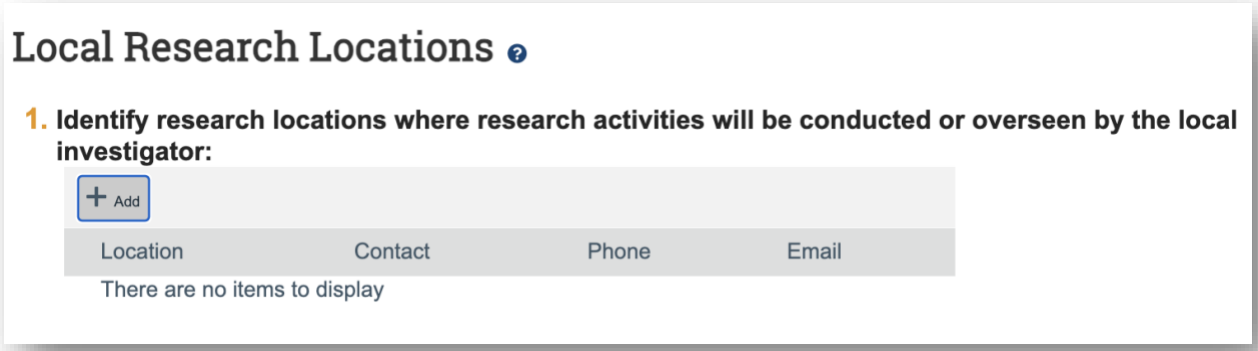
3. **Attach files related to this device.** Attach a copy of the investigator brochure and the product labeling/device instructions.

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

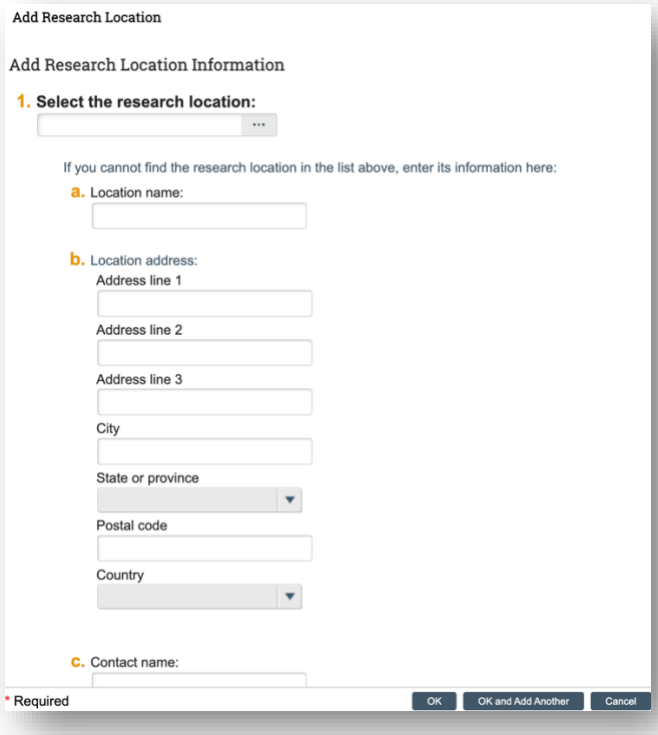
3. **Attach files:** For each IDE / HDE number, attach one of the following, (1) a Sponsor protocol with the IDE / HDE number or (2) communication from the FDA or sponsor with the IDE / HDE number.

Click **Save**. Click **Continue** to move to the next page. To exit the submission, click **Exit**.

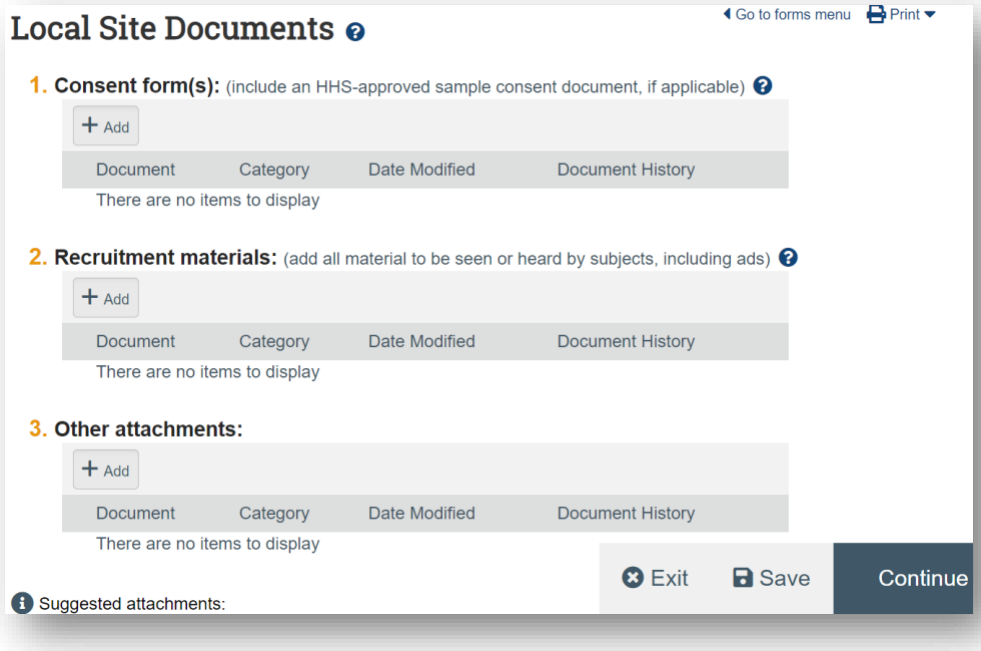
Local Research Locations



1. **Identify research locations where research activities will be conducted or overseen by the local investigator.** Click on the +Add. A pop-up window will appear. You can begin typing the research location or select the ellipses to browse the locations. If you cannot find your location, try adding % before and after your search term (i.e., %thach%). If you still cannot find the location, complete the information to add it.



Local Site Documents



1. **Consent form(s):** Attach individual Word copies of each consent, assent, parental permission, audio/video/photo release, consent/assent scripts, information letters, and/or data repository forms. Templates can be found on the IRB Endeavor Toolkit website. If there are multiple forms, use Name to identify each document with the subject group/activity (e.g. Provider Interview Consent Form). Only upload Word documents.

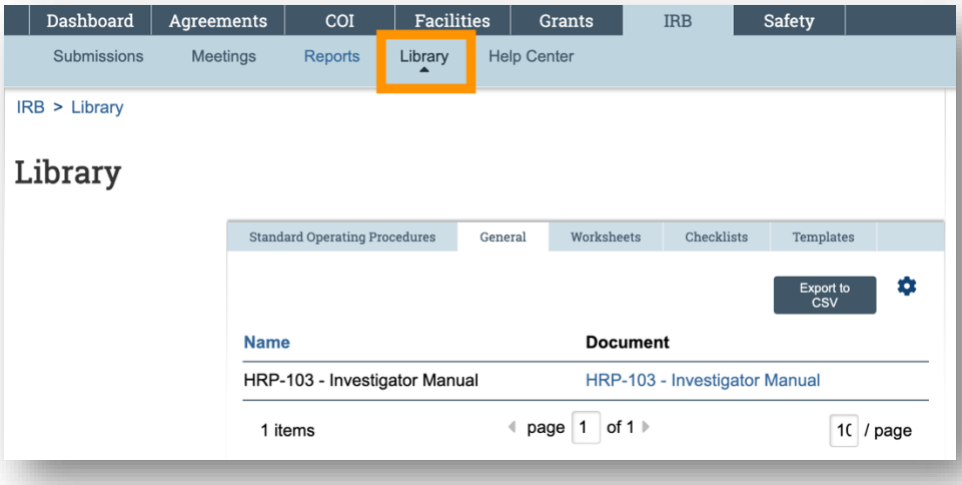
2. **Recruitment materials:** Attach Word copies of the recruitment materials. If you have multiple versions of the same type of recruitment, you can batch recruitment materials as Word uploads. For example, if you have multiple social media posts, upload one Word document "Social Media Posts" with all social media post variations. If you have multiple flyers, upload one Word document "Flyers" with all flyer variations. Zip files are not accepted. Consult HRP-315 (Worksheet – Advertisements) for guidance in the development of your recruitment materials.

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, HIPAA Authorizations, data use agreements, letters of support, mental

health safety plans, appendices, etc. Use Name to identify each document and select the document category.

Click **Save**. Click **Continue** to move to the next page. To exit the submission, click **Exit**.

Library



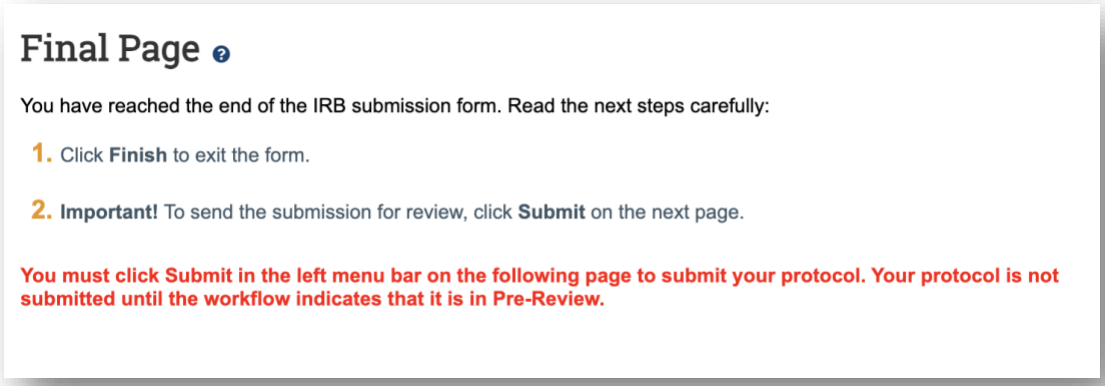
The **Library** houses templates, worksheets, checklists, SOPs, appendices, and guidance materials that you can use for reference or to download, complete, and upload with your submission. You should use the library to pull the most recent version of these documents. Documents will also be available on the AU IRB website and the Endeavor IRB Canvas site. You can search the library for documents that are referenced in the toolkit (e.g., HRP-308). If you do not find what you are looking for, use % before and after the search term (e.g., %HRP%).

When would I use the library? Some examples of when you might use the library:

- To download a protocol template
- To download a worksheet for reference/completion or a checklist for reference
- To download an appendix for inclusion with your protocol (i.e., a protocol that uses MRI would need to download HRP-901 – APPENDIX - MRI appendix and upload it under Local Site Documents → Other Attachments; a protocol collecting anonymous data would require HRP-902 – APPENDIX – Anonymous Data Collection Assurance; a protocol based on secondary use of data shouls download and complete HRP-900 – APPENDIX – Secondary Use of Data, etc.)

Finish

When you click continue, you will be directed to the 'Finish' page.

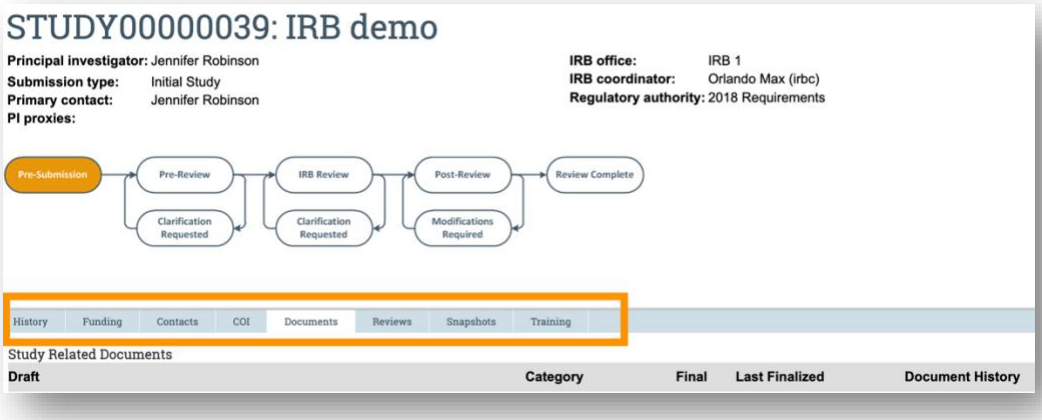


IMPORTANT: CLICKING FINISH **DOES NOT SUBMIT** YOUR PROTOCOL.

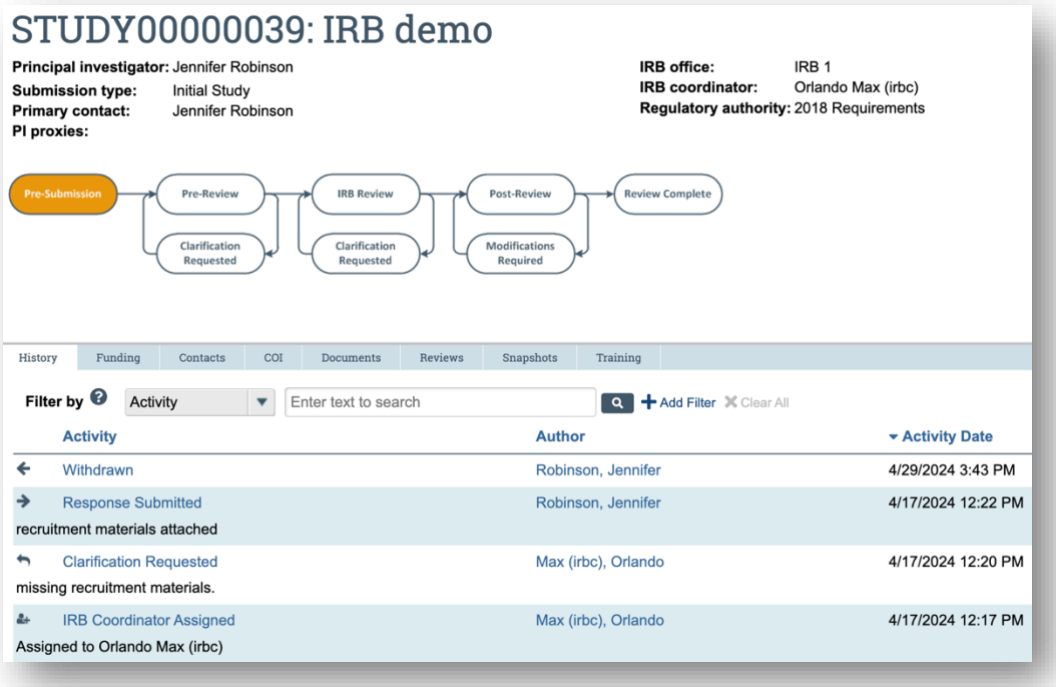
When the study is ready for IRB review, the PI must submit from the study record workspace.

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. You should now see the workflow indicating that your study is in the Pre-Submission state.

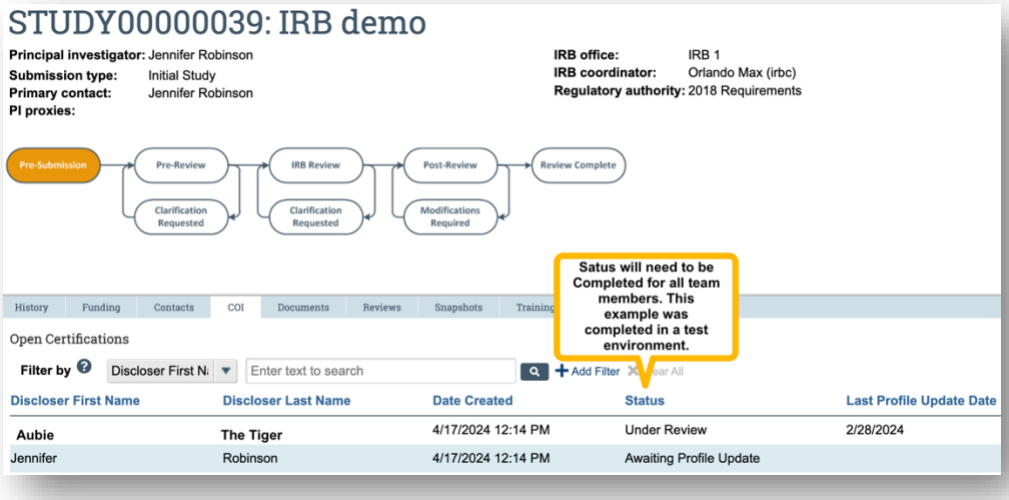
You will also now see a menu bar under the workflow diagram.



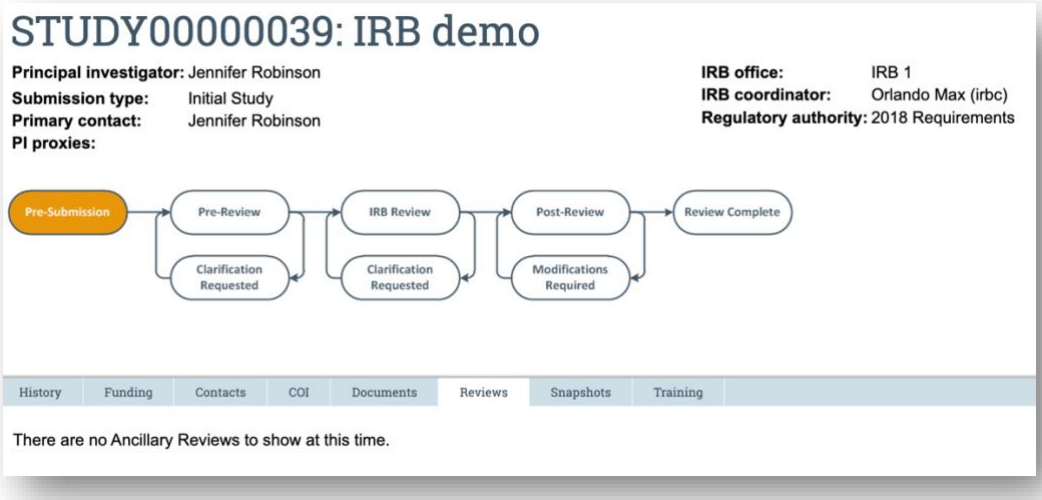
- **History:** Lists the actions that have been taken on your submission, both investigator-initiated and IRB-initiated.



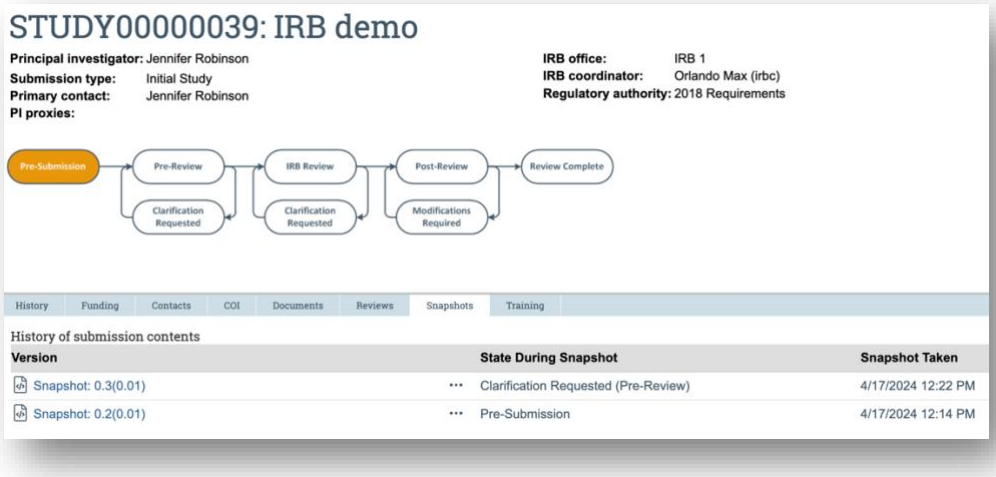
- **Funding:** Shows the funding information for your submission.
- **Contacts:** Shows the contacts associated with your study, including local site team members and guests.
- **COI:** **Check this tab to ensure all team members have a completed disclosure on file.** Your protocol will be returned at Pre-Review unless the status of all team members is “Completed”.



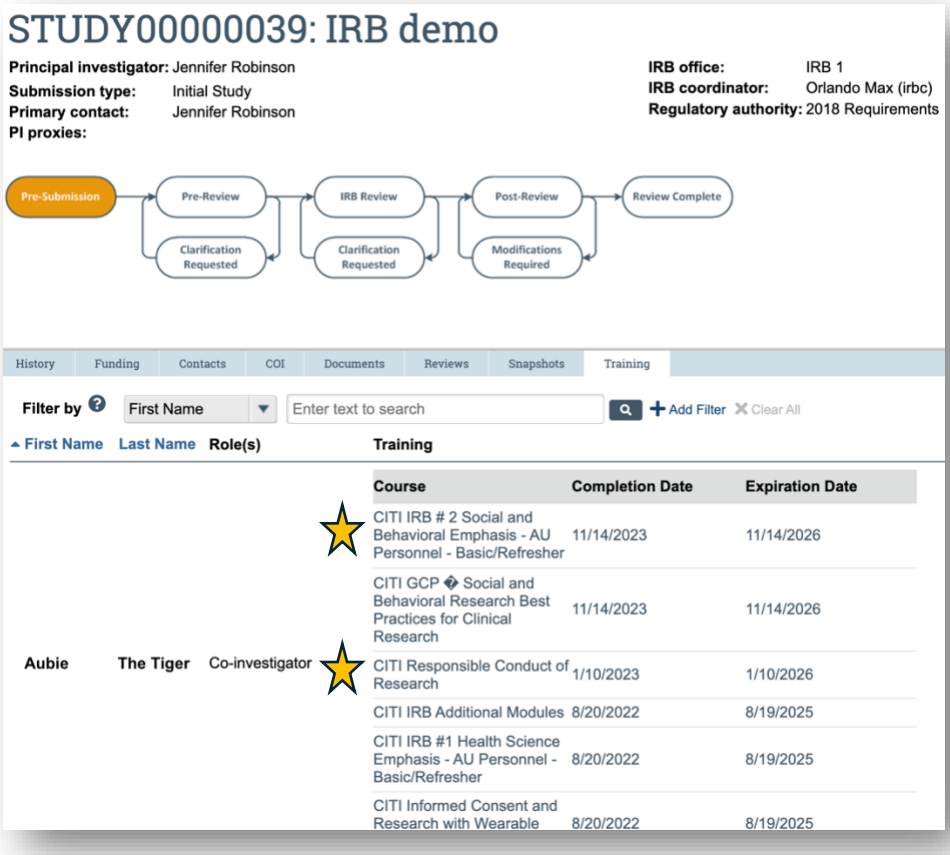
- **Documents:** Lists the documents uploaded as part of the submission process. Once your protocol is approved, this is also where you will be able to find your finalized documents.
- **Reviews:** This tab will show any ancillary reviews that have been completed.



- **Snapshots:** This tab will show a summary of your study record at different timepoints.



- **Training:** **Check this tab to ensure all team members have completed the necessary training.** Please consult HRP-103 – INVESTIGATOR MANUAL for training requirements. At minimum, you must complete IRB #1 Health Science Emphasis – AU Personnel – Basic/Refresher (ID 72743) and/or IRB #2 Social and Behavioral Emphasis – AU Personnel – Basic/Refresher (ID 72746) depending on your research, and the Responsible Conduct of Research – AU Basic RCR Training for ALL Faculty, Staff, Postdocs, and Students (ID 269966). It is possible that you may need to take both IRB #1 and IRB #2 modules based on your research area. In addition, for those engaging in research that involves minor participants, you must complete the Research with Children – SBE – Basic Course (ID 507) or Vulnerable Subjects – Research with Minors (ID 9) and Auburn University's Youth Protection Program Training available in ElevatED (CR506E) or through the AU Youth Protection Program Portal. Training is valid for a three-year period, after which time the training must be repeated. Training certificates (i.e., phlebotomy certificates, AU Youth Protections, etc.) will need to be uploaded as part of the study record under Local Site Documents → Other Attachments. **NOTE:** All AU key study personnel must have their CITI accounts affiliated with Auburn University using their non-alias user ID (i.e., aub0000 and not aubiethetiger@auburn.edu) or training records will not automatically populate, and your submission will be sent back. Investigators are responsible for ensuring all study personnel have CITI training records.



STUDY00000039: IRB demo

Principal investigator: Jennifer Robinson
Submission type: Initial Study
Primary contact: Jennifer Robinson
PI proxies:

IRB office: IRB 1
IRB coordinator: Orlando Max (irbc)
Regulatory authority: 2018 Requirements

History | Funding | Contacts | COI | Documents | Reviews | Snapshots | Training

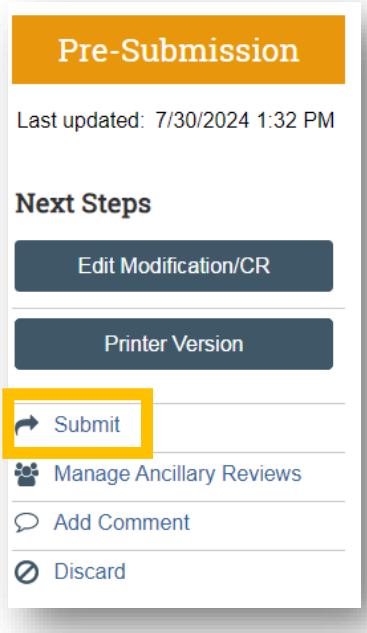
Filter by First Name | Enter text to search | Add Filter | Clear All

First Name	Last Name	Role(s)	Training	Completion Date	Expiration Date
Aubie	The Tiger	Co-investigator	CITI IRB # 2 Social and Behavioral Emphasis - AU Personnel - Basic/Refresher	11/14/2023	11/14/2026
			CITI GCP Social and Behavioral Research Best Practices for Clinical Research	11/14/2023	11/14/2026
			CITI Responsible Conduct of Research	1/10/2023	1/10/2026
			CITI IRB Additional Modules	8/20/2022	8/19/2025
			CITI IRB #1 Health Science Emphasis - AU Personnel - Basic/Refresher	8/20/2022	8/19/2025
			CITI Informed Consent and Research with Wearable	8/20/2022	8/19/2025

Submit the Study

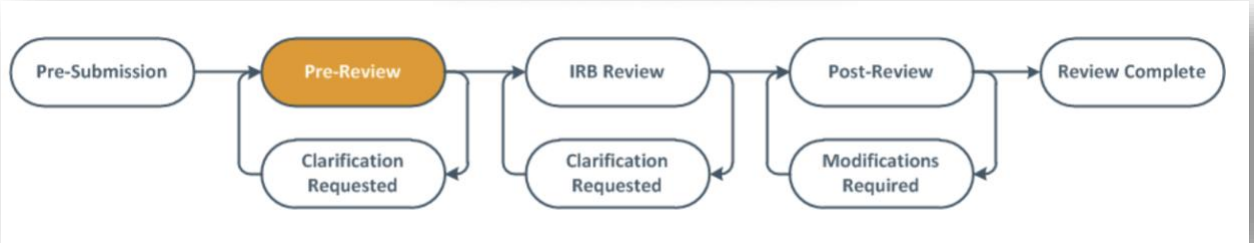
To submit a study for review, within the study record workspace:

1. Click **Submit**.

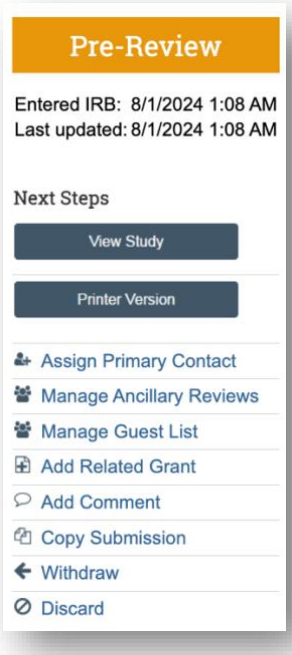


2. Click **OK** to agree to the terms.

Once you select **Submit**, the study has been submitted to the IRB and is now in the Pre-Review state. The workflow will reflect that your submission has moved from Pre-Submission to Pre-Review.



Study Record Menu Navigation



The left-hand menu is available to the Principal Investigator, Primary Contact, 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.

Manage Ancillary Reviews: The study team can initiate any Ancillary Reviews needed prior to Pre-Review. Ancillary reviews include the PIs Department Head/Chair, IACUC, IBC, MRI Safety Advisory Council, Risk Management and Safety, and other consulting bodies.

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 at this time.

Add Comment: Add comment allows you to add information for the PI, study team, or IRB staff. NOTE: Your comment is visible to anyone with access to your 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, research locations, etc. You would then go into the study record to update the new documents and submit for review.

Withdrawal: This activity will pull back your submission from Pre-Review (or wherever it is in the workflow) to Pre-Submission status. You will then be able to edit the submission.

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

Submission Checklist

- ☐ Consulted HRP-308 (Worksheet: Pre-Review) and confirmed all submission materials have been included.
- ☐ Confirmed the correct submission form has been uploaded.
- ☐ Checked the **COI** tab and confirmed that all study team members have a completed disclosure on file.
- ☐ Checked the **Training** tab and confirmed that all study team members have completed the required training and that it is not expired. Trainings that are outside of CITI have been uploaded in **Local Site Documents → Other Attachments.**
- ☐ Used relevant worksheets and checklists to ensure my study documents meet the requirements of IRB review.
- ☐ Completed the **Submit** activity in the left menu bar and confirmed that my submission went from **Pre-Submission** to **Pre-Review**.