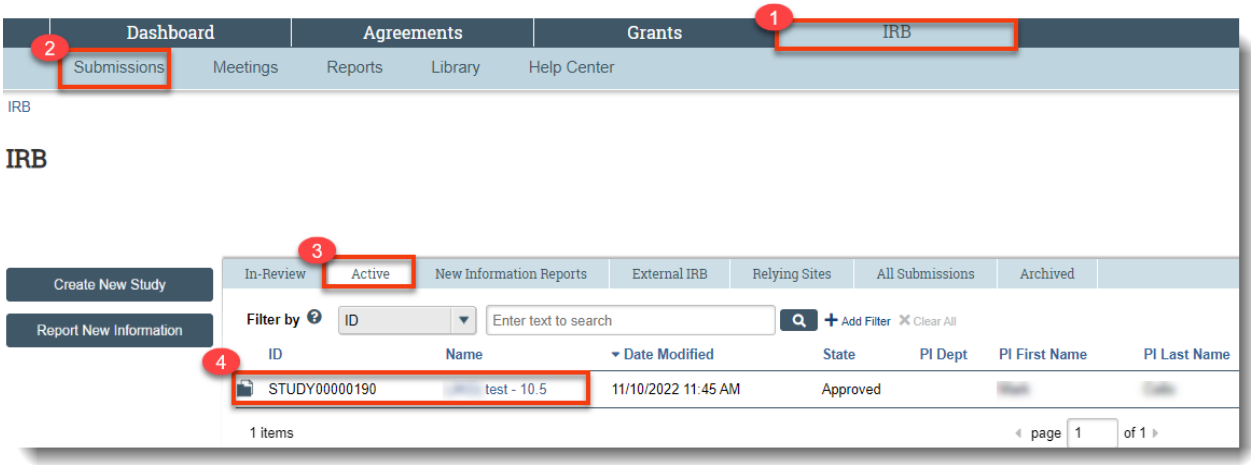
Creating a Modification to Populate a Converted IRBNet Study

How to Access the System

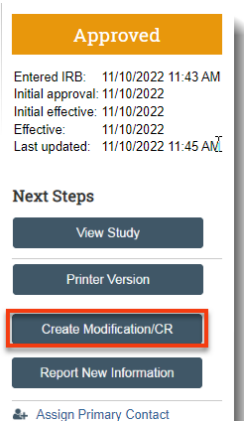
1. The RAMP submission system login can be found at https://irb.ramp.gmu.edu.
2. RAMP utilizes single sign-on (SSO). GMU users will log in with their GMU credentials.

How to Create a Modification

1. From the **IRB** tab
2. Select **Submissions** tab
3. Select **Active** tab
4. Click on the **folder symbol (** **)** or the **Name** of the submission to open.

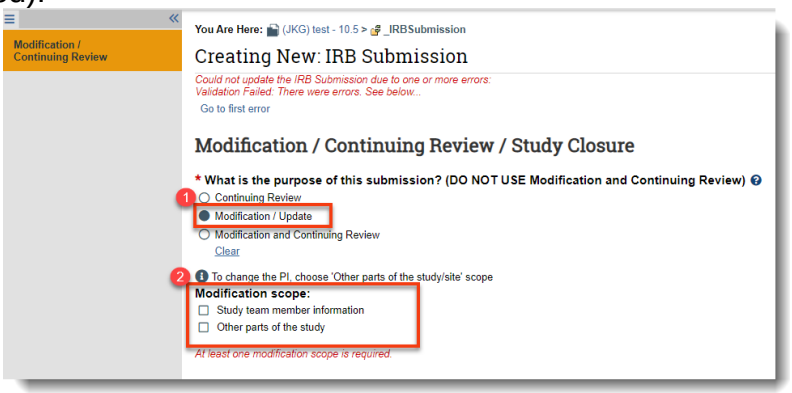


5. Select **Create Modification / CR**.



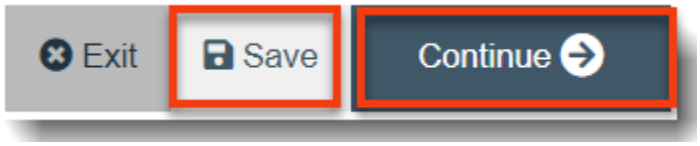
6. Select **Modification / Update**. Do not select Modification and Continuing Review. Once a response is made to "What is the purpose of this submission?," a logic driven question appears (Modification scope).

7. Choose a response for **Modification scope** (a checkbox will appear when selected).



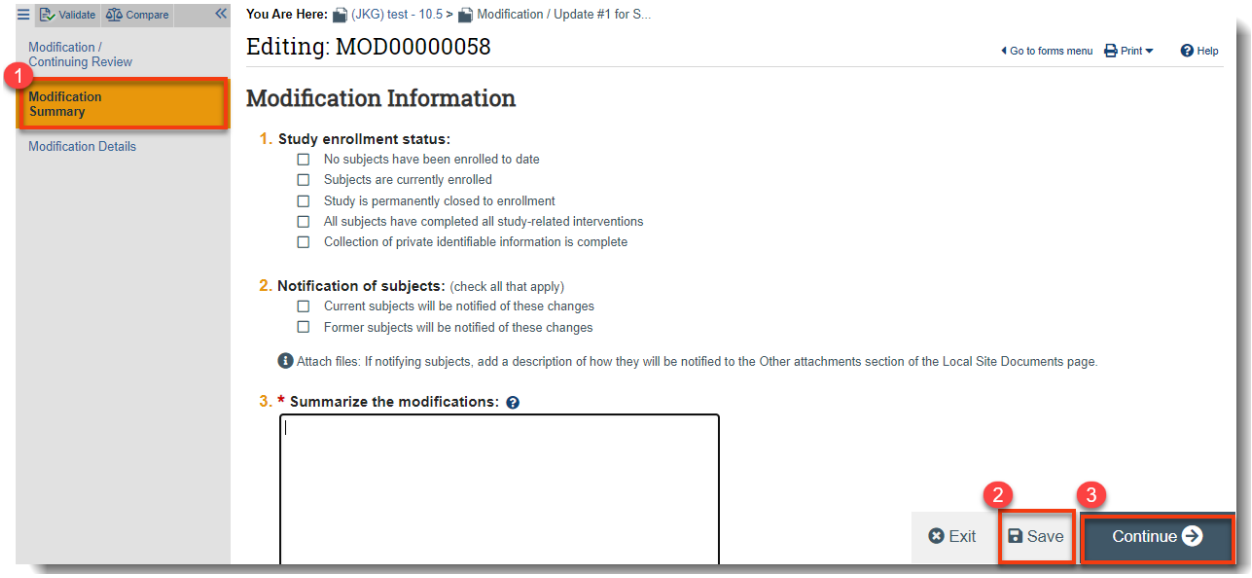
   a. Select **Study team member information** and **Other parts of the study:** This option opens all pages of the study Smartform for revision.

8. Select Save and Continue.



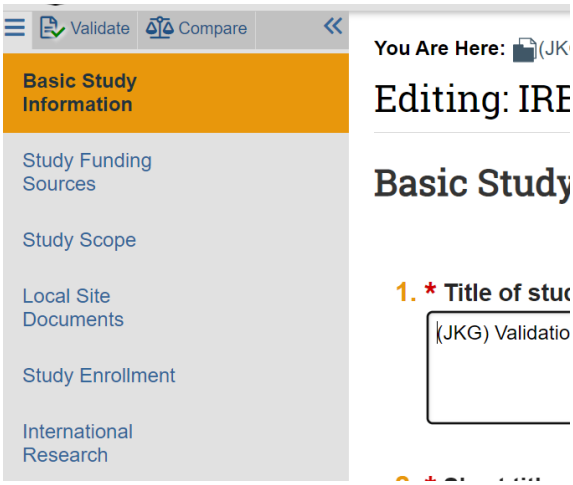
9. Complete the (1) **Modification Summary** tab. List each change in the modification summary text box. It is recommended that Population MODs do not include additional changes to approved studies as this may delay the population review. If you are making multiple changes, number each item.

10. Select (2) **Save**. Select (3) **Continue.**


Validate
Compare
Modification / Continuing Review
1
Modification Summary
Modification Details
You Are Here: (JKG) test - 10.5 > Modification / Update #1 for S...
Editing: MOD00000058
Go to forms menu
Print
Help
Modification Information
1. Study enrollment status:
No subjects have been enrolled to date
Subjects are currently enrolled
Study is permanently closed to enrollment
All subjects have completed all study-related interventions
Collection of private identifiable information is complete
2. Notification of subjects: (check all that apply)
Current subjects will be notified of these changes
Former subjects will be notified of these changes
Attach files: If notifying subjects, add a description of how they will be notified to the Other attachments section of the Local Site Documents page.
3. * Summarize the modifications:
2
3
Exit
Save
Continue

Change Study Documents

1. After selecting **Continue** on the Modification Information screen, you will be able to access the pages of the Smartform starting with the Basic Information page. Use the left hand navigation menu to select the page you would like to modify or select **Continue** on the bottom right corner to navigate through each Smartform page.



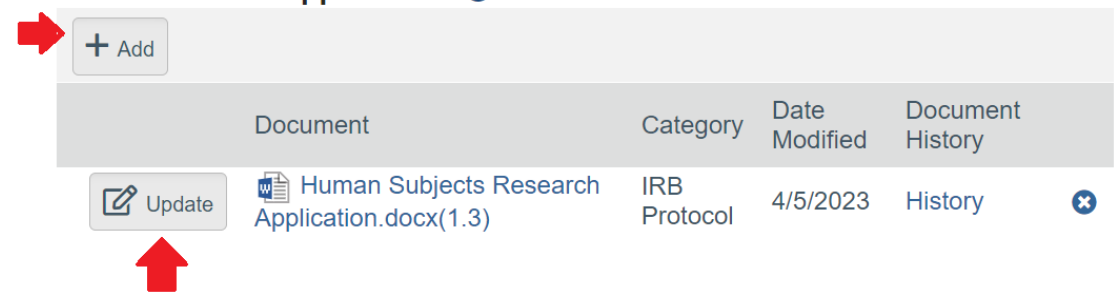
   If you select **Save and Exit** on the previous Modification Information screen, you will be brought back to the main Modification workspace. In the Modification workspace, click the blue **Edit Modification/CR** on the left-hand side to access the editable Smartform pages.

2. On the Smartform pages where documents need to be uploaded:
   a. For new document - select **+Add**
   b. To make a change to an existing document - select **Update**

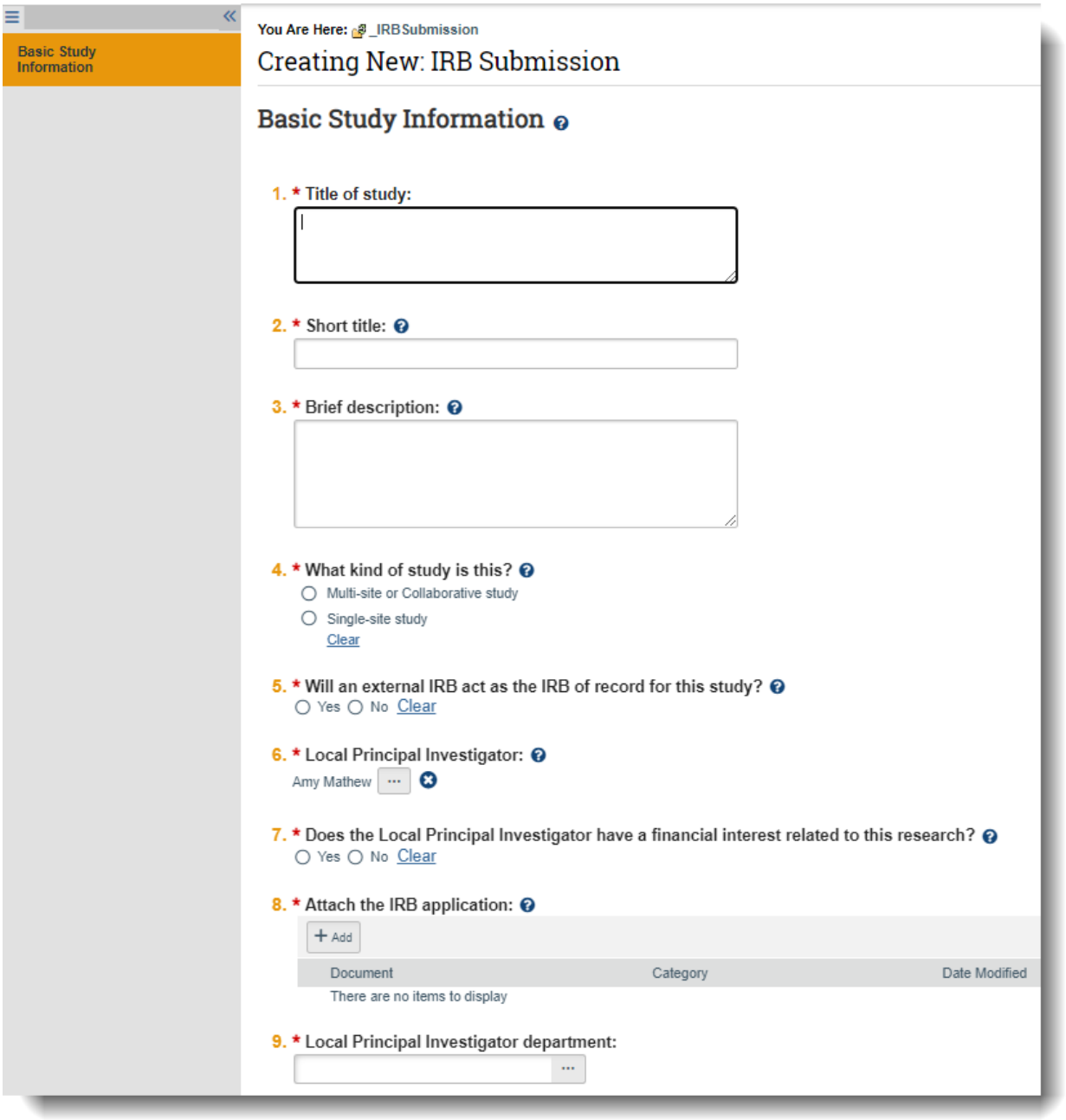
   When updating an existing document, use the “Update” button to replace the previous version. The study record should maintain the most current version of the documents.

   Use track changes in Word to document any revisions to the updated material being uploaded. At the time of upload, review the document title for any additional edits to the title such as the date or version number.

8. * Attach the IRB application:



Basic Study Information Page



1. **Title of the Study:** This should have migrated into the study record.

2. **Short Title:** This will be a duplicate of the title above. You have the option to select a short title (50 characters max) that will be used to identify your study throughout the RAMP system and on RAMP issued memos. 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…by <using interviews, surveys, tasks, intervention>

4. **What kind of study is this?:** This should have migrated into the study record.
    i. A single-site study is one where all research activities occur at one institution.
    ii. 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 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?:** This should have migrated into the study record.

    Select Yes if an IRB outside of GMU will review this study and decide whether to approve it with permission from the GMU IRB. If you are 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.

6. **Local Principal Investigator:** This should have migrated into the study record

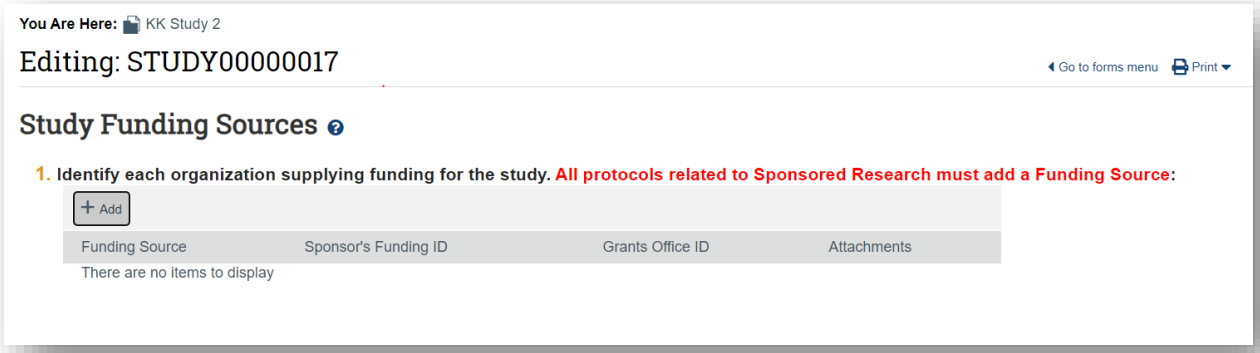
7. **Attach the IRB application:** Either a copy of the currently approved IRBNet application and addenda (if applicable) or a new study protocol using the appropriate Toolkit template

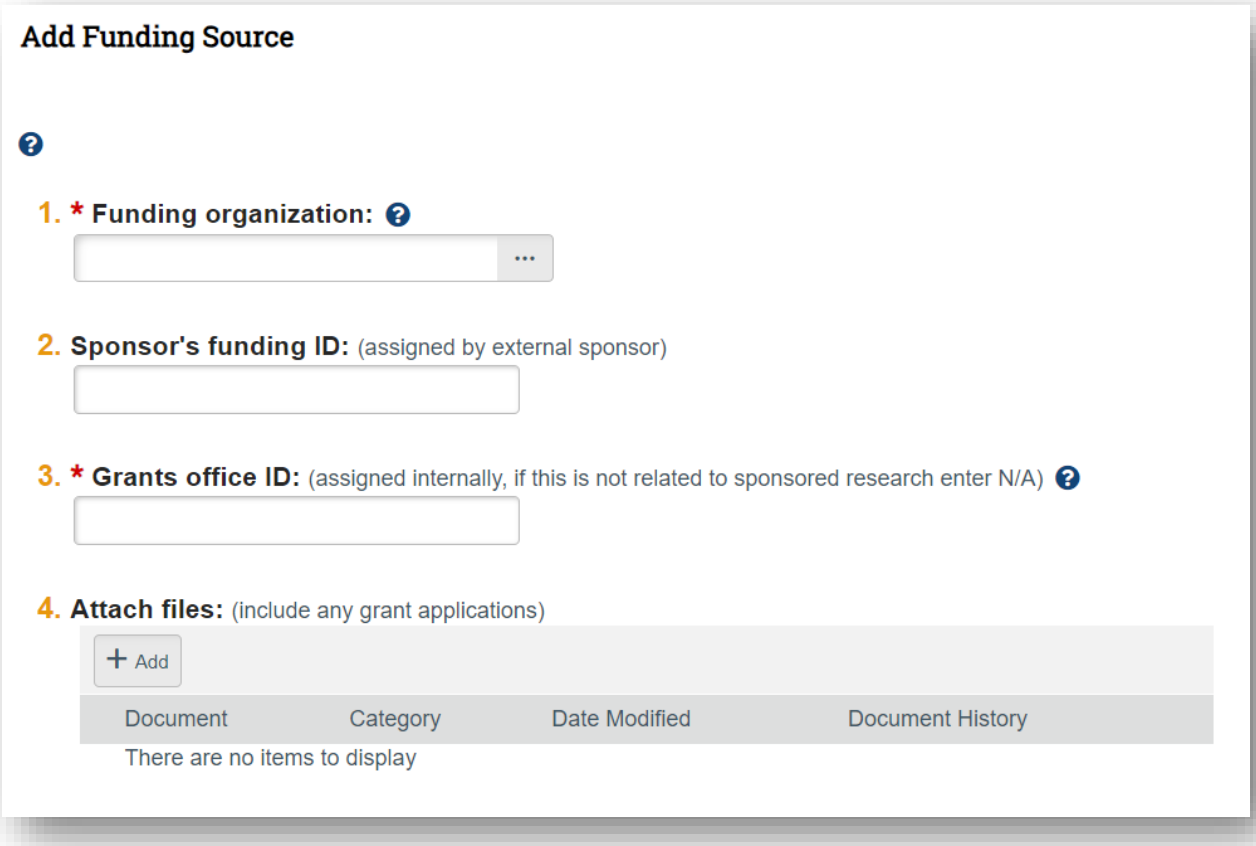
    Note: The IRB will allow the continued use of the legacy IRBNet application in lieu of a study protocol ONLY for converted studies. All new study submissions must include the appropriate protocol template.

8. 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.



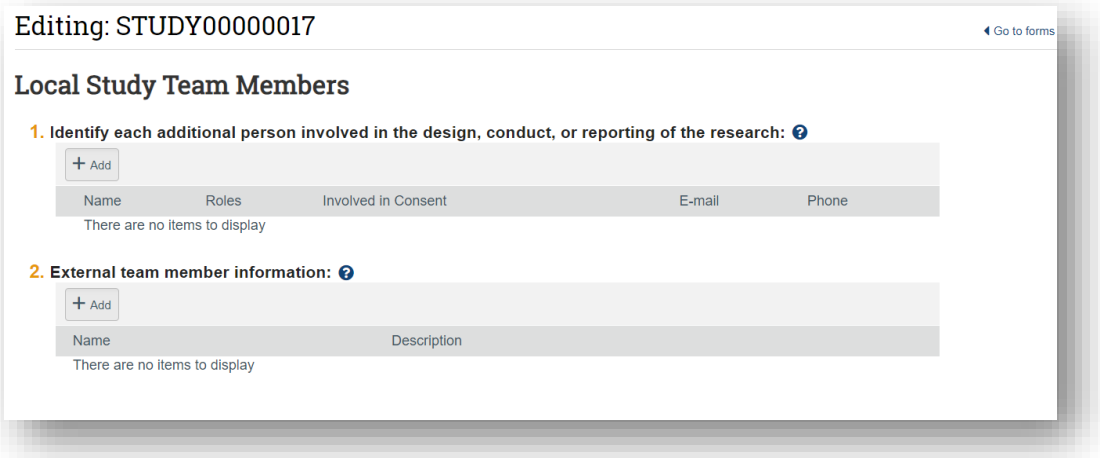


- **Funding Organization:** You can start typing the name of the organization (e.g. NIH) or select the three ellipses to access the full list of organizations. If you cannot locate the funding organization, contact the HRPP by email.

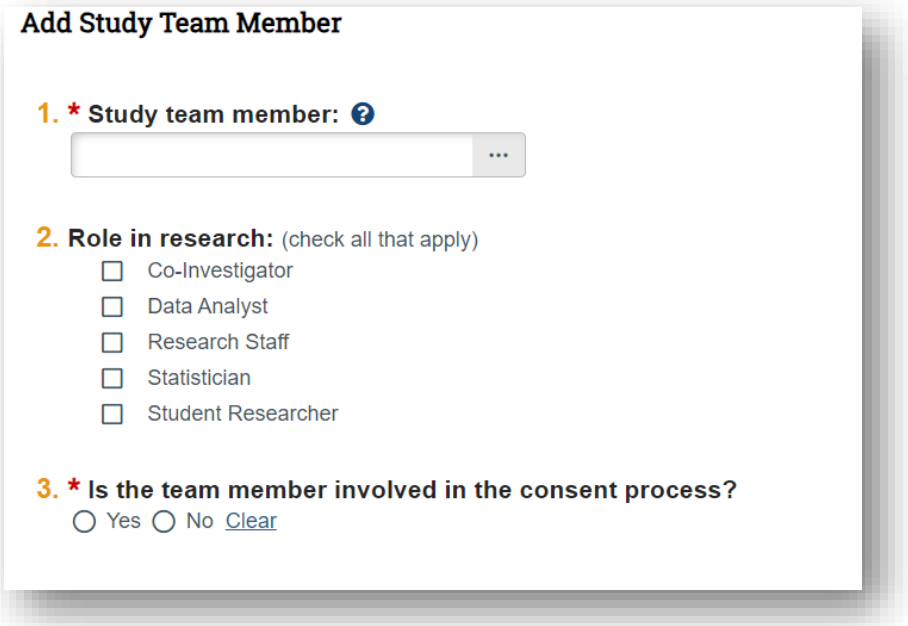
- **Sponsor's funding ID:** If there is a funding ID, include this information. Identify all external funding sources, including the applicable proposal or award number (e.g., R01HD12345 or CNS-1234567). Missing or incomplete funding source information will result in delay of award account set-up. This information is not required by the IRB.
- **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.
- **Attach files:** No documentation is required to be uploaded to this space.

2. 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 GMU 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 each GMU affiliated person 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. Note, each person who is listed on this page will be required to have active CITI training on file with the GMU IRB Office.



- **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, contact the HRPP by email. Note, this information is pulled from Workday. If an individual is a new hire, there may be a lag between systems.

- **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.

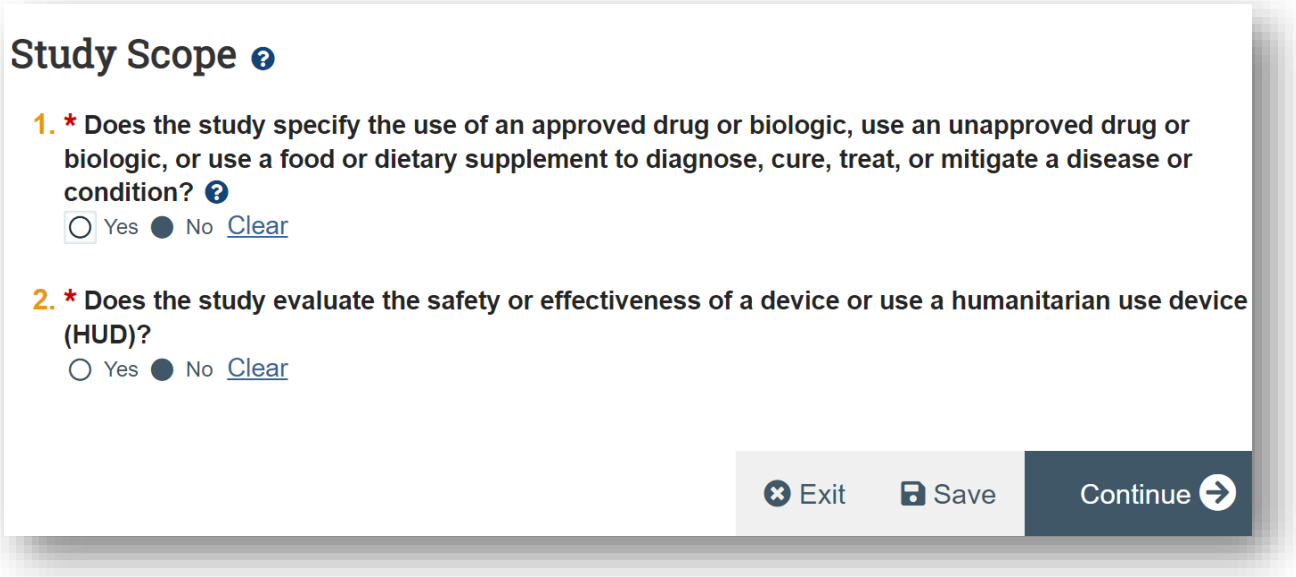
- **Does the team member have a financial interest related to this research?:** Review the help text for specific guidance on what constitutes a financial interest.

2. **Identify each additional non-GMU affiliated person involved in the design, conduct, or reporting of the research:** Attach information about members of your research team who were not affiliated with GMU and were not listed for selection in the previous question. These would be 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 GMU University or 2) acting as an employee or agent of an institution that is not engaged in the research. Contact the HRPP by email or leave a comment in the main study workspace if there are questions about who to include here. Use the +Add to attach CITI training certificates.

3. 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

This should have migrated into the study record.

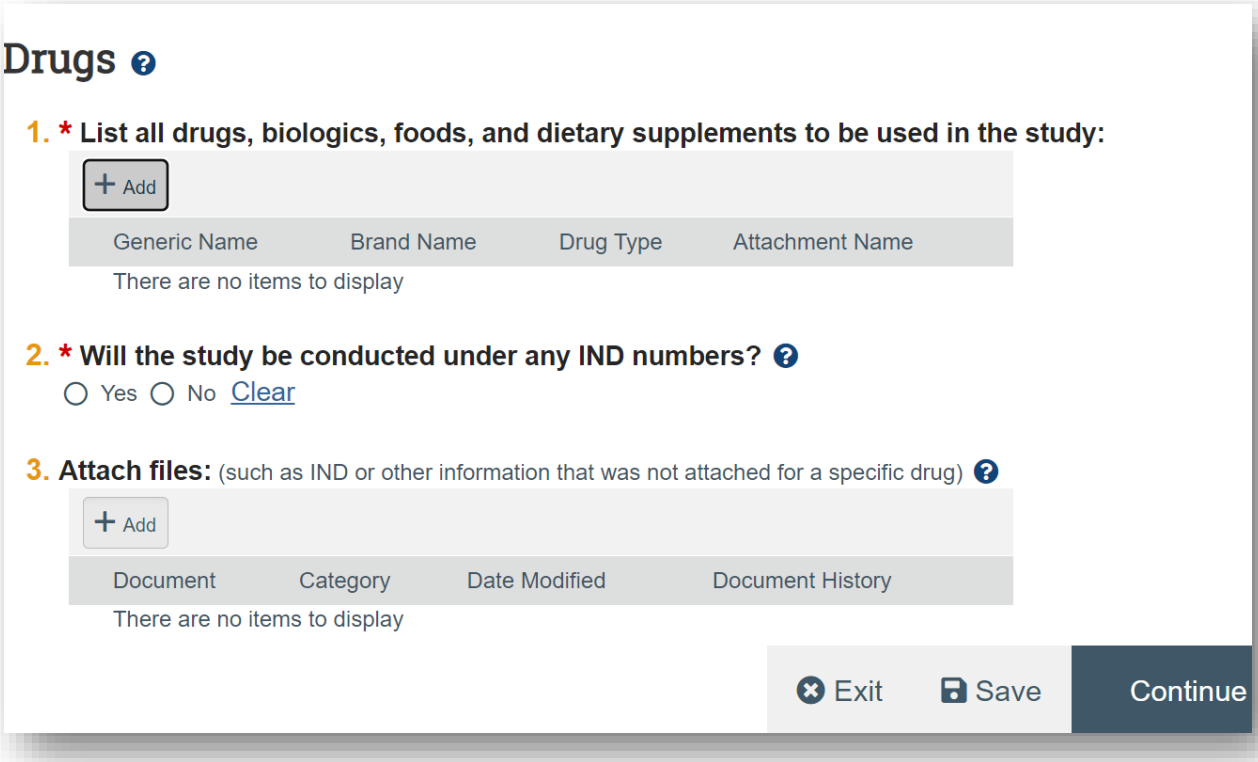


1. **Does the study specify the use of an approved drug or biologic, use an unapproved drug or biologic, or use a food or dietary supplement to diagnose, cure, treat, or mitigate a disease or condition?:** Select yes if an approved drug or biologic, an unapproved drug or biologic, or a food or dietary 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.

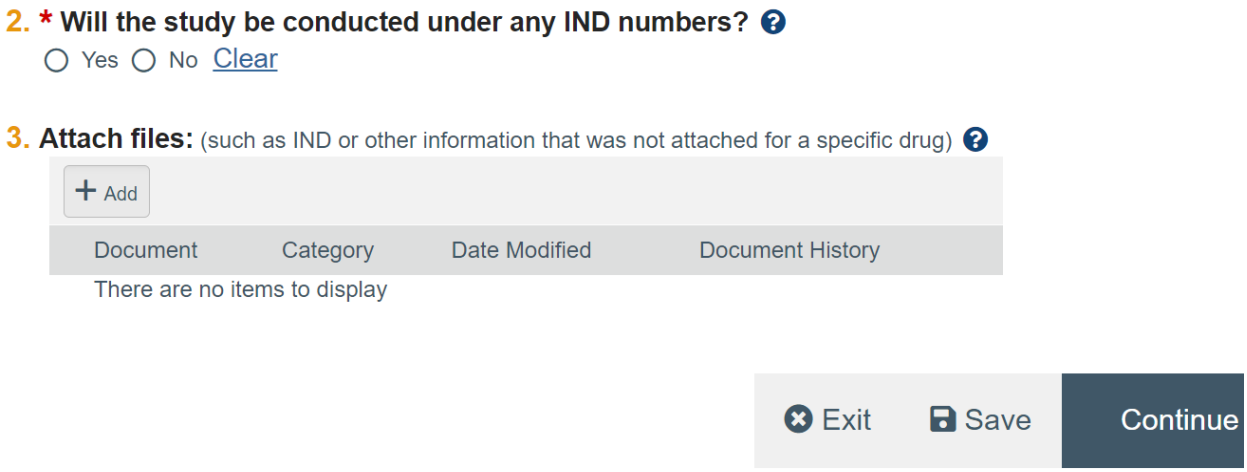
3. Click **Save**. Click **Continue** to move to the next page. To exit the submission, click **Exit**. These 3 actions are on every page.

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

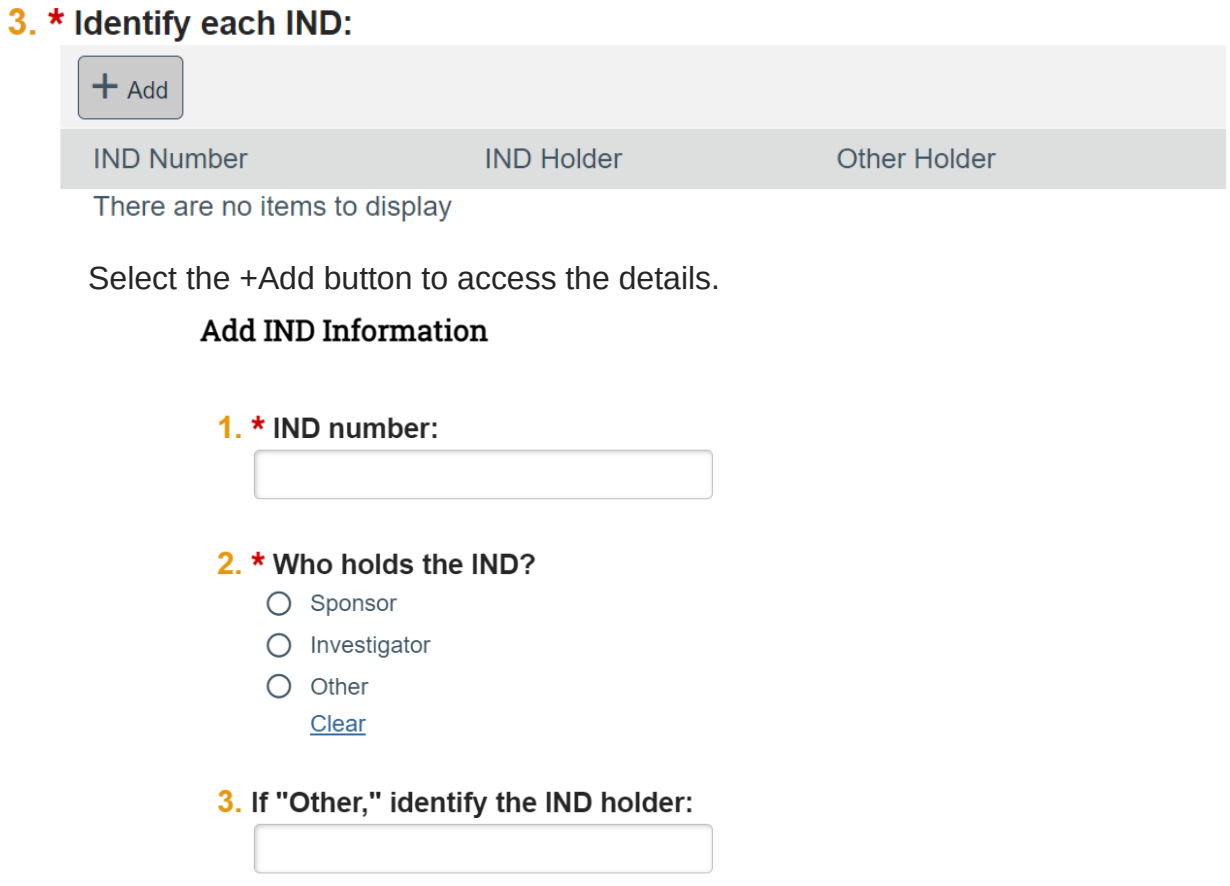


1. **List all drugs, biologics, foods, and dietary supplements to be used in the study:** This page will open if "yes" is selected for the Drug question on the Study Scope page. If there are drugs, biologics, foods, and dietary supplements under investigation in the study, select the +Add button to access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

    - **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.
    - **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."
    - **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.

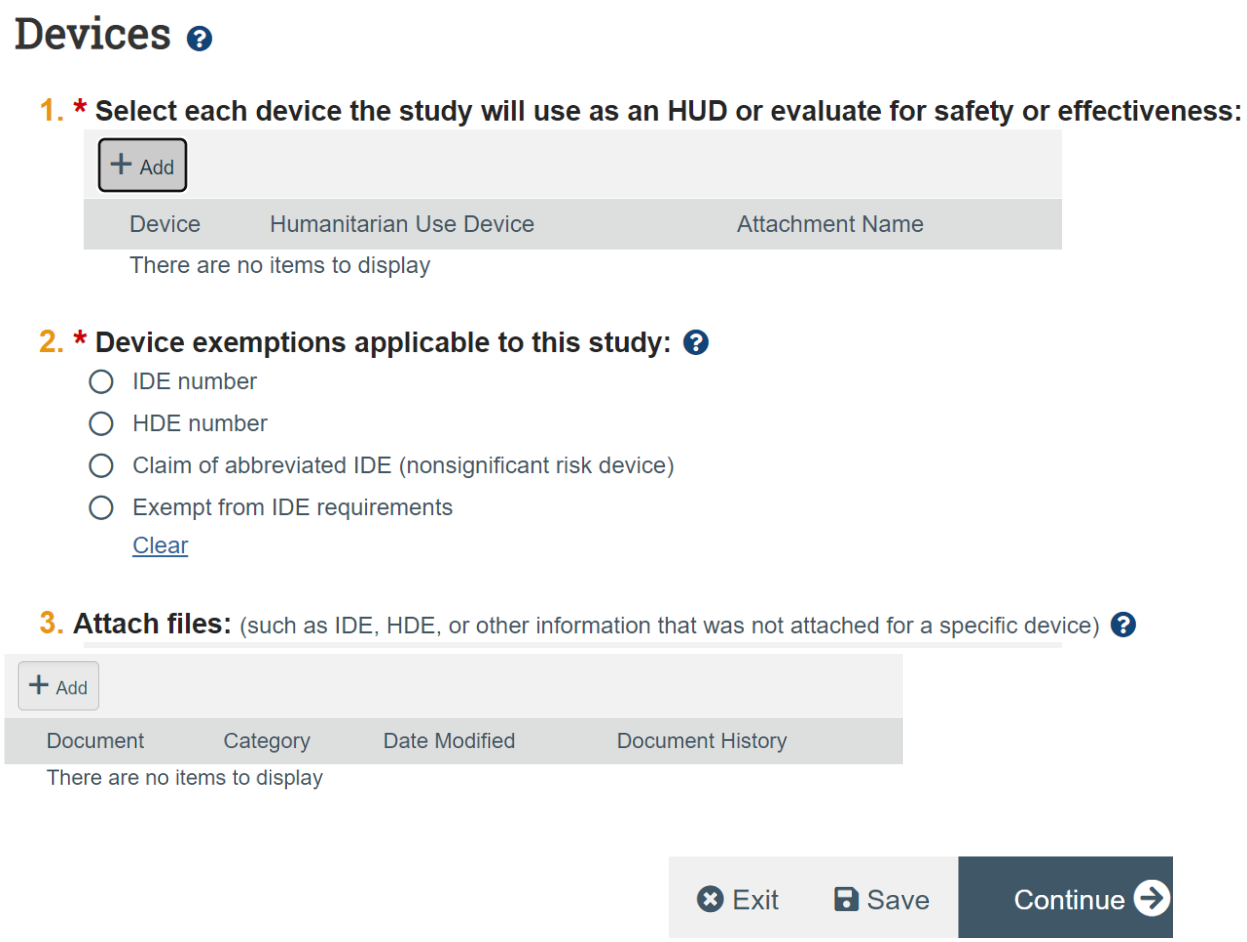


- **IND number:** Add the IND number.
- **Who holds the IND?:** Select from the available options.

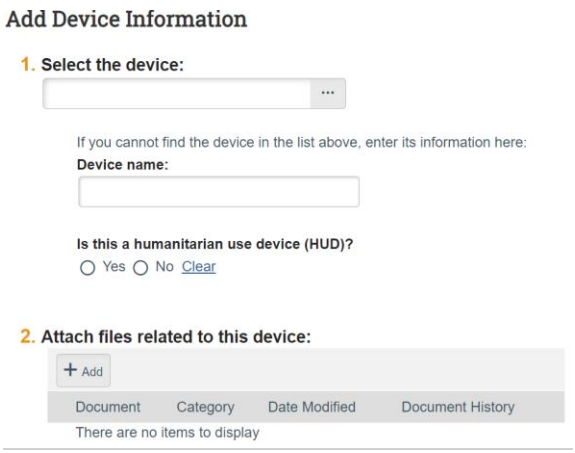
- **If "Other," identify the IND holder:** Identify the IND holder if they are not the Sponsor or the Investigator.

3. 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.



- **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.

- **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.

- **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.

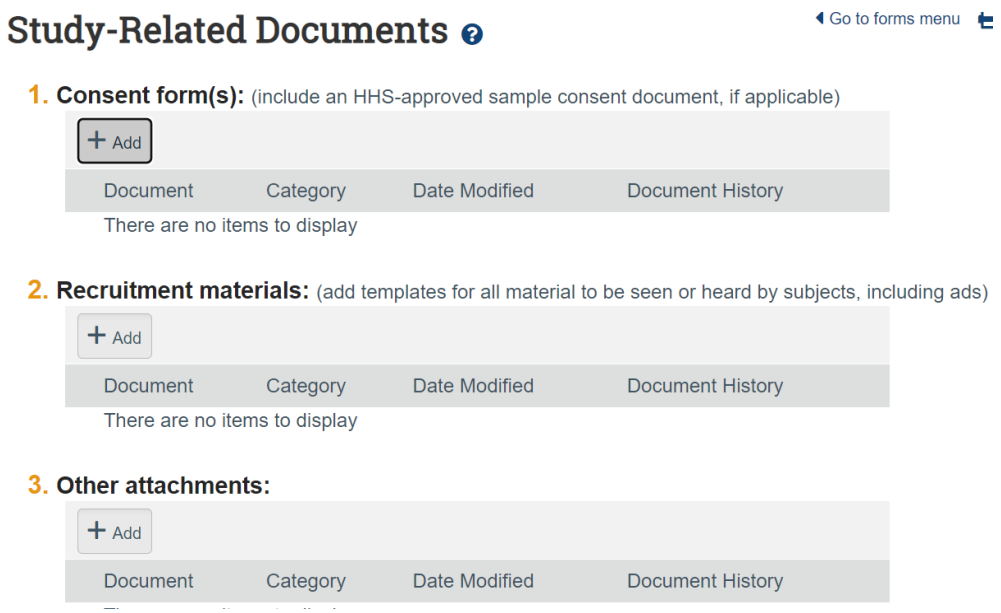
4. Click **Save**. Click **Continue** to move to the next page. To exit the submission, click **Exit**. These 3 actions are on every page.

Study-Related Documents Page

Only available if you selected "Yes" to, Multi-site or Collaborative study, on the Basic Information page. If you selected "No" to Multi-site or Collaborative study, on the Basic Information page you will not see this page and proceed to the Local Site Documents page.

Some documents and consent forms in the study will be applied to the multi-site study as a whole. On this page, only include the documents that apply to all sites. Documents that are specific to GMU sites should be uploaded to the Local Site Documents page.

You do not need to upload all documents to both Study-Related Documents and the Local Site Documents for a Multi-Site Study if all documents are the same.



1. Attach all study-related documents.

    - **Consent form(s):** Attach individual Word copies of each consent, assent, parental permission and data repository forms. 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.

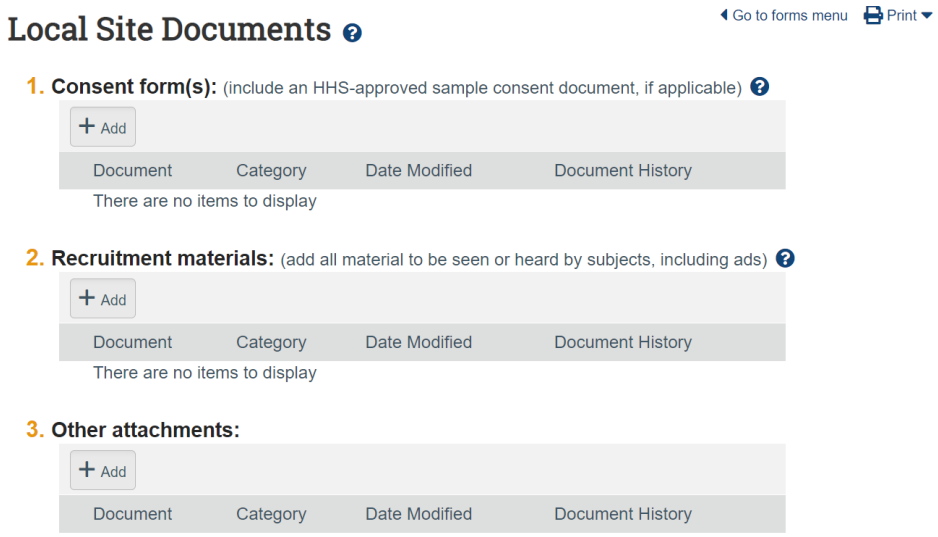
    - **Recruitment materials:** Attach Word copies of the recruitment materials. If you have multiple versions of the same type of recruitment, you can batch recruitment materials as Word uploads. For example, if you have multiple

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.

- **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, appendices, etc. Use Name to identify each document. Zip files are not accepted.

2. 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



1. Upload study documents

   - **Consent form(s):** Attach individual Word copies of each consent, assent, parental permission and data repository forms. 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.

   - **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.

   - **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. Zip files are not accepted.

2. 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 IRB. 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.

Submit a Modification

To submit a modification, 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**.