SHELL PROTOCOL: FIRST SUBMISSION IN ENDEAVOR

VERSION DATE: OCTOBER 31, 2024

AUBURN UNIVERSITY
Institutional Review Board

This PowerPoint will guide you through how to submit a modification to finish populating your shell protocol in Endeavor. Shell protocols are studies that were approved prior to implementation of Endeavor.

Key Resources

- Endeavor IRB Canvas page (https://auburn.instructure.com/courses/1546588)
- Auburn University IRB website (https://aub.ie/irb)
- IRB Office: (334) 844-5966 or irbadmin@auburn.edu
- IRB Chair: irbchair@auburn.edu

This guidance is intended solely for studies that were imported from SharePoint.

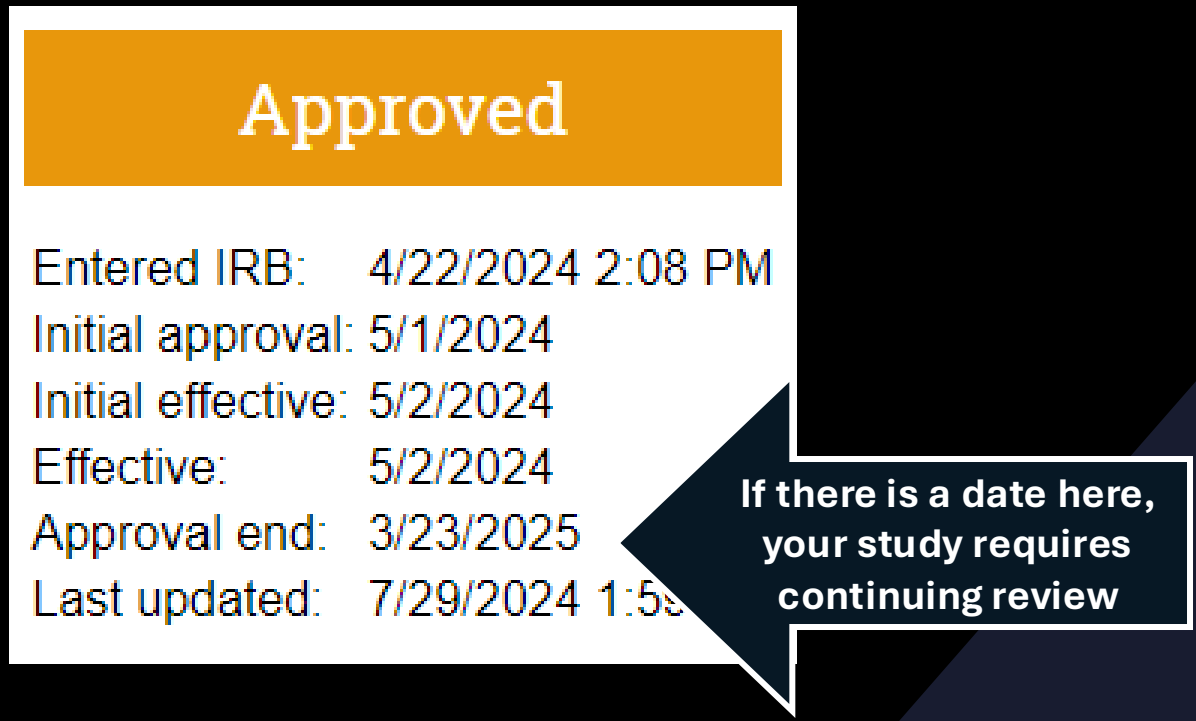
- “Shells” of all active exempt, expedited, and full board studies were imported from SharePoint to Endeavor. These “legacy” studies contain some information previously housed in SharePoint, but not all.
- During your first submission in Endeavor, you will need to finish populating your shell studies in Endeavor by filling in any missing fields or information on your online application that did not transfer from SharePoint to Endeavor.
- You will also need to upload all currently approved study materials to your shell study. **Please be aware that the only way to add or edit information in Endeavor is via a modification.**

Determine if your study requires Continuing Review (CR):

- Most minimal risk studies approved under the Revised Common Rule do not require continuing review.
- You will learn how to identify if your study requires a continuing review.

How can I tell if my study requires continuing review?

- Your initial approval letter states whether your study requires continuing review (i.e., an issued expiration date that required you to submit a renewal in the SharePoint system). This expiration date should also be reflected in Endeavor in the ‘Approval end’ field in the study view, as well as the expiration date field in the Dashboard view.
- If you do not have an expiration date in your approval letter or on your AU IRB approval stamp, your protocol does not require continuing review.



Before getting started, determine which option is needed for your first submission:

- Option A: Submit a modification only for completion of the shell protocol migration.

  This option is appropriate if you are submitting a modification to finish populating your shell study. This will require you to simply complete the new Endeavor SmartForms and upload your previously approved documents.

- Option B: Submit a modification for the completion of the shell protocol migration and to update the study procedures.

  This option is appropriate if you are submitting a modification to finish populating your shell study, and you would like to make changes to your study. During this process, you will also have the opportunity to update previously approved study procedures and/or study documents. This will require you to upload your previously approved documents, as well as transfer your study information onto the new Endeavor IRB protocol templates.

- Option C: Submit a modification and continuing review.

  This option is appropriate if you are submitting a modification to finish populating your shell study, and your protocol requires a continuing review. During this process, you will also have the opportunity to update previously approved study procedures and/or study documents. This will require you to upload your previously approved documents, as well as transfer your study information onto the new Endeavor IRB protocol templates. You will also complete the continuing review activity.

- Option D: Close your study.

  This option is appropriate if you are ready to close your study.

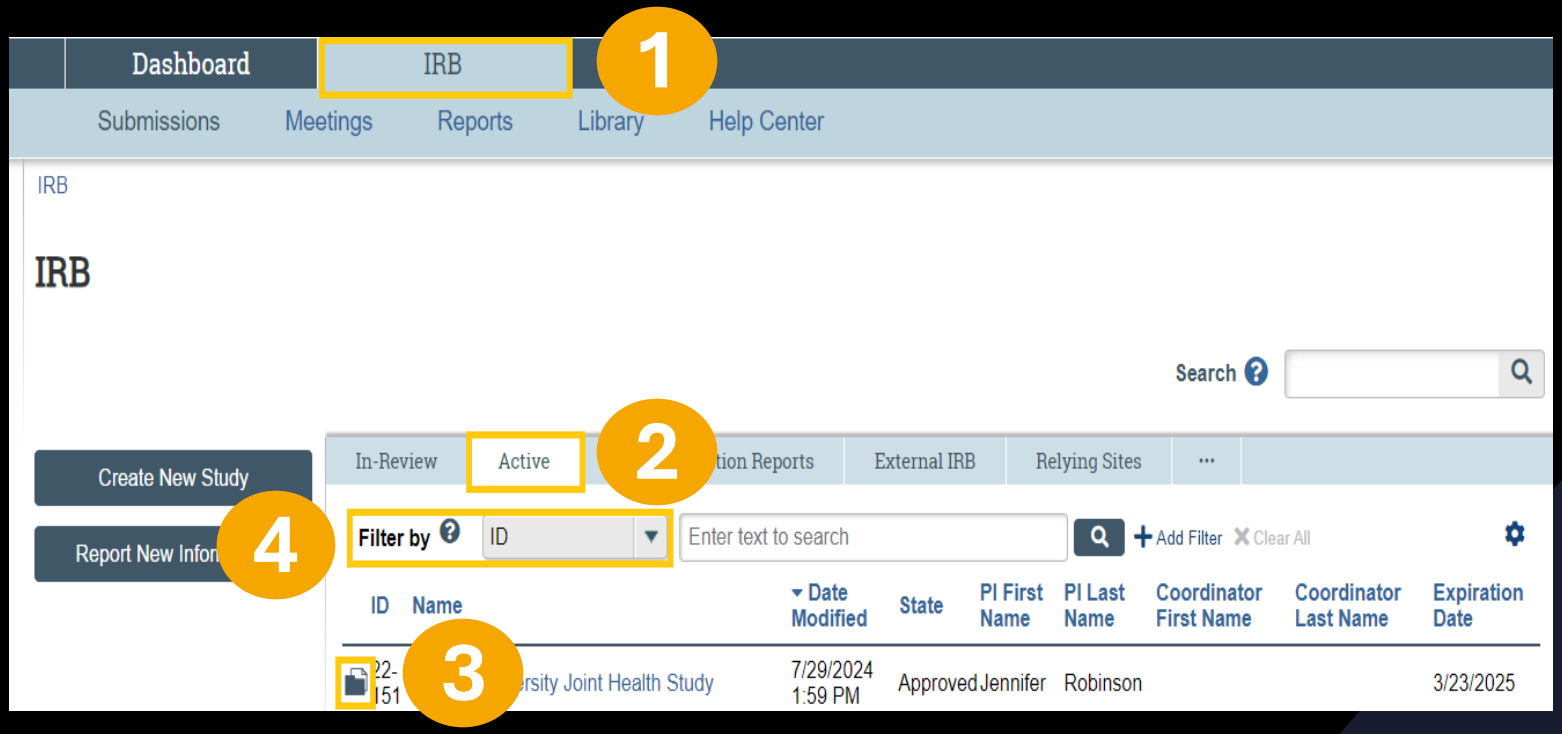
How would you like to proceed?

- Click on the following Options to be taken to the relevant slides.
  - Option A
  - Option B
  - Option C
  - Option D

OPTION A: HOW TO SUBMIT A MODIFICATION ONLY TO COMPLETE SHELL PROTOCOL MIGRATION

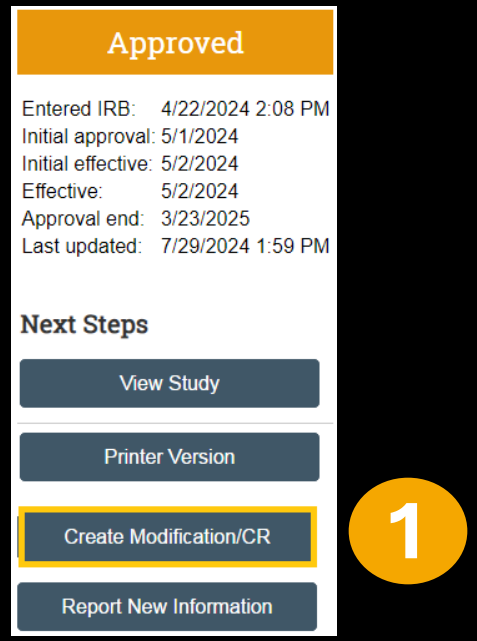
Getting Started

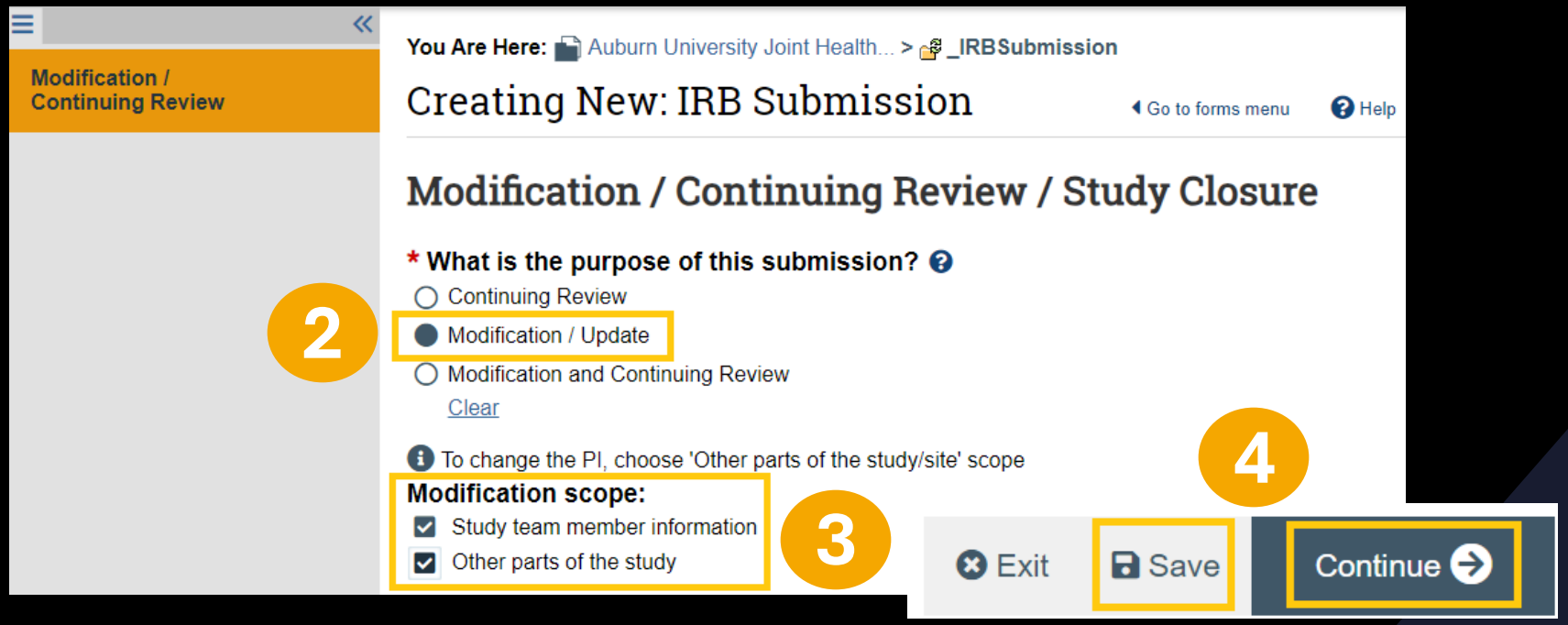
1. Navigate to the **IRB workspace**.
2. Select '**Active**'.
3. Open your study by selecting the folder symbol or the **name** of the study.
4. '**Filter by**' allows you to sort your studies by PI first and last name, expiration date, etc. You can add more than one filter by clicking on the '**+ Add Filter**'.



Creating a Modification

1. Select Create **Modification/CR**.
2. Select **Modification/Update**.
3. Under **Modification Scope** select both options.
4. Click **Save** and **Continue**.



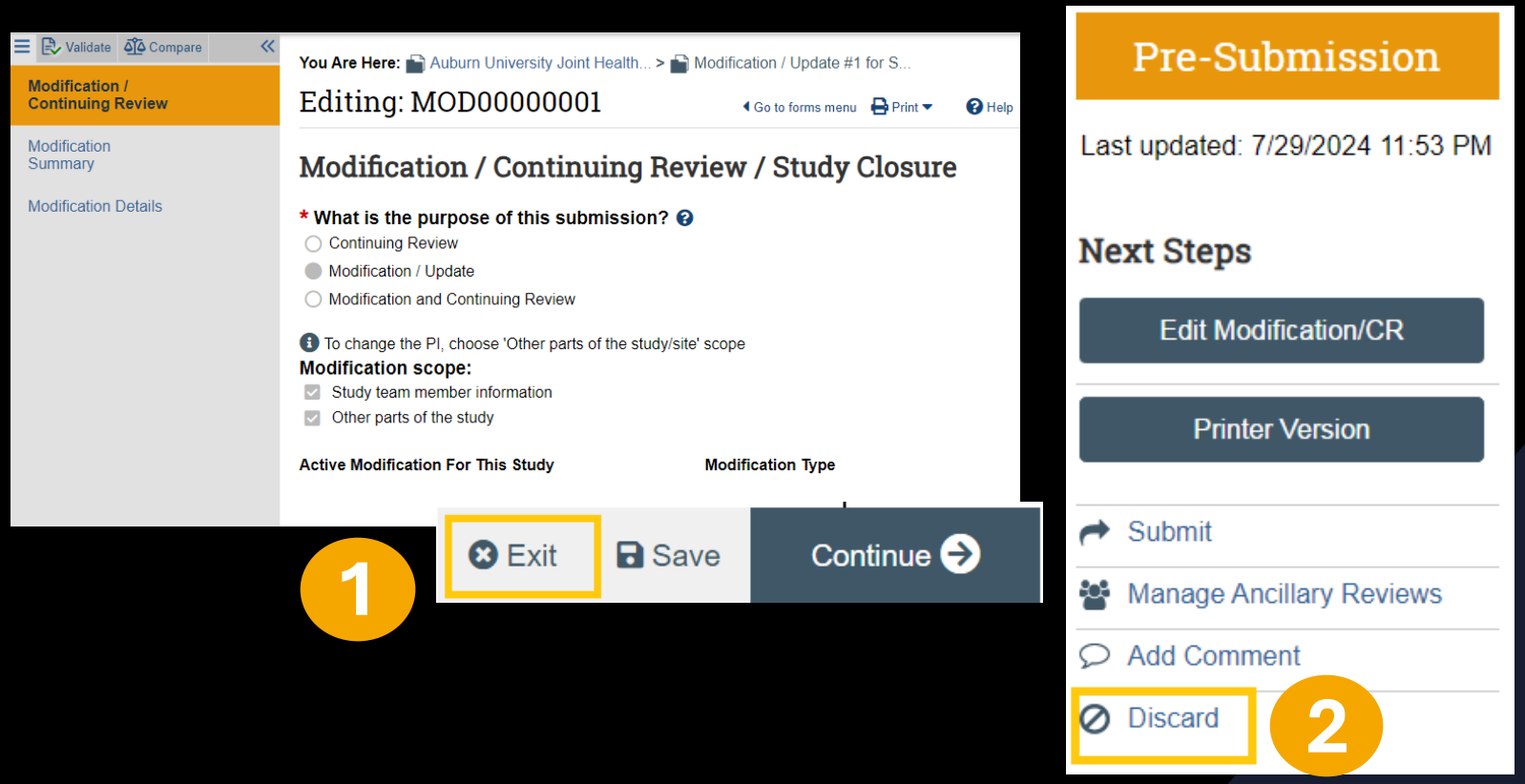


Discarding a Modification

1. Once you select **Save** or **Continue**, you will not be able to edit the purpose or scope of your modification. If an incorrect response was chosen for either '**What is the purpose of this submission?**' or '**Modification Scope**' and the form has been saved, then click **Exit** to leave the submission

2. Select **Discard** from the left menu bar. A new **Modification/CR** request will need to be created to continue with the modification request.

   NOTE: If you have an open modification request, the system will not allow you to create another modification of the same scope.



1. Complete the **Modification Summary**.
   - Provide answers to all questions.
   - In addition to completing the migration of your study, you may also take this opportunity to make planned modification to your protocol, just be sure to identify what changes are being made and upload all the appropriate documents.
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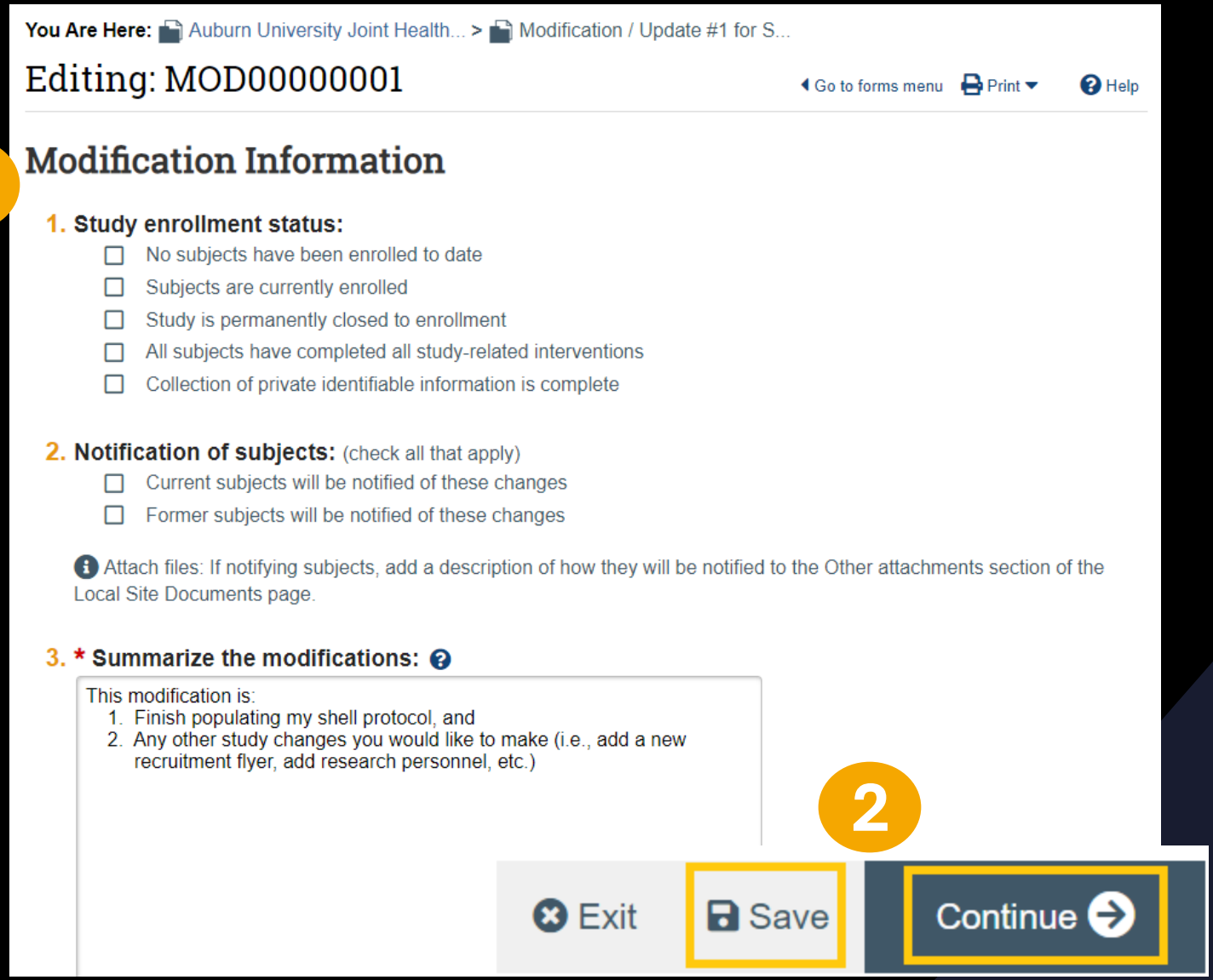
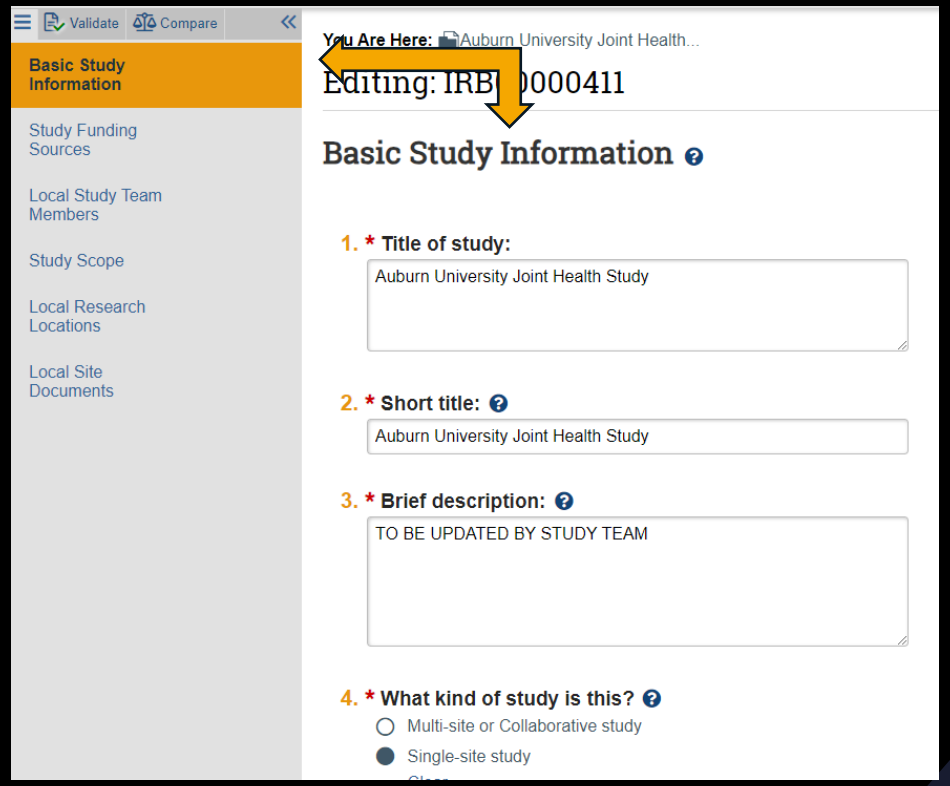
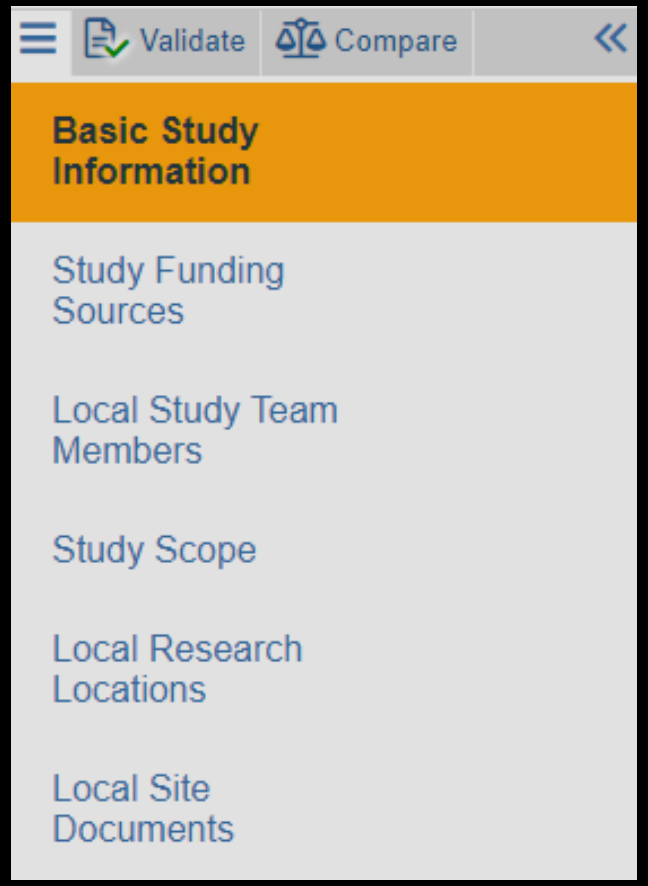
   - Once you click **Continue**, you will be re-directed to the application to make edits.



Navigate the IRB Application

1. The page navigator is located on the left side of the screen. It consists of SmartForms and allows the user to switch between the main pages of the IRB application. The page currently being viewed will be shown highlighted in orange.
2. **IMPORTANT**: During your first submission, you will need to go through every page of the application and fill in all missing data. The best approach is to navigate the application in the order it is presented and click **Save** and then **Continue** at the bottom of each page.



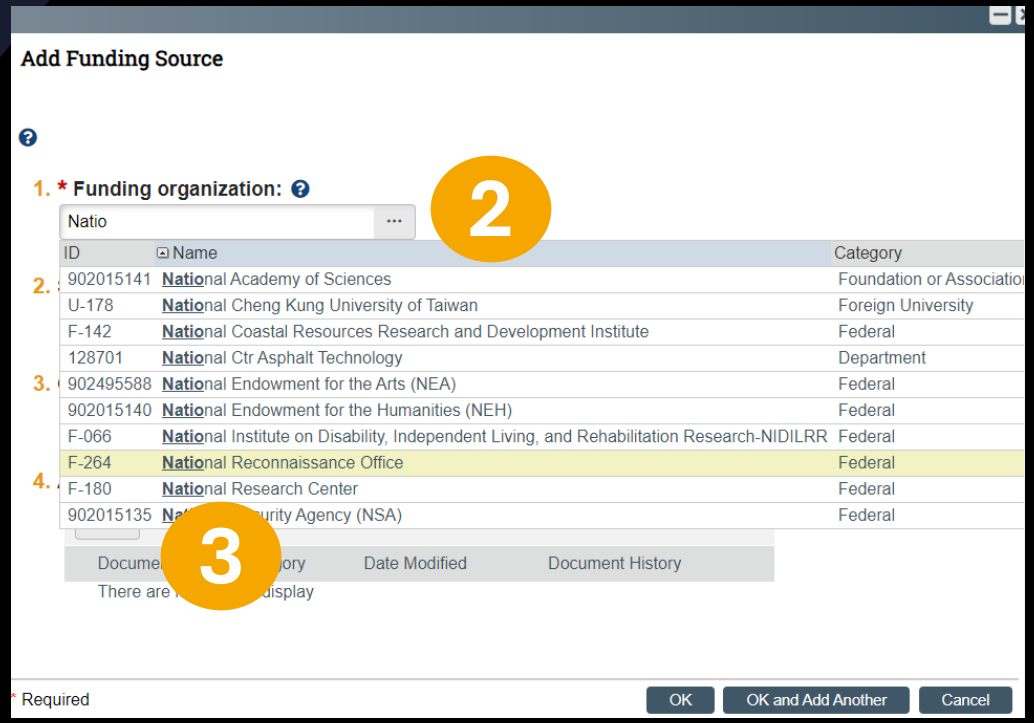


Completing Migration to Endeavor with No Study Changes

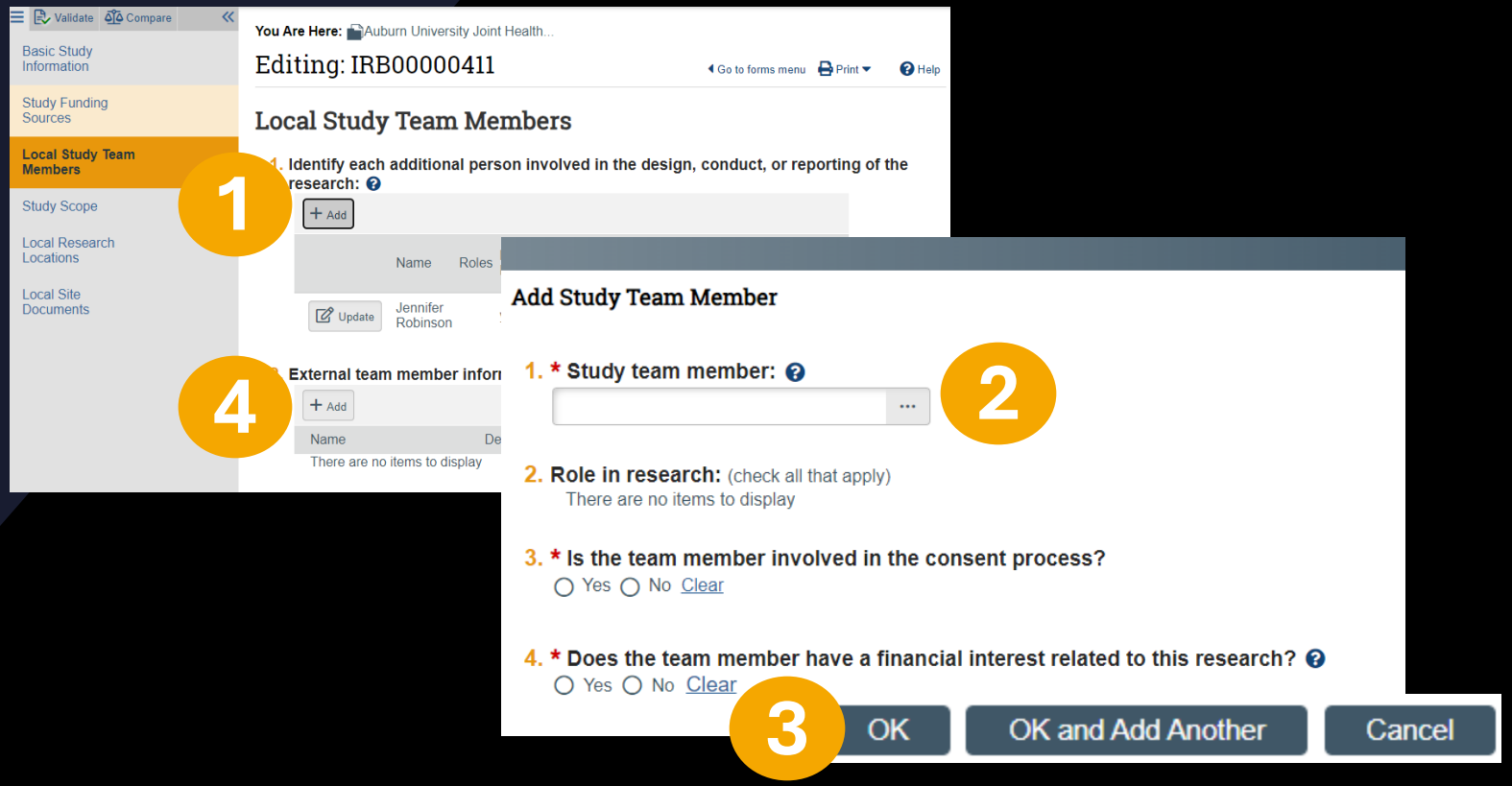
1. All questions marked with a red asterisk (*) require a response.

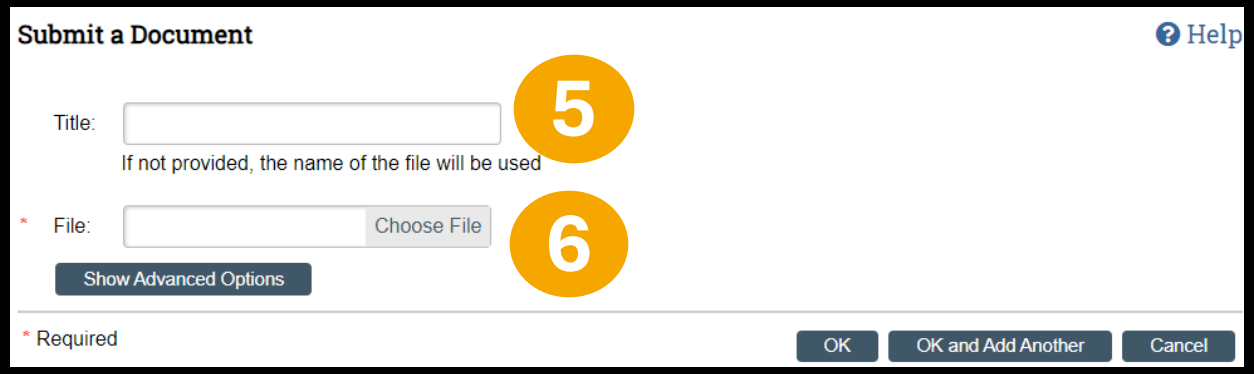
2. 'Shell' study information was migrated from SharePoint, including:
   - Study ID
   - Title of Study
   - Short Title
   - Reviewing IRB information
   - Name of the Principal Investigator (PI) (**NOTE**: If the PI was a student, the Faculty Advisor was transferred to PI status to be in-line with the PI Eligibility Statement)

3. Action items:
   - Ensure all information is accurate.
   - Attach your IRB-approved and stamped protocol packet in the Basic Study Information SmartForm when prompted (**8. *Attach the protocol**).
   - Update any information that is incorrect or missing, including funding sources, local study team members (key study personnel), and research locations.
   - If you are not making changes to your study, you do not need to upload individual documents under **Local Site Documents** at this time, as long as they are included in the IRB-approved and stamped protocol packet that you upload.

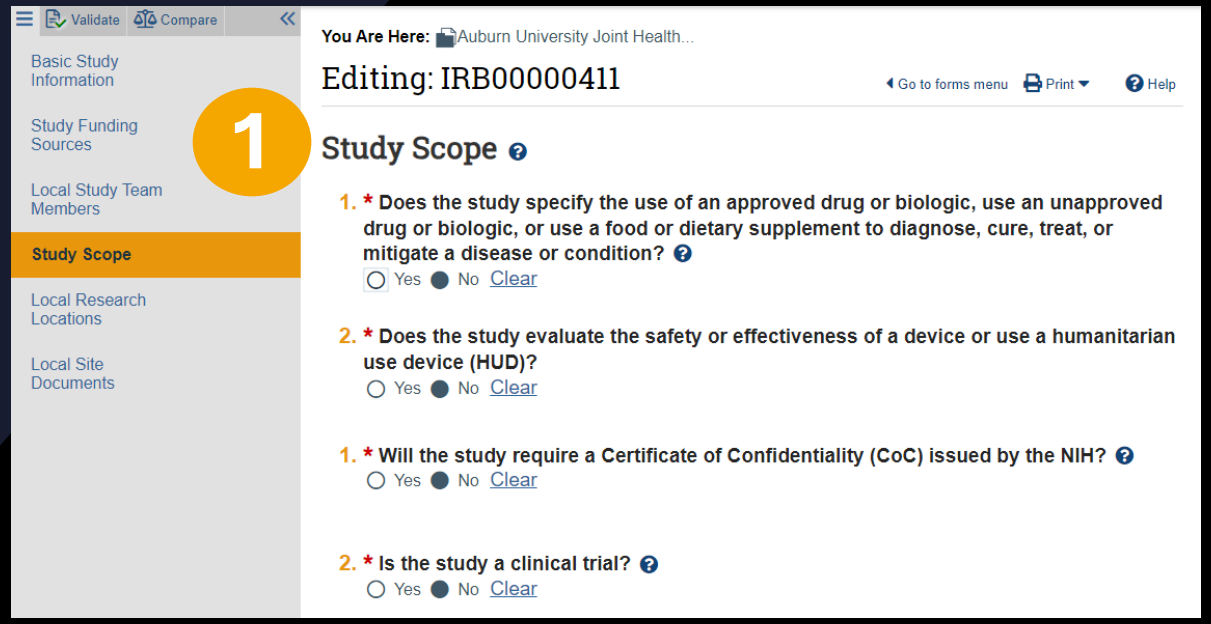


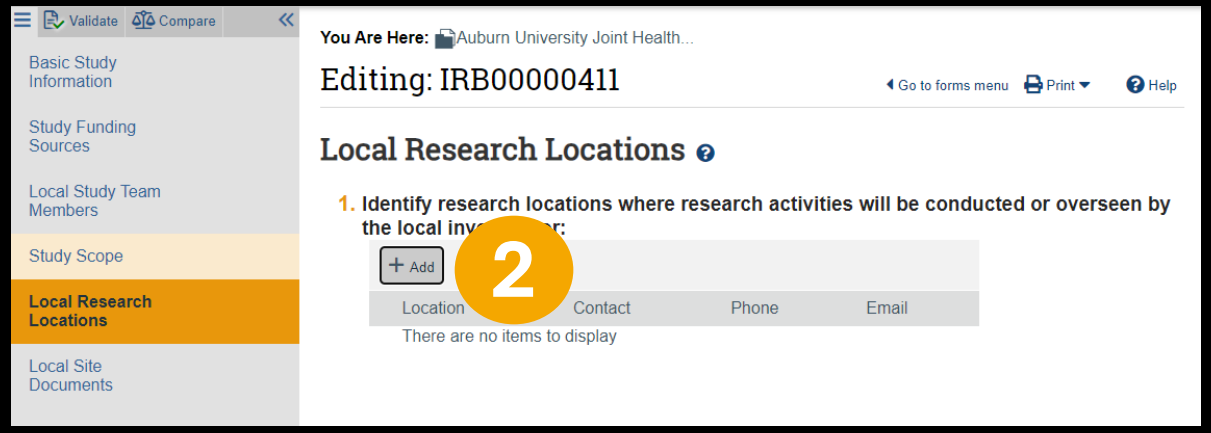
1. Add any study funding sources. To do this, click on the +Add tab.
2. This will bring up a pop-up window. You can then begin typing the funding organization and a list of pre-populated sources will generate. Select your funding source from the list. **NOTE:** When searching for a funding organization, use the '%' symbol to aid in searching. For example, if you are looking for NIH, it will not populate if you just search 'nih', but if you search %nih% you will get all entries with the 'nih', regardless of where it falls in the entry. If your funding source is not listed, please complete a support ticket at https://aub.ie/endeavorsupport.
3. Attach a copy of the grant or contract by clicking **+Add**.



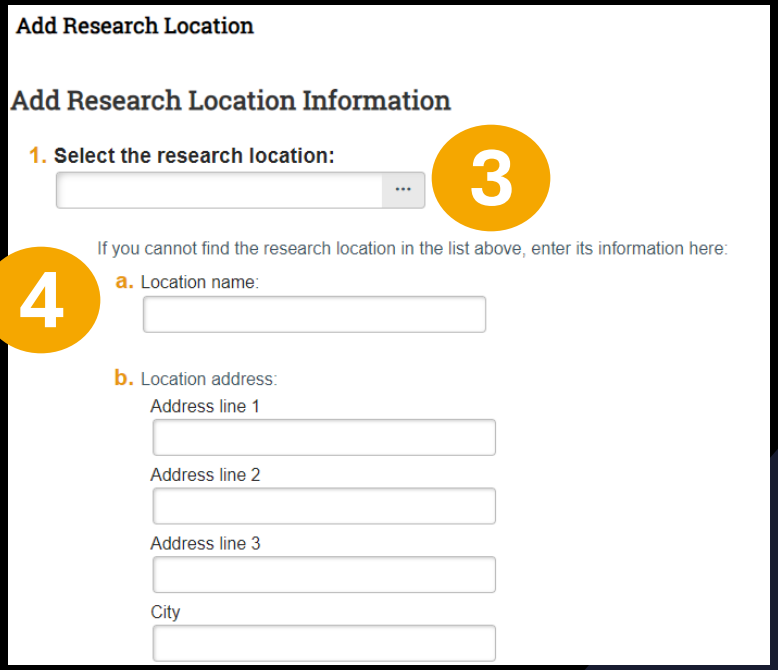


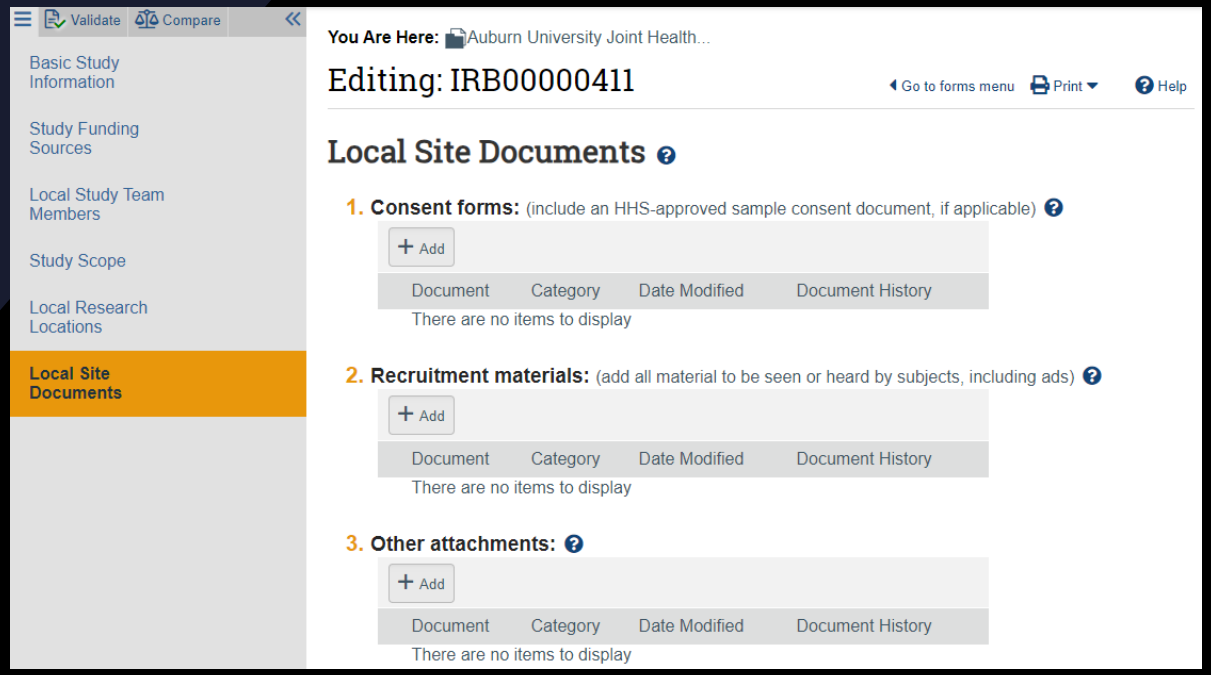
1. Add your key study personnel to the **Local Study Team Members** SmartForm.
2. Begin typing the name of the AU affiliated personnel. A list of names will populate. **NOTE:** This list is populated from an HR feed. It includes only personnel who are employed by AU. For all others (e.g., undergraduate research assistants, some categories of staff, etc.) it will be necessary to request they be added to the system. To request access for an individual, please complete a support ticket at https://aub.ie/endeavorsupport.
3. Click **OK** or **OK and Add Another** or **Cancel**.
4. If you have External Collaborators, click on **+Add** under **External Team Member Information**.
5. In the **Title** field, type in the external team member's name.
6. For **File**, upload a single documents with training certificates and information about the team member's affiliation, degree(s), and role(s) in the research project. Click **OK**, **Ok and Add Another**, or **Cancel**.



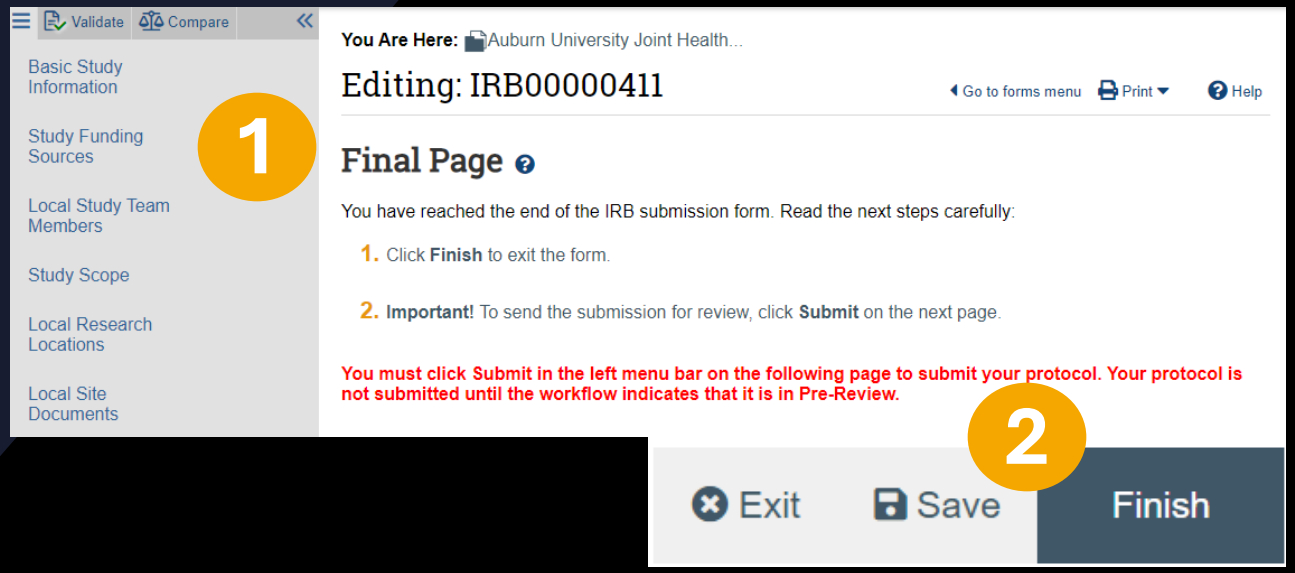


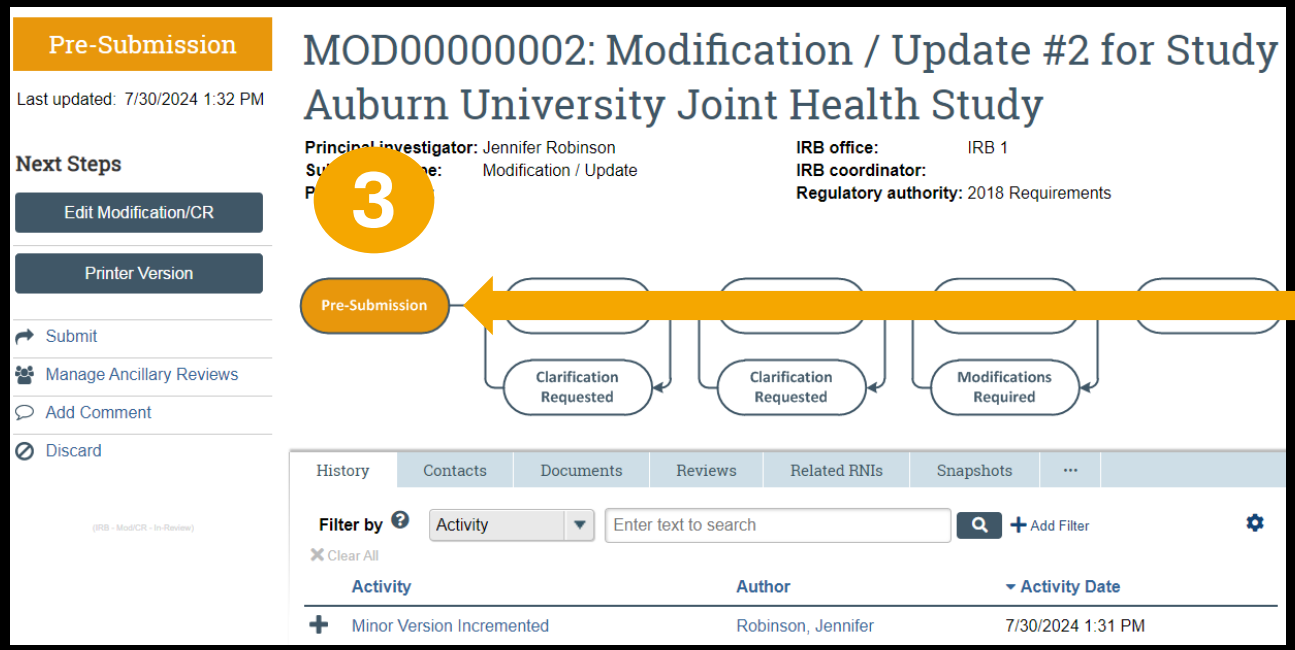
1. Answer the Study Scope questions. Add any drugs or devices used in the research.
2. Add all of the locations where research activities occur. Select **+Add**.
3. You will be able to type in a location and a pre-populated list will generate. If you have trouble finding your location, try putting '%' around the word. For example %thach% will bring up all entries with 'Thach' in the name.
4. If you cannot find your location, you can complete the form to add the location. Click **OK**, **Ok and Add Another**, or **Cancel**.



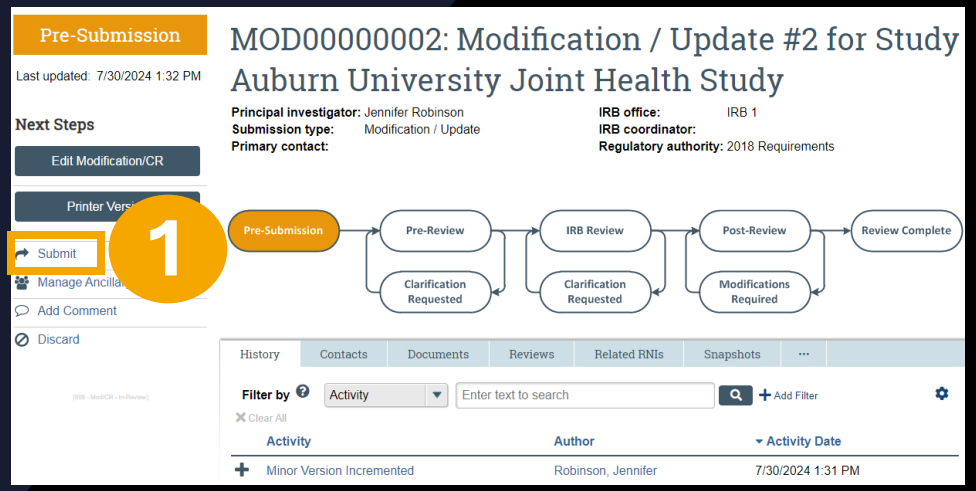


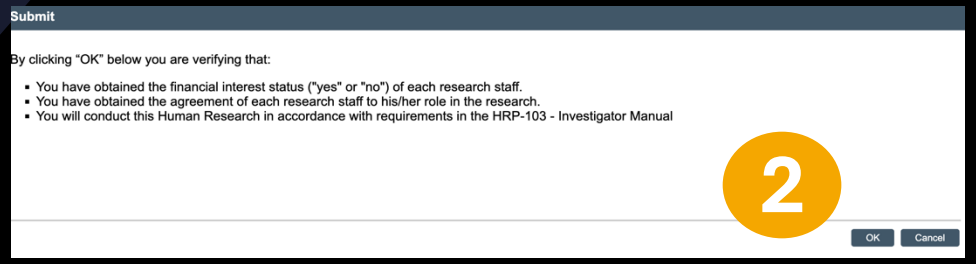
1. If you uploaded your most recent IRB-approved protocol packet that includes all elements of your protocol (i.e., the protocol review form, informed consent documents, recruitment materials, data collection forms, etc.), and you are not making study changes, you do not need to upload any additional materials here.
2. If your study requires continuing review, you will need to eventually convert all your study materials to Endeavor templates at the first CR submission. Please click here for detailed instructions.
3. Click **Continue**.

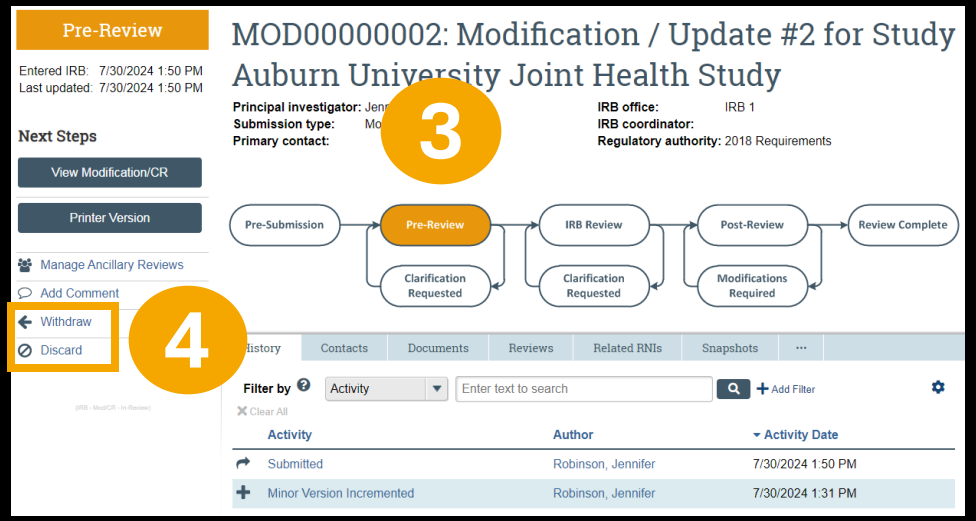




1. You will then be presented with a **Final Page** screen.
2. Click **Finish** to be routed back to the study view. **NOTE: CLICKING FINISH DOES NOT SUBMIT YOUR REQUEST**.
3. When you are routed back to the study screen, you will now see a workflow diagram. Your protocols place within the workflow is indicated by a solid orange fill. **Pre-Submission** means that it has not been submitted to the AU IRB.







1. You will need to click **Submit** in the left menu bar to submit your request.
2. You must agree to the assurances to complete the **Submit** activity.
3. Your request is not submitted until you see the workflow bubble move to **Pre-Review.**
4. Congratulations! You have submitted your request. If you need to withdraw your request, you can use the **Withdraw** function in the left menu. Withdrawing will allow you to make changes and re-submit. Discarding will delete the submission.

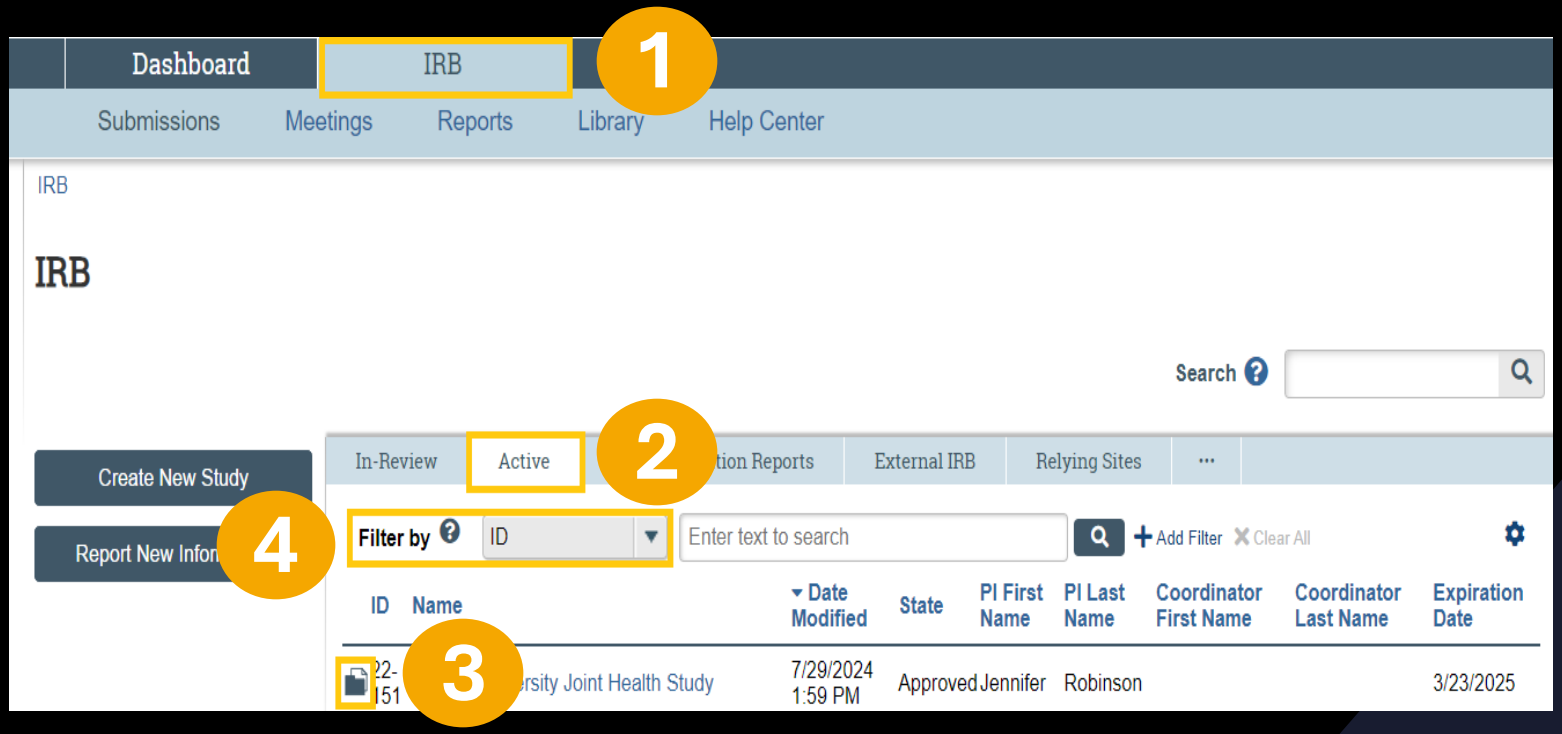
OPTION B: HOW TO SUBMIT A MODIFICATION TO COMPLETE SHELL PROTOCOL MIGRATION AND UPDATE YOUR STUDY

Completing Migration to Endeavor WITH Study Changes

- During your initial submission, you may choose to complete the shell protocol migration *and* update or revise your approved protocol. To complete these activities, you will need to:
  - Copy and paste all your study information into Endeavor templates. No SharePoint forms will be accepted after August 1, 2024.
  - Upload your previously approved, most recent IRB documents under Local Site Documents → Other Attachments.

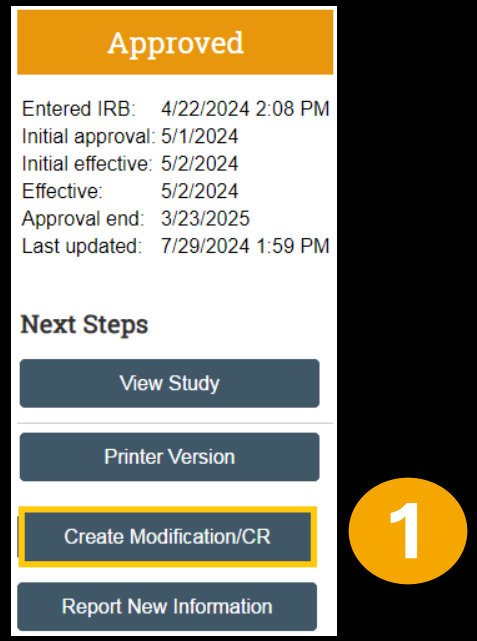
Getting Started

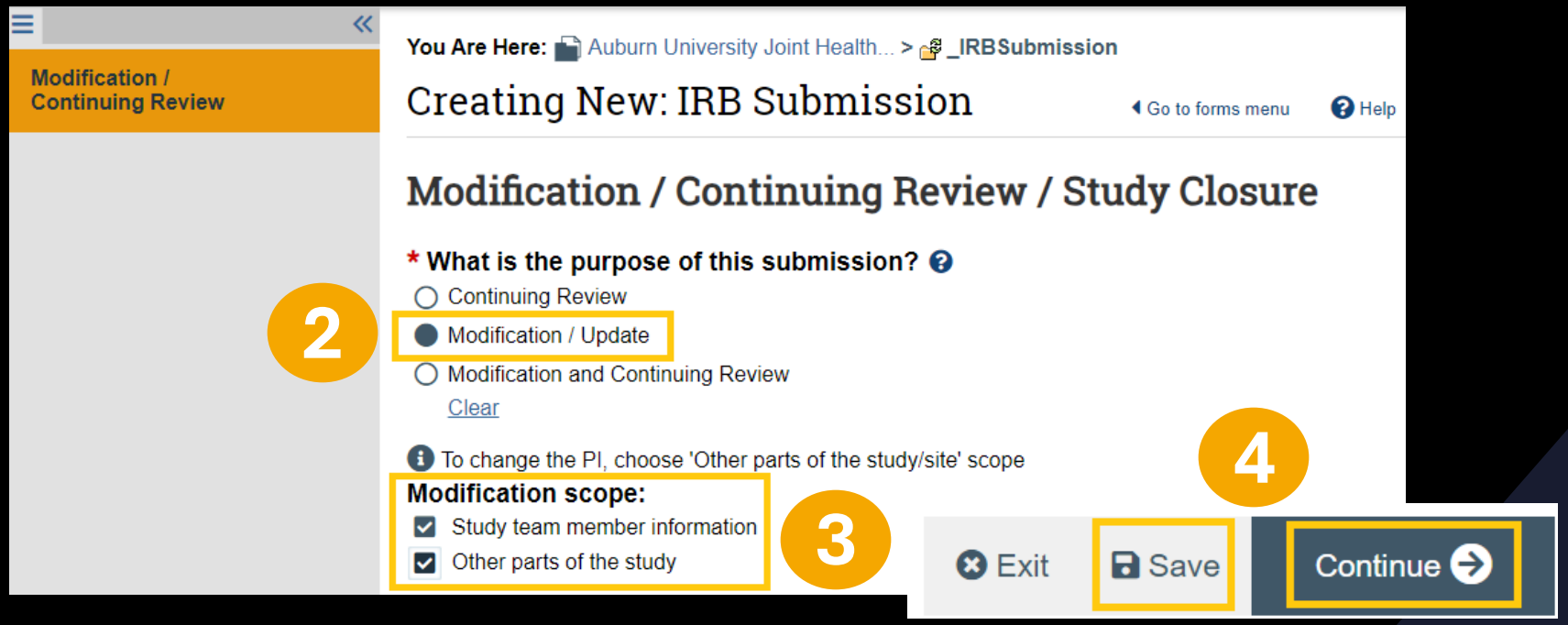
1. Navigate to the **IRB workspace**.
2. Select '**Active**'.
3. Open your study by selecting the folder symbol or the **name** of the study.
4. '**Filter by**' allows you to sort your studies by PI first and last name, expiration date, etc. You can add more than one filter by clicking on the '**+ Add Filter**'.



Creating a Modification

1. Select Create **Modification/CR**.
2. Select **Modification/Update**.
3. Under **Modification Scope** select both options.
4. Click **Save** and **Continue**.





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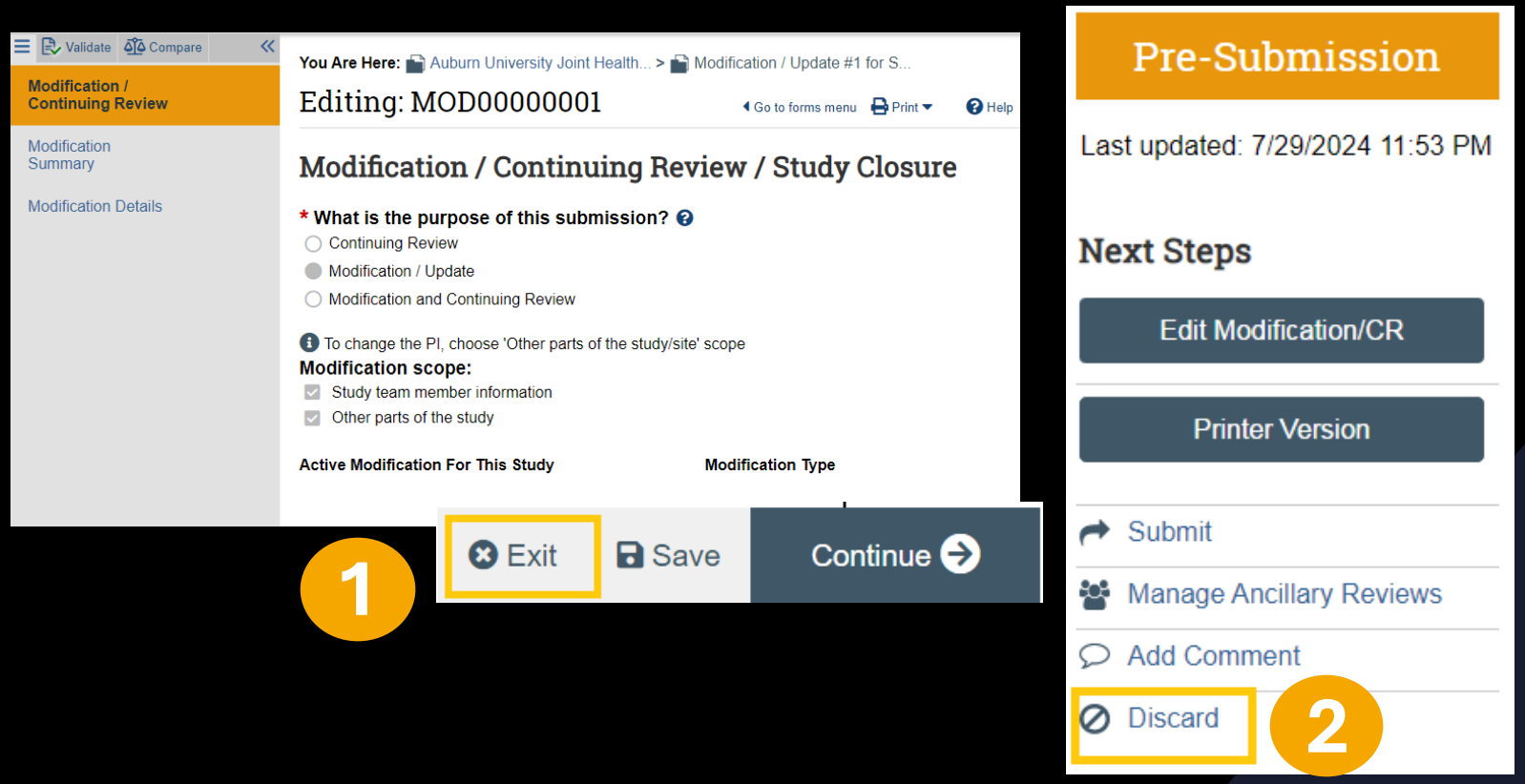

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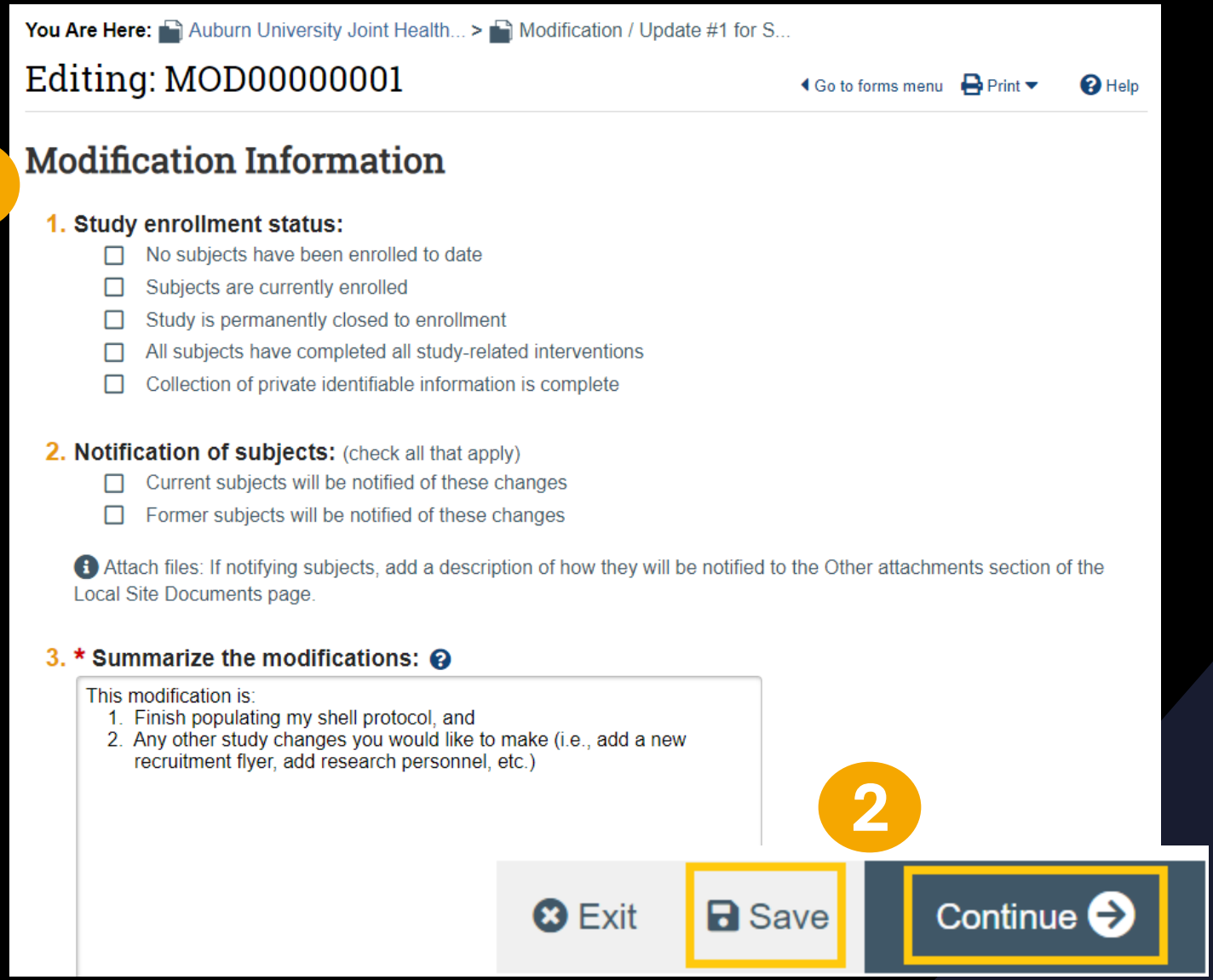

Navigate the IRB Application

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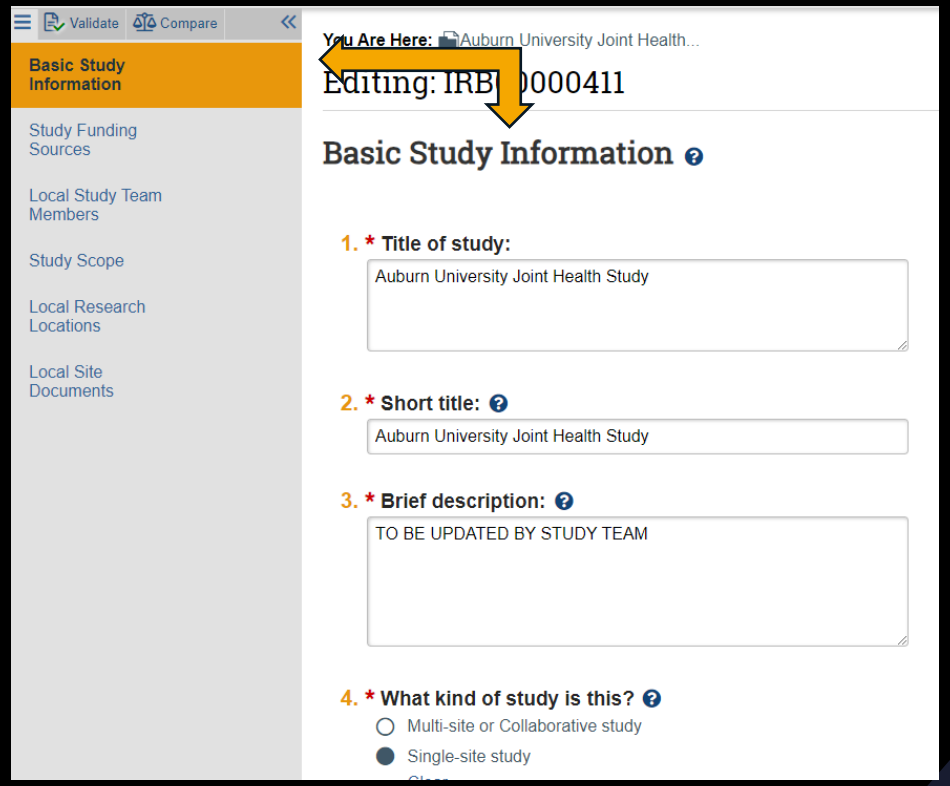
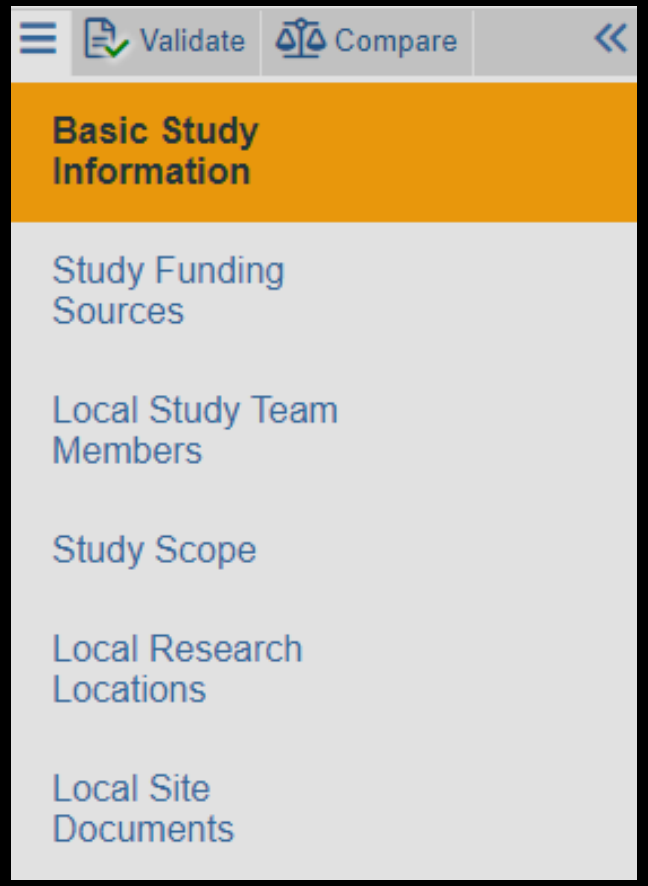


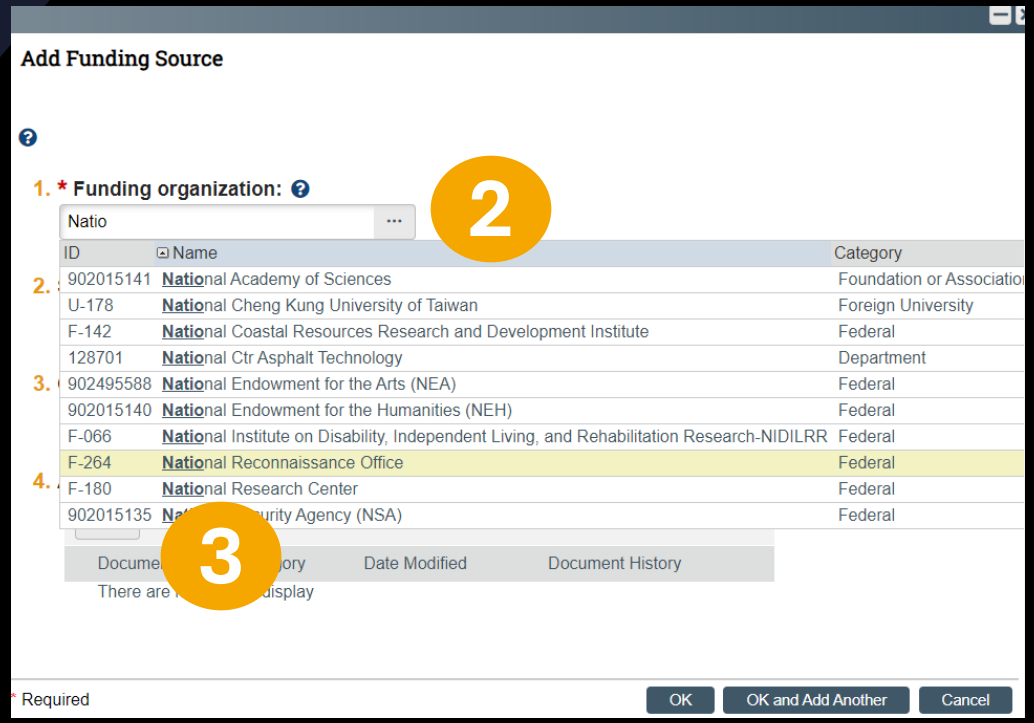


Completing Migration to Endeavor with No Study Changes

1. All questions marked with a red asterisk (*) require a response.
2. 'Shell' study information was migrated from SharePoint, including:
   - Study ID
   - Title of Study
   - Short Title
   - Reviewing IRB information
   - Name of the Principal Investigator (PI) (**NOTE**: If the PI was a student, the Faculty Advisor was transferred to PI status to be in-line with the PI Eligibility Statement)
3. Action items:
   - Ensure all information is accurate.
   - Transfer all your currently approved study documents onto Endeavor templates. This includes the protocol template, informed consent document(s), recruitment materials, etc. These documents must be in Microsoft Word format. Use Track Changes to show revisions to original study materials. The AU IRB will only accept Endeavor templates beginning August 1, 2024.
   - Update any information that is incorrect or missing, including basic information, funding sources, local study team members (key study personnel), and research locations.
   - Be sure to attach your IRB-approved and stamped protocol packet under **Local Site Documents → Other Attachments**.

Protocol Templates

- You will be asked to upload a protocol in the **Basic Study Information** SmartForm.
- There are two primary research protocol templates:
  - HRP-503 – TEMPLATE – Protocol: Use this template for expedited and full-board studies
  - HRP-503a – TEMPLATE – Exempt Protocol: Use this template for exempt studies
- Transfer your IRB-approved protocol information into the Microsoft Word template most applicable to your study. Once you have completed the transfer, turn on Track Changes and add missing information, update relevant sections with revisions, etc.
- Be sure to upload the Microsoft Word version of the template. **NOTE:** Do not convert it to a PDF.



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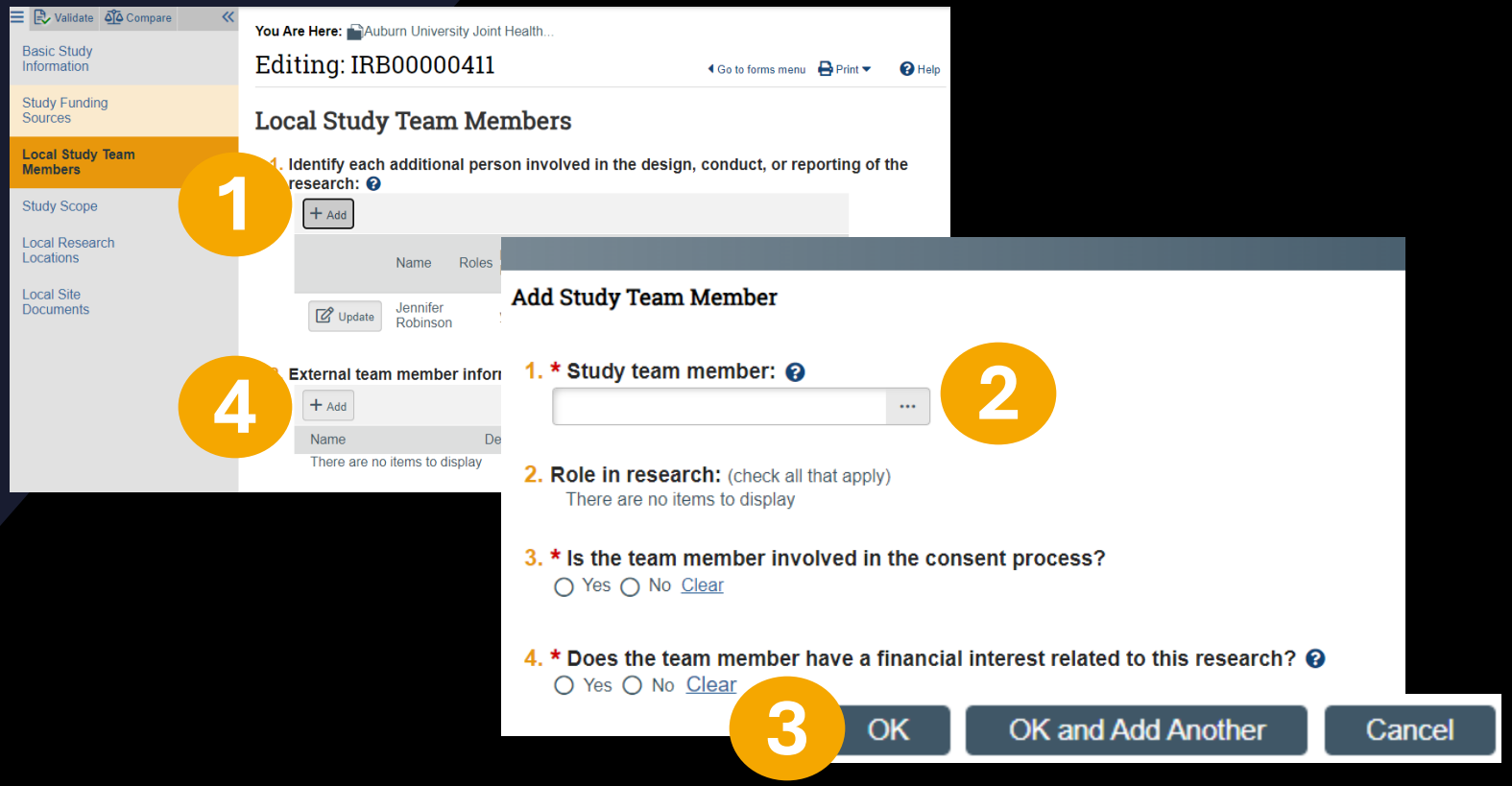
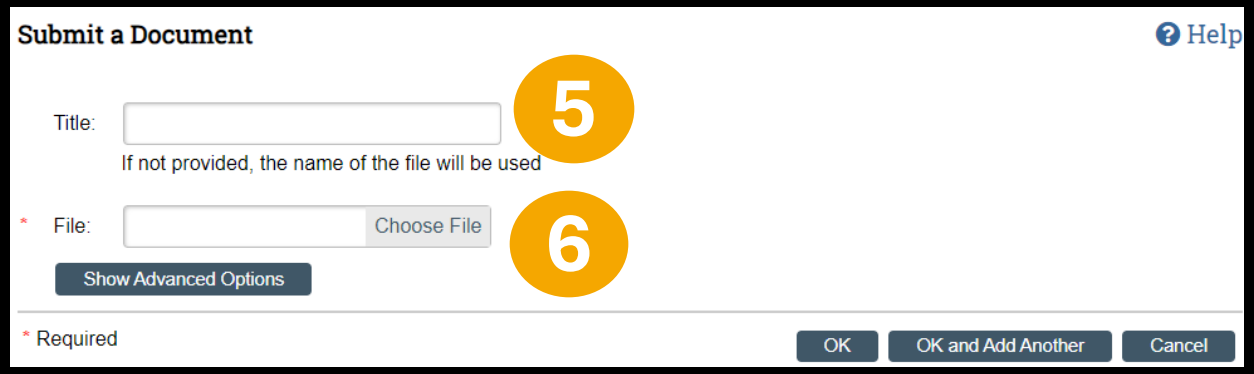
3. Attach a copy of the grant or contract by clicking **+Add**.





1. Add your key study personnel to the **Local Study Team Members** SmartForm.
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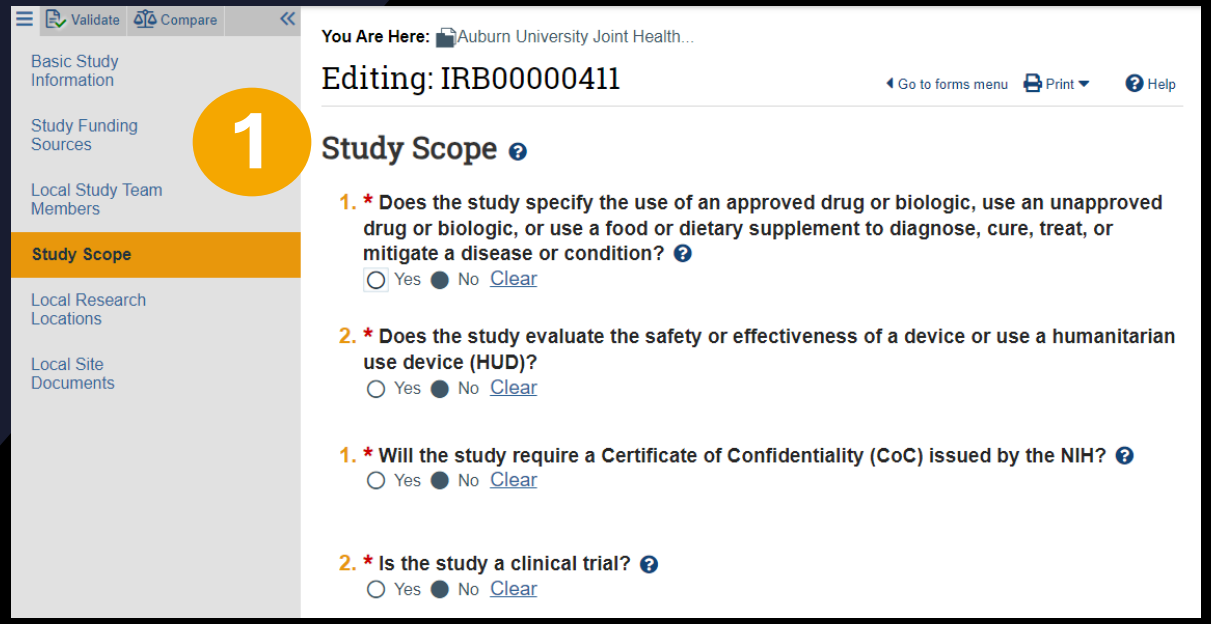
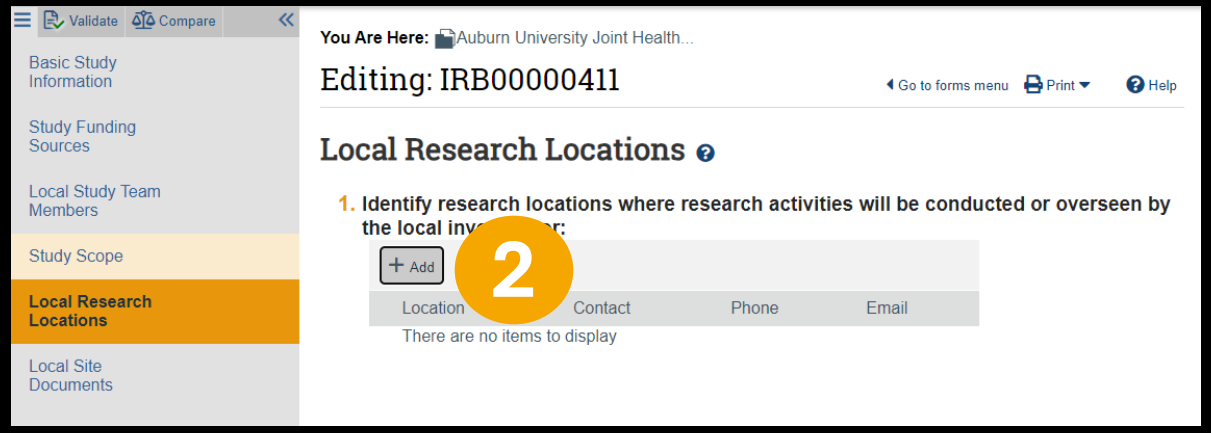
3. Click **OK** or **OK and Add Another** or **Cancel**.
4. If you have External Collaborators, click on **+Add** under **External Team Member Information**.
5. In the **Title** field, type in the external team member's name.
6. For **File**, upload a single documents with training certificates and information about the team member's affiliation, degree(s), and role(s) in the research project. Click **OK**, **Ok and Add Another**, or **Cancel**.





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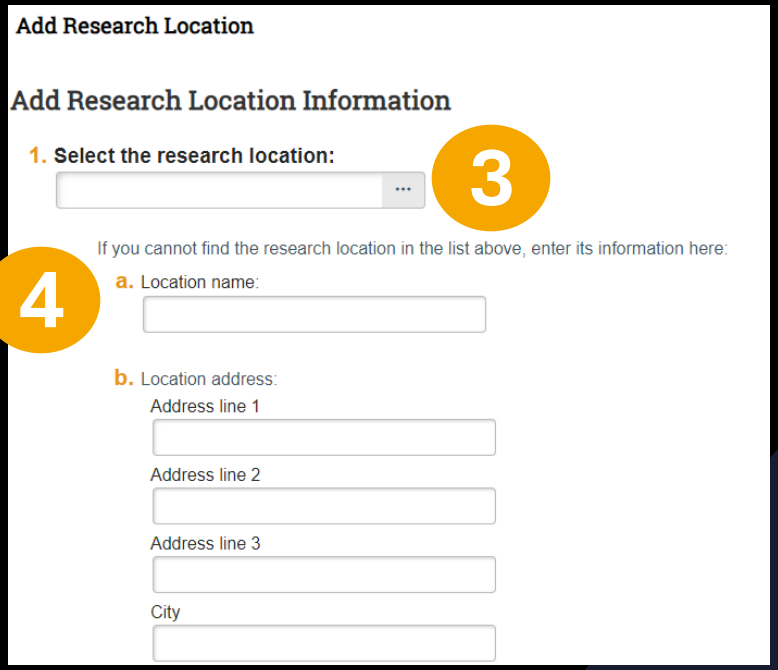

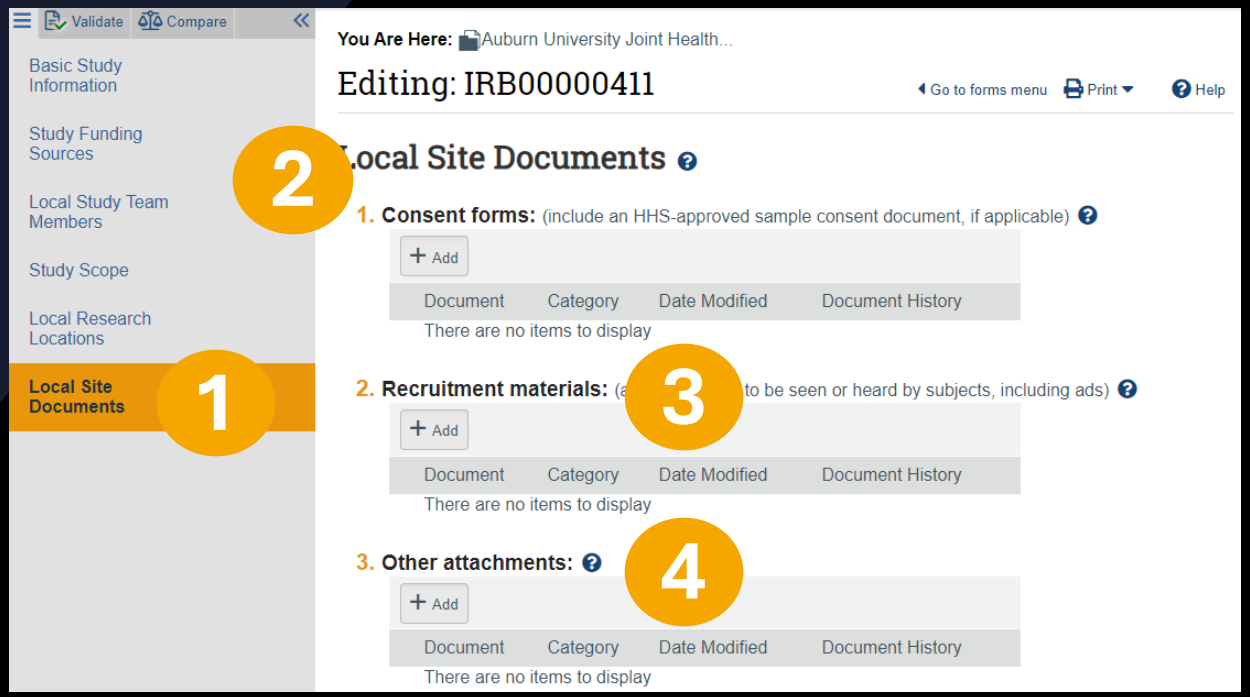

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2. In the **Local Site Documents** SmartForm, upload your Endeavor consent documents under **Consent Forms**. There are several consent/assent templates available.
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   - HRP-582 – TEMPLATE - Informed Consent Script

3. Upload any recruitment materials in section 2. Please refer to HRP-334 – WORKSHEET – Recruitment Materials for additional information.

4. Upload any other attachments in Section 3. Examples of **Other Attachments** include:
   - Data collection instruments
   - Letters of support/permission
   - Debriefing forms
   - Vendor vetting documentation
   - Scripts
   - Data use agreements
   - Conflict of Interest (COI) management plans
   - Referral lists
   - Emergency Action Plans (EAPs)
   - Data Safety Monitoring Board (DSMB) plans
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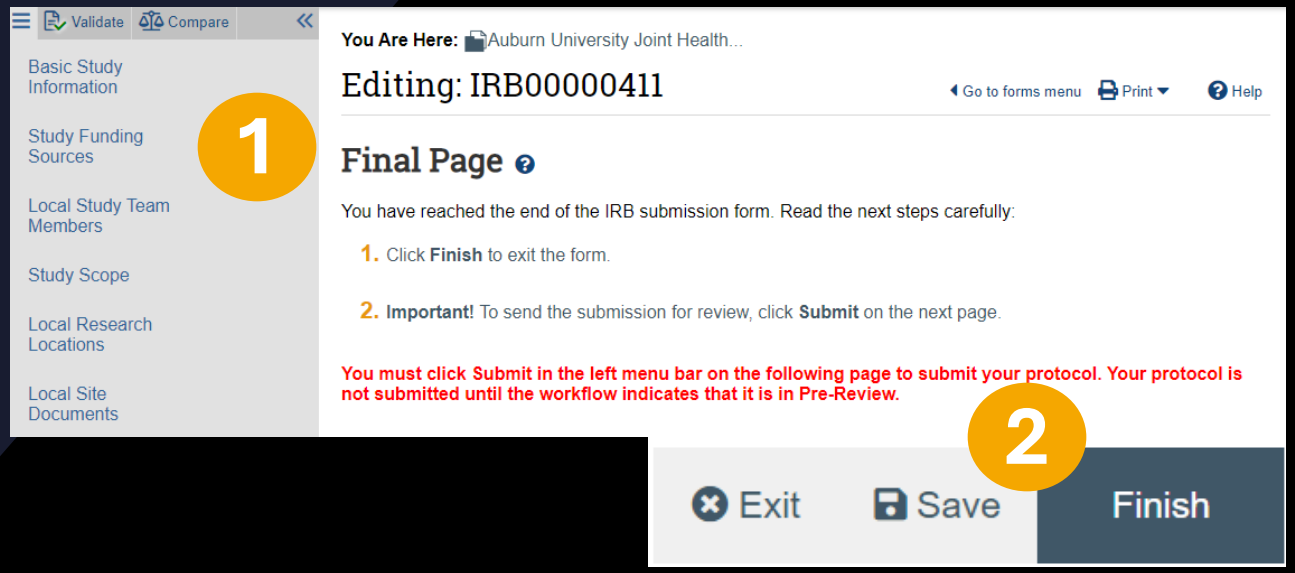
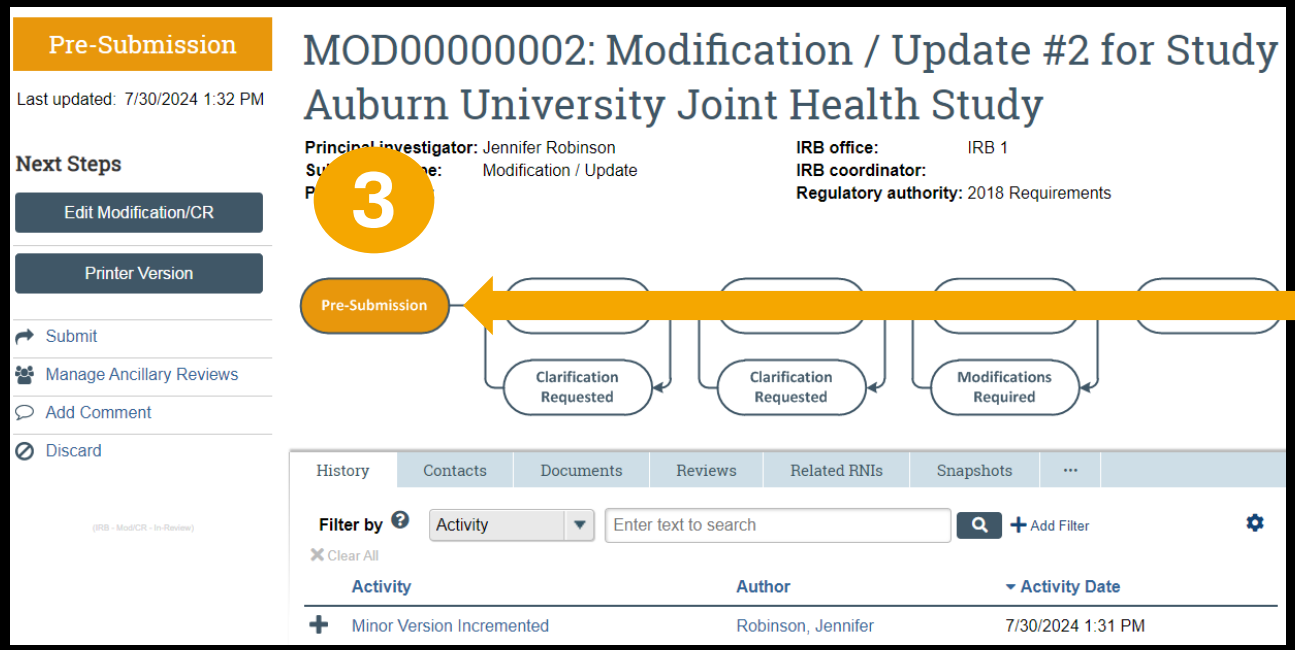
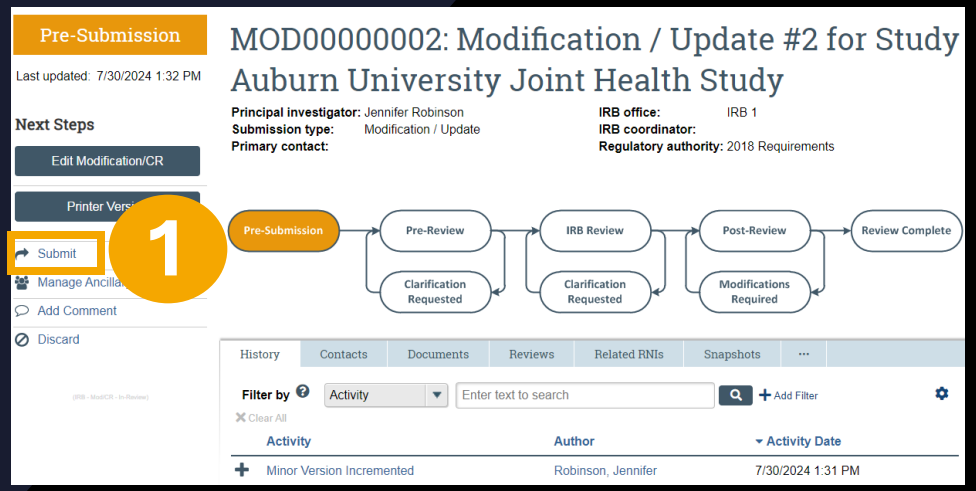
   - Recruitment materials (i.e., flyers, social media posts, etc.)
   - Additional training certificates that are external to CITI (i.e., phlebotomy certificates, youth protection training, etc.)
   - Clinical trial registration confirmation
   - Relevant appendices (i.e., mental health safety plan, MRI appendix (HRP-901), anonymous data collection assurance (HRP-902), etc.)

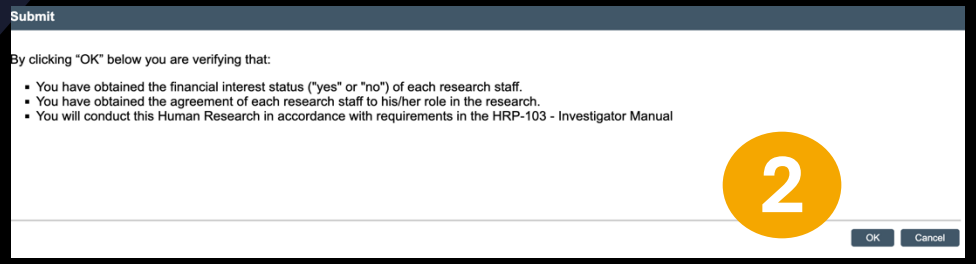
5. Click **Continue**.

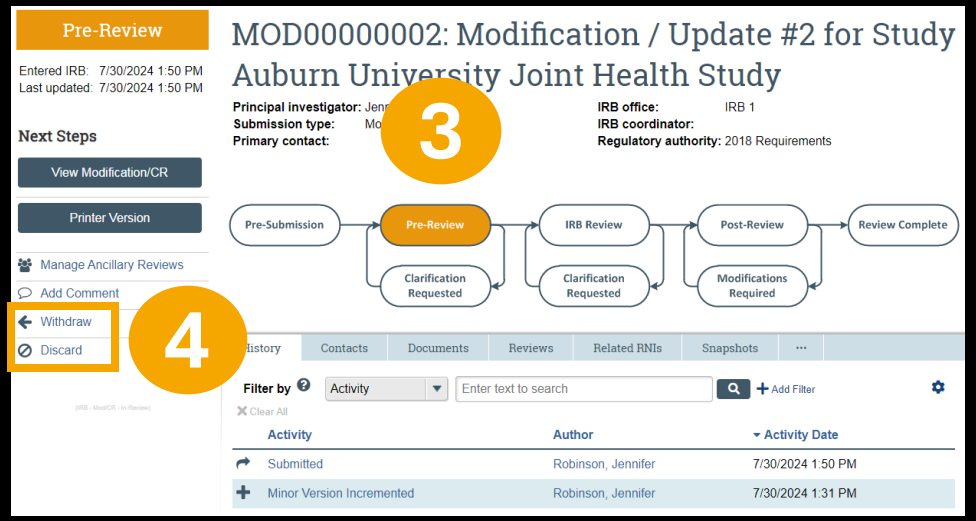




1. You will then be presented with a **Final Page** screen.
2. Click **Finish** to be routed back to the study view. **NOTE: CLICKING FINISH DOES NOT SUBMIT YOUR REQUEST**.
3. When you are routed back to the study screen, you will now see a workflow diagram. Your protocols place within the workflow is indicated by a solid orange fill. **Pre-Submission** means that it has not been submitted to the AU IRB.







1. You will need to click **Submit** in the left menu bar to submit your request.
2. You must agree to the assurances to complete the **Submit** activity.
3. Your request is not submitted until you see the workflow bubble move to **Pre-Review.**
4. Congratulations! You have submitted your request. If you need to withdraw your request, you can use the **Withdraw** function in the left menu. Withdrawing will allow you to make changes and re-submit. Discarding will delete the submission.

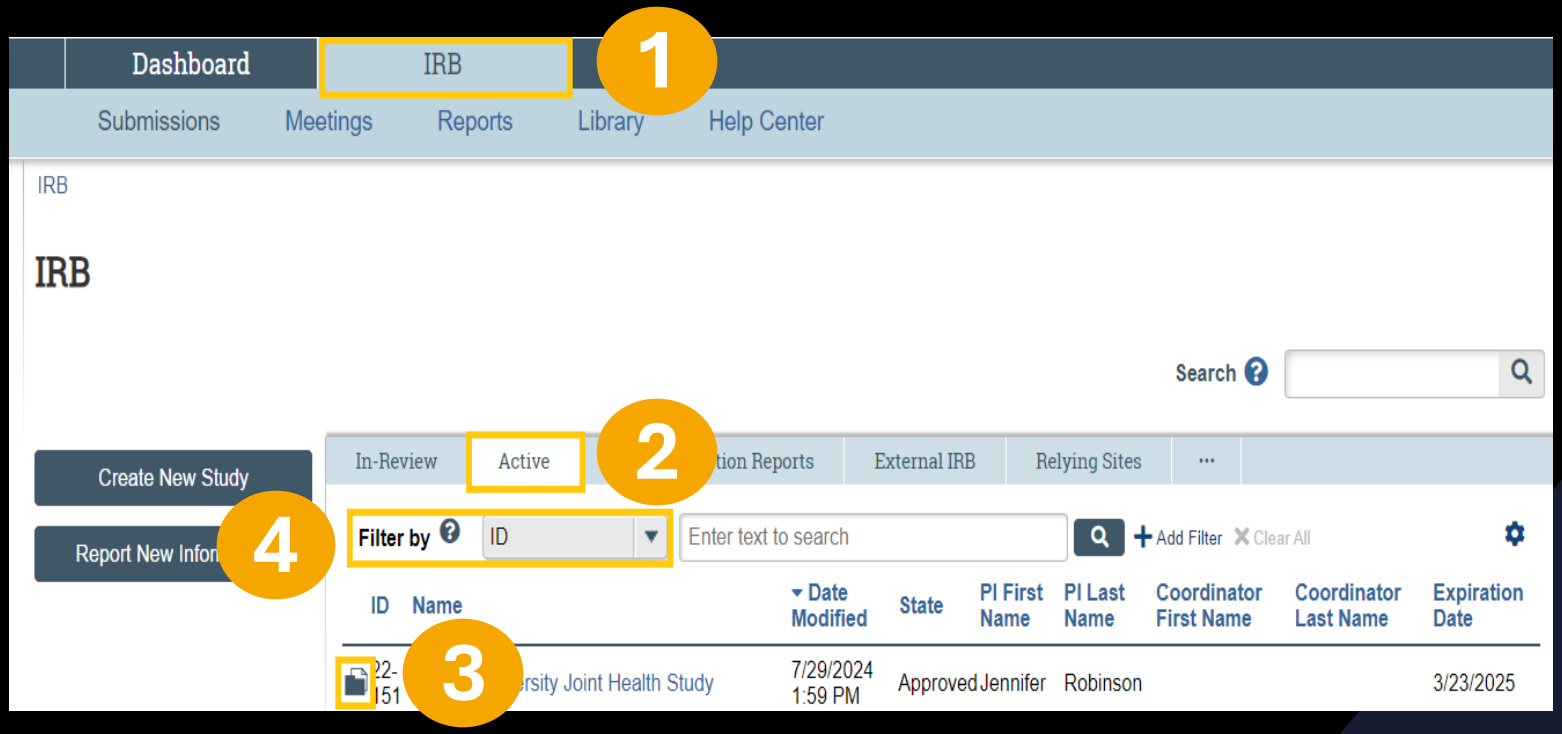
OPTION C: HOW TO SUBMIT A MODIFICATION TO COMPLETE SHELL PROTOCOL MIGRATION AND REQUEST CONTINUING REVIEW

Completing Migration to Endeavor and Continuing Review Activity

- During your initial submission, you may choose to complete the shell protocol migration *and* request continuing review. This only applies to studies in which an expiration date is assigned at approval. To complete these activities, you will need to:
  - Complete the **Continuing Review (CR)** request.
  - Copy and paste all your study information into Endeavor templates. No SharePoint forms will be accepted after August 1, 2024.
  - Upload your previously approved, most recent IRB documents under Local Site Documents → Other Attachments.

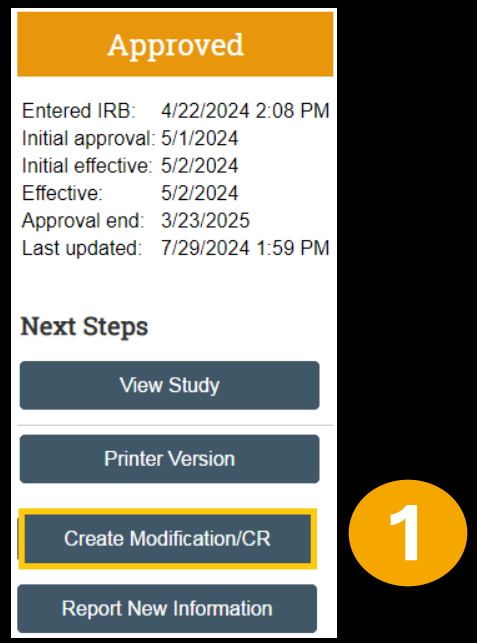
Getting Started

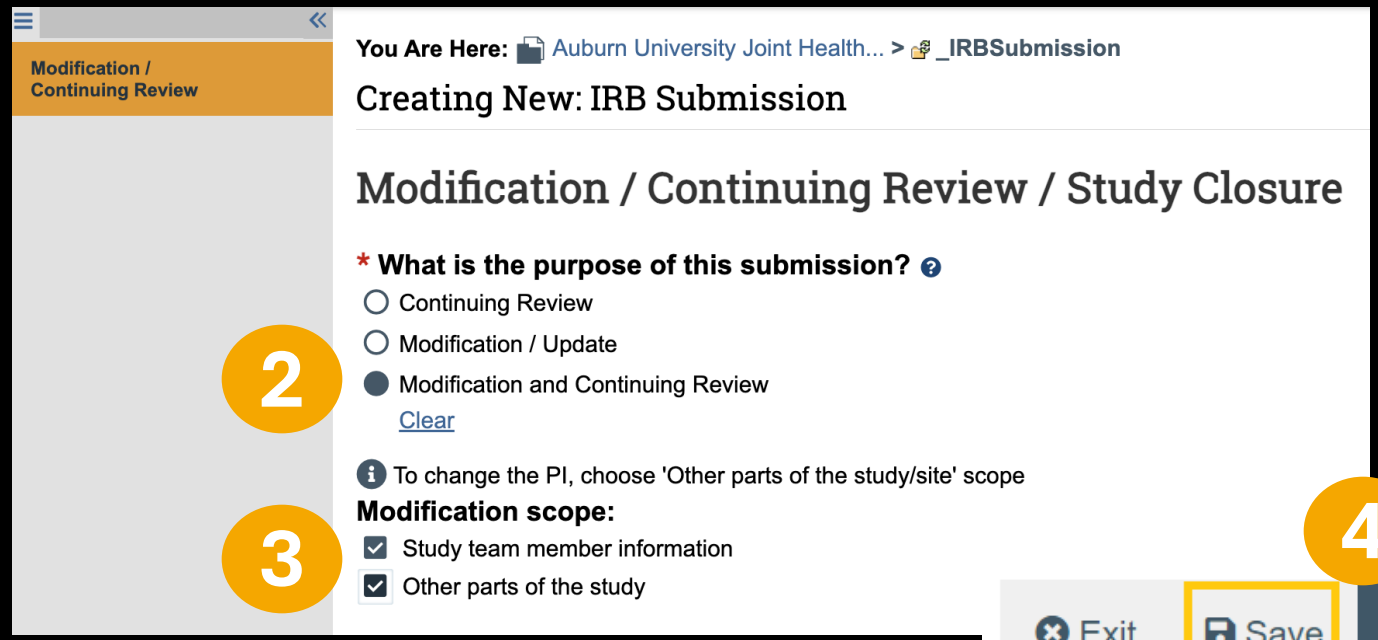
1. Navigate to the **IRB workspace**.
2. Select '**Active**'.
3. Open your study by selecting the folder symbol or the **name** of the study.
4. '**Filter by**' allows you to sort your studies by PI first and last name, expiration date, etc. You can add more than one filter by clicking on the '**+ Add Filter**'.



Creating a Modification & Continuing Review (CR)

1. Select Create **Modification/CR**.
2. Select **Modification and Continuing Review**.
3. Under **Modification Scope** select both options.
4. Click **Save** and **Continue**.



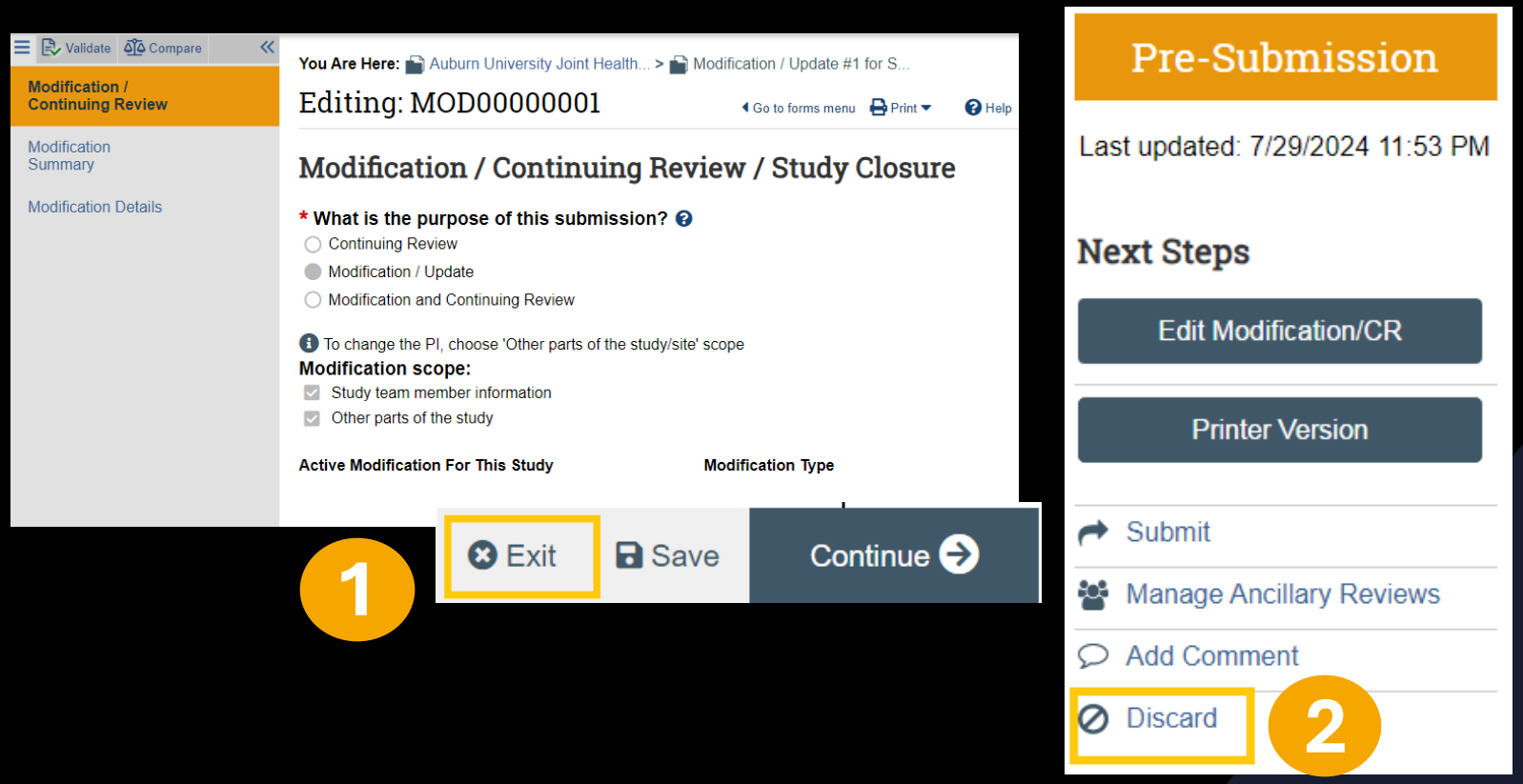


Discarding a Modification & CR

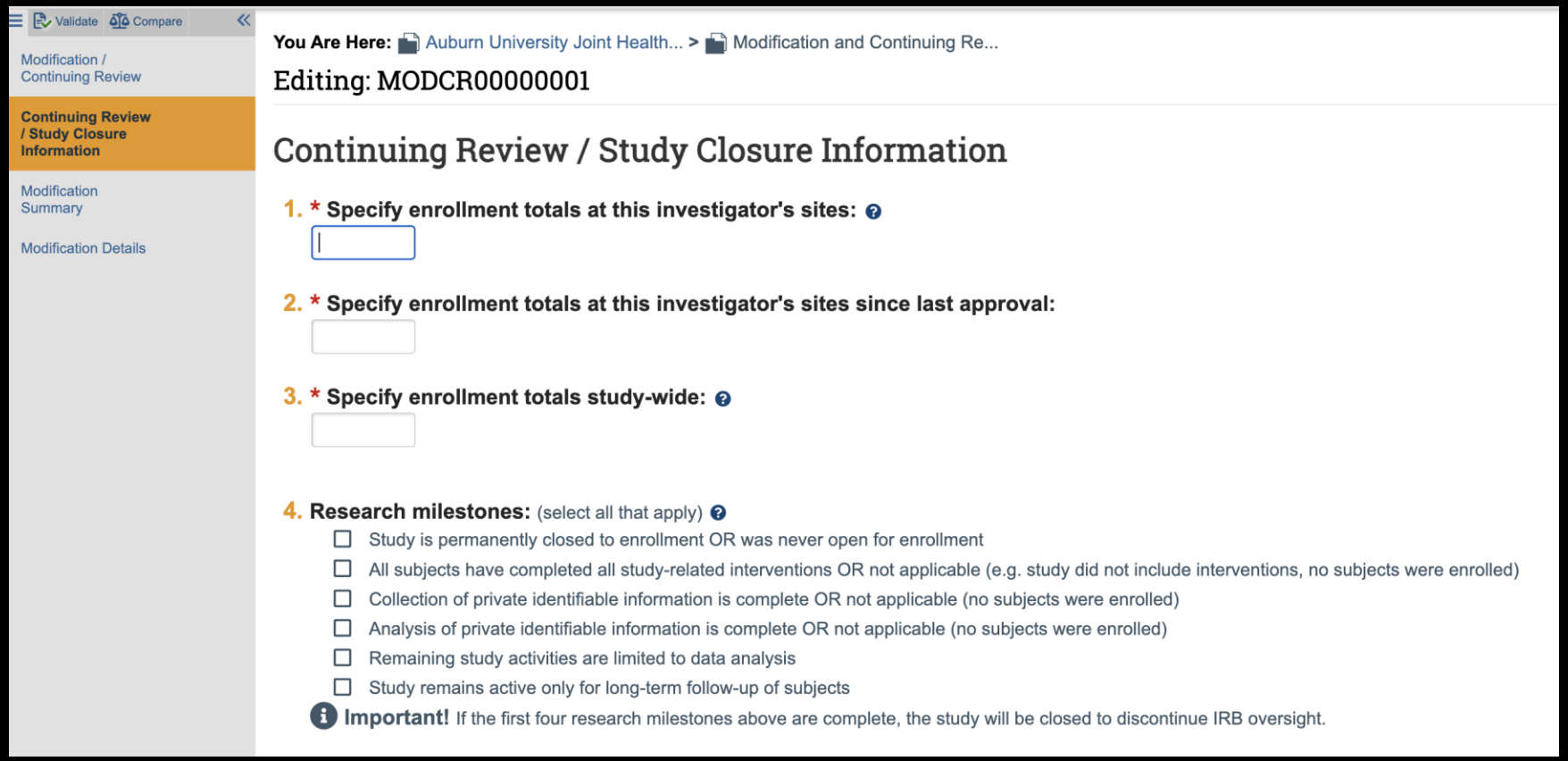
1. Once you select **Save** or **Continue**, you will not be able to edit the purpose or scope of your modification. If an incorrect response was chosen for either '**What is the purpose of this submission?**' or '**Modification Scope**' and the form has been saved, then click **Exit** to leave the submission

2. Select **Discard** from the left menu bar. A new **Modification/CR** request will need to be created to continue with the modification request.

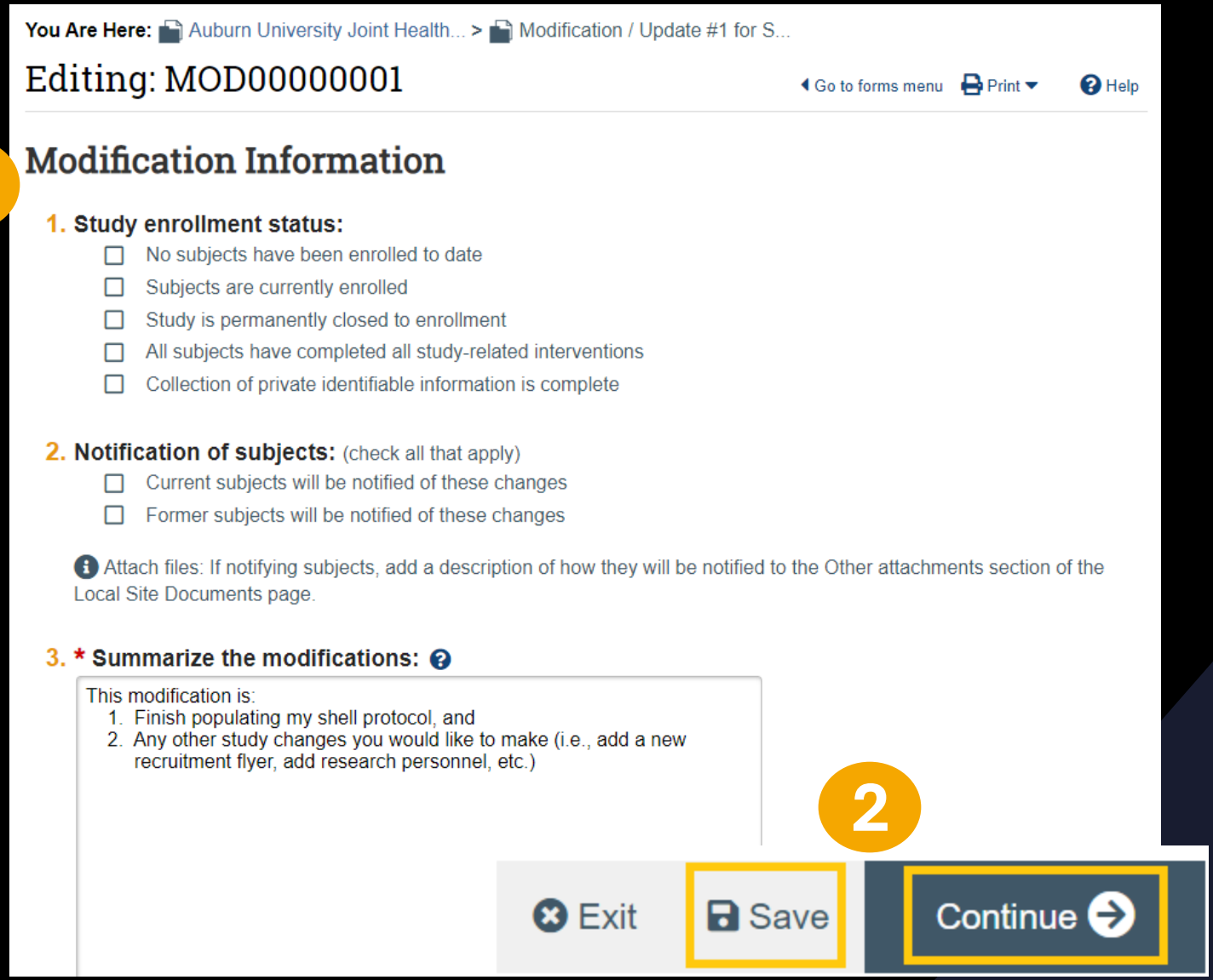
   NOTE: If you have an open modification request, the system will not allow you to create another modification of the same scope.



Complete the **Continuing Review** activity. The information requested on the CR SmartForm is nearly identical to what was requested on the old renewal forms. Read carefully over Question 4 and select only the response(s) that apply. If none apply, do not check any boxes.

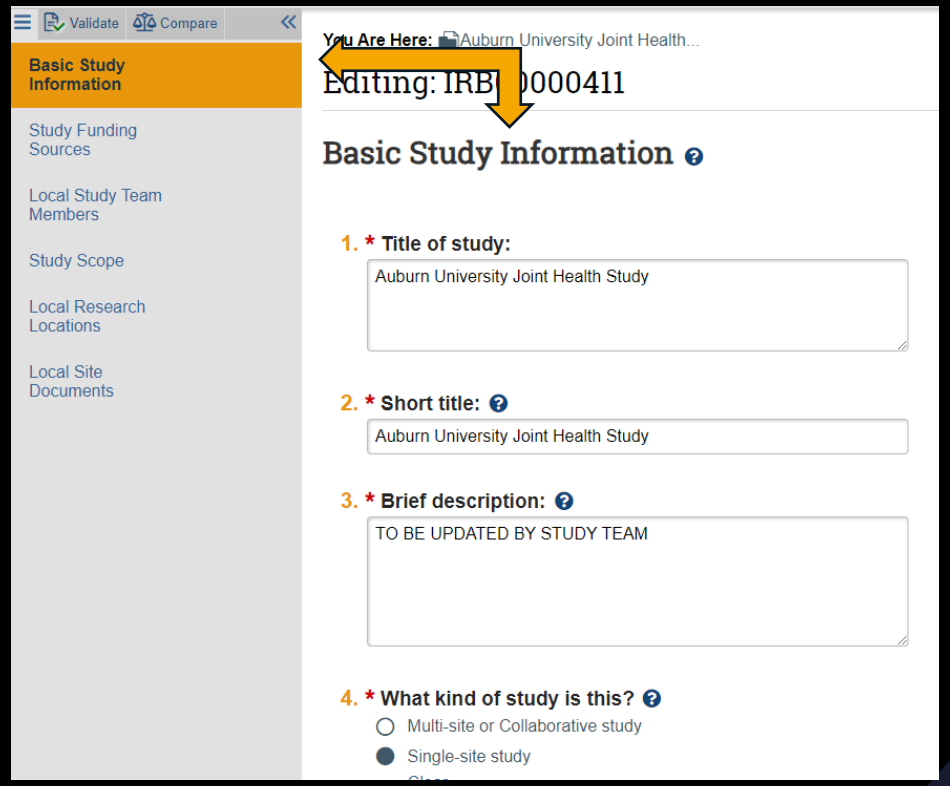


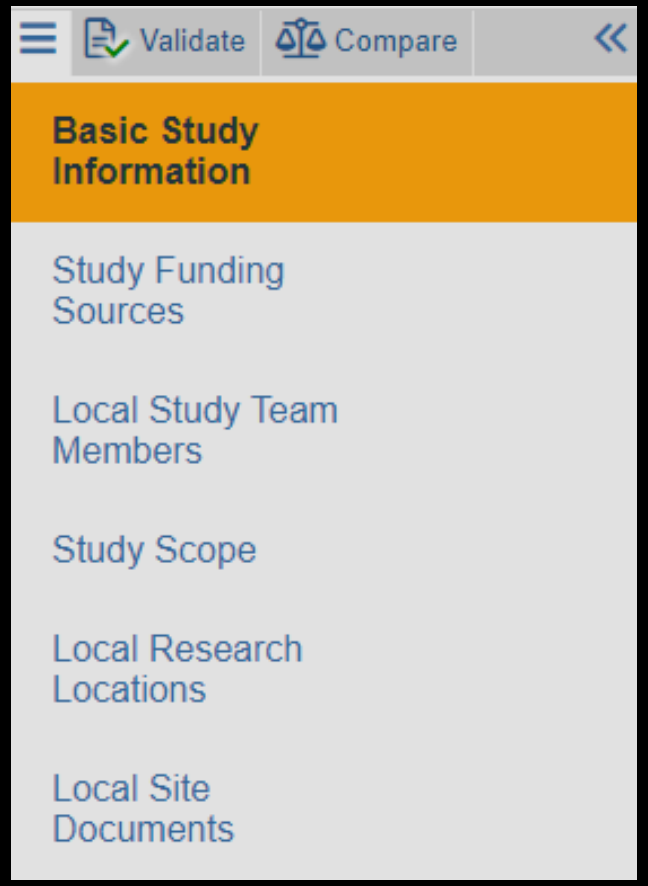
1. Complete the **Modification Summary**.
   - Provide answers to all questions.
   - In addition to completing the migration of your study, you may also take this opportunity to make planned modification to your protocol, just be sure to identify what changes are being made and upload all the appropriate documents.
2. Select **Save** and then **Continue**.
   - Once you click **Continue**, you will be re-directed to the application to make edits.



Navigate the IRB Application

1. The page navigator is located on the left side of the screen. It consists of SmartForms and allows the user to switch between the main pages of the IRB application. The page currently being viewed will be shown highlighted in orange.
2. **IMPORTANT**: During your first submission, you will need to go through every page of the application and fill in all missing data. The best approach is to navigate the application in the order it is presented and click **Save** and then **Continue** at the bottom of each page.



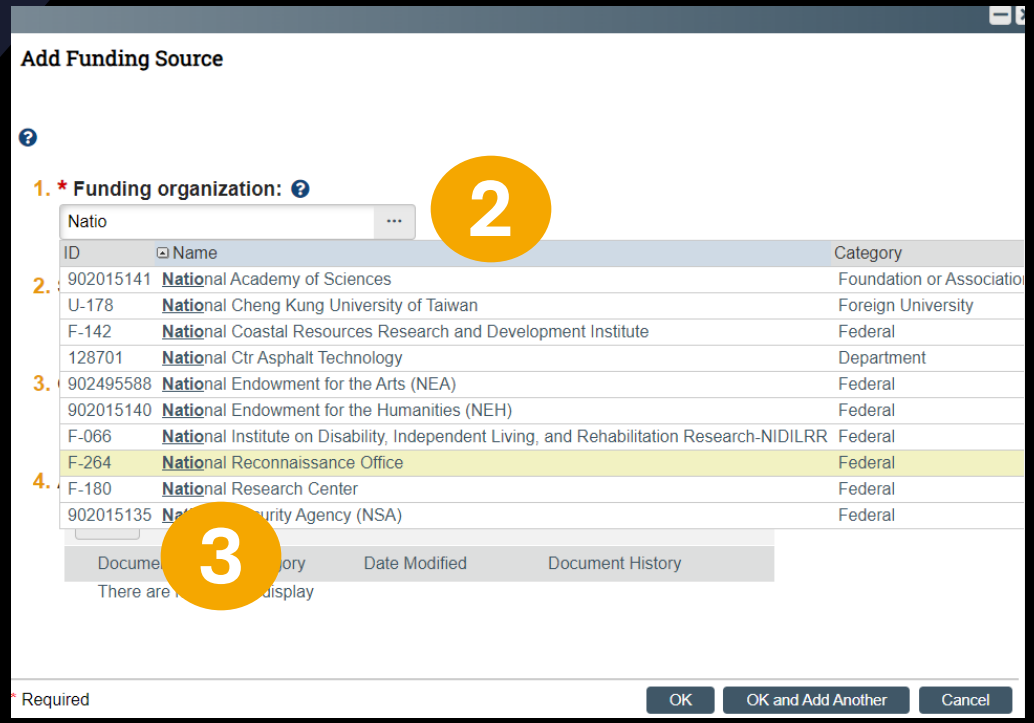


Completing Migration to Endeavor with No Study Changes

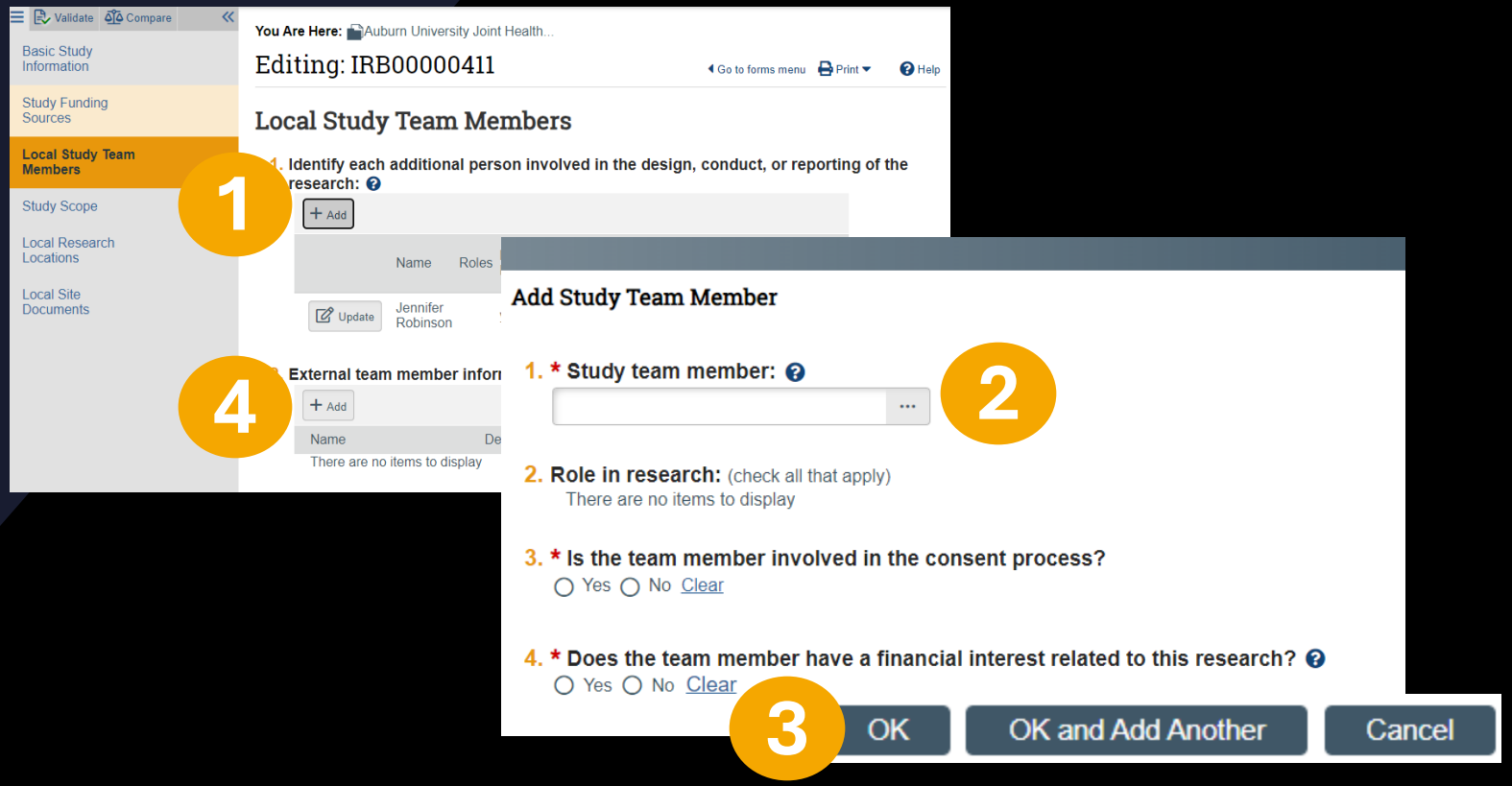
1. All questions marked with a red asterisk (*) require a response.
2. 'Shell' study information was migrated from SharePoint, including:
   - Study ID
   - Title of Study
   - Short Title
   - Reviewing IRB information
   - Name of the Principal Investigator (PI) (**NOTE**: If the PI was a student, the Faculty Advisor was transferred to PI status to be in-line with the PI Eligibility Statement)
3. Action items:
   - Ensure all information is accurate.
   - Transfer all your currently approved study documents onto Endeavor templates. This includes the protocol template, informed consent document(s), recruitment materials, etc. These documents must be in Microsoft Word format. Use Track Changes to show revisions to original study materials. The AU IRB will only accept Endeavor templates beginning August 1, 2024.
   - Update any information that is incorrect or missing, including basic information, funding sources, local study team members (key study personnel), and research locations.
   - Be sure to attach your IRB-approved and stamped protocol packet under **Local Site Documents → Other Attachments**.

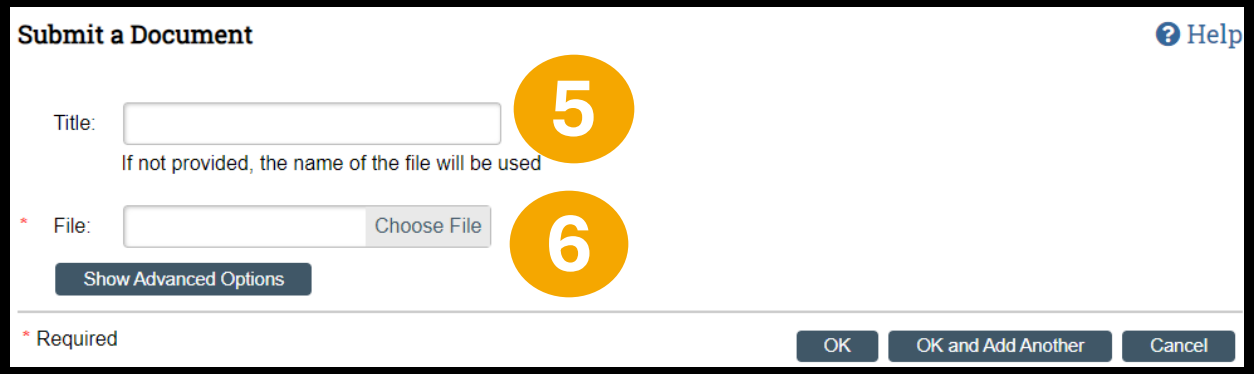
Protocol Templates

- You will be asked to upload a protocol in the **Basic Study Information** SmartForm.
- There are two primary research protocol templates:
  - HRP-503 – TEMPLATE – Protocol: Use this template for expedited and full-board studies
  - HRP-503a – TEMPLATE – Exempt Protocol: Use this template for exempt studies
- Transfer your IRB-approved protocol information into the Microsoft Word template most applicable to your study. Once you have completed the transfer, turn on Track Changes and add missing information, update relevant sections with revisions, etc.
- Be sure to upload the Microsoft Word version of the template. **NOTE:** Do not convert it to a PDF.



1. Add any study funding sources. To do this, click on the +Add tab.
2. This will bring up a pop-up window. You can then begin typing the funding organization and a list of pre-populated sources will generate. Select your funding source from the list. **NOTE:** When searching for a funding organization, use the '%' symbol to aid in searching. For example, if you are looking for NIH, it will not populate if you just search 'nih', but if you search %nih% you will get all entries with the 'nih', regardless of where it falls in the entry. If your funding source is not listed, please complete a support ticket at https://aub.ie/endeavorsupport.
3. Attach a copy of the grant or contract by clicking **+Add**.





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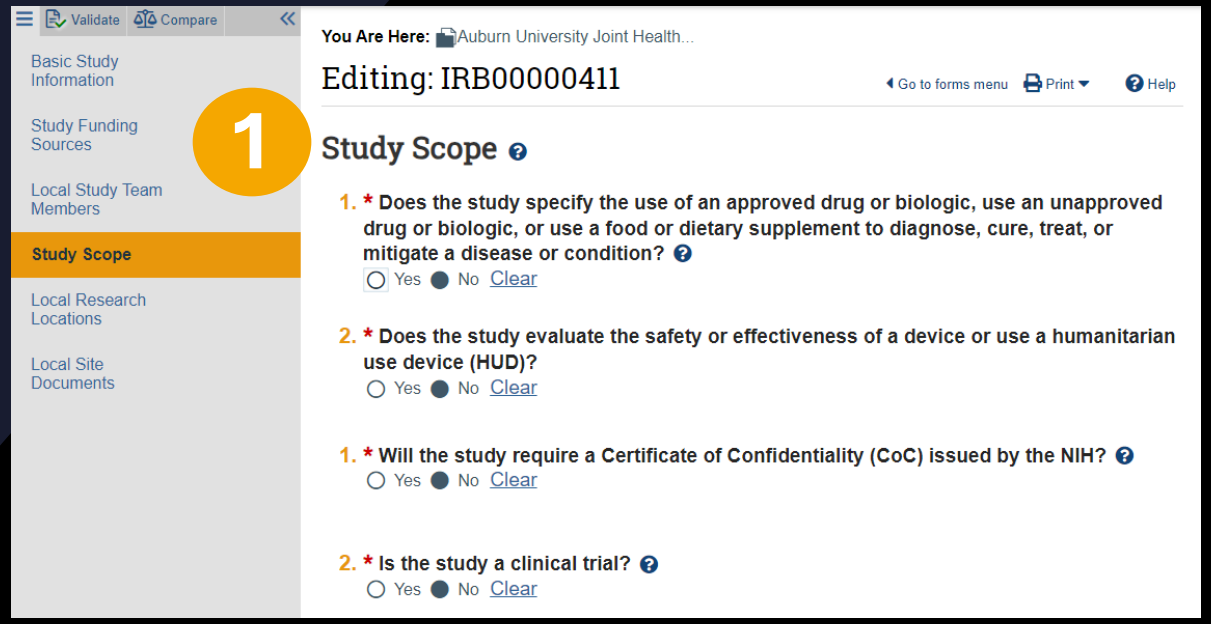

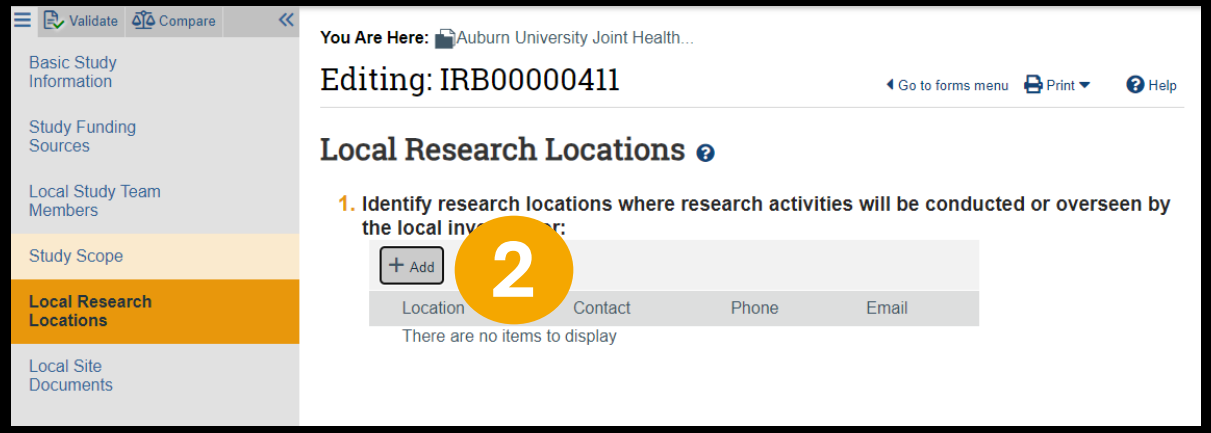

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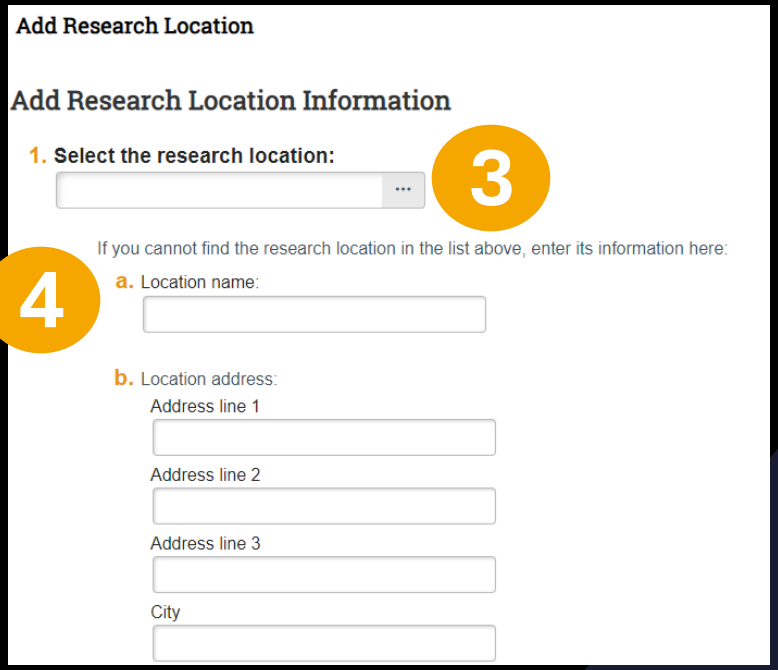

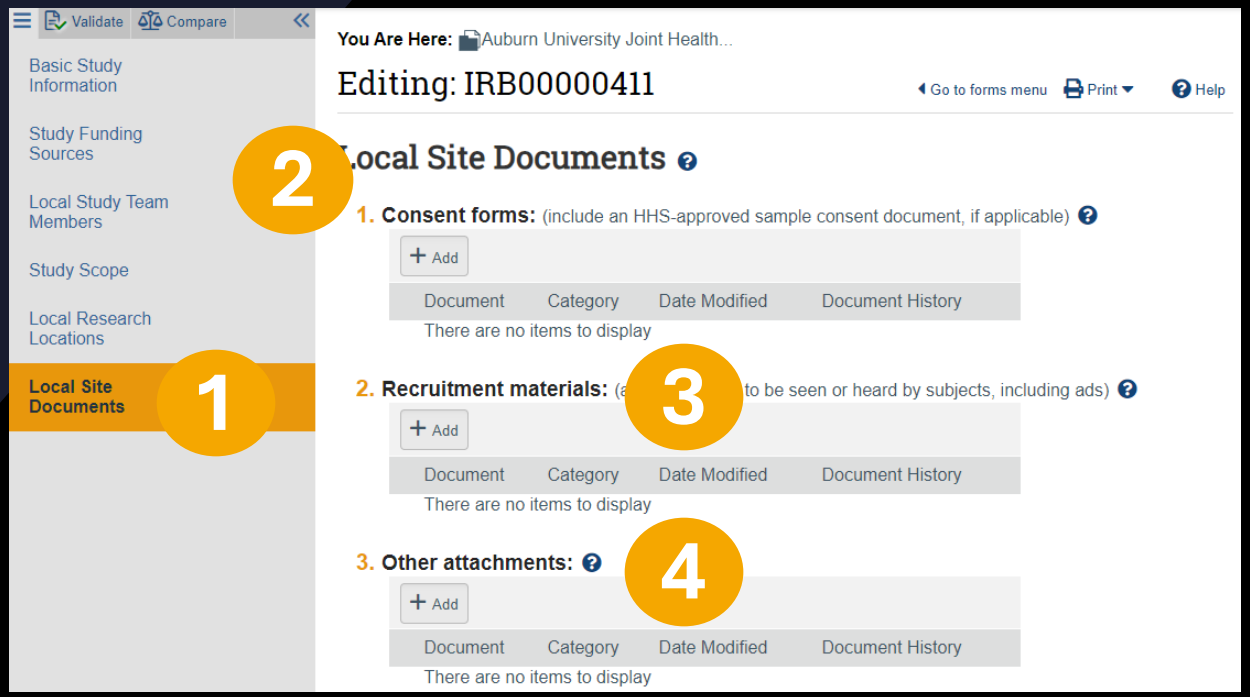

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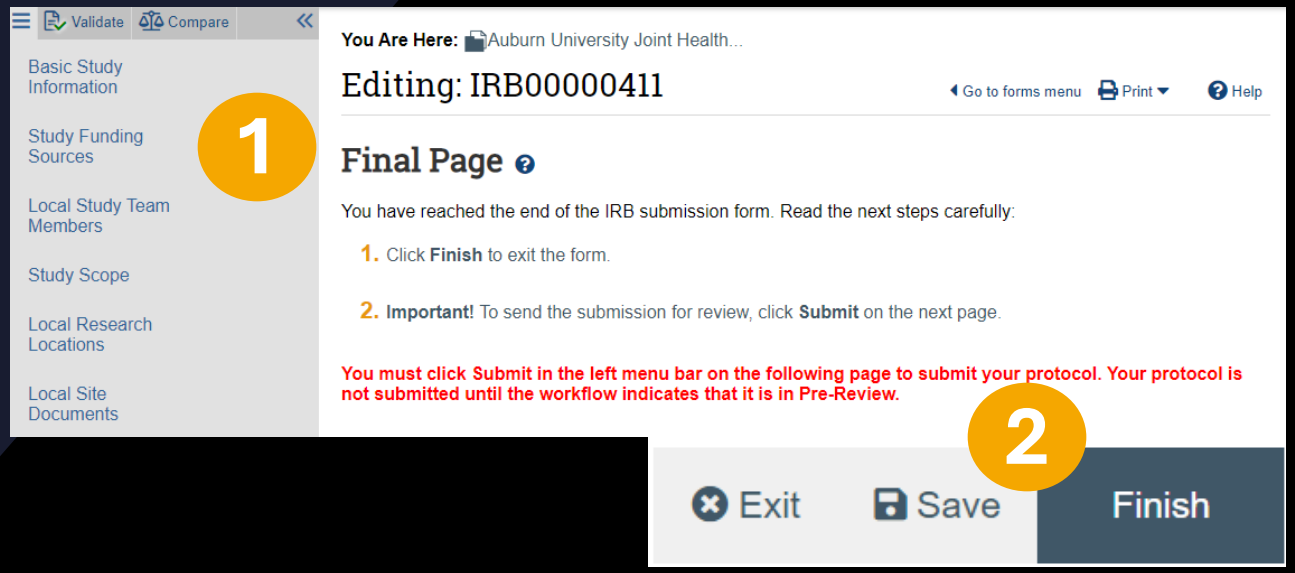
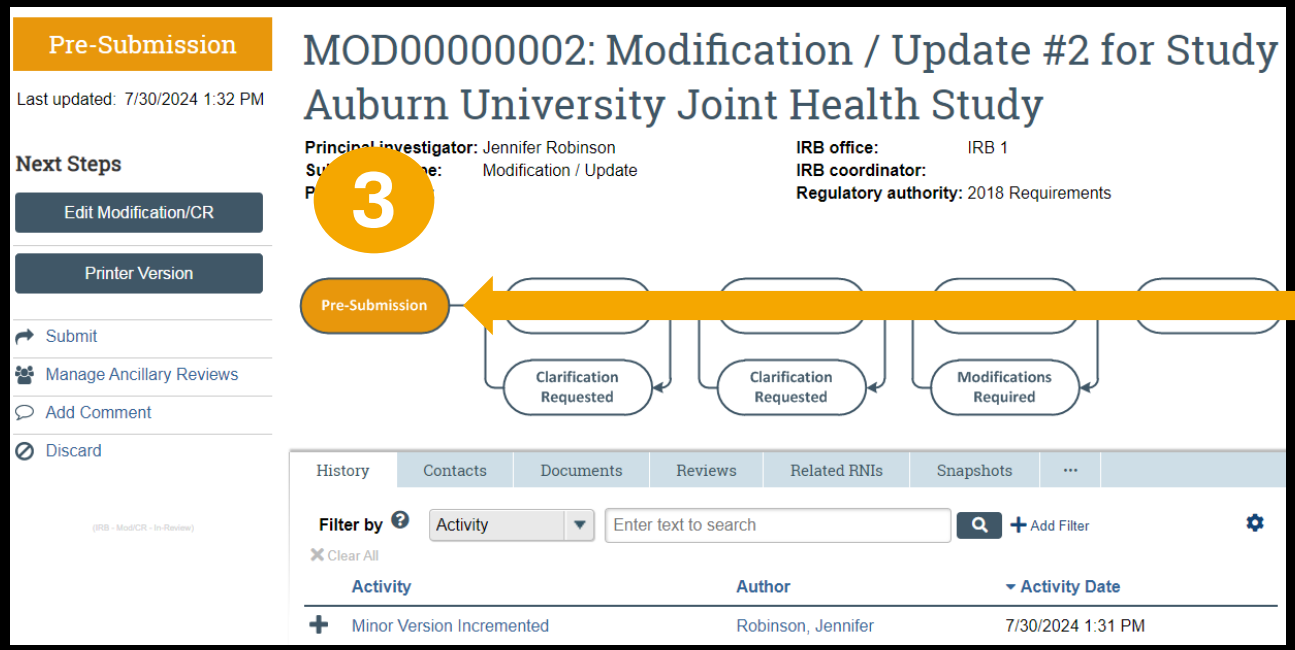
5. Click **Continue**.





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2. Click **Finish** to be routed back to the study view. **NOTE: CLICKING FINISH DOES NOT SUBMIT YOUR REQUEST**.
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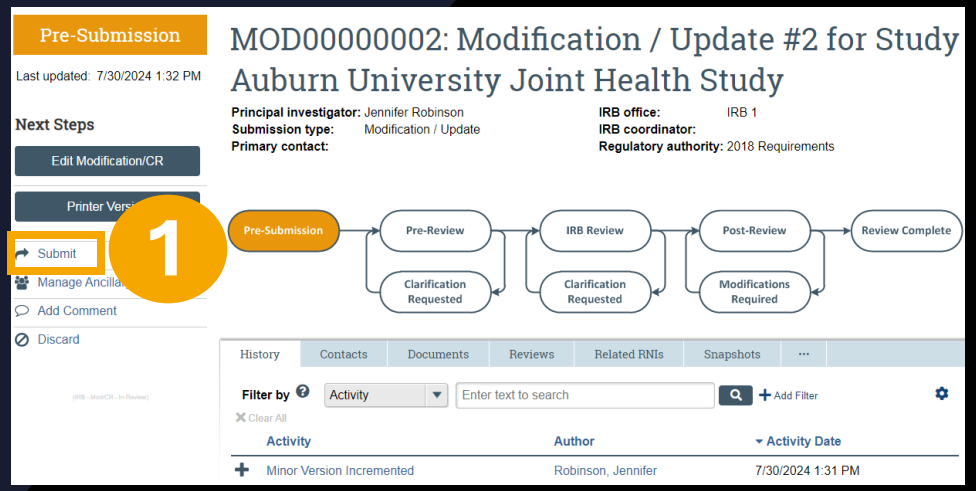

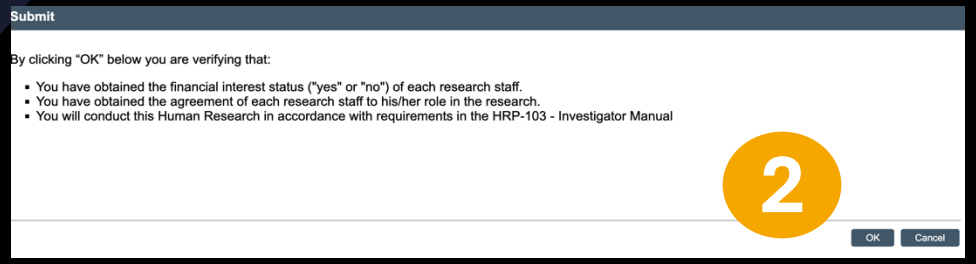

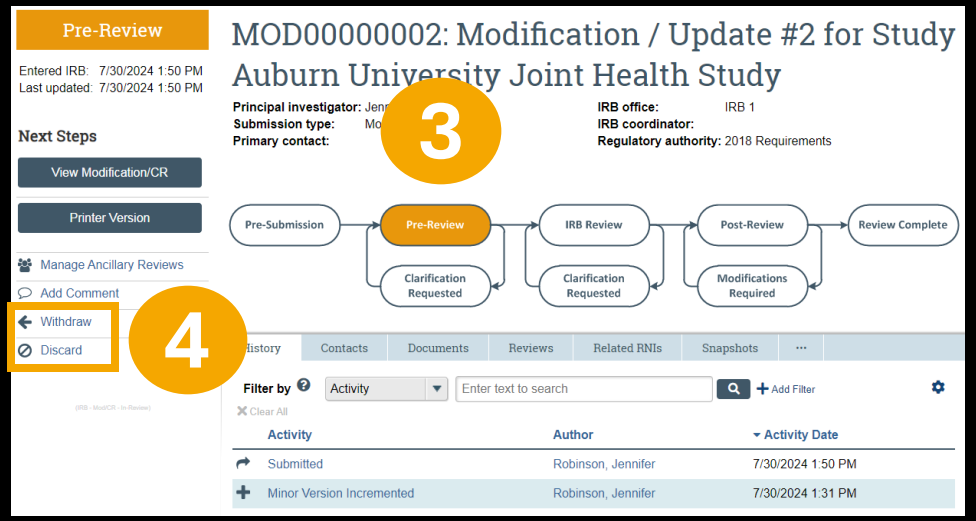

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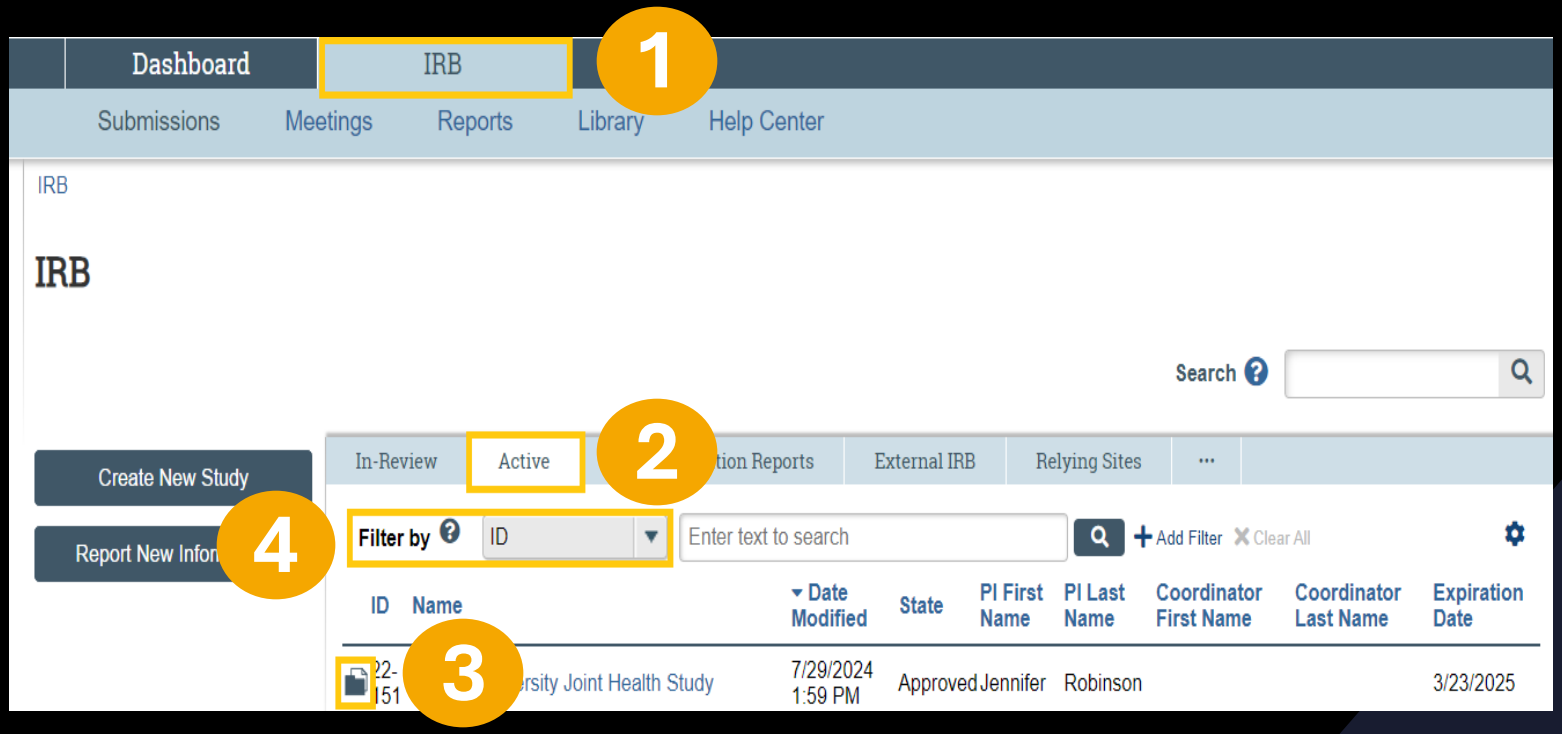
2. You must agree to the assurances to complete the **Submit** activity.
3. Your request is not submitted until you see the workflow bubble move to **Pre-Review.**
4. Congratulations! You have submitted your request. If you need to withdraw your request, you can use the **Withdraw** function in the left menu. Withdrawing will allow you to make changes and re-submit. Discarding will delete the submission.

OPTION D: CLOSING A STUDY

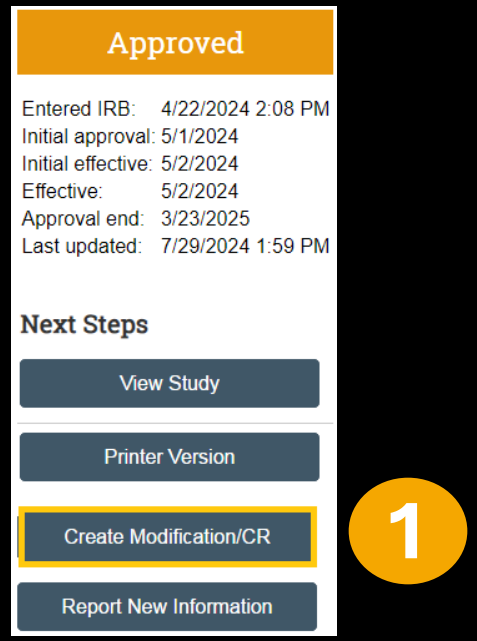
Getting Started

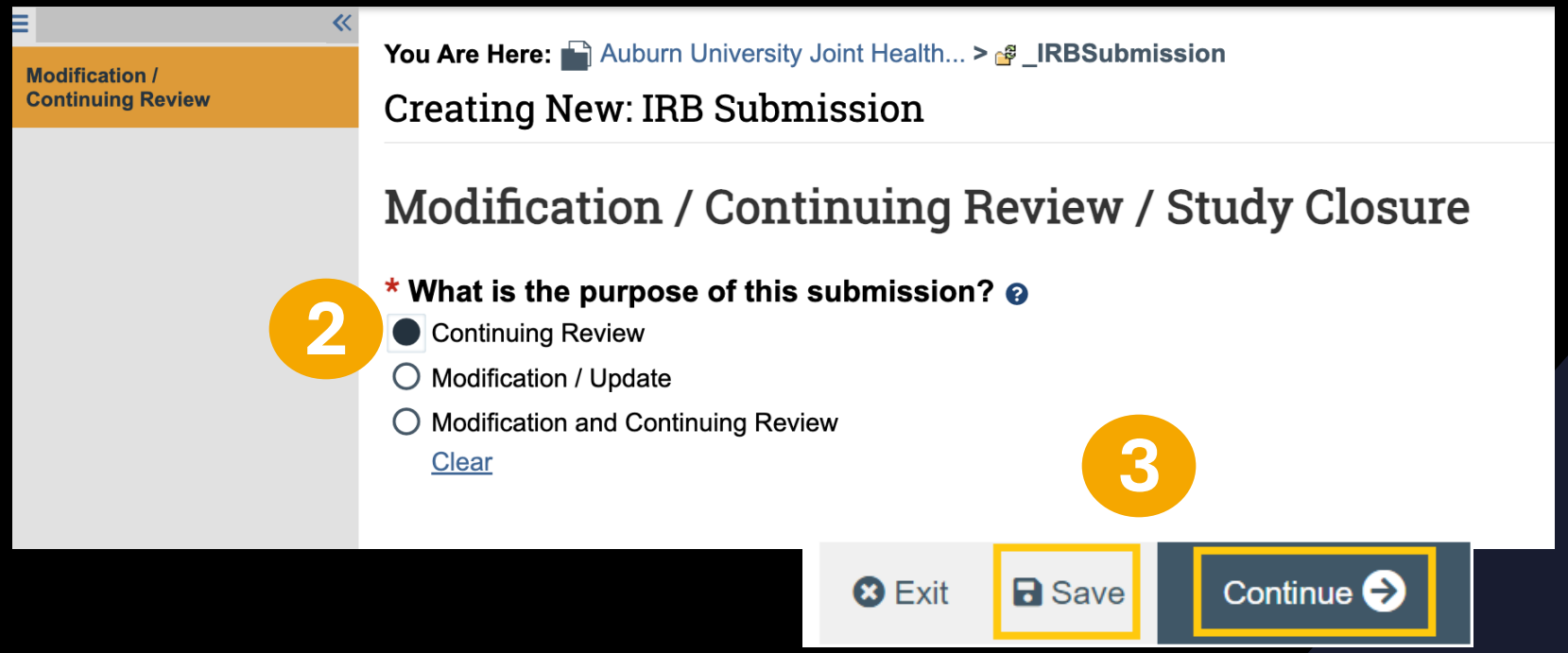
1. Navigate to the **IRB workspace**.
2. Select '**Active**'.
3. Open your study by selecting the folder symbol or the **name** of the study.
4. '**Filter by**' allows you to sort your studies by PI first and last name, expiration date, etc. You can add more than one filter by clicking on the '**+ Add Filter**'.



Creating a Modification

1. Select Create **Modification/CR**.
2. Select **Continuing Review**.
3. Click **Save** and **Continue**.



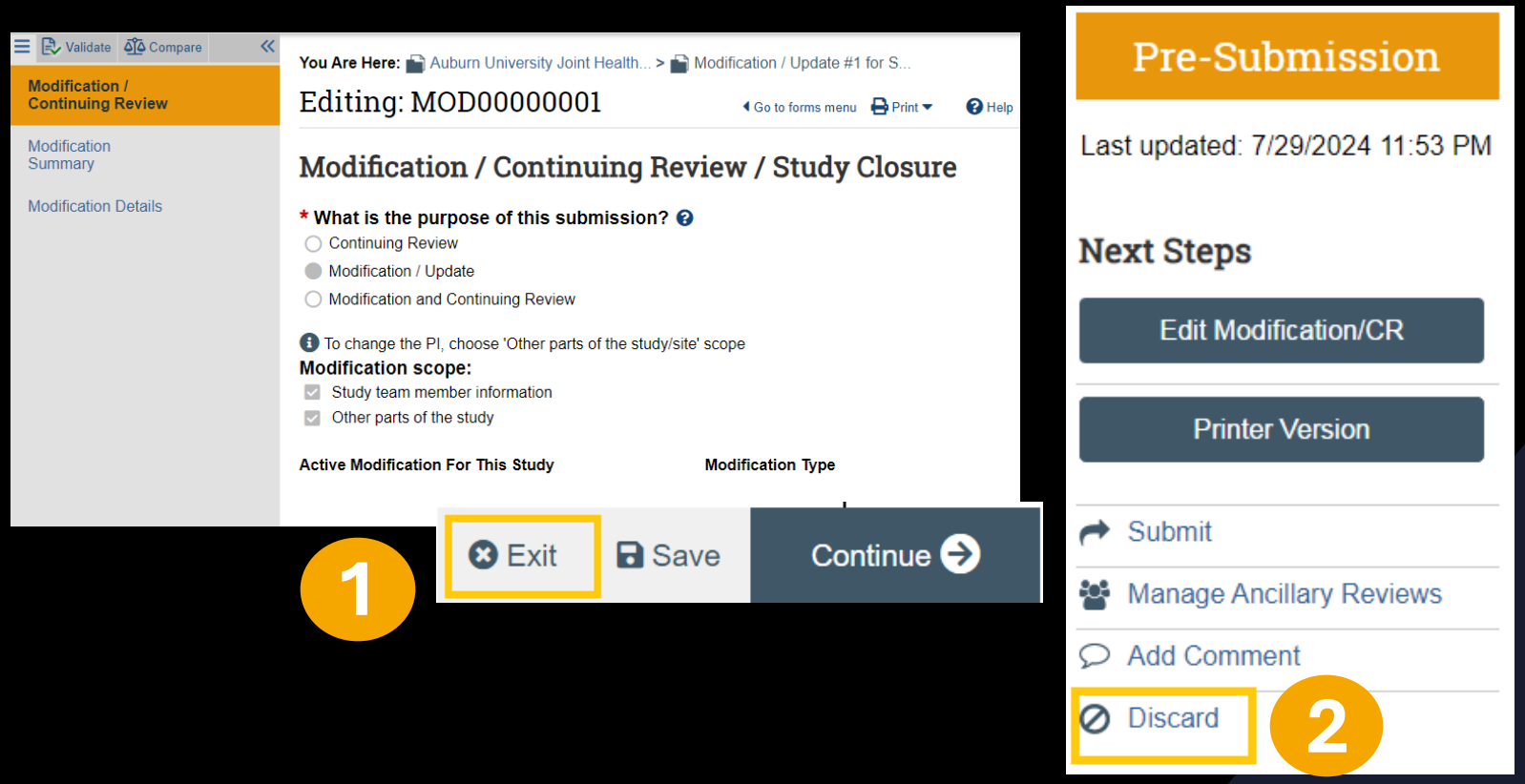


Discarding a Modification

1. Once you select **Save** or **Continue**, you will not be able to edit the purpose or scope of your modification. If an incorrect response was chosen for either '**What is the purpose of this submission?**' or '**Modification Scope**' and the form has been saved, then click **Exit** to leave the submission

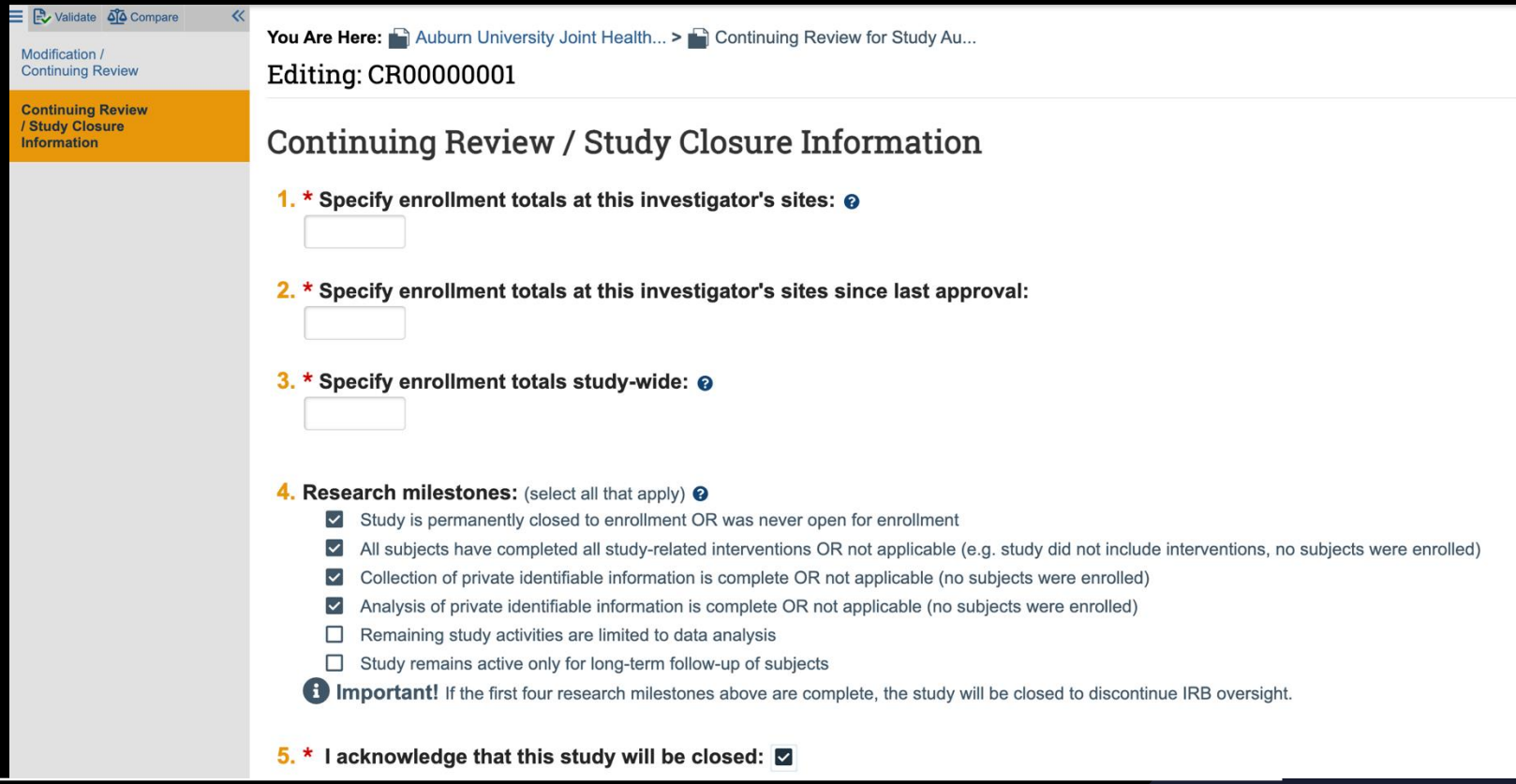
2. Select **Discard** from the left menu bar. A new **Modification/CR** request will need to be created to continue with the modification request.

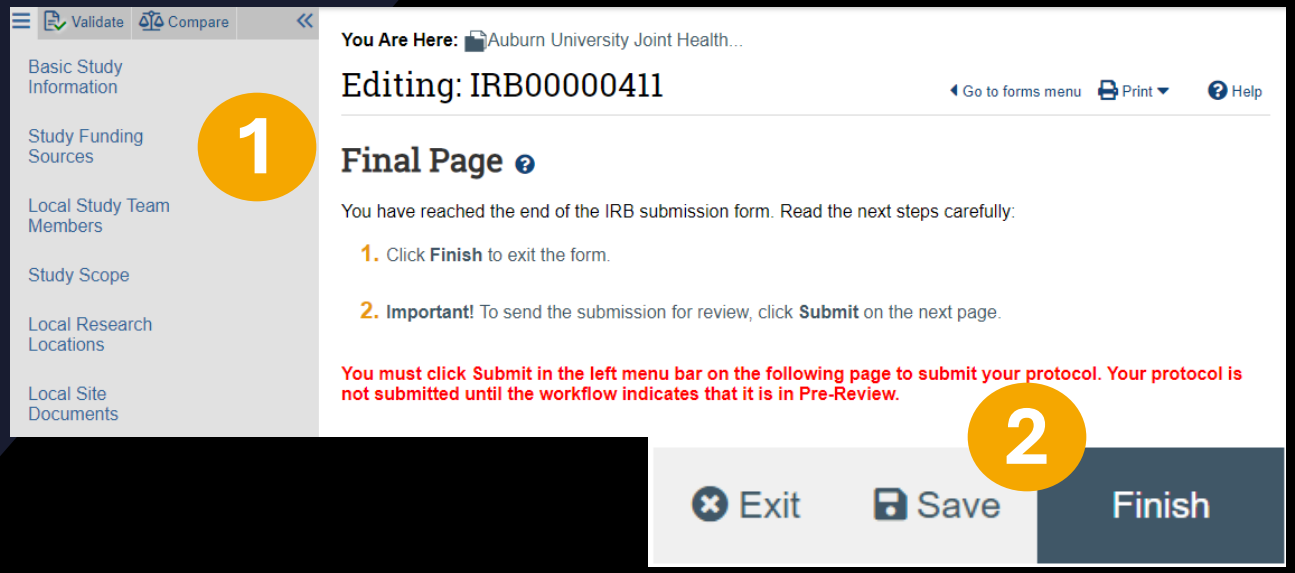
   NOTE: If you have an open modification request, the system will not allow you to create another modification of the same scope.

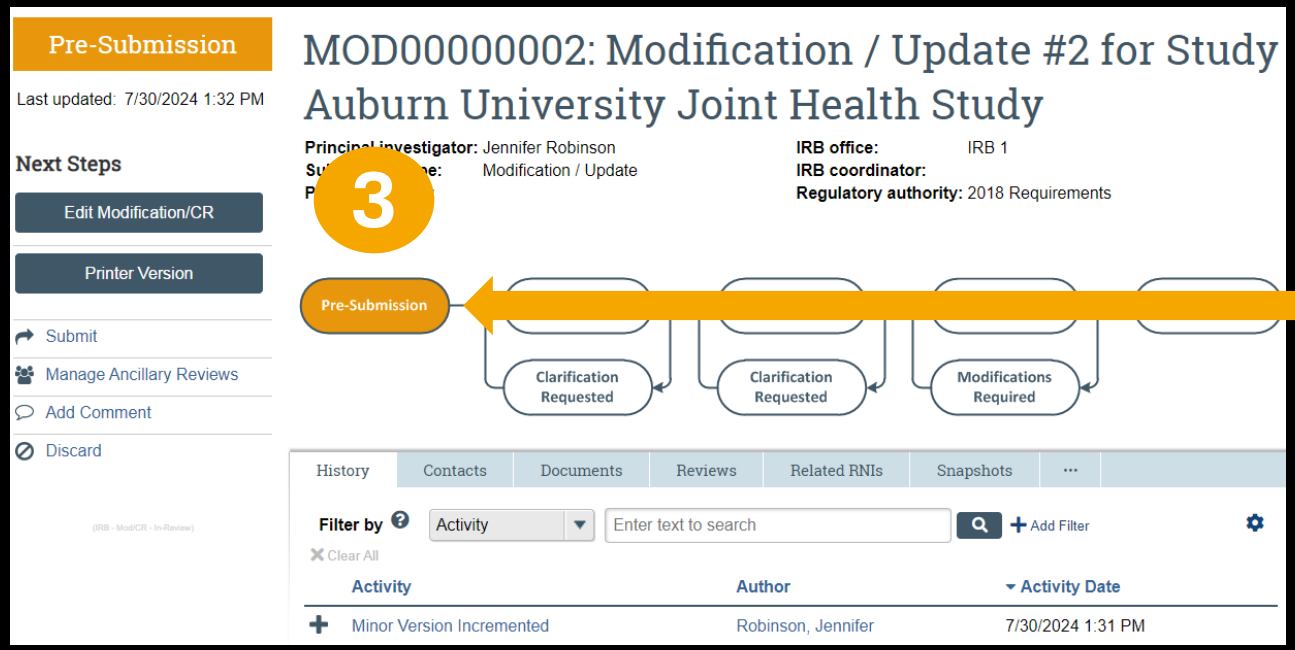


Closing the Study

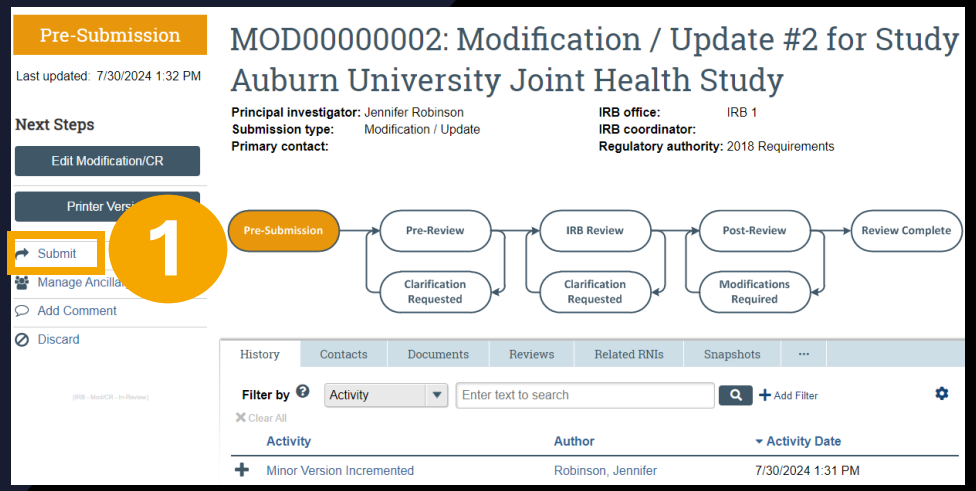
1. All questions with a red asterisk (*) require a response.
2. Select the first 4 milestones in **Question 4**.
3. Select ‘I acknowledge that this study will be closed’ in **Question 5**.
4. Complete the rest of the form, then click **Save** and then **Continue**.

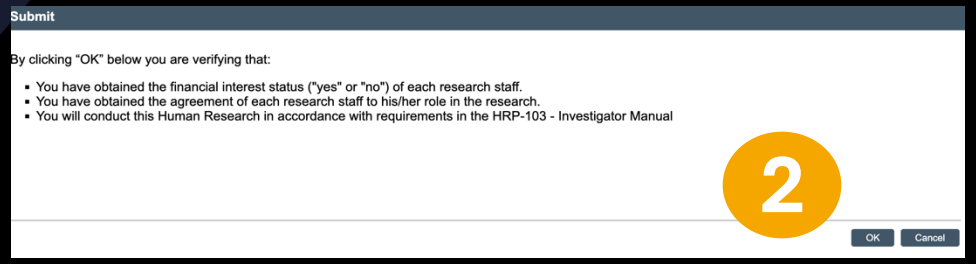


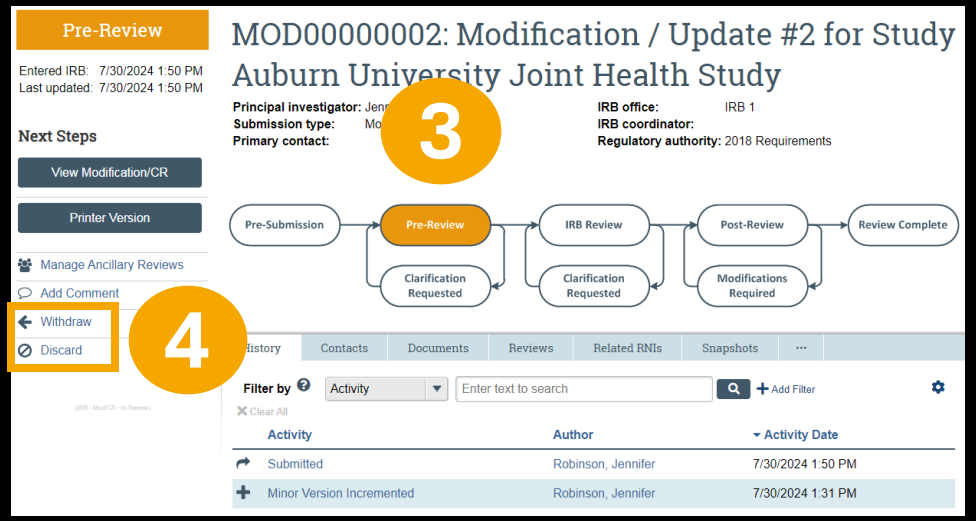




1. You will then be presented with a **Final Page** screen.
2. Click **Finish** to be routed back to the study view. **NOTE: CLICKING FINISH DOES NOT SUBMIT YOUR REQUEST**.
3. When you are routed back to the study screen, you will now see a workflow diagram. Your protocols place within the workflow is indicated by a solid orange fill. **Pre-Submission** means that it has not been submitted to the AU IRB.







1. You will need to click **Submit** in the left menu bar to submit your request.
2. You must agree to the assurances to complete the **Submit** activity.
3. Your request is not submitted until you see the workflow bubble move to **Pre-Review.**
4. Congratulations! You have submitted your request. If you need to withdraw your request, you can use the **Withdraw** function in the left menu. Withdrawing will allow you to make changes and re-submit. Discarding will delete the submission.