

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.

Approved

Entered IRB: 4/22/2024 2:08 PM

Initial approval: 5/1/2024

Initial effective: 5/2/2024

Effective: 5/2/2024

Approval end: 3/23/2025

Last updated: 7/29/2024 1:58

If there is a date here,
your study requires
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

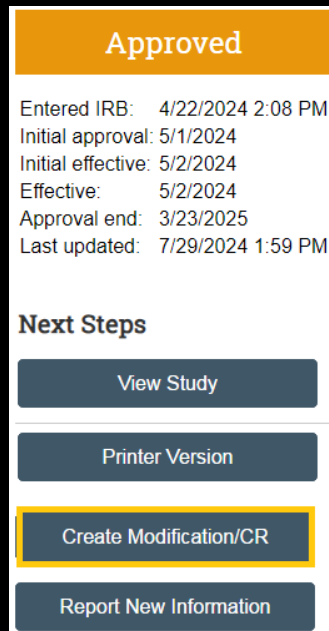
1. Navigate to the **IRB workspace**.
2. Select '**Active**'.
3. Open your study by selecting the folder symbol or the **name** of the study.
4. '**Filter by**' allows you to sort your studies by PI first and last name, expiration date, etc. You can add more than one filter by clicking on the '**+ Add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

The screenshot shows the IRB workspace interface. At the top, there is a navigation bar with tabs: Dashboard, IRB (highlighted with a yellow box and a red circle with the number 1), Submissions, Meetings, Reports, Library, and Help Center. Below this, there is a sub-navigation bar with tabs: In-Review, Active (highlighted with a yellow box and a red circle with the number 2), Pending Reports, External IRB, and Relying Sites. On the left side, there are two buttons: 'Create New Study' and 'Report New Information' (highlighted with a yellow box and a red circle with the number 4). The main content area displays a list of studies. The first study is highlighted with a yellow box and a red circle with the number 3. The study details are as follows:

ID	Name	Date Modified	State	PI First Name	PI Last Name	Coordinator First Name	Coordinator Last Name	Expiration Date
22-151	University Joint Health Study	7/29/2024 1:59 PM	Approved	Jennifer	Robinson			3/23/2025

Creating a Modification

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



Approved

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Last updated: 7/29/2024 1:59 PM

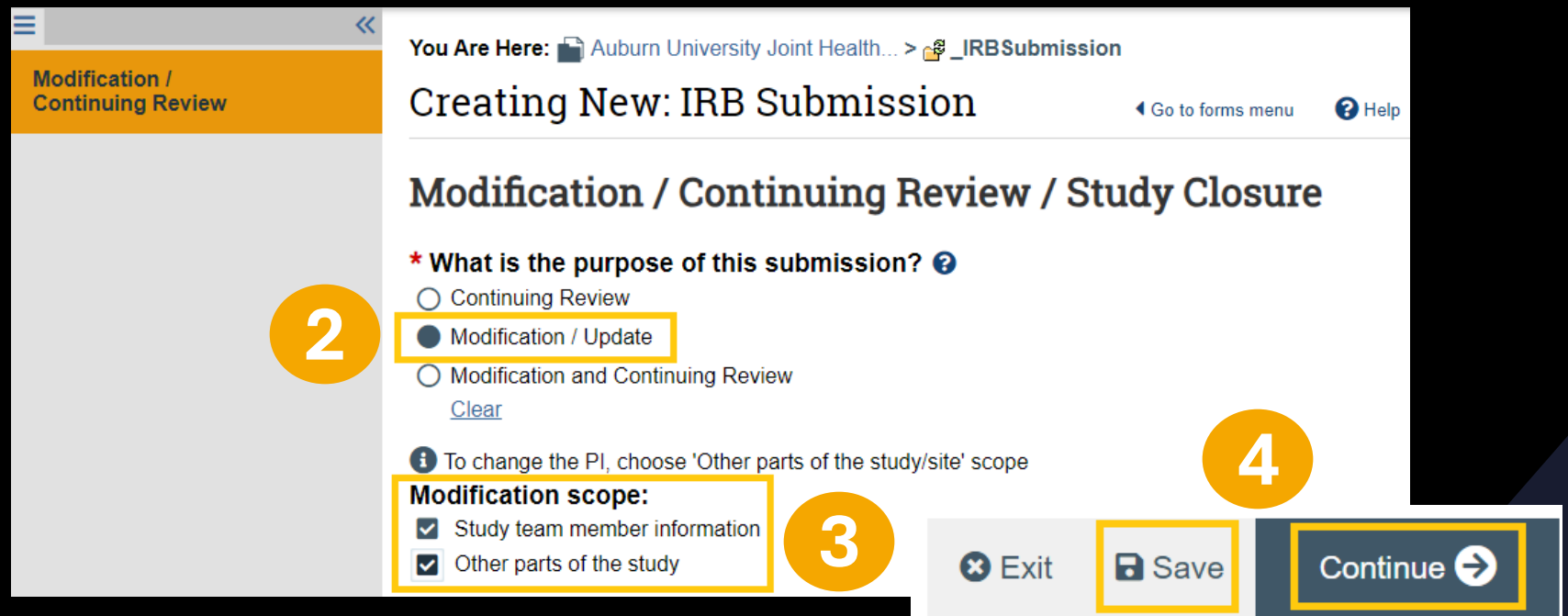
Next Steps

[View Study](#)

[Printer Version](#)

Create Modification/CR

[Report New Information](#)



Modification / Continuing Review

You Are Here: Auburn University Joint Health... > _IRBSubmission

Creating New: IRB Submission

[Go to forms menu](#) [Help](#)

Modification / Continuing Review / Study Closure

* What is the purpose of this submission? ?

☐ Continuing Review

Modification / Update

☐ Modification and Continuing Review

[Clear](#)

To change the PI, choose 'Other parts of the study/site' scope

Modification scope:

☒ Study team member information

☒ Other parts of the study

[Exit](#) [Save](#) [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.

Validation Compare

You Are Here: Auburn University Joint Health... > Modification / Update #1 for S...

Editing: MOD00000001

Go to forms menu Print Help

Modification / Continuing Review / Study Closure

* What is the purpose of this submission?

☐ Continuing Review

☒ Modification / Update

☐ Modification and Continuing Review

To change the PI, choose 'Other parts of the study/site' scope

Modification scope:

☒ Study team member information

☒ Other parts of the study

Active Modification For This Study

Modification Type

Exit Save Continue

Pre-Submission

Last updated: 7/29/2024 11:53 PM

Next Steps

Edit Modification/CR

Printer Version

Submit

Manage Ancillary Reviews

Add Comment

Discard

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.

You Are Here: Auburn University Joint Health... > Modification / Update #1 for S...

Editing: MOD00000001 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:**

This modification is:

1. Finish populating my shell protocol, and
2. Any other study changes you would like to make (i.e., add a new recruitment flyer, add research personnel, etc.)

Exit Save

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.

The screenshot displays the IRB application interface. On the left, a sidebar contains a list of navigation items: 'Basic Study Information' (highlighted in orange), 'Study Funding Sources', 'Local Study Team Members', 'Study Scope', 'Local Research Locations', and 'Local Site Documents'. The main content area is titled 'Basic Study Information' and contains four numbered sections:

- 1. * **Title of study:** A text input field containing 'Auburn University Joint Health Study'.
- 2. * **Short title:** A text input field containing 'Auburn University Joint Health Study'.
- 3. * **Brief description:** A text input field containing 'TO BE UPDATED BY STUDY TEAM'.
- 4. * **What kind of study is this?** Two radio button options: 'Multi-site or Collaborative study' (unselected) and 'Single-site study' (selected).

At the top of the main content area, there is a breadcrumb trail: 'You Are Here: Auburn University Joint Health...' followed by 'Editing: IRB 0000411'. An orange arrow points from the breadcrumb text down to the 'Basic Study Information' title.

Basic Study Information

Study Funding Sources

Local Study Team Members

Study Scope

Local Research Locations

Local Site Documents

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.

You Are Here: Auburn University Joint Health...

Editing: IRB00000411

Go to forms menu Print Help

Study Funding Sources

1. Identify each organization supplying funding for the study:

+ Add

Funding Source	Sponsor's Funding ID	Grants Office ID	Attachments
There are no items to display			

Basic Study Information

Study Funding Sources

Local Study Team Members

Study Scope

Local Research Locations

Local Site Documents

Add Funding Source

1. * Funding organization: ?

Natio

2

ID	Name	Category
902015141	National Academy of Sciences	Foundation or Association
U-178	National Cheng Kung University of Taiwan	Foreign University
F-142	National Coastal Resources Research and Development Institute	Federal
128701	National Ctr Asphalt Technology	Department
902495588	National Endowment for the Arts (NEA)	Federal
902015140	National Endowment for the Humanities (NEH)	Federal
F-066	National Institute on Disability, Independent Living, and Rehabilitation Research-NIDILRR	Federal
F-264	National Reconnaissance Office	Federal
F-180	National Research Center	Federal
902015135	National Security Agency (NSA)	Federal

3

Document History Date Modified Document History

There are no items to display

* Required

OK OK and Add Another Cancel

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.

Validate Compare

You Are Here: Auburn University Joint Health...

Editing: IRB00000411

Go to forms menu Print Help

Basic Study Information

Study Funding Sources

Local Study Team Members

Study Scope

Local Research Locations

Local Site Documents

1. Identify each additional person involved in the design, conduct, or reporting of the research: ?

+ Add

Name	Roles
Jennifer Robinson	

Update

External team member information

+ Add

Name	De
There are no items to display	

Add Study Team Member

1. * Study team member: ?

2. Role in research: (check all that apply)
There are no items to display

3. * Is the team member involved in the consent process?
☐ Yes ☐ No [Clear](#)

4. * Does the team member have a financial interest related to this research? ?
☐ Yes ☐ No [Clear](#)

OK OK and Add Another Cancel

Submit a Document

Help

Title:

If not provided, the name of the file will be used

* File: Choose File

Show Advanced Options

* Required

OK OK and Add Another Cancel

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**.

Validate Compare

You Are Here: Auburn University Joint Health...

Editing: IRB00000411

Go to forms menu Print Help

1 Study Scope ?

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? ?

☐ Yes ☒ No [Clear](#)

2. * Does the study evaluate the safety or effectiveness of a device or use a humanitarian use device (HUD)?

☐ Yes ☒ No [Clear](#)

1. * Will the study require a Certificate of Confidentiality (CoC) issued by the NIH? ?

☐ Yes ☒ No [Clear](#)

2. * Is the study a clinical trial? ?

☐ Yes ☒ No [Clear](#)

Validate Compare

You Are Here: Auburn University Joint Health...

Editing: IRB00000411

Go to forms menu Print Help

Local Research Locations ?

1. Identify research locations where research activities will be conducted or overseen by the local investigator:

[+ Add](#)

Location	Contact	Phone	Email
There are no items to display			

2

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**.

Add Research Location

Add Research Location Information

1. Select the research location:

3

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

4

a. Location name:

b. Location address:

Address line 1

Address line 2

Address line 3

City

Validate Compare

Basic Study Information

Study Funding Sources

Local Study Team Members

Study Scope

Local Research Locations

Local Site Documents

You Are Here: Auburn University Joint Health...

Editing: IRB00000411

Go to forms menu Print Help

Local Site Documents ?

1. **Consent forms:** (include an HHS-approved sample consent document, if applicable) ?

+ Add

Document	Category	Date Modified	Document History
There are no items to display			

2. **Recruitment materials:** (add all material to be seen or heard by subjects, including ads) ?

+ Add

Document	Category	Date Modified	Document History
There are no items to display			

3. **Other attachments:** ?

+ Add

Document	Category	Date Modified	Document History
There are no items to display			

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**.

Validate Compare

You Are Here: Auburn University Joint Health...

Editing: IRB00000411

Go to forms menu Print Help

1 Final Page

You have reached the end of the IRB submission form. Read the next steps carefully:

1. Click **Finish** to exit the form.
2. **Important!** To send the submission for review, click **Submit** on the next page.

You must click **Submit** in the left menu bar on the following page to submit your protocol. Your protocol is not submitted until the workflow indicates that it is in **Pre-Review**.

Exit Save **2** Finish

Pre-Submission

Last updated: 7/30/2024 1:32 PM

Next Steps

Edit Modification/CR

Printer Version

Submit

Manage Ancillary Reviews

Add Comment

Discard

3 MOD00000002: Modification / Update #2 for Study Auburn University Joint Health Study

Principal investigator: Jennifer Robinson
Submission type: Modification / Update

IRB office: IRB 1
IRB coordinator:
Regulatory authority: 2018 Requirements

Pre-Submission

Clarification Requested

Clarification Requested

Modifications Required

History Contacts Documents Reviews Related RNIs Snapshots ...

Filter by Activity Enter text to search

Clear All

Activity	Author	Activity Date
Minor Version Incremented	Robinson, Jennifer	7/30/2024 1:31 PM

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.

Pre-Submission

MOD00000002: Modification / Update #2 for Study
Auburn University Joint Health Study

Principal investigator: Jennifer Robinson
Submission type: Modification / Update
Primary contact:

IRB office: IRB 1
IRB coordinator:
Regulatory authority: 2018 Requirements

Last updated: 7/30/2024 1:32 PM

Next Steps

Edit Modification/CR

Printer Version

1 Submit

Manage Ancillary

Add Comment

Discard

Workflow:

```
graph LR; A[Pre-Submission] --> B[Pre-Review]; A --> C[Clarification Requested]; B --> D[IRB Review]; C --> D; D --> E[Post-Review]; D --> F[Clarification Requested]; E --> G[Review Complete]; F --> H[Modifications Required]; H --> G
```

History | Contacts | Documents | Reviews | Related RNIs | Snapshots | ...

Filter by Activity Enter text to search + Add Filter

Clear All

Activity	Author	Activity Date
Minor Version Incremented	Robinson, Jennifer	7/30/2024 1:31 PM

Submit

By clicking "OK" below you are verifying that:

- You have obtained the financial interest status ("yes" or "no") of each research staff.
- You have obtained the agreement of each research staff to his/her role in the research.
- You will conduct this Human Research in accordance with requirements in the HRP-103 - Investigator Manual

2

OK Cancel

Pre-Review

MOD00000002: Modification / Update #2 for Study
Auburn University Joint Health Study

Principal investigator: Jennifer Robinson
Submission type: Modification / Update
Primary contact:

IRB office: IRB 1
IRB coordinator:
Regulatory authority: 2018 Requirements

Entered IRB: 7/30/2024 1:50 PM
Last updated: 7/30/2024 1:50 PM

Next Steps

View Modification/CR

Printer Version

Manage Ancillary Reviews

Add Comment

4 Withdraw

Discard

Workflow:

```
graph LR; A[Pre-Submission] --> B[Pre-Review]; A --> C[Clarification Requested]; B --> D[IRB Review]; C --> D; D --> E[Post-Review]; D --> F[Clarification Requested]; E --> G[Review Complete]; F --> H[Modifications Required]; H --> G
```

History | Contacts | Documents | Reviews | Related RNIs | Snapshots | ...

Filter by Activity Enter text to search + Add Filter

Clear All

Activity	Author	Activity Date
Submitted	Robinson, Jennifer	7/30/2024 1:50 PM
Minor Version Incremented	Robinson, Jennifer	7/30/2024 1:31 PM

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

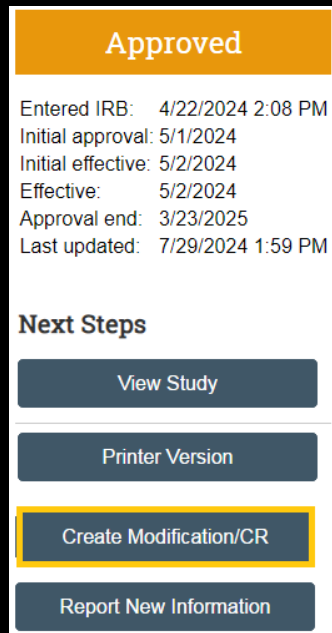
1. Navigate to the **IRB workspace**.
2. Select '**Active**'.
3. Open your study by selecting the folder symbol or the **name** of the study.
4. '**Filter by**' allows you to sort your studies by PI first and last name, expiration date, etc. You can add more than one filter by clicking on the '**+ Add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

The screenshot shows the IRB workspace interface. At the top, the 'IRB' tab is highlighted with a yellow box and a callout '1'. Below it, the 'Active' filter is selected with a yellow box and a callout '2'. On the left, the 'Filter by' dropdown is highlighted with a yellow box and a callout '4', and the 'ID' filter is selected with a yellow box and a callout '3'. The main table displays a list of studies, with the first row highlighted. The table has columns for ID, Name, Date Modified, State, PI First Name, PI Last Name, Coordinator First Name, Coordinator Last Name, and Expiration Date.

ID	Name	Date Modified	State	PI First Name	PI Last Name	Coordinator First Name	Coordinator Last Name	Expiration Date
22-151	University Joint Health Study	7/29/2024 1:59 PM	Approved	Jennifer	Robinson			3/23/2025

Creating a Modification

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



Approved

Entered IRB: 4/22/2024 2:08 PM
Initial approval: 5/1/2024
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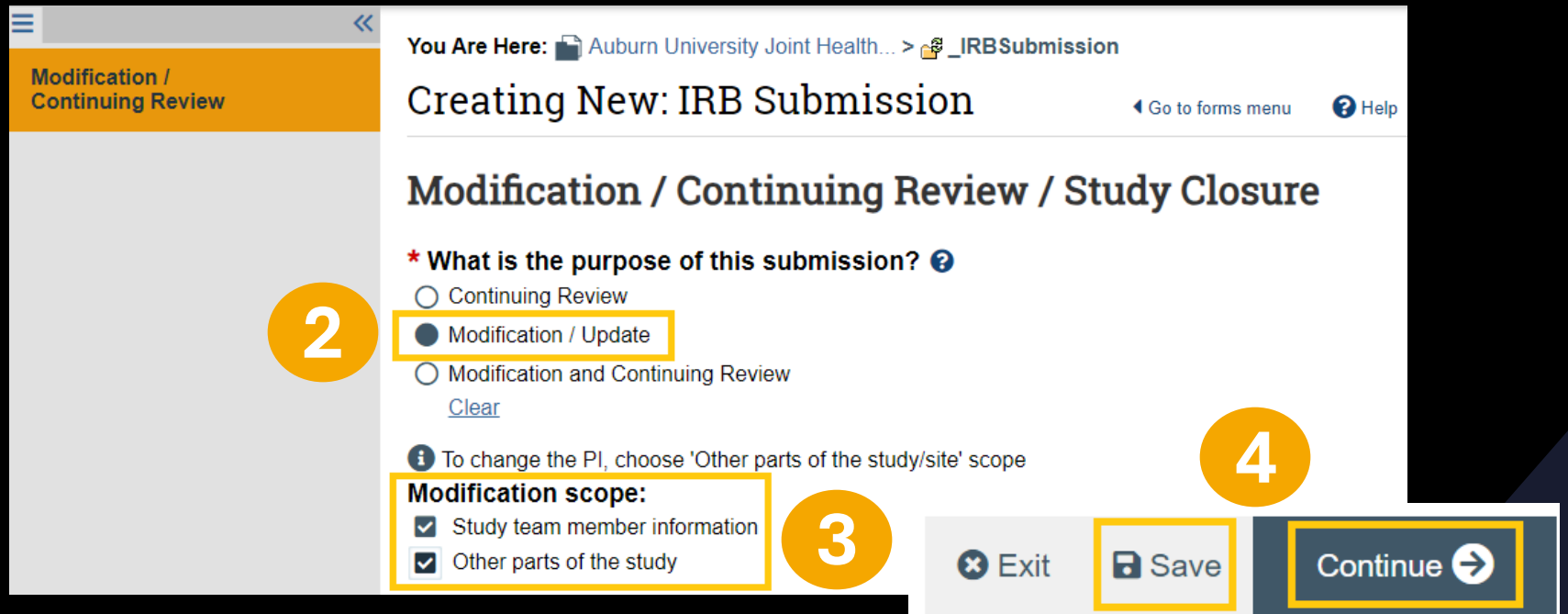
Next Steps

[View Study](#)

[Printer Version](#)

Create Modification/CR

[Report New Information](#)



Modification / Continuing Review

You Are Here: Auburn University Joint Health... > _IRBSubmission

Creating New: IRB Submission

[Go to forms menu](#) [Help](#)

Modification / Continuing Review / Study Closure

* What is the purpose of this submission? ?

☐ Continuing Review

Modification / Update

☐ Modification and Continuing Review

[Clear](#)

To change the PI, choose 'Other parts of the study/site' scope

Modification scope:

☒ Study team member information

☒ Other parts of the study

[Exit](#) [Save](#) [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.

Validation Compare

You Are Here: Auburn University Joint Health... > Modification / Update #1 for S...

Editing: MOD000000001

Go to forms menu Print Help

Modification / Continuing Review / Study Closure

* What is the purpose of this submission?

☐ Continuing Review

☐ Modification / Update

☐ Modification and Continuing Review

To change the PI, choose 'Other parts of the study/site' scope

Modification scope:

☒ Study team member information

☒ Other parts of the study

Active Modification For This Study

Modification Type

Exit Save Continue

1

Pre-Submission

Last updated: 7/29/2024 11:53 PM

Next Steps

Edit Modification/CR

Printer Version

Submit

Manage Ancillary Reviews

Add Comment

Discard

2

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.

You Are Here: Auburn University Joint Health... > Modification / Update #1 for S...

Editing: MOD00000001 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:

This modification is:

1. Finish populating my shell protocol, and
2. Any other study changes you would like to make (i.e., add a new recruitment flyer, add research personnel, etc.)

Exit Save

Navigate the IRB Application

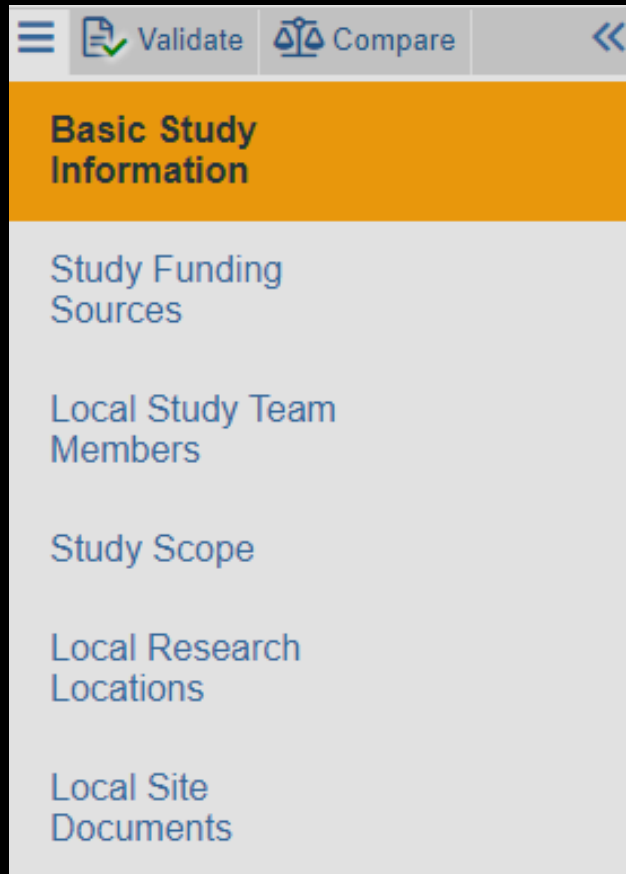
1. The page navigator is located on the left side of the screen. It consists of SmartForms and allows the user to switch between the main pages of the IRB application. The page currently being viewed will be shown highlighted in orange.
2. **IMPORTANT:** During your first submission, you will need to 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.

The screenshot displays the IRB application interface. On the left, a sidebar contains a list of navigation items: 'Basic Study Information' (highlighted in orange), 'Study Funding Sources', 'Local Study Team Members', 'Study Scope', 'Local Research Locations', and 'Local Site Documents'. The main content area is titled 'Basic Study Information' and contains four numbered sections:

- 1. * Title of study: A text input field containing 'Auburn University Joint Health Study'.
- 2. * Short title: A text input field containing 'Auburn University Joint Health Study'.
- 3. * Brief description: A text input field containing 'TO BE UPDATED BY STUDY TEAM'.
- 4. * What kind of study is this?: A radio button selection area with two options: 'Multi-site or Collaborative study' (unselected) and 'Single-site study' (selected).

At the top of the main content area, there is a breadcrumb trail: 'You Are Here: Auburn University Joint Health...' followed by 'Editing: IRB 0000411'. A yellow arrow points from the breadcrumb trail to the 'Basic Study Information' title.

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.
-

You Are Here: Auburn University Joint Health...

Editing: IRB00000411

Go to forms menu Print Help

Study Funding Sources

1. Identify each organization supplying funding for the study:

+ Add

Funding Source	Sponsor's Funding ID	Grants Office ID	Attachments
There are no items to display			

Basic Study Information

Study Funding Sources

Local Study Team Members

Study Scope

Local Research Locations

Local Site Documents

Add Funding Source

1. * Funding organization: ?

Natio ...

2.

ID	Name	Category
902015141	National Academy of Sciences	Foundation or Association
U-178	National Cheng Kung University of Taiwan	Foreign University
F-142	National Coastal Resources Research and Development Institute	Federal
128701	National Ctr Asphalt Technology	Department
902495588	National Endowment for the Arts (NEA)	Federal
902015140	National Endowment for the Humanities (NEH)	Federal
F-066	National Institute on Disability, Independent Living, and Rehabilitation Research-NIDILRR	Federal
F-264	National Reconnaissance Office	Federal
F-180	National Research Center	Federal
902015135	National Security Agency (NSA)	Federal

3.

Document History Date Modified Document History

There are no items to display

* Required

OK OK and Add Another Cancel

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.

Validate Compare

You Are Here: Auburn University Joint Health...

Editing: IRB00000411

Go to forms menu Print Help

Basic Study Information

Study Funding Sources

Local Study Team Members

Study Scope

Local Research Locations

Local Site Documents

1. Identify each additional person involved in the design, conduct, or reporting of the research: ?

+ Add

Name	Roles
Jennifer Robinson	

Update

External team member information

+ Add

Name	De
There are no items to display	

Add Study Team Member

1. * Study team member: ?

2. Role in research: (check all that apply)
There are no items to display

3. * Is the team member involved in the consent process?
☐ Yes ☐ No [Clear](#)

4. * Does the team member have a financial interest related to this research? ?
☐ Yes ☐ No [Clear](#)

3 OK OK and Add Another Cancel

Submit a Document

Help

Title:

If not provided, the name of the file will be used

* File: Choose File

Show Advanced Options

* Required

5

6

OK OK and Add Another Cancel

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**.

Validate Compare

You Are Here: Auburn University Joint Health...

Editing: IRB00000411

Go to forms menu Print Help

1 Study Scope ?

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? ?

☐ Yes ☒ No [Clear](#)

2. * Does the study evaluate the safety or effectiveness of a device or use a humanitarian use device (HUD)?

☐ Yes ☒ No [Clear](#)

1. * Will the study require a Certificate of Confidentiality (CoC) issued by the NIH? ?

☐ Yes ☒ No [Clear](#)

2. * Is the study a clinical trial? ?

☐ Yes ☒ No [Clear](#)

Validate Compare

You Are Here: Auburn University Joint Health...

Editing: IRB00000411

Go to forms menu Print Help

Local Research Locations ?

1. Identify research locations where research activities will be conducted or overseen by the local investigator:

[+ Add](#)

Location	Contact	Phone	Email
There are no items to display			

2

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**.

Add Research Location

Add Research Location Information

1. Select the research location:

3

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

4

a. Location name:

b. Location address:

Address line 1

Address line 2

Address line 3

City

Validate Compare

You Are Here: Auburn University Joint Health...

Editing: IRB00000411

Go to forms menu Print Help

Basic Study Information

Study Funding Sources

Local Study Team Members

Study Scope

Local Research Locations

Local Site Documents

2 Local Site Documents

1

1. Consent forms: (include an HHS-approved sample consent document, if applicable)

+ Add

Document	Category	Date Modified	Document History
There are no items to display			

2. Recruitment materials: (to be seen or heard by subjects, including ads)

+ Add

Document	Category	Date Modified	Document History
There are no items to display			

3

3. Other attachments:

+ Add

Document	Category	Date Modified	Document History
There are no items to display			

4

1. You will need to transfer all of your currently approved IRB documents onto Endeavor templates. Once you have transferred your currently approved information, turn on [Track Changes](#) in Microsoft Word, add any missing information, and modify the materials as you wish.
2. In the **Local Site Documents** SmartForm, upload your Endeavor consent documents under **Consent Forms**. There are several consent/assent templates available.
 - HRP-502 – TEMPLATE - Consent Document
 - HRP-502a – TEMPLATE - SBS Consent Document
 - HRP-576 – TEMPLATE – Audio, Video, Photo Release
 - HRP-578 – TEMPLATE – Minor Assent
 - HRP-579 – TEMPLATE – Minor Assent Script
 - HRP-580 – TEMPLATE – Parental Permission
 - HRP-581 – TEMPLATE – Information Letter
 - 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
 - Data security plans
 - 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**.

Validate Compare

You Are Here: Auburn University Joint Health...

Editing: IRB00000411

Go to forms menu Print Help

1 Final Page

You have reached the end of the IRB submission form. Read the next steps carefully:

1. Click **Finish** to exit the form.
2. **Important!** To send the submission for review, click **Submit** on the next page.

You must click **Submit** in the left menu bar on the following page to submit your protocol. Your protocol is not submitted until the workflow indicates that it is in **Pre-Review**.

Exit Save **2** Finish

Pre-Submission

Last updated: 7/30/2024 1:32 PM

Next Steps

Edit Modification/CR

Printer Version

Submit

Manage Ancillary Reviews

Add Comment

Discard

3 MOD00000002: Modification / Update #2 for Study Auburn University Joint Health Study

Principal investigator: Jennifer Robinson
Submission type: Modification / Update

IRB office: IRB 1
IRB coordinator:
Regulatory authority: 2018 Requirements

Pre-Submission

Clarification Requested

Clarification Requested

Modifications Required

History Contacts Documents Reviews Related RNIs Snapshots ...

Filter by Activity Enter text to search

Clear All

Activity	Author	Activity Date
Minor Version Incremented	Robinson, Jennifer	7/30/2024 1:31 PM

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.

Pre-Submission

MOD00000002: Modification / Update #2 for Study
Auburn University Joint Health Study

Principal investigator: Jennifer Robinson
Submission type: Modification / Update
Primary contact:

IRB office: IRB 1
IRB coordinator:
Regulatory authority: 2018 Requirements

Last updated: 7/30/2024 1:32 PM

Next Steps

Edit Modification/CR

Printer Version

1 Submit

Manage Ancillary

Add Comment

Discard

Workflow:

```
graph LR; A[Pre-Submission] --> B[Pre-Review]; A --> C[Clarification Requested]; B --> D[IRB Review]; C --> D; D --> E[Post-Review]; D --> F[Clarification Requested]; E --> G[Review Complete]; F --> H[Modifications Required]; H --> G
```

History | Contacts | Documents | Reviews | Related RNIs | Snapshots | ...

Filter by Activity Enter text to search + Add Filter

Clear All

Activity	Author	Activity Date
Minor Version Incremented	Robinson, Jennifer	7/30/2024 1:31 PM

Submit

By clicking "OK" below you are verifying that:

- You have obtained the financial interest status ("yes" or "no") of each research staff.
- You have obtained the agreement of each research staff to his/her role in the research.
- You will conduct this Human Research in accordance with requirements in the HRP-103 - Investigator Manual

2

OK Cancel

Pre-Review

MOD00000002: Modification / Update #2 for Study
Auburn University Joint Health Study

Principal investigator: Jennifer Robinson
Submission type: Modification / Update
Primary contact:

IRB office: IRB 1
IRB coordinator:
Regulatory authority: 2018 Requirements

Entered IRB: 7/30/2024 1:50 PM
Last updated: 7/30/2024 1:50 PM

Next Steps

View Modification/CR

Printer Version

Manage Ancillary Reviews

Add Comment

4 Withdraw

Discard

Workflow:

```
graph LR; A[Pre-Submission] --> B[Pre-Review]; A --> C[Clarification Requested]; B --> D[IRB Review]; C --> D; D --> E[Post-Review]; D --> F[Clarification Requested]; E --> G[Review Complete]; F --> H[Modifications Required]; H --> G
```

History | Contacts | Documents | Reviews | Related RNIs | Snapshots | ...

Filter by Activity Enter text to search + Add Filter

Clear All

Activity	Author	Activity Date
Submitted	Robinson, Jennifer	7/30/2024 1:50 PM
Minor Version Incremented	Robinson, Jennifer	7/30/2024 1:31 PM

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**'.

The screenshot shows the IRB workspace interface. At the top, the 'IRB' tab is highlighted with a yellow box and a callout '1'. Below it, the 'Active' filter is selected with a yellow box and a callout '2'. On the left, the 'Filter by' dropdown is highlighted with a yellow box and a callout '4', and the 'ID' filter is selected. In the table, the first study entry is highlighted with a yellow box and a callout '3'. The table has columns for ID, Name, Date Modified, State, PI First Name, PI Last Name, Coordinator First Name, Coordinator Last Name, and Expiration Date.

ID	Name	Date Modified	State	PI First Name	PI Last Name	Coordinator First Name	Coordinator Last Name	Expiration Date
22-151	University Joint Health Study	7/29/2024 1:59 PM	Approved	Jennifer	Robinson			3/23/2025

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.

The screenshot displays the IRB submission system interface. On the left, a sidebar shows the 'Approved' status and a 'Next Steps' section with buttons for 'View Study', 'Printer Version', 'Create Modification/CR' (highlighted with a yellow border and a large orange circle with the number 1), and 'Report New Information'. The main content area is titled 'Modification / Continuing Review' and shows the breadcrumb 'You Are Here: Auburn University Joint Health... > _IRBSubmission'. Below this, the title 'Creating New: IRB Submission' is followed by 'Modification / Continuing Review / Study Closure'. A section titled '* What is the purpose of this submission?' contains three radio button options: 'Continuing Review', 'Modification / Update', and 'Modification and Continuing Review' (selected, with a large orange circle with the number 2). A 'Clear' link is below these options. An information icon and text state: 'To change the PI, choose 'Other parts of the study/site' scope'. Below this, the 'Modification scope:' section has two checked checkboxes: 'Study team member information' and 'Other parts of the study' (with a large orange circle with the number 3). At the bottom right, there are three buttons: 'Exit', 'Save' (highlighted with a yellow border and a large orange circle with the number 4), and 'Continue' (highlighted with a yellow border and a right arrow icon).

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.

Validation Compare

You Are Here: Auburn University Joint Health... > Modification / Update #1 for S...

Editing: MOD00000001

Go to forms menu Print Help

Modification / Continuing Review / Study Closure

* What is the purpose of this submission?

☐ Continuing Review

☐ Modification / Update

☐ Modification and Continuing Review

To change the PI, choose 'Other parts of the study/site' scope

Modification scope:

☒ Study team member information

☒ Other parts of the study

Active Modification For This Study

Modification Type

Exit Save Continue

Pre-Submission

Last updated: 7/29/2024 11:53 PM

Next Steps

Edit Modification/CR

Printer Version

Submit

Manage Ancillary Reviews

Add Comment

Discard

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.

The screenshot shows a web application interface for a Continuing Review. On the left is a sidebar with navigation links: 'Modification / Continuing Review' (active), 'Continuing Review / Study Closure Information', 'Modification Summary', and 'Modification Details'. The main content area has a breadcrumb trail: 'You Are Here: Auburn University Joint Health... > Modification and Continuing Re...'. Below this, it says 'Editing: MODCR00000001'. The title of the section is 'Continuing Review / Study Closure Information'. There are four numbered questions: 1. 'Specify enrollment totals at this investigator's sites:' with a text input field. 2. 'Specify enrollment totals at this investigator's sites since last approval:' with a text input field. 3. 'Specify enrollment totals study-wide:' with a text input field. 4. 'Research milestones: (select all that apply)' with a list of six checkboxes. An information icon and 'Important!' text follow the list, stating that if the first four milestones are complete, the study will be closed to discontinue IRB oversight.

Validate Compare

Modification / Continuing Review

Continuing Review / Study Closure Information

Modification Summary

Modification Details

You Are Here: Auburn University Joint Health... > Modification and Continuing Re...

Editing: MODCR00000001

Continuing Review / Study Closure Information

1. * Specify enrollment totals at this investigator's sites: ?

2. * Specify enrollment totals at this investigator's sites since last approval:

3. * Specify enrollment totals study-wide: ?

4. Research milestones: (select all that apply) ?

- ☐ Study is permanently closed to enrollment OR was never open for enrollment
- ☐ All subjects have completed all study-related interventions OR not applicable (e.g. study did not include interventions, no subjects were enrolled)
- ☐ Collection of private identifiable information is complete OR not applicable (no subjects were enrolled)
- ☐ Analysis of private identifiable information is complete OR not applicable (no subjects were enrolled)
- ☐ Remaining study activities are limited to data analysis
- ☐ Study remains active only for long-term follow-up of subjects



i Important! If the first four research milestones above are complete, the study will be closed to discontinue IRB oversight.

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.

You Are Here:  Auburn University Joint Health... >  Modification / Update #1 for S...

Editing: MOD00000001 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)

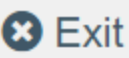

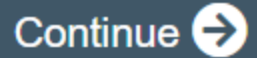
- ☐ Current subjects will be notified of these changes
- ☐ Former subjects will be notified of these changes

 **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: 

This modification is:

1. Finish populating my shell protocol, and
2. Any other study changes you would like to make (i.e., add a new recruitment flyer, add research personnel, etc.)

Navigate the IRB Application

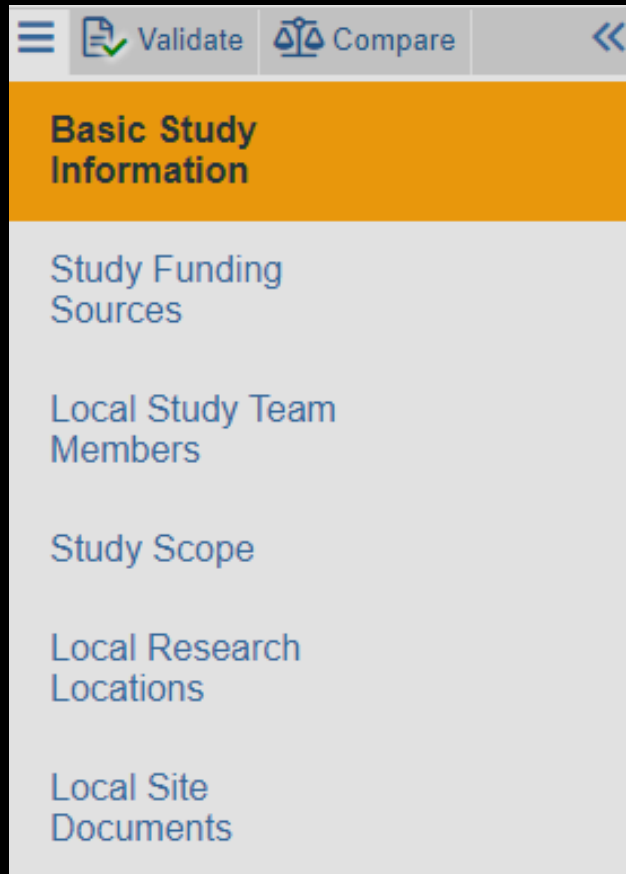
1. The page navigator is located on the left side of the screen. It consists of SmartForms and allows the user to switch between the main pages of the IRB application. The page currently being viewed will be shown highlighted in orange.
2. **IMPORTANT:** During your first submission, you will need to 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.

The screenshot displays the IRB application interface. On the left, a sidebar contains a list of navigation items: 'Basic Study Information' (highlighted in orange), 'Study Funding Sources', 'Local Study Team Members', 'Study Scope', 'Local Research Locations', and 'Local Site Documents'. The main content area is titled 'Basic Study Information' and contains four numbered sections:

- 1. * Title of study: A text input field containing 'Auburn University Joint Health Study'.
- 2. * Short title: A text input field containing 'Auburn University Joint Health Study'.
- 3. * Brief description: A text input field containing 'TO BE UPDATED BY STUDY TEAM'.
- 4. * What kind of study is this?: A radio button selection area with two options: 'Multi-site or Collaborative study' (unselected) and 'Single-site study' (selected).

At the top of the main content area, there is a breadcrumb trail: 'You Are Here: Auburn University Joint Health...' followed by 'Editing: IRB 0000411'. An orange arrow points from the breadcrumb trail down to the 'Basic Study Information' title.

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.
-

You Are Here: Auburn University Joint Health...

Editing: IRB00000411

Go to forms menu Print Help

Study Funding Sources

1. Identify each organization supplying funding for the study:

+ Add

Funding Source	Sponsor's Funding ID	Grants Office ID	Attachments
There are no items to display			

Basic Study Information

Study Funding Sources

Local Study Team Members

Study Scope

Local Research Locations

Local Site Documents

Add Funding Source

1. * Funding organization: ?

Natio

2

ID	Name	Category
902015141	National Academy of Sciences	Foundation or Association
U-178	National Cheng Kung University of Taiwan	Foreign University
F-142	National Coastal Resources Research and Development Institute	Federal
128701	National Ctr Asphalt Technology	Department
902495588	National Endowment for the Arts (NEA)	Federal
902015140	National Endowment for the Humanities (NEH)	Federal
F-066	National Institute on Disability, Independent Living, and Rehabilitation Research-NIDILRR	Federal
F-264	National Reconnaissance Office	Federal
F-180	National Research Center	Federal
902015135	National Security Agency (NSA)	Federal

3

Document History Date Modified Document History

There are no items to display

* Required

OK OK and Add Another Cancel

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.

Validate Compare

You Are Here: Auburn University Joint Health...

Editing: IRB00000411

Go to forms menu Print Help

Basic Study Information

Study Funding Sources

Local Study Team Members

1. Identify each additional person involved in the design, conduct, or reporting of the research: ?

+ Add

Study Scope

Local Research Locations

Local Site Documents

4

Name	Roles
Jennifer Robinson	

Add Study Team Member

1. * Study team member: ?
2. Role in research: (check all that apply)
There are no items to display
3. * Is the team member involved in the consent process?
☐ Yes ☐ No [Clear](#)
4. * Does the team member have a financial interest related to this research? ?
☐ Yes ☐ No [Clear](#)

3

OK OK and Add Another Cancel

Submit a Document

Help

Title:

If not provided, the name of the file will be used

* File: Choose File

Show Advanced Options

* Required

5

6

OK OK and Add Another Cancel

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**.

Validate Compare

You Are Here: Auburn University Joint Health...

Editing: IRB00000411

Go to forms menu Print Help

1 Study Scope ?

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? ?

☐ Yes ☒ No [Clear](#)

2. * Does the study evaluate the safety or effectiveness of a device or use a humanitarian use device (HUD)?

☐ Yes ☒ No [Clear](#)

1. * Will the study require a Certificate of Confidentiality (CoC) issued by the NIH? ?

☐ Yes ☒ No [Clear](#)

2. * Is the study a clinical trial? ?

☐ Yes ☒ No [Clear](#)

Validate Compare

You Are Here: Auburn University Joint Health...

Editing: IRB00000411

Go to forms menu Print Help

Local Research Locations ?

1. Identify research locations where research activities will be conducted or overseen by the local investigator:

[+ Add](#)

Location	Contact	Phone	Email
There are no items to display			

2

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**.

Add Research Location

Add Research Location Information

1. Select the research location:

3

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

4

a. Location name:

b. Location address:

Address line 1

Address line 2

Address line 3

City

You Are Here: Auburn University Joint Health...

Editing: IRB00000411

Go to forms menu Print Help

Local Site Documents

- 1. Consent forms:** (include an HHS-approved sample consent document, if applicable)
 - + Add
 - Document Category Date Modified Document History
 - There are no items to display
- 2. Recruitment materials:** (to be seen or heard by subjects, including ads)
 - + Add
 - Document Category Date Modified Document History
 - There are no items to display
- 3. Other attachments:**
 - + Add
 - Document Category Date Modified Document History
 - There are no items to display

1. You will need to transfer all of your currently approved IRB documents onto Endeavor templates. Once you have copied and pasted all your currently approved information, turn on **Track Changes** in Microsoft Word, add any missing information, and modify the materials as you wish.
2. In the **Local Site Documents** SmartForm, upload your Endeavor consent documents under **Consent Forms**. There are several consent/assent templates available.
 - HRP-502 – TEMPLATE - Consent Document
 - HRP-502a – TEMPLATE - SBS Consent Document
 - HRP-576 – TEMPLATE – Audio, Video, Photo Release
 - HRP-578 – TEMPLATE – Minor Assent
 - HRP-579 – TEMPLATE – Minor Assent Script
 - HRP-580 – TEMPLATE – Parental Permission
 - HRP-581 – TEMPLATE – Information Letter
 - 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
 - Data security plans
 - 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 Are Here: Auburn University Joint Health...

Editing: IRB00000411

Go to forms menu Print Help

Final Page

You have reached the end of the IRB submission form. Read the next steps carefully:

1. Click **Finish** to exit the form.
2. **Important!** To send the submission for review, click **Submit** on the next page.

You must click Submit in the left menu bar on the following page to submit your protocol. Your protocol is not submitted until the workflow indicates that it is in Pre-Review.

2

Exit Save Finish

Pre-Submission

Last updated: 7/30/2024 1:32 PM

MOD00000002: Modification / Update #2 for Study Auburn University Joint Health Study

Principal investigator: Jennifer Robinson
Submission type: Modification / Update

IRB office: IRB 1
IRB coordinator:
Regulatory authority: 2018 Requirements

3

Pre-Submission

Clarification Requested

Clarification Requested

Modifications Required

History Contacts Documents Reviews Related RNIs Snapshots ...

Filter by Activity Enter text to search + Add Filter

Clear All

Activity	Author	Activity Date
Minor Version Incremented	Robinson, Jennifer	7/30/2024 1:31 PM

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.

Pre-Submission

MOD00000002: Modification / Update #2 for Study
Auburn University Joint Health Study

Principal investigator: Jennifer Robinson
Submission type: Modification / Update
Primary contact:

IRB office: IRB 1
IRB coordinator:
Regulatory authority: 2018 Requirements

Last updated: 7/30/2024 1:32 PM

Next Steps

Edit Modification/CR

Printer Version

1 Submit

Manage Ancillary

Add Comment

Discard

Workflow diagram: Pre-Submission → Pre-Review → IRB Review → Post-Review → Review Complete. Pre-Review includes Clarification Requested. IRB Review includes Clarification Requested. Post-Review includes Modifications Required.

History | Contacts | Documents | Reviews | Related RNIs | Snapshots | ...

Filter by: Activity | Enter text to search | + Add Filter

Clear All

Activity	Author	Activity Date
+ Minor Version Incremented	Robinson, Jennifer	7/30/2024 1:31 PM

Submit

By clicking "OK" below you are verifying that:

- You have obtained the financial interest status ("yes" or "no") of each research staff.
- You have obtained the agreement of each research staff to his/her role in the research.
- You will conduct this Human Research in accordance with requirements in the HRP-103 - Investigator Manual

2

OK Cancel

Pre-Review

MOD00000002: Modification / Update #2 for Study
Auburn University Joint Health Study

Principal investigator: Jennifer Robinson
Submission type: Modification / Update
Primary contact:

IRB office: IRB 1
IRB coordinator:
Regulatory authority: 2018 Requirements

Entered IRB: 7/30/2024 1:50 PM
Last updated: 7/30/2024 1:50 PM

Next Steps

View Modification/CR

Printer Version

Manage Ancillary Reviews

Add Comment

4 Withdraw

Discard

Workflow diagram: Pre-Submission → Pre-Review → IRB Review → Post-Review → Review Complete. Pre-Review includes Clarification Requested. IRB Review includes Clarification Requested. Post-Review includes Modifications Required.

History | Contacts | Documents | Reviews | Related RNIs | Snapshots | ...

Filter by: Activity | Enter text to search | + Add Filter

Clear All

Activity	Author	Activity Date
Submitted	Robinson, Jennifer	7/30/2024 1:50 PM
+ Minor Version Incremented	Robinson, Jennifer	7/30/2024 1:31 PM

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 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**'.

The screenshot shows the IRB workspace interface. At the top, the 'IRB' tab is highlighted with a yellow box and a callout '1'. Below it, the 'Active' filter is selected with a yellow box and callout '2'. On the left, the 'Filter by' dropdown is highlighted with a yellow box and callout '4', and the 'ID' filter is selected. In the table, the first study entry is highlighted with a yellow box and callout '3'. The table has columns for ID, Name, Date Modified, State, PI First Name, PI Last Name, Coordinator First Name, Coordinator Last Name, and Expiration Date.

ID	Name	Date Modified	State	PI First Name	PI Last Name	Coordinator First Name	Coordinator Last Name	Expiration Date
22-151	University Joint Health Study	7/29/2024 1:59 PM	Approved	Jennifer	Robinson			3/23/2025

Creating a Modification

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

Approved

Entered IRB: 4/22/2024 2:08 PM
Initial approval: 5/1/2024
Initial effective: 5/2/2024
Effective: 5/2/2024
Approval end: 3/23/2025
Last updated: 7/29/2024 1:59 PM

Next Steps

[View Study](#)

[Printer Version](#)

[Create Modification/CR](#)

[Report New Information](#)

1

Modification / Continuing Review

You Are Here: Auburn University Joint Health... > _IRBSubmission

Creating New: IRB Submission

Modification / Continuing Review / Study Closure

*** What is the purpose of this submission?**

☒ Continuing Review

☐ Modification / Update

☐ Modification and Continuing Review

[Clear](#)

[Exit](#)

[Save](#)

[Continue](#)

2

3

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.

Validation Compare

You Are Here: Auburn University Joint Health... > Modification / Update #1 for S...

Editing: MOD00000001

Go to forms menu Print Help

Modification / Continuing Review / Study Closure

* What is the purpose of this submission?

☐ Continuing Review

☒ Modification / Update

☐ Modification and Continuing Review

To change the PI, choose 'Other parts of the study/site' scope

Modification scope:

☒ Study team member information

☒ Other parts of the study

Active Modification For This Study

Modification Type

Exit Save Continue

Pre-Submission

Last updated: 7/29/2024 11:53 PM

Next Steps

Edit Modification/CR

Printer Version

Submit

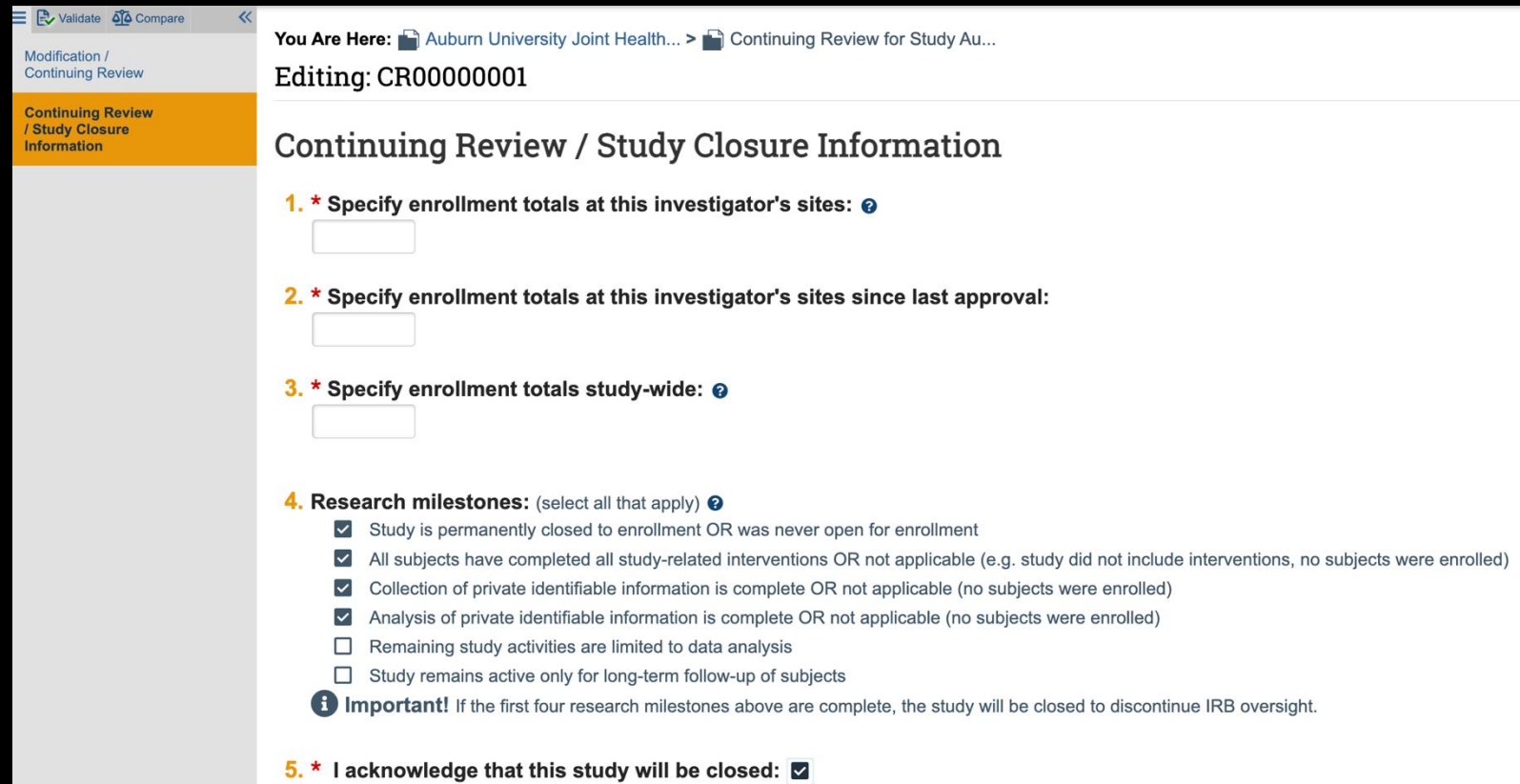
Manage Ancillary Reviews

Add Comment

Discard

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**.



The screenshot shows a web application interface for 'Continuing Review / Study Closure Information'. The left sidebar has a menu with 'Modification / Continuing Review' and 'Continuing Review / Study Closure Information' (highlighted in orange). The main content area shows the form title 'Continuing Review / Study Closure Information' and a breadcrumb trail 'You Are Here: Auburn University Joint Health... > Continuing Review for Study Au...'. Below this is the text 'Editing: CR00000001'. The form contains five numbered questions:

1. * Specify enrollment totals at this investigator's sites: ?
2. * Specify enrollment totals at this investigator's sites since last approval:
3. * Specify enrollment totals study-wide: ?
4. Research milestones: (select all that apply) ?
 - ☒ Study is permanently closed to enrollment OR was never open for enrollment
 - ☒ All subjects have completed all study-related interventions OR not applicable (e.g. study did not include interventions, no subjects were enrolled)
 - ☒ Collection of private identifiable information is complete OR not applicable (no subjects were enrolled)
 - ☒ Analysis of private identifiable information is complete OR not applicable (no subjects were enrolled)
 - ☐ Remaining study activities are limited to data analysis
 - ☐ Study remains active only for long-term follow-up of subjects
5. * I acknowledge that this study will be closed: ☒

Below question 4, there is an important note: **i Important!** If the first four research milestones above are complete, the study will be closed to discontinue IRB oversight.

Validate Compare

You Are Here: Auburn University Joint Health...

Editing: IRB00000411

Go to forms menu Print Help

1 Final Page

You have reached the end of the IRB submission form. Read the next steps carefully:

1. Click **Finish** to exit the form.
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You must click **Submit** in the left menu bar on the following page to submit your protocol. Your protocol is not submitted until the workflow indicates that it is in **Pre-Review**.

Exit Save **2** Finish

Pre-Submission

Last updated: 7/30/2024 1:32 PM

Next Steps

Edit Modification/CR

Printer Version

Submit

Manage Ancillary Reviews

Add Comment

Discard

3 MOD00000002: Modification / Update #2 for Study Auburn University Joint Health Study

Principal investigator: Jennifer Robinson
Submission type: Modification / Update

IRB office: IRB 1
IRB coordinator:
Regulatory authority: 2018 Requirements

Pre-Submission

Clarification Requested

Clarification Requested

Modifications Required

History Contacts Documents Reviews Related RNIs Snapshots ...

Filter by Activity Enter text to search

Clear All

Activity	Author	Activity Date
Minor Version Incremented	Robinson, Jennifer	7/30/2024 1:31 PM

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Pre-Submission

MOD00000002: Modification / Update #2 for Study
Auburn University Joint Health Study

Principal investigator: Jennifer Robinson
Submission type: Modification / Update
Primary contact:

IRB office: IRB 1
IRB coordinator:
Regulatory authority: 2018 Requirements

Last updated: 7/30/2024 1:32 PM

Next Steps

Edit Modification/CR

Printer Version

1 Submit

Manage Ancillary

Add Comment

Discard

Workflow:

```
graph LR; A[Pre-Submission] --> B[Pre-Review]; A --> C[Clarification Requested]; B --> C; C --> B; B --> D[IRB Review]; C --> D; D --> E[Post-Review]; D --> F[Clarification Requested]; E --> F; F --> E; E --> G[Review Complete]; F --> G
```

History | Contacts | Documents | Reviews | Related RNIs | Snapshots | ...

Filter by Activity Enter text to search + Add Filter

Clear All

Activity	Author	Activity Date
Minor Version Incremented	Robinson, Jennifer	7/30/2024 1:31 PM

Submit

By clicking "OK" below you are verifying that:

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- You have obtained the agreement of each research staff to his/her role in the research.
- You will conduct this Human Research in accordance with requirements in the HRP-103 - Investigator Manual

2 OK Cancel

Pre-Review

MOD00000002: Modification / Update #2 for Study
Auburn University Joint Health Study

Principal investigator: Jennifer Robinson
Submission type: Modification / Update
Primary contact:

IRB office: IRB 1
IRB coordinator:
Regulatory authority: 2018 Requirements

Entered IRB: 7/30/2024 1:50 PM
Last updated: 7/30/2024 1:50 PM

Next Steps

View Modification/CR

Printer Version

Manage Ancillary Reviews

Add Comment

4 Withdraw

Discard

Workflow:

```
graph LR; A[Pre-Submission] --> B[Pre-Review]; A --> C[Clarification Requested]; B --> C; C --> B; B --> D[IRB Review]; C --> D; D --> E[Post-Review]; D --> F[Clarification Requested]; E --> F; F --> E; E --> G[Review Complete]; F --> G
```

History | Contacts | Documents | Reviews | Related RNIs | Snapshots | ...

Filter by Activity Enter text to search + Add Filter

Clear All

Activity	Author	Activity Date
Submitted	Robinson, Jennifer	7/30/2024 1:50 PM
Minor Version Incremented	Robinson, Jennifer	7/30/2024 1:31 PM

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