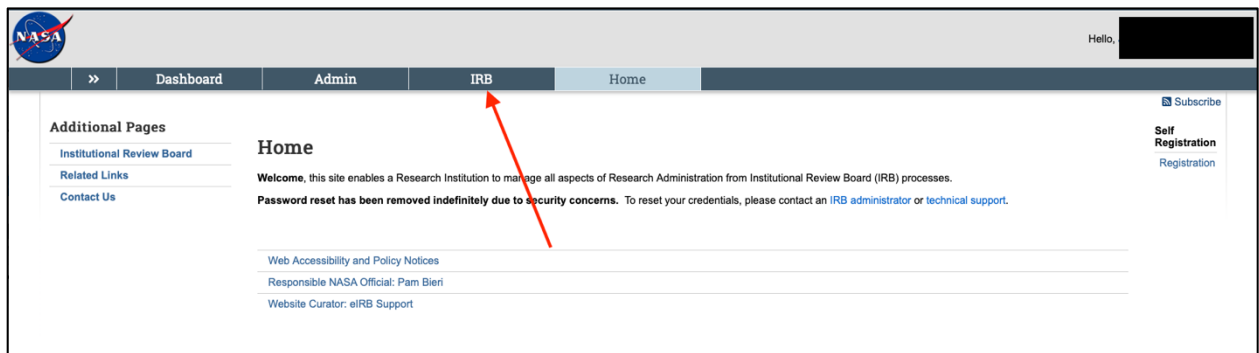


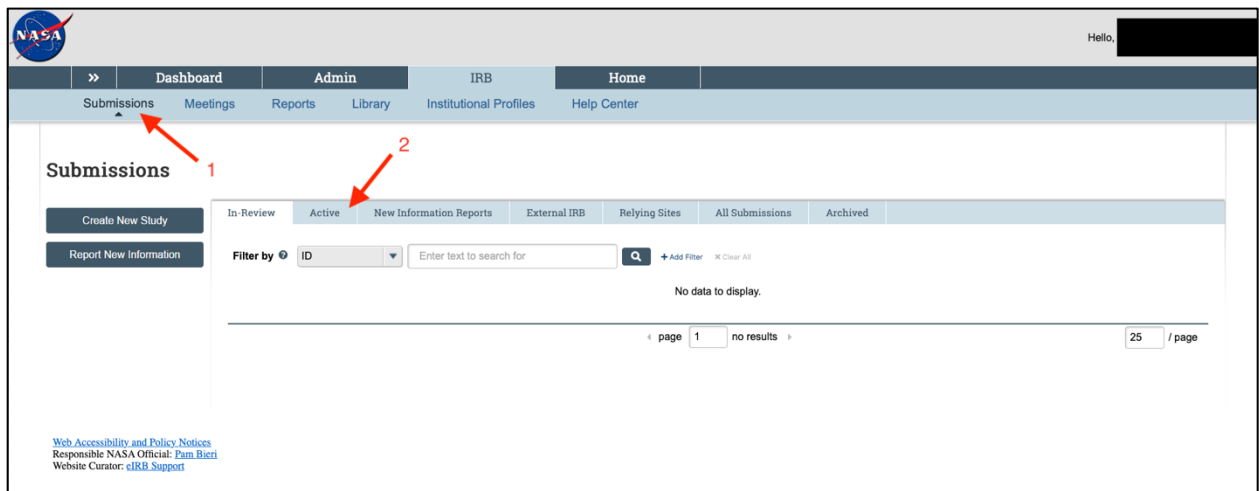
## NASA IRB Huron Guide for Researchers Submitting a Modification and Continuing Review

Please note, you can submit a modification alone (MOD), a continuing review alone (CR), or both combined (MODCR). This manual will specifically review submitting a combined modification and continuing review. **Note: A MODCR is required if you need to attach documents to your continuing review (e.g. updated Financial Conflict of Interest Forms and/or CITI certificates). A CR alone will not allow you to upload documents.**

1. Visit <https://eirb.jsc.nasa.gov/EIRB/> and click “Login” at the top right corner of the screen. Enter your user name and password and click “Login.”
2. In the top navigator bar, click “IRB.”



3. Then, click “Submission” in the top navigator bar, then click the “Active” tab.



# NASA IRB Huron Guide for Researchers

## Submitting a Modification and Continuing Review

4. Click on the title of the study of interest.

The screenshot shows the NASA IRB Submissions interface. At the top, there is a navigation bar with tabs for Dashboard, Admin, IRB, and Home. Below this is a secondary navigation bar with links for Submissions, Meetings, Reports, Library, Institutional Profiles, and Help Center. The main content area is titled 'Submissions' and features a 'Create New Study' and 'Report New Information' button on the left. A table of submissions is displayed with columns for ID, Name, Date Modified, State, PI First Name, PI Last Name, Coordinator First Name, Coordinator Last Name, and Expiration Date. The first entry is a study titled 'How-To Guide for Researchers' with a date modified of 12/3/2020 5:43 AM and a state of 'Approved'. A red arrow points to the title of this study. At the bottom left, there is a footer with links for 'Web Accessibility and Policy Notices', 'Responsible NASA Official: Pam Bieri', and 'Website Curator: eIRB Support'.

5. Click on “Create Modification/CR” on the left side of the screen.

The screenshot shows the details page for the study 'How-To Guide for Researchers'. The page is titled 'Approved' and 'STUDY [redacted] How-To Guide for Researchers'. It displays various details including the Principal Investigator, Submission type, Primary contact, PI proxies, IRB office, IRB coordinator, Letter, and Regulatory authority. A flowchart shows the review process: Pre-Submission, Pre-Review, IRB Review, Post-Review, and Review Complete. The 'Pre-Review' and 'IRB Review' stages have 'Clarification Requested' options. The 'Post-Review' stage has 'Modifications Required' options. On the left side, under 'Next Steps', there are buttons for 'View Study', 'Printer Version', 'Create Modification/CR', and 'Report New Information'. A red arrow points to the 'Create Modification/CR' button. At the bottom, there is a 'History' section with tabs for Funding, Contacts, Documents, Follow-on Submissions, Reviews, and Snapshots. A search bar is located at the bottom of the page.

# NASA IRB Huron Guide for Researchers

## Submitting a Modification and Continuing Review

6. Select “Modification and Continuing Review.” Note, if you have already previously submitted a modification that is currently under review, you will only see “Continuing Review” as a selection. If you have already previously submitted a continuing review that is currently under review, you will only “Modification/Update” as a selection.

If you are only changing study team members, click only “Study team member information” under scope. If you are changing other parts of the study, click “Other parts of the study.” If you are changing both, select both. Once finished, click “Continue” at the bottom right of the screen.

You Are Here: How-To Guide for Researchers > 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](#)

**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](#)

7. Answer required questions 1 through 3. Select all that apply for number 4 but please note, if you select the first four responses, you are indicating you want to close the study and discontinue IRB oversight. When finished, click “Continue.”

You Are Here: How-To Guide for Researchers > Modification and Continuing Re...

### Editing: MODCR

Continuing Review / Study Closure Information

- \* Specify enrollment totals at this investigator's sites:**
- \* Specify enrollment totals at this investigator's sites since last approval:**
- \* Specify enrollment totals study-wide:**
- 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

**Important!** If the first four research milestones above are complete, the study will be closed to discontinue IRB oversight.
- \* Do any investigators or research staff have a financial interest related to the research that was not described in a previous application?**  
 Yes  No [Clear](#)
- Check the items that are true since the last IRB approval for all sites involved in the study: (initial review or last continuing review)**
  - NO subjects experienced unexpected harm
  - Anticipated adverse events have NOT taken place with greater frequency or severity than expected
  - NO subjects withdrew from the study
  - NO unanticipated problems involving risks to subjects or others

[Exit](#) [Save](#) [Continue](#)

## NASA IRB Huron Guide for Researchers

### Submitting a Modification and Continuing Review


8. Select all that apply for numbers 1 and 2. Note, if you select that you are notifying subjects of the modification, attach a description of how they will be notified in the “Other attachments” section of the “Local Site Documents” page. Clearly summarize all modifications in number 3. Once finished, click “Continue” on the bottom right of the screen.

You Are Here: [How-To Guide for Researchers](#) > [Modification / Update #1 for S...](#)


Editing: MOD [REDACTED] ◀ 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

**i** 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:** 

✕ Exit 💾 Save Continue →



## NASA IRB Huron Guide for Researchers Submitting a Modification and Continuing Review

- 9. Basic Study Information** – make adjustments to these areas as needed. If changing the protocol file, track all changes and upload a new document in number 8. NOTE: Please be sure to accept all **old** tracked changes from previously approved versions. Click “Continue” when finished. You will progress your way through each of the study areas listed in the left panel.

The screenshot shows the 'Basic Study Information' form in the NASA IRB system. The form is titled 'Editing: IRB [redacted]' and is part of a 'How-To Guide for Researchers'. The form contains the following sections:

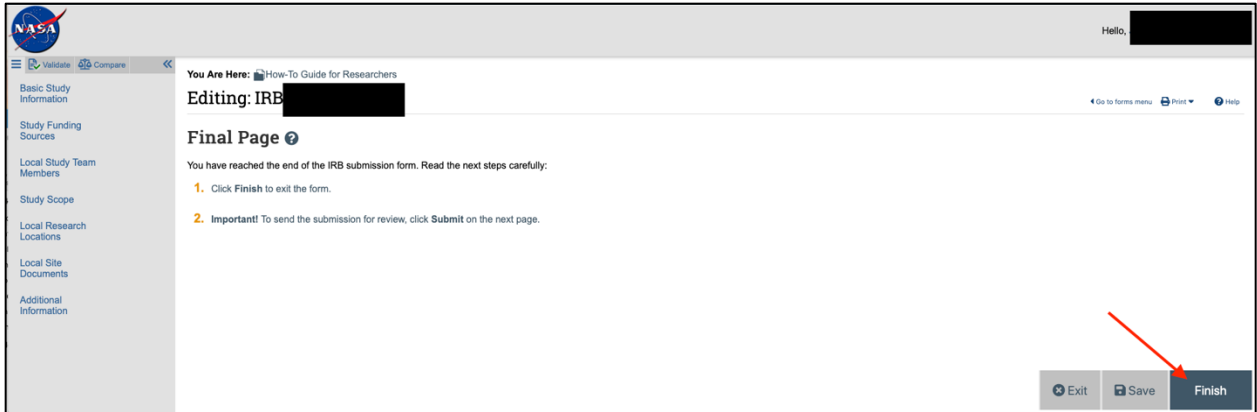
- Title of study:** A text input field containing 'How-To Guide for Researchers: Creating a New Submission'.
- Short title:** A text input field containing 'How-To Guide for Researchers'.
- Brief description:** A text input field containing 'This is a test template to create a guide for researchers in using the e-IRB System'.
- What kind of study is this?:** Radio buttons for 'Multi-site or Collaborative study' and 'Single-site study'. The 'Single-site study' option is selected.
- Will an external IRB act as the IRB of record for this study?:** Radio buttons for 'Yes' and 'No'. The 'No' option is selected.
- Local principal investigator:** A dropdown menu showing 'Jessica Kisenwether'.
- Does the local principal investigator have a financial interest related to this research?:** Radio buttons for 'Yes' and 'No'. The 'No' option is selected.
- Attach the protocol:** A table with columns for Document, Category, Date Modified, and Document History. The table contains one row: 'Test Protocol File.docx(0.01)' under Document, 'IRB Protocol' under Category, '12/1/2020' under Date Modified, and 'History' under Document History.

At the bottom right of the form, there are three buttons: 'Exit', 'Save', and 'Continue'. A red arrow points to the 'Continue' button.

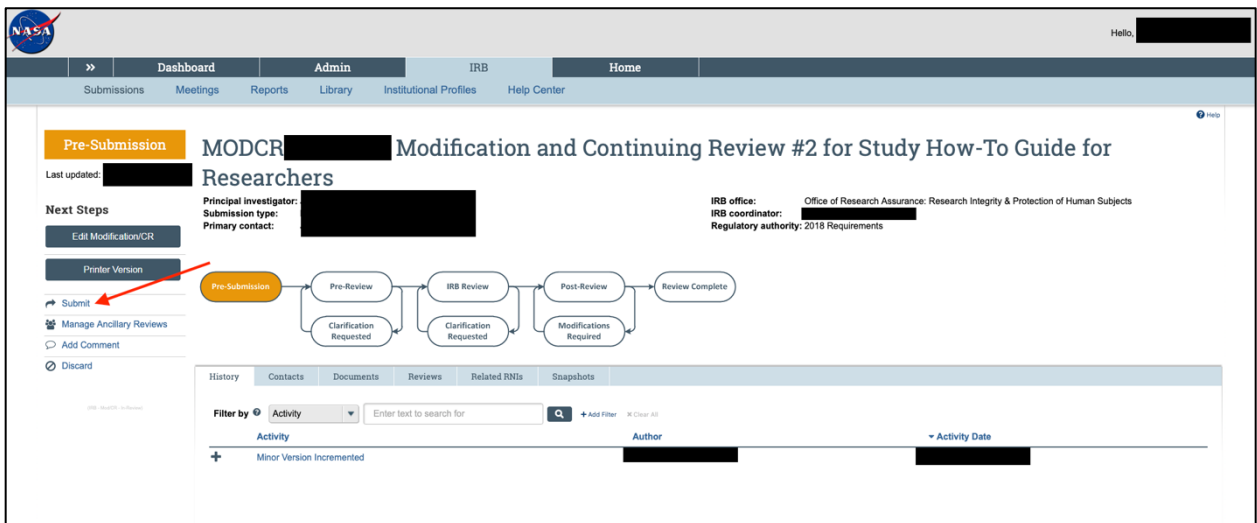
- 10.** Continue through the application, make changes as needed, and clicking “Continue” to proceed. **If adding new study personnel, be sure to upload CITI training certificates and Financial Conflict of Interest Disclosure forms for each individual under Local Study Team Members>External team member information. You will also need to attach updated CITI training certificates and Financial Conflict of Interest Disclosure Forms for all key personnel listed on the study.** Remember to track changes on all other uploaded documents. Once finished with all sections, click “Finish.”

# NASA IRB Huron Guide for Researchers

## Submitting a Modification and Continuing Review



11. Click "Submit" on the left to submit to the IRB Office.



12. A new screen will open. Click "OK" to verify.

## NASA IRB Huron Guide for Researchers

### Submitting a Modification and Continuing Review

Submit

By signing 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

OK Cancel

13. Enter your e-IRB user name and password. Then click "Submit."

Submit

By signing 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

Confirm Credentials close window

Please confirm your login credentials:

Username:

Password:

Submit

OK Cancel

# NASA IRB Huron Guide for Researchers

## Submitting a Modification and Continuing Review

14. The continuing review and modification status will show as “Pre-Review” when successfully submitted.

The screenshot displays the NASA IRB Huron web application interface. At the top, there is a navigation bar with tabs for Dashboard, Admin, IRB, and Home. Below this is a secondary navigation bar with links for Submissions, Meetings, Reports, Library, Institutional Profiles, and Help Center. The main content area is titled "MODCR [redacted] Modification and Continuing Review #2 for Study How-To Guide for Researchers".

On the left side, there is a sidebar with a "Pre-Review" status indicator highlighted in a red box. Below this, there are sections for "Entered IRB:", "Last updated:", "Next Steps" (with buttons for "View Modification/CR" and "Printer Version"), and a list of actions including "Submit Pre-Review", "Request Pre-Review Clarification", "Assign Coordinator", "Manage Ancillary Reviews", "Add Comment", "Withdraw", and "Discard".

The main content area includes a flowchart showing the review process: Pre-Submission -> Pre-Review (highlighted in a red box) -> IRB Review -> Post-Review -> Review Complete. There are also boxes for "Clarification Requested" and "Modifications Required".

Below the flowchart, there is a "History" section with tabs for Contacts, Documents, Reviews, Related RNI's, and Snapshots. The "Activity" tab is selected, showing a list of activities with columns for "Activity", "Author", and "Activity Date". The activities listed are "Submitted" and "Minor Version Incremented", both with redacted author names.