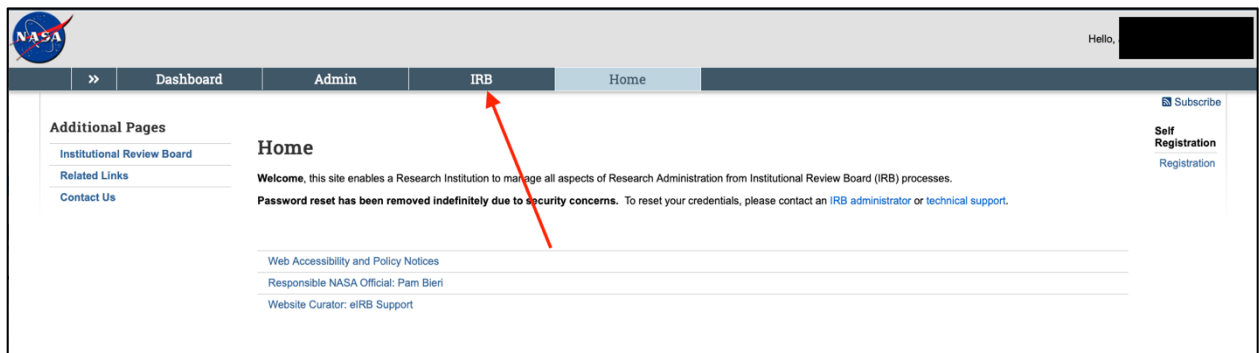


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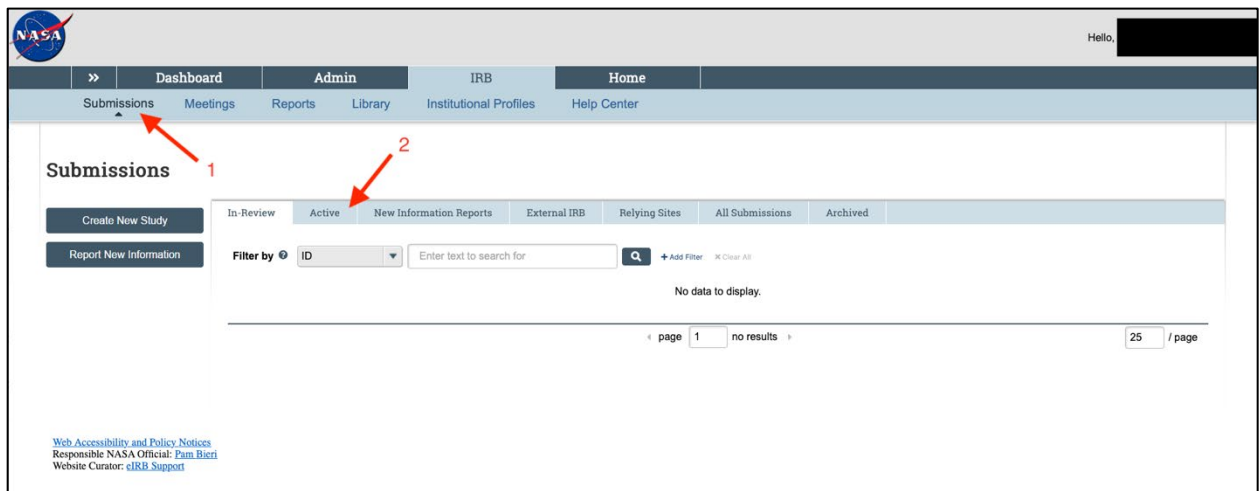
Submitting a Modification and Continuing Review

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.



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

The screenshot shows the NASA IRB Submissions page. The top navigation bar includes links 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 sidebar with buttons for 'Create New Study' and 'Report New Information'. The main table lists submissions with columns for ID, Name, Date Modified, State, PI First Name, PI Last Name, Coordinator First Name, Coordinator Last Name, and Expiration Date. A red arrow points to the title 'How-To Guide for Researchers' in the Name column. The table shows 1 item on page 1 of 1.

Web Accessibility and Policy Notices
Responsible NASA Official: Pam Bieri
Website Curator: eIRB Support

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

The screenshot shows the NASA IRB study details page for 'How-To Guide for Researchers'. The top navigation bar is the same as the previous screenshot. The main content area displays the study title and a status of 'Approved'. Below this is a flowchart showing the review process: Pre-Submission, Pre-Review, IRB Review, Post-Review, and Review Complete. A red arrow points to the 'Create Modification/CR' button in the 'Next Steps' section. The page also includes a sidebar with buttons for 'View Study', 'Printer Version', 'Create Modification/CR', and 'Report New Information'. The main content area includes fields for Principal investigator, Submission type, Primary contact, PI proxies, IRB office, IRB coordinator, Letter, and Regulatory authority. A 'Send Letter' button is located at the bottom left.

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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.

NOTE: Check both boxes “Study team member information” and “Other parts of the study” under scope, if you need to upload documents - even if both may not apply. Without doing so, you may not be able to upload any necessary documents to accompany the modification. 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

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

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

5. * 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](#)

6. 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](#)

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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 ➔

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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 Huron system. The form is titled 'Editing: IRB [redacted]' and includes a sidebar with navigation links. The main content area contains the following sections:

- Title of study:** A text box containing 'How-To Guide for Researchers: Creating a New Submission'.
- Short title:** A text box containing 'How-To Guide for Researchers'.
- Brief description:** A text box 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' (selected). A 'Clear' link is below.
- Will an external IRB act as the IRB of record for this study?** Radio buttons for 'Yes' and 'No'.
- 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' (selected). A 'Clear' link is below.
- Attach the protocol:** A table with columns 'Document', 'Category', 'Date Modified', and 'Document History'. It shows one entry: 'Test Protocol File.docx(0.01)' with category 'IRB Protocol' and date '12/1/2020'. Below the table are 'Update' and 'Add' buttons.

At the bottom right, 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.”

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This screenshot shows the 'Final Page' of the NASA IRB Huron submission form. The page title is 'Editing: IRB [redacted]'. The main heading is 'Final Page'. Below this, instructions state: '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.' At the bottom right, there are three buttons: 'Exit', 'Save', and 'Finish'. A red arrow points to the 'Finish' button.

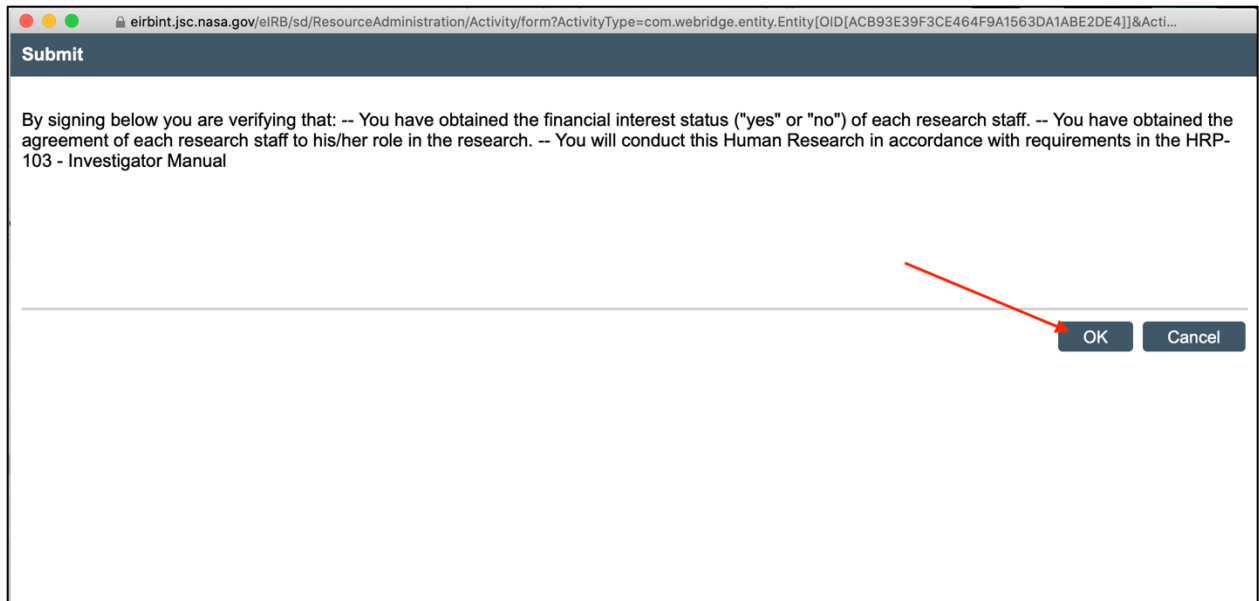
11. Click “Submit” on the left to submit to the IRB Office.

This screenshot shows the NASA IRB Huron system interface for a 'Pre-Submission' of a 'Modification and Continuing Review #2 for Study How-To Guide for Researchers'. The page includes a 'Next Steps' section with buttons for 'Edit Modification/CR', 'Printer Version', and 'Submit'. A red arrow points to the 'Submit' button. Below this is a flowchart showing the process: Pre-Submission -> Pre-Review -> IRB Review -> Post-Review -> Review Complete. The 'Pre-Review' and 'IRB Review' steps have a 'Clarification Requested' loop. The 'Post-Review' step has a 'Modifications Required' loop. The 'History' section at the bottom shows a table with columns for Activity, Author, and Activity Date. The first entry is 'Minor Version Incremented'.

12. A new screen will open. Click “OK” to verify.

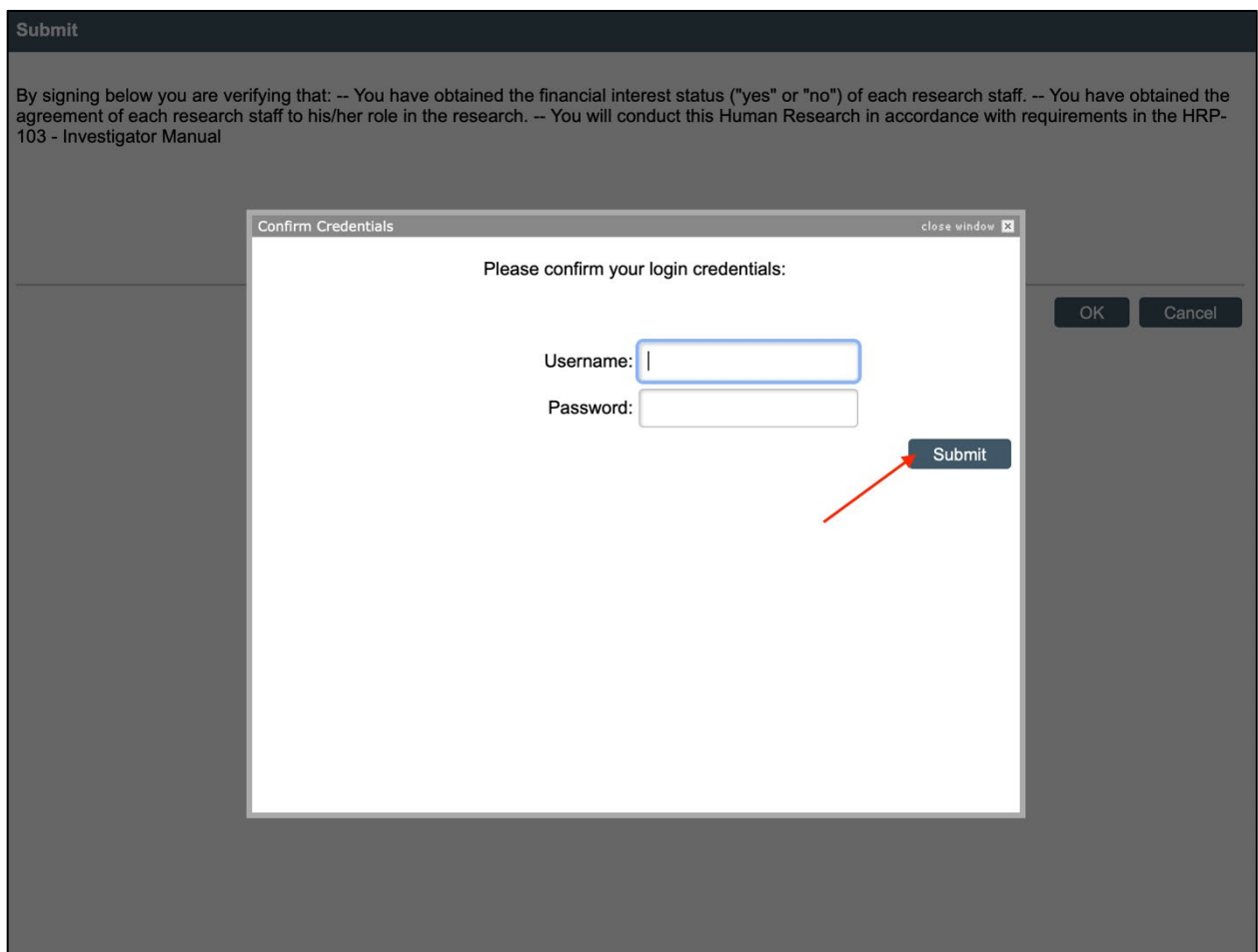
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The screenshot shows a web browser window with the URL `eirbint.jsc.nasa.gov/eIRB/sd/ResourceAdministration/Activity/form?ActivityType=com.webbridge.entity.Entity[OID[ACB93E39F3CE464F9A1563DA1ABE2DE4]]&Acti...`. The page has a dark blue header with the word "Submit" in white. Below the header, there is a paragraph of text: "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". At the bottom right of the form, there are two buttons: "OK" and "Cancel". A red arrow points from the right side of the text area towards the "OK" button.

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



The screenshot shows a "Confirm Credentials" dialog box overlaid on a "Submit" form. The dialog box has a title bar with "Confirm Credentials" and a "close window" button. Inside the dialog, it says "Please confirm your login credentials:". Below this, there are two input fields: "Username:" and "Password:". To the right of the "Password:" field is a "Submit" button. A red arrow points from the bottom right of the dialog box towards the "Submit" button. In the background, the "Submit" form is visible, showing the same verification text and "OK" and "Cancel" buttons as in the previous screenshot.

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



The screenshot displays the NASA IRB Huron system interface. At the top, the NASA logo is on the left, and a user greeting "Hello, [redacted]" is on the right. Below this is a navigation bar with tabs: Dashboard, Admin, IRB, and Home. Under the IRB tab, there are 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". It shows the Principal investigator, Submission type, and Primary contact, all redacted. The IRB office is listed as "Office of Research Assurance: Research Integrity & Protection of Human Subjects", the IRB coordinator is redacted, and the Regulatory authority is "2018 Requirements". A "Next Steps" section includes buttons for "View Modification/CR" and "Printer Version", and a list of actions: "Submit Pre-Review", "Request Pre-Review Clarification", "Assign Coordinator", "Manage Ancillary Reviews", "Add Comment", "Withdraw", and "Discard". A workflow diagram shows the process from "Pre-Submission" to "Pre-Review" (highlighted with a red box), then to "IRB Review", "Post-Review", and "Review Complete". Below the diagram is a "History" section with tabs for Contacts, Documents, Reviews, Related RNIs, and Snapshots. The "Reviews" tab is active, showing a table with columns for Activity, Author, and Activity Date. The table lists "Submitted" and "Minor Version Incremented" activities, both with redacted authors and dates.