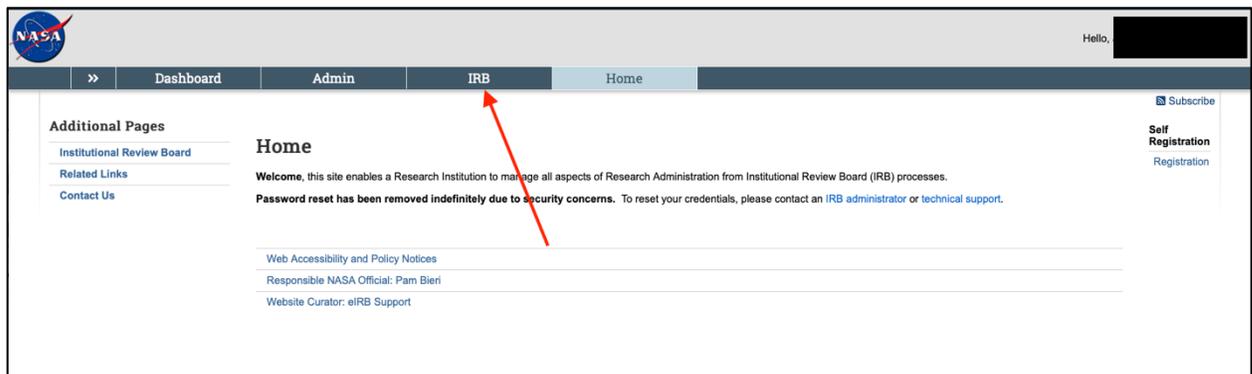


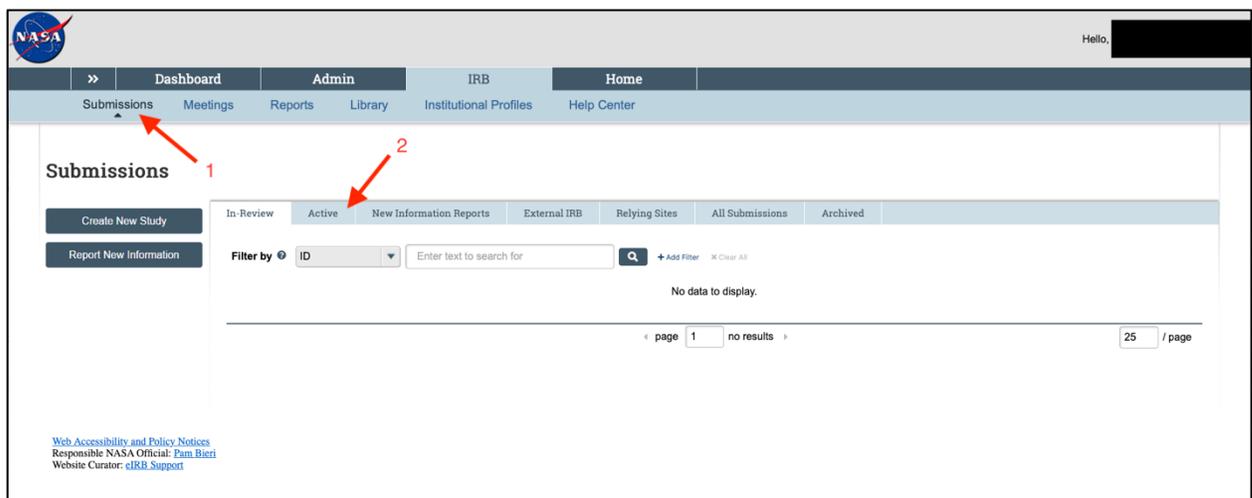
NASA IRB Huron Guide for Researchers Submitting a Study Modification

Please note, you can submit a modification alone (MOD), a continuing review alone (CR), or a modification and continuation combined (MODCR). This manual will specifically review submitting a study modification alone.

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.”



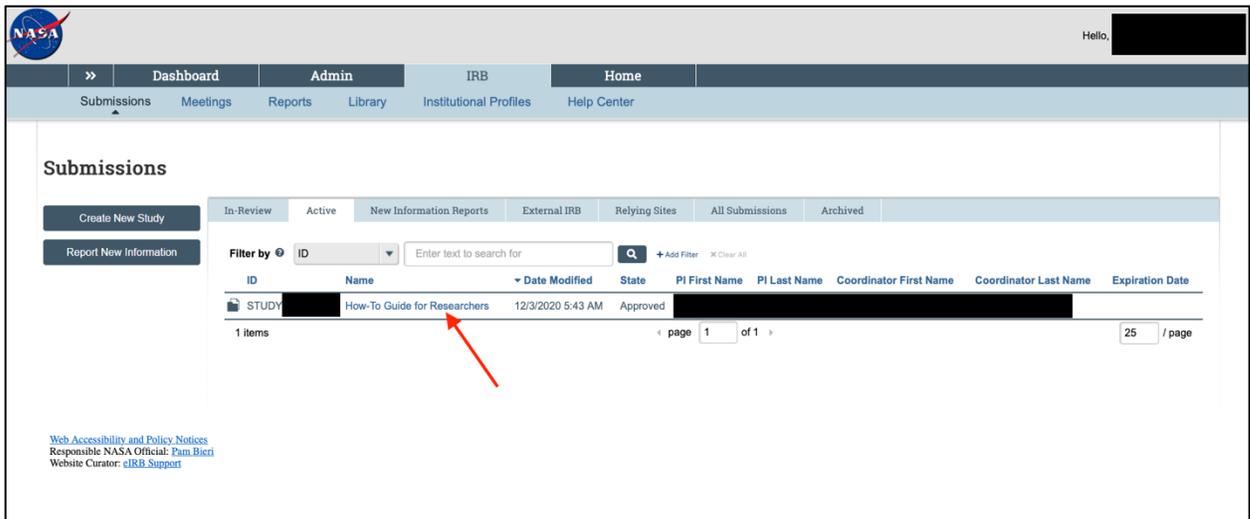
3. Then, click “Submission” in the top navigator bar, then click the “Active” tab.



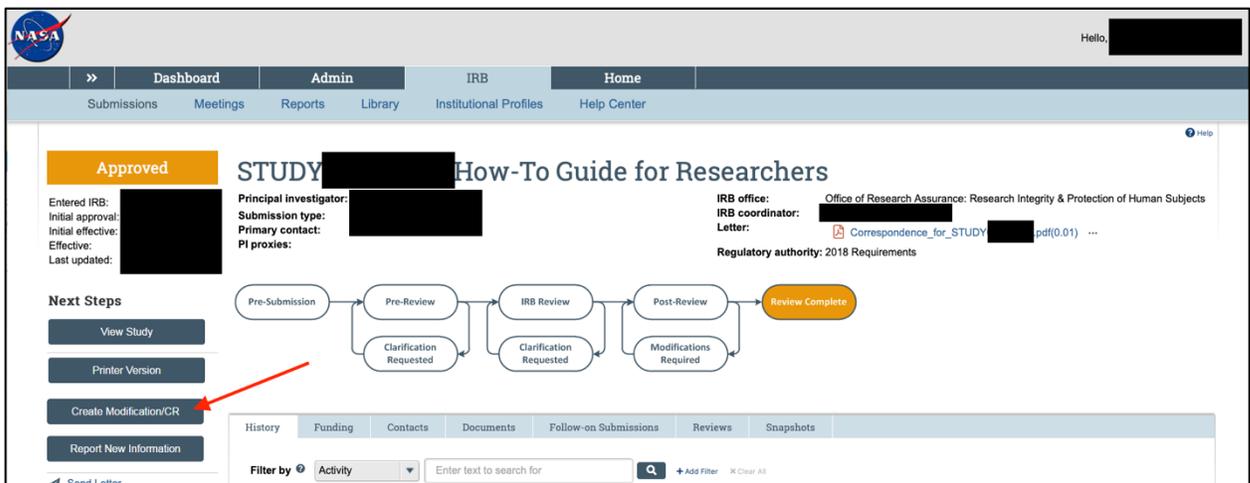
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4. Click on the title of the study of interest.



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



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6. Select “Modification/Update.” If you have already previously submitted a continuing review that is currently under review, you will only see “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.

The screenshot displays the NASA IRB Huron web application interface. The top left corner features the NASA logo. The top right corner shows a user greeting: "Hello, [redacted]". The breadcrumb trail reads: "You Are Here: How-To Guide for Researchers > IRBSubmission". The main heading is "Creating New: IRB Submission". Below this, the form is titled "Modification / Continuing Review / Study Closure". The first question is "What is the purpose of this submission?". It has three radio button options: "Continuing Review", "Modification / Update" (which is selected and highlighted with a red arrow), and "Modification and Continuing Review". There is a "Clear" link below these options. The second question is "To change the PI, choose 'Other parts of the study/site' scope". Below this is the "Modification scope:" section, which contains two checkboxes: "Study team member information" and "Other parts of the study". A red arrow points to the "Other parts of the study" checkbox. At the bottom right of the form, there are three buttons: "Exit", "Save", and "Continue". A red arrow points to the "Continue" button.

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7. 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

! 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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- Basic Study Information** – make adjustments to these areas as needed. If changing the protocol file, track all changes and upload a new document(s) in number 8. Click “Continue” when finished. You will progress your way through each of the study areas listed in the left panel.

Basic Study Information

- Title of study:**
How-To Guide for Researchers: Creating a New Submission
- Short title:**
How-To Guide for Researchers
- Brief description:**
This is a test template to create a guide for researchers in using the e-IRB System
- What kind of study is this?**
 Multi-site or Collaborative study
 Single-site study
[Clear](#)
- Will an external IRB act as the IRB of record for this study?**
 Yes No
- Local principal investigator:**
Jessica Kisenwether
- Does the local principal investigator have a financial interest related to this research?**
 Yes No [Clear](#)
- Attach the protocol:**

Document	Category	Date Modified	Document History
+ Add			
Update Test Protocol File.docx(0.01)	IRB Protocol	12/1/2020	History

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

- 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.** Remember to track changes on all other uploaded documents. Once finished with all sections, click “Finish.”

Final Page

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

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

[Exit](#) [Save](#) [Finish](#)

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

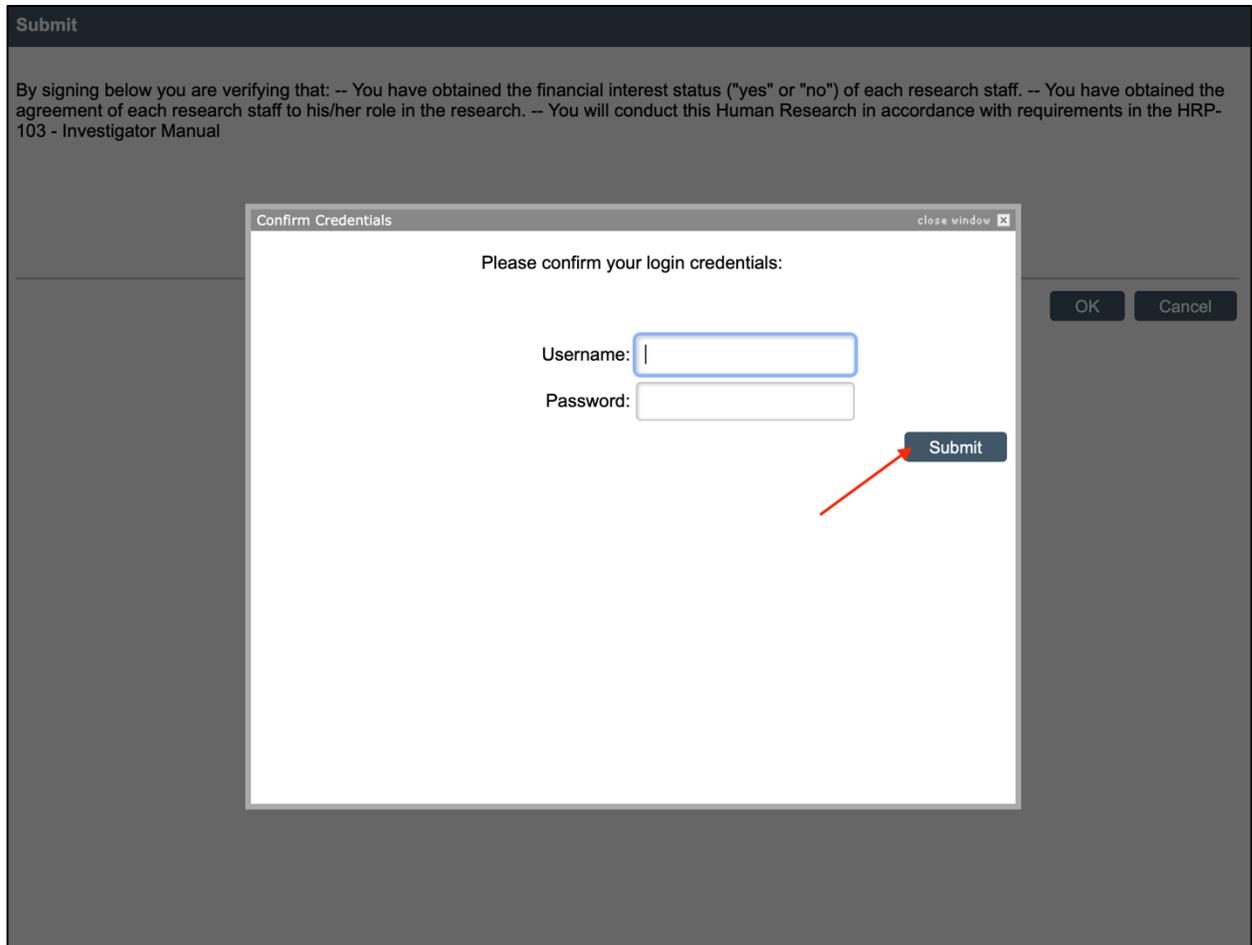
The screenshot shows the NASA IRB web application interface. At the top, there is a navigation bar with tabs for Dashboard, Admin, IRB, and Home. Below this is a secondary navigation bar with links for Submissions, Meetings, Reports, Library, Institutional Profiles, and Help Center. The main content area displays the title "MOD [redacted] Modification / Update #1 for Study How-To Guide for Researchers". It includes fields for "Last updated:", "Principal investigator:", "Submission type:", "Primary contact:", "IRB office:", "IRB coordinator:", and "Regulatory authority:". A "Next Steps" section contains buttons for "Edit Modification/CR", "Printer Version", and "Submit" (highlighted with a red arrow). A flowchart illustrates the process: Pre-Submission (highlighted) leads to Pre-Review, which can lead to IRB Review or Clarification Requested. IRB Review can lead to Post-Review or Clarification Requested. Post-Review can lead to Modifications Required or Review Complete. Below the flowchart is a table with columns for Activity, Author, and Activity Date. The first row shows "Minor Version Incremented" with a red arrow pointing to the "Submit" button in the "Next Steps" section.

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

The screenshot shows a "Submit" verification screen. The title bar indicates the URL: "eirbint.jsc.nasa.gov/eIRB/sd/ResourceAdministration/Activity/form?ActivityType=com.webbridge.entity.Entity[OID[ACB93E39F3CE464F9A1563DA1ABE2DE4]]&Acti...". The main content area contains the 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, there are two buttons: "OK" and "Cancel". A red arrow points to the "OK" button.

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12. Enter your e-IRB user name and password. Then click “Submit.”



The screenshot shows a web interface with a dark grey background. At the top left, there is a header labeled "Submit". 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". In the center of the page, a white dialog box titled "Confirm Credentials" is open. The dialog box contains the text "Please confirm your login credentials:" followed by two input fields: "Username:" and "Password:". A red arrow points to a "Submit" button located at the bottom right of the dialog box. To the right of the dialog box, there are two buttons: "OK" and "Cancel".

13. The modification status will show as “Pre-Review” when successfully submitted.

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Submitting a Study Modification

The screenshot displays the NASA IRB Huron web application interface. At the top, there is a navigation bar with the NASA logo on the left and a 'Hello, [redacted]' greeting on the right. Below the navigation bar are tabs for 'Dashboard', 'Admin', 'IRB', and 'Home'. A secondary navigation bar contains links for 'Submissions', 'Meetings', 'Reports', 'Library', 'Institutional Profiles', and 'Help Center'. The main content area features a 'Pre-Review' tab highlighted in orange. The title of the page is 'MOD [redacted] Modification / Update #1 for Study How-To Guide for Researchers'. Below the title, there are fields for 'Entered IRB:', 'Last updated:', 'Principal investigator:', 'Submission type:', 'Primary contact:', 'IRB office:', 'IRB coordinator:', and 'Regulatory authority: 2018 Requirements'. A 'Next Steps' section includes buttons for 'View Modification/CR' and 'Printer Version'. A flowchart illustrates the process: Pre-Submission leads to Pre-Review (highlighted in orange), which can lead to IRB Review or Post-Review. IRB Review and Post-Review can lead to Review Complete. There are also loops for 'Clarification Requested' between Pre-Submission and Pre-Review, and between IRB Review and Post-Review. A sidebar on the left contains a list of actions: 'Submit Pre-Review', 'Request Pre-Review Clarification', 'Assign Coordinator', 'Manage Ancillary Reviews', 'Add Comment', 'Withdraw', and 'Discard'. Below the flowchart, there is a 'History' section with tabs for 'Contacts', 'Documents', 'Reviews', 'Related RNIs', and 'Snapshots'. A search bar is present with the text 'Filter by Activity' and a search input field. Below the search bar, there is a table with columns for 'Activity', 'Author', and 'Activity Date'. The table shows one entry: 'Submitted' by [redacted] on [redacted].