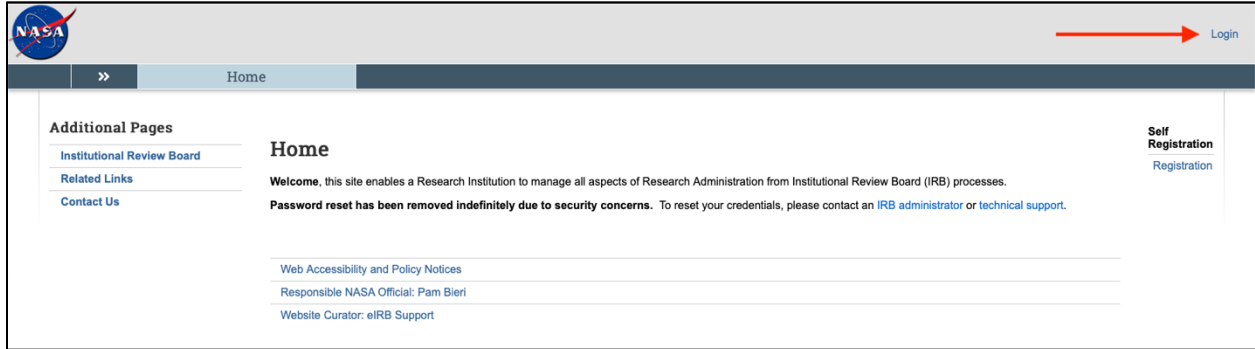


NASA IRB Huron Guide for Researchers

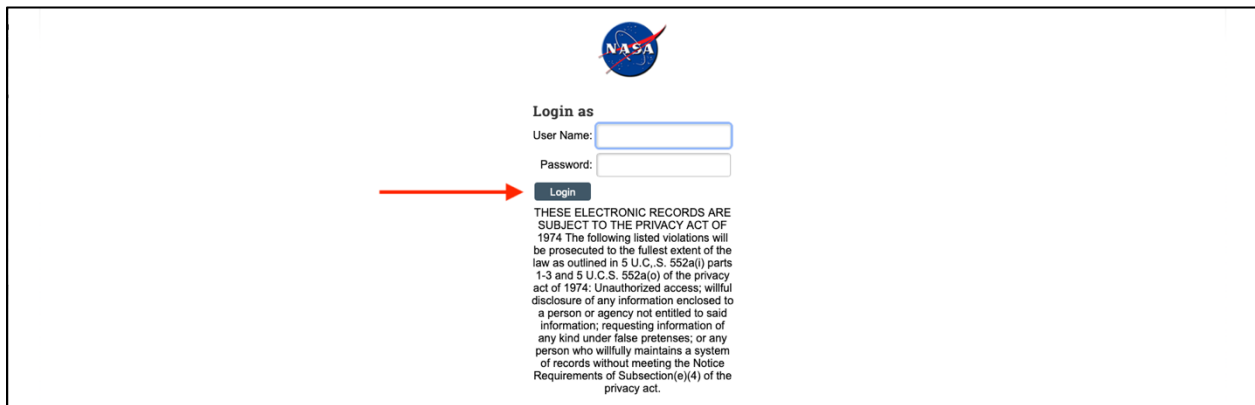
How to Submit a New Study

Before you begin, gather files and information about your study. For more details on documents you may want to attach to a study, see the [Checklist of Information to Attach](#).

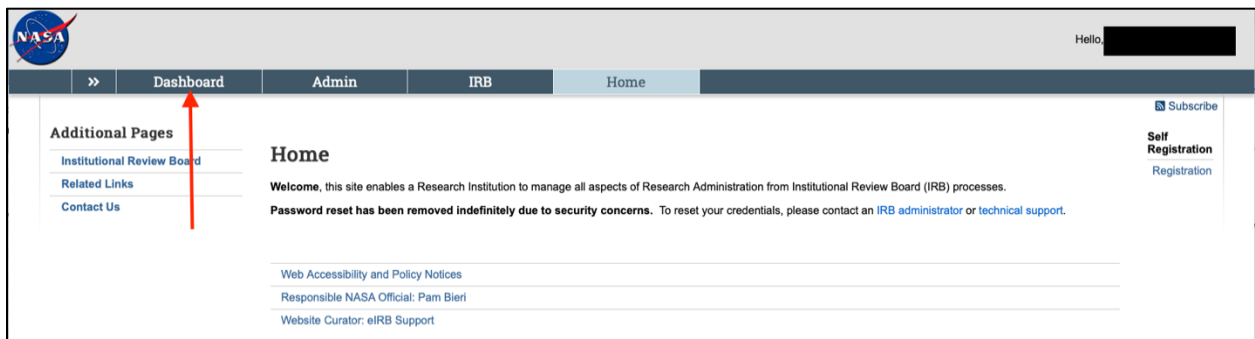
1. Visit <https://eirb.jsc.nasa.gov/EIRB/> and click “Login” at the top right corner of the screen.



2. Enter your User Name and Password. Click “Login.”

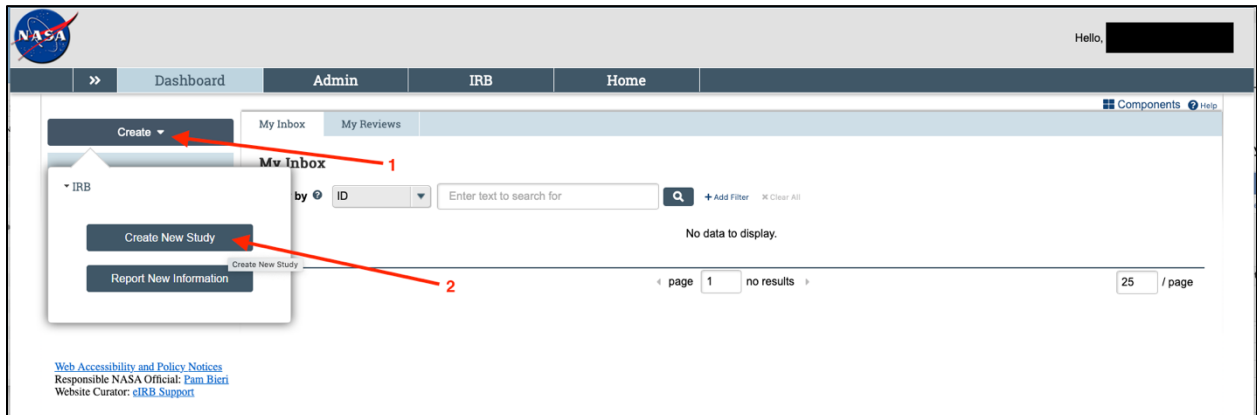


3. Click “Dashboard” on the top menu bar.



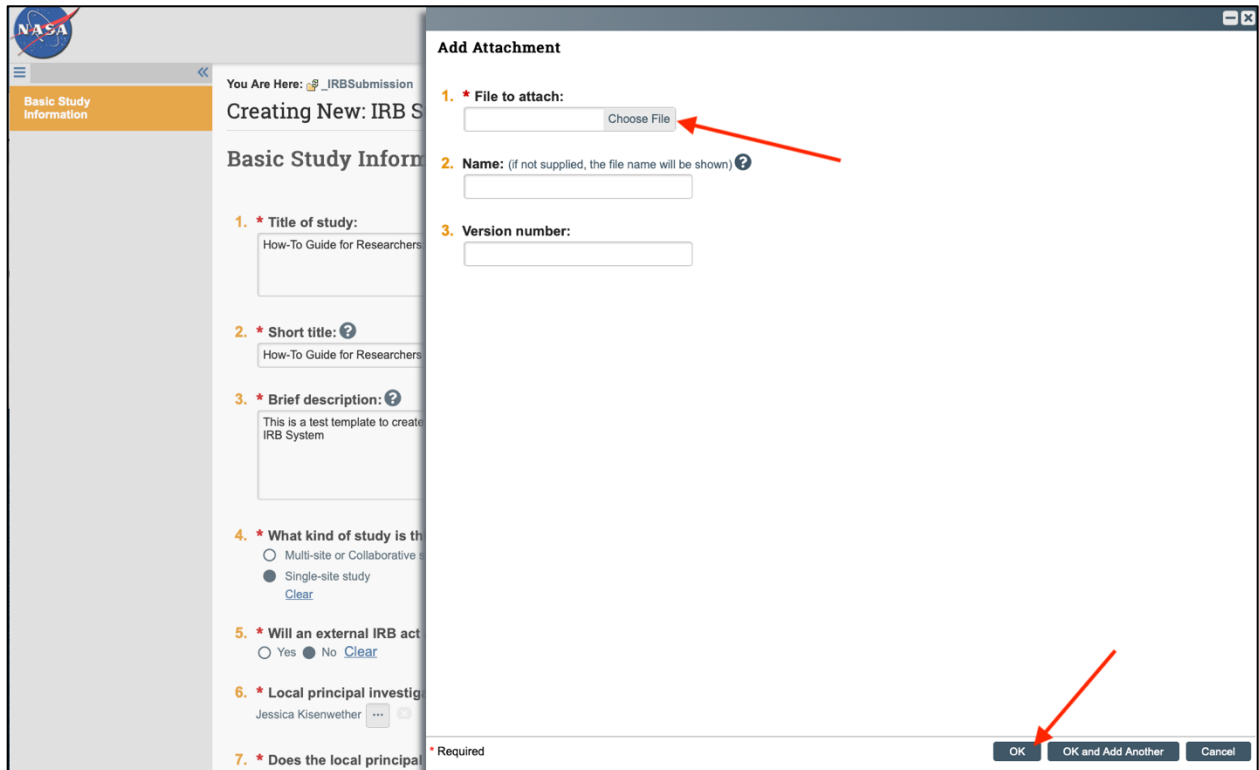
NASA IRB Huron Guide for Researchers
How to Submit a New Study

4. Select “Create” in the left panel and then select “Create New Study.”



5. Basic Study Information - Complete sections 1 through 8. Note, all sections are required as indicated by a red asterisk (*). Using the relevant Center protocol template, upload a word document in section 8.

When attaching the protocol, click “+ Add”. A new screen will appear. You will need to locate the file on your computer. You may add several files if necessary by clicking “OK and Add Another.” Once all documents are uploaded, click “OK.”



NASA IRB Huron Guide for Researchers

How to Submit a New Study

- Once finished completing sections 1 through 8, or at any time in the protocol entry process, you may either save the information and return later to complete by clicking “Save” in the bottom left of the screen or continue with the protocol entry by clicking “Continue.” **Note: please include the Center before the study title. For example JSC: Study Title, Langley: Study Title, Ames: Study Title, or Kennedy: Study Title.**

The screenshot shows a web application interface for creating a new IRB submission. The top left corner features the NASA logo. The main header area includes the text "You Are Here: > IRBSubmission" and "Creating New: IRB Submission". A navigation bar on the left is labeled "Basic Study Information". The main content area is titled "Basic Study Information" and contains eight numbered sections:

- Title of study:** A text input field.
- Short title:** A text input field.
- Brief description:** A text area.
- What kind of study is this?** Radio buttons for "Multi-site or Collaborative study" and "Single-site study", with a "Clear" link below.
- Will an external IRB act as the IRB of record for this study?** Radio buttons for "Yes" and "No", with a "Clear" link below.
- 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", with a "Clear" link below.
- Attach the protocol:** A table with columns "Document", "Category", "Date Modified", and "Document History". Below the table, it says "There are no items to display".

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

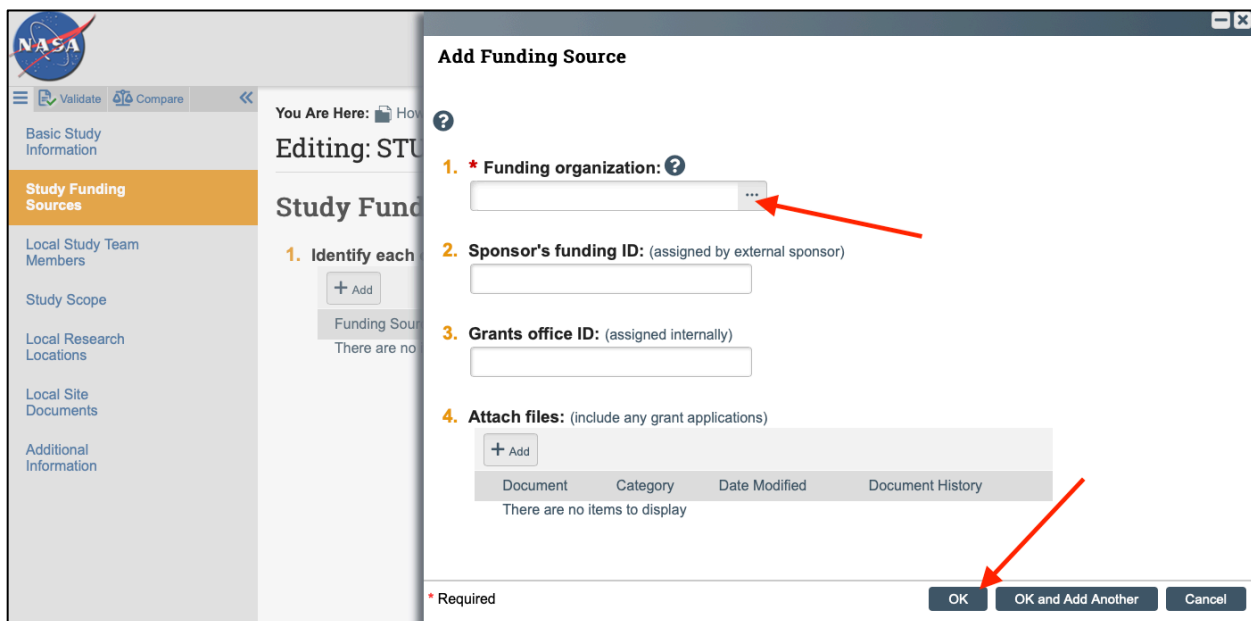
NASA IRB Huron Guide for Researchers
How to Submit a New Study

7. Study Funding Sources

- a. If you **do not have** a funding source, simply select “Continue” at the bottom right of the screen.
- b. If you **do have** a funding source, enter the Study Funding Source information by clicking “+ Add.” A new screen will appear.



8. Once selected, you will be prompted in the new screen to select the Funding Organization (a required entry). Click the three dots shown below to select a funding source. This is a progressive search. Start typing the name of the organization and you will be presented with a list to pick from. If your funding source does not appear, select “other” from the list. Once complete, you may either add an additional funding source or exit the screen to continue the protocol entry by clicking “OK.” Then, click “Continue” at the bottom right of the screen.



NASA IRB Huron Guide for Researchers
How to Submit a New Study

9. Local Study Team Members - Add all local study team members and external team member information if applicable by clicking on “+ Add” in the corresponding areas. **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.**
- a. If you **do not have** additional study team members click “Continue” at the bottom right of the screen.

The screenshot shows the NASA IRB Huron web application interface. The top left features the NASA logo and navigation links like 'Validate' and 'Compare'. The user is logged in as 'Hello, [redacted]'. The page title is 'You Are Here: How-To Guide for Researchers' and the current page is 'Editing: STUDY [redacted]'. The main content area is titled 'Local Study Team Members'. It contains two numbered sections: '1. Identify each additional person involved in the design, conduct, or reporting of the research: ?' and '2. External team member information: ?'. Each section has a '+ Add' button with a red arrow pointing to it. The first section has a table with columns: Name, Roles, Financial Interest, Involved in Consent, E-mail, and Phone. The second section has a table with columns: Name and Description. At the bottom right, there are three buttons: 'Exit', 'Save', and 'Continue' with a right arrow. A red arrow points to the 'Continue' button.

10. If you **do have** additional study team members, select “+ Add” a new screen will appear. Select the three dots shown below to find study team members. This is a progressive search. Start typing the name of the study team member and you will be presented with a list of individuals to pick from. Indicate the team member’s role in the research and indicate Yes or No responses for required sections 3 and 4. Once finished, you may add another study team member by clicking “OK and Add Another” or finish by selecting “OK” at the bottom right of the screen. Once you have added all study team members, click “Continue” at the bottom right of the screen.

NASA IRB Huron Guide for Researchers

How to Submit a New Study

Add Study Team Member

1. * Study team member: ?

2. Role in research: (check all that apply)

- Co-Investigator
- Data Analyst
- Research Assistant
- Statistician
- Lay Observer
- Study Coordinator
- Collaborator

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](#)

* Required

OK OK and Add Another Cancel

11. Study Scope – Answer required questions 1 and 2. Once completed, click “Continue” at the bottom right of the screen. If you selected “yes” to question 1 and/or question 2, new areas will appear in the application process (Drugs and/or Devices). These sections will appear after Local Research Locations. You will be prompted to add additional information.

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](#)

Exit Save Continue

12. Local Research Locations – By clicking “+ Add” a new screen will appear to add research locations. Select the three dots under “Select the research location” do to so. Once completed, you may add another research location or click “OK” to exit this screen. When research location(s) is/are added, you may click “Continue” at the bottom right of the screen to proceed with the protocol entry.

NASA IRB Huron Guide for Researchers

How to Submit a New Study

The screenshot shows a web application interface for adding a research location. On the left is a sidebar with the NASA logo and navigation links: 'Validate', 'Compare', 'Basic Study Information', 'Study Funding Sources', 'Local Study Team Members', 'Study Scope', 'Local Research Locations' (highlighted), 'Local Site Documents', and 'Additional Information'. The main content area is titled 'Add Research Location Information' and includes a breadcrumb 'You Are Here: How-To Guide for Researchers' and 'Editing: STUDY [redacted]'. Below this is a section 'Local Research Locations' with a '+ Add' button and a table with one row: 'Location' and the text 'There are no items to display'. The main form area is titled '1. Select the research location:' and features a search input field with a dropdown arrow. Below this is a note: 'If you cannot find the research location in the list above, enter its information here:'. The form contains several fields: 'a. Location name:' (text input), 'b. Location address:' (three stacked text inputs for 'Address line 1', 'Address line 2', and 'Address line 3'), 'City' (text input), 'State or province' (dropdown menu), 'Postal code' (text input), 'Country' (dropdown menu), 'c. Contact name:' (text input), and 'd. Contact phone:' (text input). At the bottom right, there are three buttons: 'OK', 'OK and Add Another', and 'Cancel'. A red arrow points to the search dropdown arrow, and another red arrow points to the 'OK' button.

The screenshot shows the 'Local Research Locations' section of the web application. The sidebar is identical to the previous screenshot. The main content area shows 'Editing: STUDY [redacted]' and a section 'Local Research Locations' with a '+ Add' button and a table with one row: 'Location' and the text 'There are no items to display'. Below the table is a section '1. Identify research locations where research activities will be conducted or overseen by the local investigator:'. At the bottom right, there are three buttons: 'Exit', 'Save', and 'Continue' (highlighted with a red arrow).

13. Local Site Documents – In this section, you will add all consent forms, recruitment materials such as scripts, flyers, etc., and other relevant study documentation such as surveys, interview questions, and instrumentation descriptions. You may also reference [Checklist of Information to Attach](#) for guidance. Simply click on the “+ Add” button in each corresponding area. A new window will open (please see guidance provide in #5 of this document) and you will locate the files on your computer

NASA IRB Huron Guide for Researchers

How to Submit a New Study

to upload. Once finished, click “OK” in the bottom right of the new screen and continue with your protocol entry by clicking “Continue” in the bottom right corner of the screen.

The screenshot displays the NASA IRB Huron web application interface. On the left is a sidebar with a NASA logo and navigation links: 'Basic Study Information', 'Study Funding Sources', 'Local Study Team Members', 'Study Scope', 'Local Research Locations', 'Local Site Documents' (highlighted in orange), and 'Additional Information'. The main content area shows the user is editing a study. It features three sections for document uploads: '1. Consent forms: (include an HHS-approved sample consent document, if applicable)', '2. Recruitment materials: (add all material to be seen or heard by subjects, including ads)', and '3. Other attachments:'. Each section has an '+ Add' button and a table with columns for 'Document', 'Category', 'Date Modified', and 'Document History'. Below these is a 'Suggested attachments' section with a list of items. At the bottom right, there are three buttons: 'Exit', 'Save', and 'Continue'. Red arrows point to the '+ Add' button in the first section and the 'Continue' button.

NASA IRB Huron Guide for Researchers

How to Submit a New Study

14. Additional Information – Answer all 5 required questions. Click “Continue” in the bottom right corner of the screen when completed.

The screenshot shows the NASA IRB Huron system interface. The top left features the NASA logo and navigation links for 'Validate' and 'Compare'. The top right shows a user greeting 'Hello, [redacted]'. The main content area is titled 'Additional Information' and contains five numbered questions:

1. * Does your study involve astronauts? Yes No [Clear](#)
2. * Does your study involve International astronauts? Yes No [Clear](#)
3. * Is this an engineering/hardware evaluation [human in the loop] study? Yes No [Clear](#)
4. * Does this protocol involve genetic testing?: Yes No [Clear](#)
5. * Medical Monitor:

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

15. Final Page – If ready to submit, click “Finish.”

The screenshot shows the 'Final Page' of the NASA IRB Huron submission form. The page contains the following text:

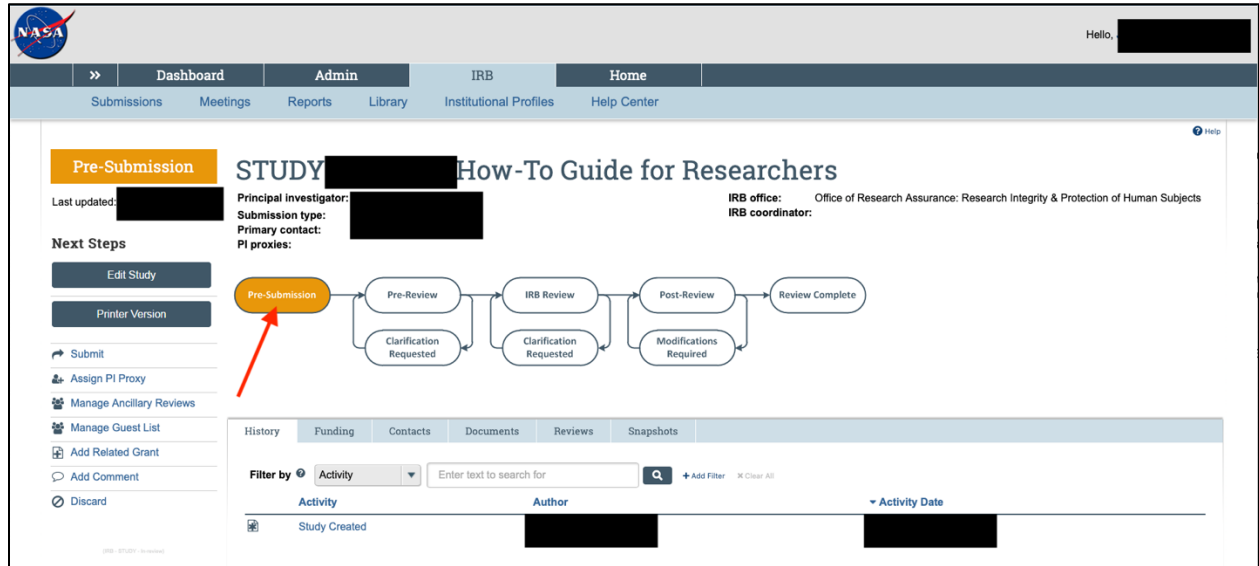
You have reached the end of the IRB submission form. Read the next steps carefully:

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

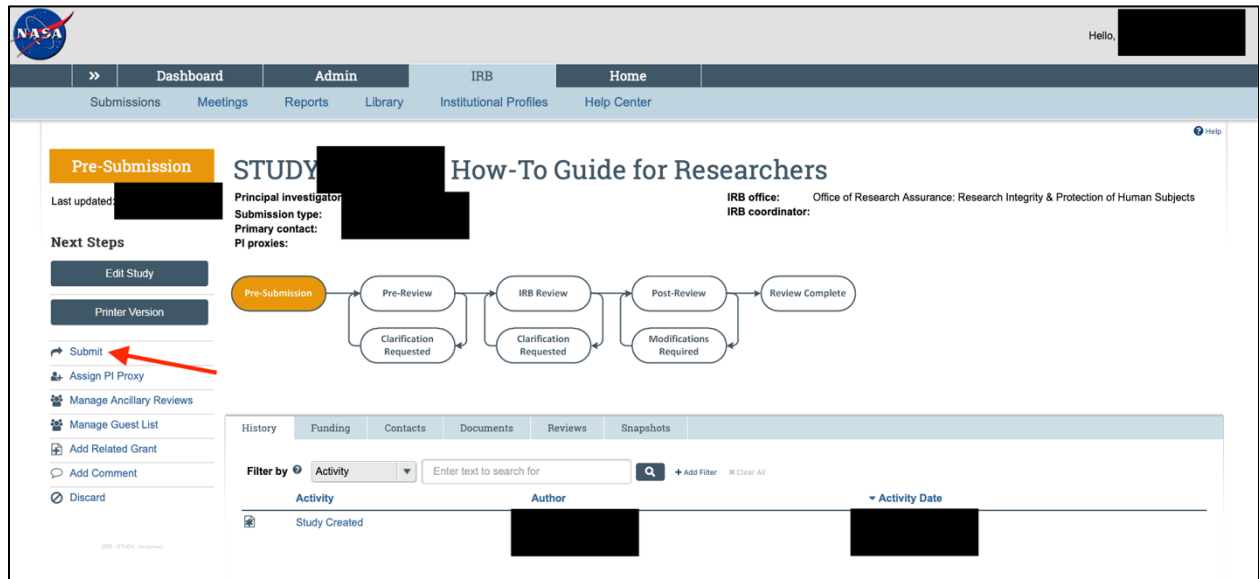
In the bottom right corner, there are three buttons: 'Exit', 'Save', and 'Finish'. A red arrow points to the 'Finish' button.

NASA IRB Huron Guide for Researchers
How to Submit a New Study

16. You will see the screen below indicating the Study is now in the “Pre-Submission” phase. **The study has not been submitted to the IRB.**



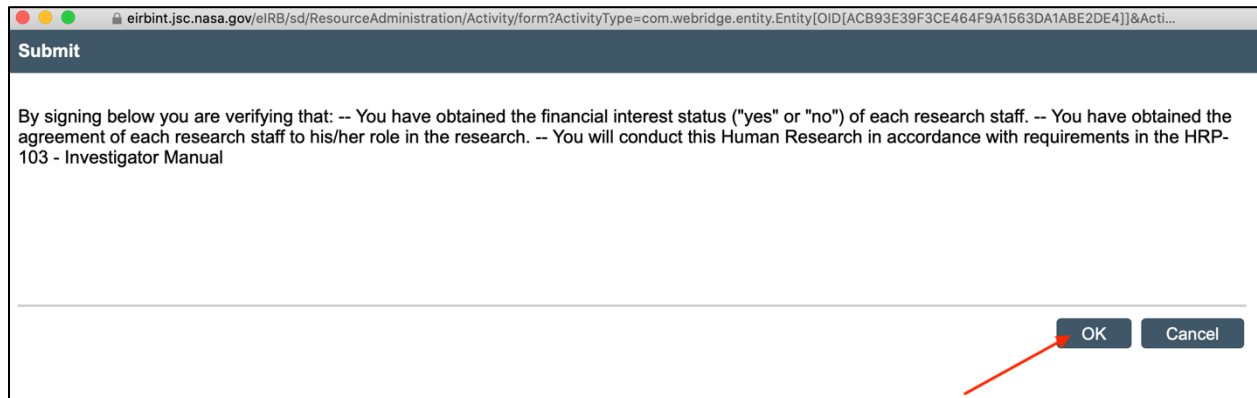
17. You may make adjustments to the protocol in this stage before submission. When ready to submit to the IRB office, click “Submit” on the left side of the screen.



NASA IRB Huron Guide for Researchers

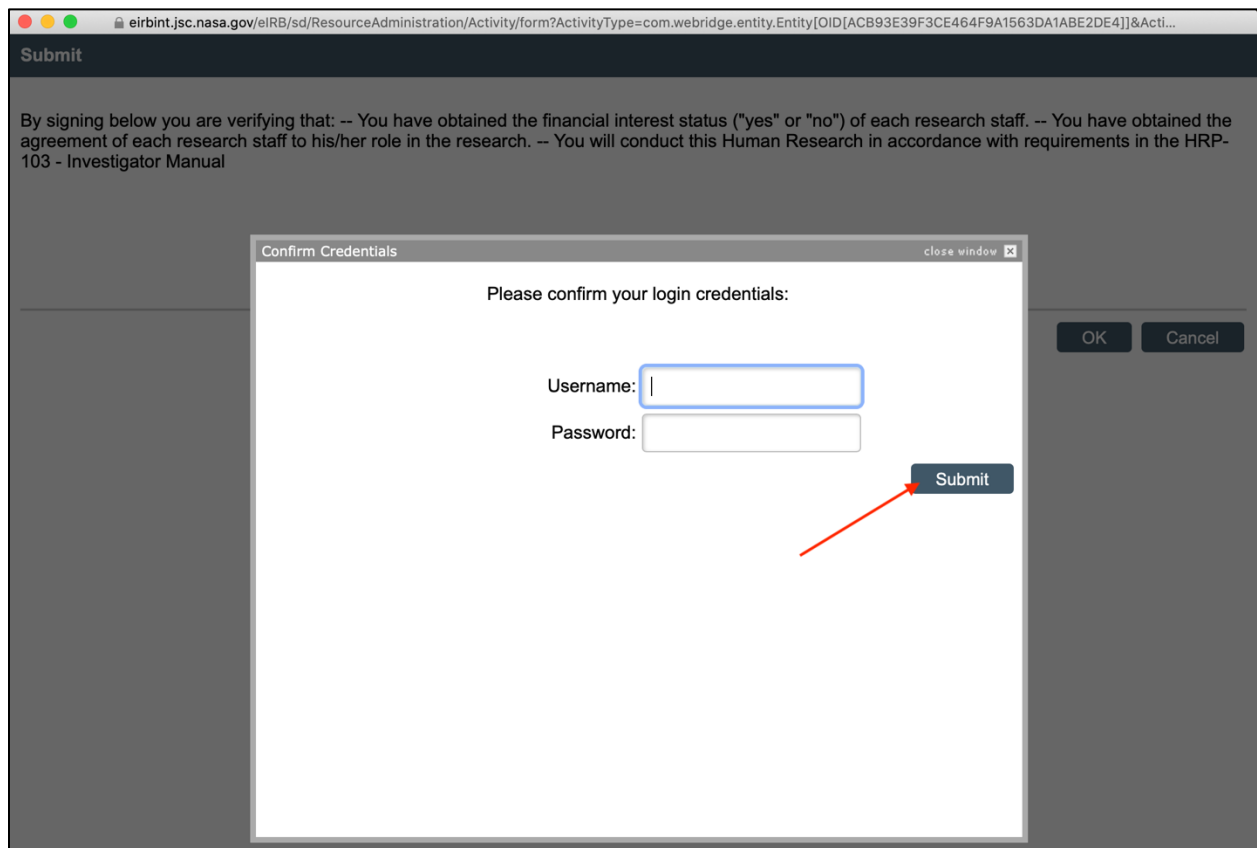
How to Submit a New Study

18. Once selected, a new screen will open as shown below. Click “OK” to verify.



The screenshot shows a web browser window with the URL `eirbint.jsc.nasa.gov/elRB/sd/ResourceAdministration/Activity/form?ActivityType=com.webridge.entity.Entity[OID[ACB93E39F3CE464F9A1563DA1ABE2DE4]]&Acti...`. The page title is "Submit". The main content area contains the following 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 page, there are two buttons: "OK" and "Cancel". A red arrow points to the "OK" button.

19. An additional pop-up window will appear. Enter your e-IRB user name and password, then click “submit.”



The screenshot shows the same "Submit" screen as in the previous image, but with a "Confirm Credentials" pop-up window overlaid. The pop-up window has a title bar with "Confirm Credentials" and a "close window" button. The main text inside the pop-up is "Please confirm your login credentials:". Below this text are two input fields: "Username:" and "Password:". To the right of the "Password:" field is a "Submit" button. A red arrow points to the "Submit" button. In the background, the "OK" and "Cancel" buttons from the main screen are visible.

NASA IRB Huron Guide for Researchers

How to Submit a New Study

20. When successfully submitted to the IRB, the study will be the “Pre-Review” state as shown below.

The screenshot displays the NASA IRB system interface. At the top, there is a NASA logo and 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 features a 'Pre-Review' status indicator in a yellow box. The study title is 'STUDY [redacted] How-To Guide for Researchers'. Key information includes: Entered IRB: [redacted], Last updated: [redacted], Principal investigator: [redacted], Submission type: [redacted], Primary contact: [redacted], PI proxies: [redacted], IRB office: Office of Research Assurance: Research Integrity & Protection of Human Subjects, and IRB coordinator: [redacted].

Next Steps

- View Study
- Printer Version
- Assign Coordinator
- Assign PI Proxy
- Manage Ancillary Reviews
- Manage Guest List
- Add Related Grant
- Add Comment
- Withdraw
- Discard

A flowchart illustrates the study process: Pre-Submission leads to Pre-Review (highlighted with a red arrow), which can lead to IRB Review or Clarification Requested. IRB Review can lead to Post-Review or Clarification Requested. Post-Review can lead to Review Complete or Modifications Required. Clarification Requested can lead back to Pre-Review or forward to IRB Review or Post-Review.

History

Activity	Author	Activity Date
Submitted	[redacted]	[redacted]
Study Created	[redacted]	[redacted]

Checklist for Information to Attach

While editing the study, several forms provide places to attach related files. In some cases, a template file is provided directly on the form for download, such as the protocol.

When attaching each file, name it as you want it to appear on the IRB approval letter.

Attach the information listed below (if relevant to your study) to the location identified.

Protocol: (Basic Information page)

- NASA protocol template [or approved NASA agency specific template]
 - Flight and Complement templates as appropriate
- Scientific Merit Review (if applicable)
- Safety and/or Radiation Assessment Review [*contact the NASA IRB Safety Representative with questions prior to submission*]
- Complete sponsor protocol (optional)

Funding Information: (Funding Sources page, with each source)

- Grant award letter

Drug details: (Drugs page, with each drug, or on main Drugs page if not specific to one drug)

- Package insert
- Investigator brochure
- Verification of each IND number (one of these):
 - Sponsor protocol with the IND number
 - Communication from the FDA or sponsor with the IND number

Device details: (Devices page, with each device, or on main Devices page if not specific to one device)

- Product labeling/device instructions
- Investigator brochure
- Verification of each IDE of HDE number (one of these):
 - Sponsor protocol with the IDE/HDE number
 - Communication from the FDA or sponsor with the IDE/HDE number

Recruitment and consent details: (Local Site Documents page)

- Consent documents:
 - NASA Consent form template [or approved NASA agency specific template]
 - The HRMRB consent template must be used to consent astronaut subjects
- All material to be seen or heard by subjects, such as:
 - Evaluation instruments and surveys
 - Advertisements, including printed, audio, and video
 - Recruitment materials and scripts

NASA IRB Huron Guide for Researchers

How to Submit a New Study

- Foreign-language versions of materials for subjects
- Supporting document and other attachments:
 - Financial Conflict of Interest Disclosures
 - CITI certificates

All other relevant documents: (Study-Related Documents page)

- Consent document templates for use by participating sites
- Recruitment materials templates for use by participating sites
- Other supporting documents needed by participating sites
- IRB approval letters from institutions other than NASA
- Reliance Acknowledgments