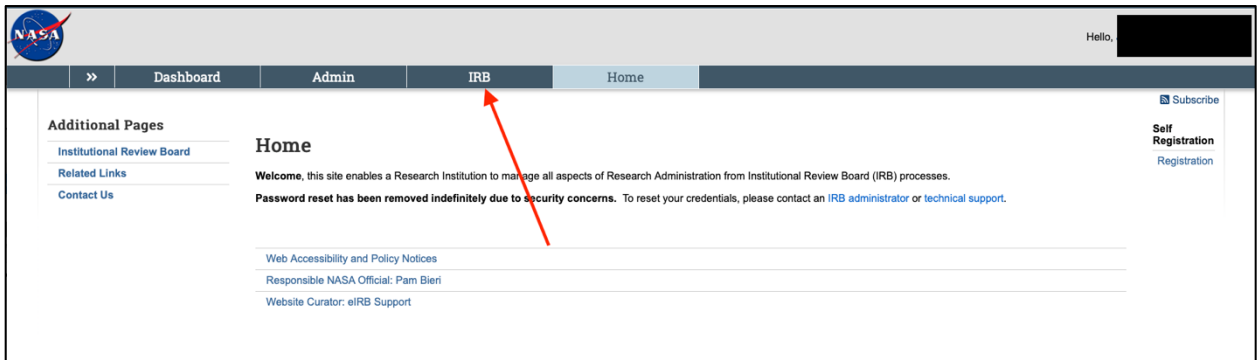


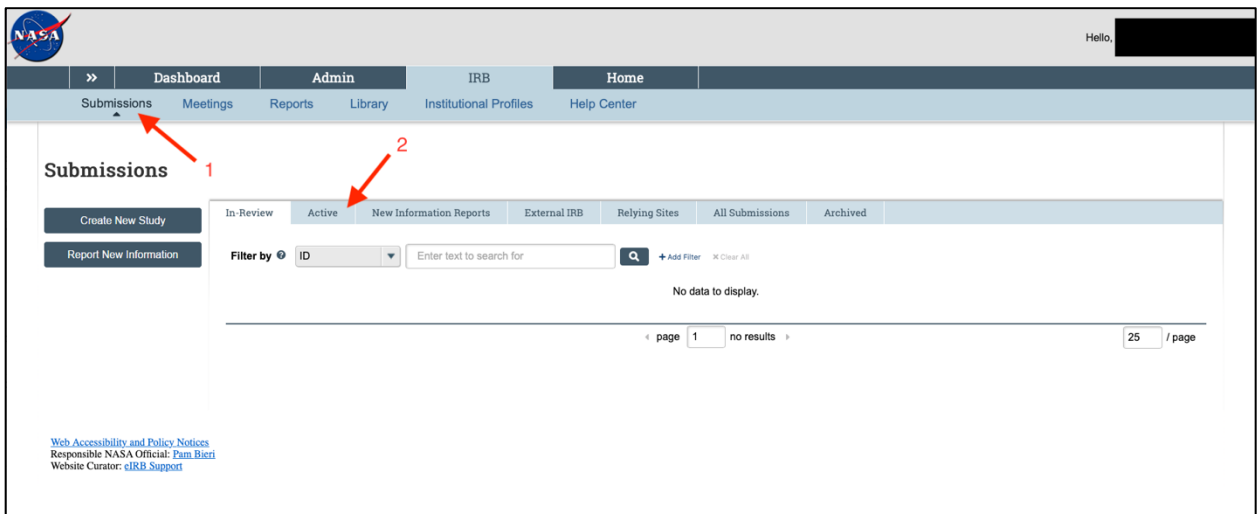
NASA IRB Huron Guide for Researchers

Report New Information

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 Dashboard, Admin, IRB, and Home. Below this is a secondary navigation bar with 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. A single entry is visible: 'STUDY [redacted] How-To Guide for Researchers' with a date of '12/3/2020 5:43 AM' and a state of 'Approved'. A red arrow points to the title 'How-To Guide for Researchers'. At the bottom left, there is a footer with 'Web Accessibility and Policy Notices', 'Responsible NASA Official: Pam Bisci', and 'Website Curator: eIRB Support'.

5. Click on “Report New Information” on the left side of the screen.

The screenshot shows the details page for the study 'STUDY [redacted] How-To Guide for Researchers'. The page is marked as 'Approved'. It displays key information such as the Principal Investigator, Submission type, Primary contact, and PI proxies. It also lists the IRB office (Office of Research Assurance: Research Integrity & Protection of Human Subjects), the IRB coordinator, and the Letter (Correspondence_for_STUDY: [redacted]). The Regulatory authority is noted as '2018 Requirements'. A flowchart illustrates the review process: Pre-Submission 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 leads to Review Complete. Below the flowchart, there are tabs for History, Funding, Contacts, Documents, Follow-on Submissions, Reviews, and Snapshots. A 'Next Steps' section on the left contains buttons for 'View Study', 'Printer Version', 'Create Modification/CR', and 'Report New Information'. A red arrow points to the 'Report New Information' button. At the bottom, there is a 'Filter by' section with a dropdown menu set to 'Activity' and a search box.

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- Complete numbers 1 through 4. Click “Continue” on the bottom right of the screen. **Please note, if you indicate that a study revision and/or a revised consent document is needed, you will also need to submit a study modification for review.**

If you are entering a **Breach of Confidentiality RNI**, please state
1) whether the breach included personnel internal (including contract employees such as KBR, Leidos, etc.) or external to NASA, and
2) state whether you have already submitted the Breach to the SOC.

Reportable New Information

- RNI short title:** (uniquely identify this new information report)
- * Date you became aware of the information:**
- Identify the categories that represent the new information:** (check all that apply)
Risk: Information that indicates a new or increased risk, or a safety issue. For example:
 - New information (e.g., an interim analysis, safety monitoring report, publication in the literature, sponsor report, or investigator finding) indicates an increase in the frequency or magnitude of a previously known risk, or uncovers a new risk.
 - An investigator brochure, package insert, or device labeling is revised to indicate an increase in the frequency or magnitude of a previously known risk, or to describe a new risk.
 - Withdrawal, restriction, or modification of a marketed approval of a drug, device, or biologic used in a research protocol.
 - Protocol violation that harmed subjects or others or that indicates subjects or others might be at increased risk of harm.
 - Complaint of a subject that indicates subjects or others might be at increased risk of harm or at risk of a new harm.
 - Any changes significantly affecting the conduct of the research.**Harm:** Any harm experienced by a subject or other individual that, in the opinion of the investigator, is unexpected and at least probably related to the research procedures.
 - A harm is “**unexpected**” when its specificity or severity is inconsistent with risk information previously reviewed and approved by the IRB in terms of nature, severity, frequency, and characteristics of the study population.
 - A harm is “**probably related**” to the research procedures if, in the opinion of the investigator, the research procedures more likely than not caused the harm. **Non-compliance:** Non-compliance with the federal regulations governing human research or with the requirements or determinations of the IRB, or an allegation of such non-compliance. **Audit:** Audit, inspection, or inquiry by a federal agency. **Report:** Written reports of study monitors. **Researcher error:** Failure to follow the protocol due to the action or inaction of the investigator or research staff. **Confidentiality:** Breach of confidentiality. **Unreviewed change:** Change to the protocol taken without prior IRB review to eliminate an apparent immediate hazard to a subject. **Incarceration:** Incarceration of a subject in a study not approved by the IRB to involve prisoners. **Complaint:** Complaint of a subject that cannot be resolved by the research team. **Suspension:** Premature suspension or termination of the research by the sponsor, investigator, or institution.
Unanticipated adverse device effect: Any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a device, if that

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7. Click “Submit RNI” on the left side of the screen to submit the RNI to the IRB Office.

The screenshot shows the NASA IRB web application interface. At the top, there is a NASA logo and a navigation bar with tabs for Dashboard, Admin, IRB, and Home. Below the navigation bar, there are sub-tabs for Submissions, Meetings, Reports, Library, Institutional Profiles, and Help Center. The main content area displays the 'Pre-Submission' screen for 'Test RNI'. It includes fields for 'Last updated', 'Reported by', 'Submission type', and 'IRB office: Office of Research Assurance: Research Integrity & Protection of Human Subjects'. A flowchart shows the process steps: Pre-Submission, Pre-Review, IRB Review, Post-Review, and Review Complete. A sidebar on the left contains a list of actions: Submit RNI (highlighted with a red arrow), Add Related Submission, Add Comment, Copy Submission, and Discard. Below the sidebar, there is a table with columns for Activity, Author, and Activity Date.

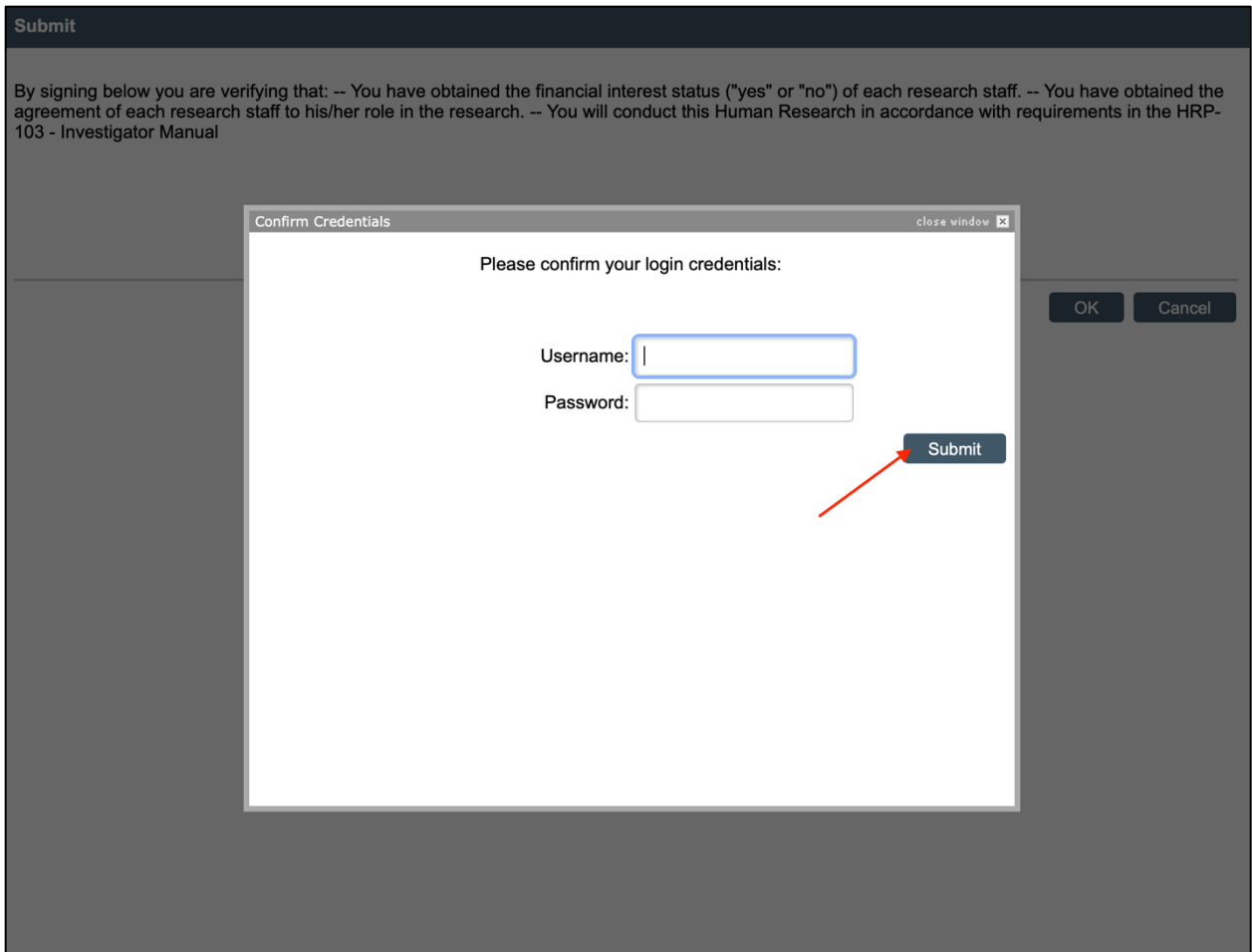
8. A new screen will open. Click “OK” to verify.

The screenshot shows the 'Submit RNI' verification screen. The title bar indicates the URL: `eirbint.jsc.nasa.gov/eIRB/sd/ResourceAdministration/Activity/form?ActivityType=com.webridge.entity.Entity[OID[636EBBDFE1141D4CBE4AB7293795C011]]&Activ...`. The main content area contains the text: 'By signing below you are verifying that:' followed by a bulleted list of verification requirements: 'The information you have submitted is complete and correct to the best of your knowledge.' and 'The information you have submitted has been done so 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.

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

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10. The Report of New Information status will show as “Pre-Review” when successfully submitted.

