

## NASA IRB Huron Guide for Researchers Responding to Requests for Clarification

If a reviewer has questions or requires you to change your submission, you will receive an email.

Be sure to review the request details and then respond to the request.

1. If you have the email, Click the submission ID link (indicated with the red arrow) in the email to view reviewer comments.

To: [name]

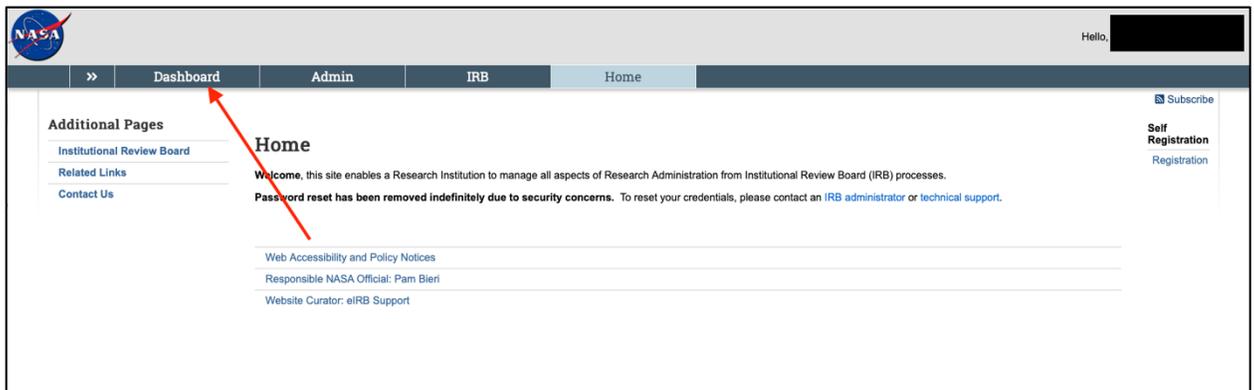
Link: [STUDY00000000](#) ←

P.I.: [name]

Title: [study title]

Description: Sample

If you do not have the email, visit <https://eirb.jsc.nasa.gov/EIRB/> and click “Login” at the top right corner of the screen. Enter your User Name and Password. Click “Login.” Then, click “Dashboard” in the top navigator panel.



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2. You will find your study under “My Inbox.” The state will be either “Clarification Requested (Pre-Review)” or “Clarification Requested (Designated Review).” Click on the name of the study to open it.

The screenshot shows the 'My Inbox' section of the NASA IRB system. At the top, there are navigation tabs for Dashboard, Admin, IRB, and Home. Below these, there are tabs for 'My Inbox' and 'My Reviews'. The 'My Inbox' tab is active, displaying a table with the following columns: ID, Name, Date Created, Date Modified, State, and Coordinator. A single row is visible with the name 'How-To Guide for Researchers' and the state 'Clarification Requested (Designated Review)'. A red arrow points to the study name. On the left, there is a 'Recently Viewed' section and a 'Create' dropdown menu. At the bottom left, there are links for 'Web Accessibility and Policy Notices', 'Responsible NASA Official: Pam Bieri', and 'Website Curator: eIRB Support'.

3. After opening the study, you will see the study status is “Clarification Requested.” You can view the outlined requests right on this page under the “History” tab, or you can click on “Clarification Requested ...” language in blue (indicated with a red arrow) to open the requested clarifications.

The screenshot shows the study detail page for 'How-To Guide for Researchers'. At the top, there are navigation tabs for Submissions, Meetings, Reports, Library, Institutional Profiles, and Help Center. The study title is 'STUDY [redacted] How-To Guide for Researchers'. The status is 'Clarification Requested (Designated Review)'. The page includes fields for Principal Investigator, Submission type, Primary contact, PI proxies, IRB office, IRB coordinator, and Regulatory authority. A flowchart shows the review process: Pre-Submission, Pre-Review, IRB Review, Post-Review, and Review Complete. The 'Clarification Requested' step is highlighted in a red box. Below the flowchart, there is a 'History' tab with sub-tabs for Funding, Contacts, Documents, Reviews, and Snapshots. The 'History' tab is active, showing a list of activities. A red arrow points to the activity 'Clarification Requested by Designated Reviewer'. The activity list includes: 'Clarification Requested by Designated Reviewer' (with a list of instructions: 1. please upload the research team member COIs and CITIs, 2. please modify the Consent form to reflect the appropriate risk level, 3. please change your answer in the eIRB to include a study location), 'IRB Coordinator Assigned', 'Submitted', and 'Study Created'. The 'Author' and 'Activity Date' columns are redacted with black boxes.

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4. Click "Edit Study" to change the e-IRB smart form or upload your newly changed documents (with tracked changes) into the protocol itself. To submit your response, click on "Submit Response" in the left panel.

The screenshot displays the NASA IRB Huron web application interface. At the top, there is a NASA logo and a user greeting "Hello, [redacted]". The navigation bar includes "Dashboard", "Admin", "IRB", and "Home", with sub-links for "Submissions", "Meetings", "Reports", "Library", "Institutional Profiles", and "Help Center".

The main content area is titled "STUDY [redacted] How-To Guide for Researchers". It shows the following details:

- Clarification Requested (Designated Review)** (highlighted in orange)
- Principal investigator: [redacted]
- Submission type: [redacted]
- Primary contact: [redacted]
- PI proxies: [redacted]
- IRB office: Office of Research Assurance: Research Integrity & Protection of Human Subjects
- IRB coordinator: [redacted]
- Regulatory authority: 2018 Requirements

A workflow diagram shows the process: Pre-Submission → Pre-Review → IRB Review → Post-Review → Review Complete. A "Clarification Requested" step is highlighted in orange, with arrows indicating it can lead to "IRB Review" or "Modifications Required".

Below the diagram, there are "Next Steps" buttons: "Edit Study" and "Printer Version".

A sidebar on the left contains a list of actions, with "Submit Response" highlighted by a red arrow. Other actions include "Assign Coordinator", "Assign PI Proxy", "Manage Ancillary Reviews", "Manage Guest List", "Add Related Grant", "Add Comment", "Withdraw", and "Discard".

The main activity log is titled "History" and includes tabs for "Funding", "Contacts", "Documents", "Reviews", and "Snapshots". It features a search bar and a filter dropdown set to "Activity". The log contains the following entries:

| Activity  | Author     | Activity Date |
|---|------------|---------------|
| Clarification Requested by Designated Reviewer  | [redacted] | [redacted]    |
| 1. please upload the research team member COIs and CITIs<br>2. please modify the Consent form to reflect the appropriate risk level<br>3. please change your answer in the eIRB to include a study location |            |               |
| IRB Coordinator Assigned  | [redacted] | [redacted]    |
| Assigned to   | [redacted] | [redacted]    |
| Submitted   | [redacted] | [redacted]    |
| Study Created   | [redacted] | [redacted]    |

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5. A new window will open. Please see instructions on the image below. When finished click "OK."

The image shows a browser window titled "Submit Response" with the URL `eirbint.jsc.nasa.gov/elRB/sd/ResourceAdministration/Activity/form?ActivityType=com.webridge.entity.Entity[OID[5AF42EFE442CF349BD8649471A64987E]]&Acti...`. The form contains the following sections:

- 1. Notes:** A large text area with a red "1" and the text "Explain your response to the reviewer here." inside it.
- 2. Supporting documents:** A section with a red "2" and the text "Track all changes on uploaded documents." to its right. It includes a "+ Add" button with a red arrow pointing to it, a "Name" header, and the text "There are no items to display".
- 3:** A red "3" with an arrow pointing to the "OK" button at the bottom right of the form.

At the bottom right, there are two buttons: "OK" and "Cancel".

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6. Another new window will open. You will enter your e-IRB user name and password. Click “submit” to continue.

Confirm Credentials close window

Please confirm your login credentials:

Username:

Password:

7. You will then return to the main study window. The response has been successfully submitted to the IRB office. The study status now shows as either “Pre-Review” or “IRB Review.”

NASA Hello, [redacted]

Dashboard Admin IRB Home

Submissions Meetings Reports Library Institutional Profiles Help Center

**Non-Committee Review**

**STUDY [redacted] How-To Guide for Researchers**

Principal investigator: [redacted] IRB office: Office of Research Assurance; Research Integrity & Protection of Human Subjects

Submission type: [redacted] IRB coordinator: [redacted]

Primary contact: [redacted] Regulatory authority: 2018 Requirements

PI proxies: [redacted]

Entered IRB: [redacted]

Last updated: [redacted]

**Next Steps**

Review Study

Printer Version

Assign Coordinator

Assign PI Proxy

Manage Ancillary Reviews

Manage Guest List

Add Related Grant

Add Comment

Withdraw

Discard

IRB [redacted]

Pre-Submission → Pre-Review → **IRB Review** → Post-Review → Review Complete

Clarification Requested → Clarification Requested → Modifications Required

History Pending Contacts Documents **Reviews** Snapshots

Filter by Activity

| Activity  | Author     | Activity Date |
|---|------------|---------------|
| Response Submitted  | [redacted] | [redacted]    |
| Clarification Requested by Designated Reviewer  | [redacted] | [redacted]    |
| 1. please upload the research team member COIs and CITIs<br>2. please modify the Consent form to reflect the appropriate risk level<br>3. please change your answer in the eIRB to include a study location | [redacted] | [redacted]    |
| IRB Coordinator Assigned  | [redacted] | [redacted]    |
| Assigned to [redacted]  | [redacted] | [redacted]    |
| Submitted   | [redacted] | [redacted]    |
| Study Created   | [redacted] | [redacted]    |

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