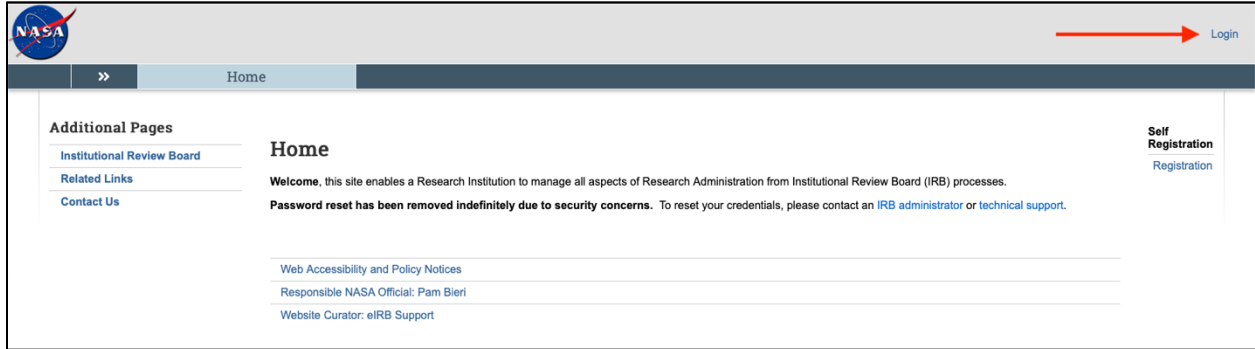NASA IRB Huron Guide for Researchers
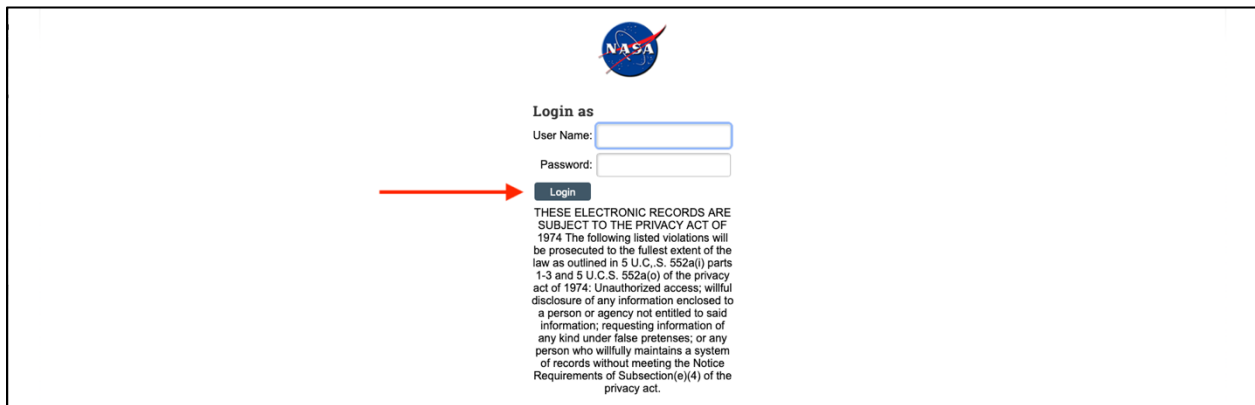How to Submit a New Study

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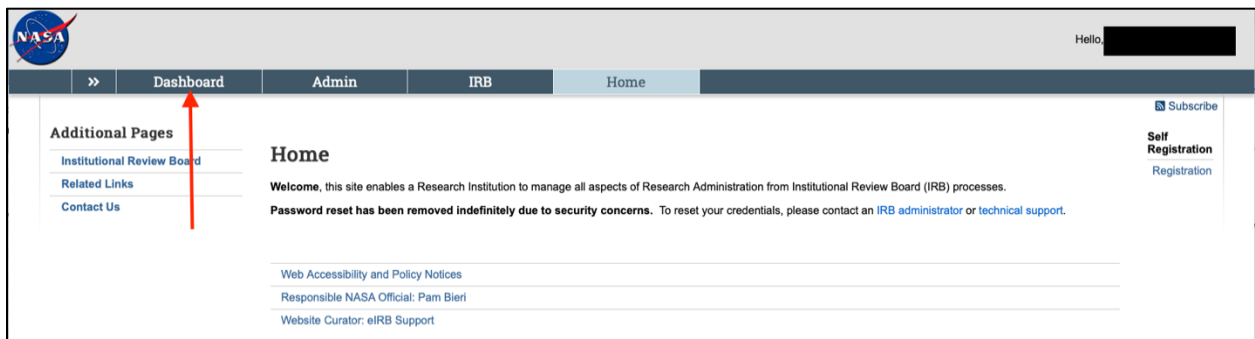
1. Visit https://eirb.jsc.nasa.gov/EIRB/ and click "Login" at the top right corner of the screen.

2. Enter your User Name and Password. Click "Login."

3. Click "Dashboard" on the top menu bar.
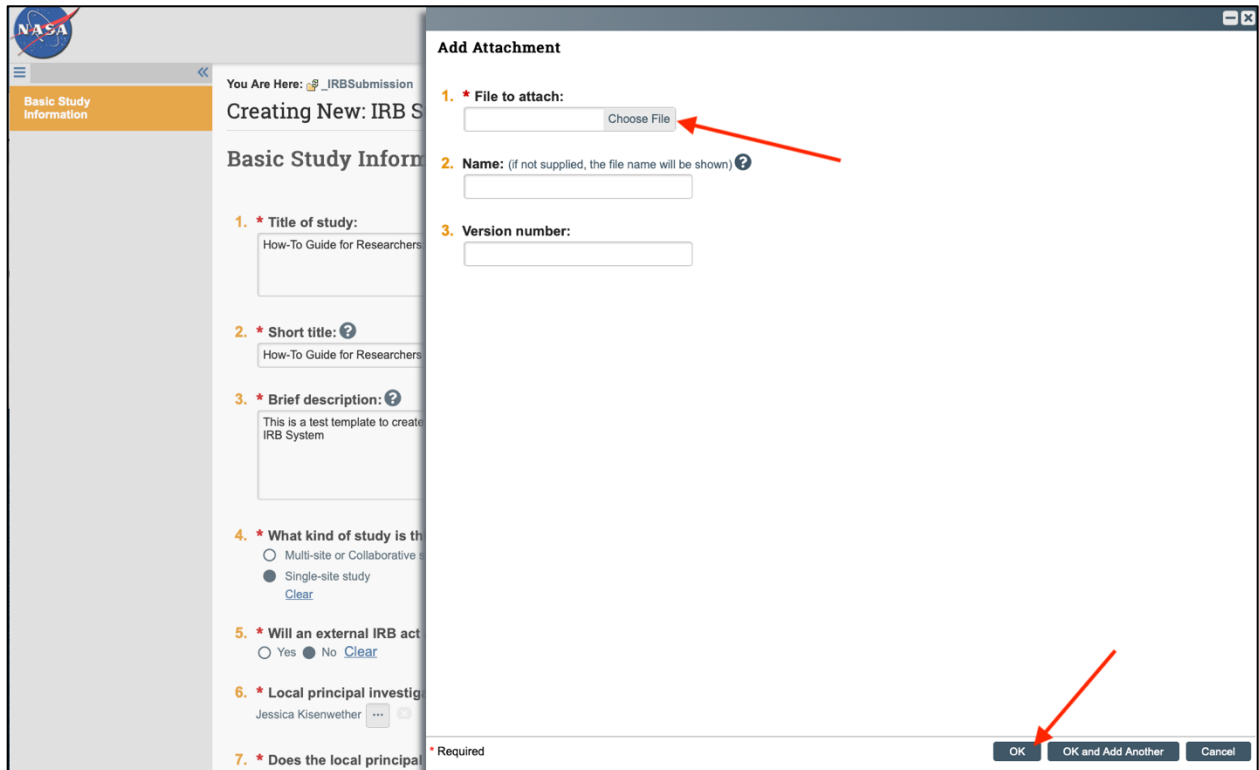
4. Select "Create" in the left panel and then select "Create New Study."
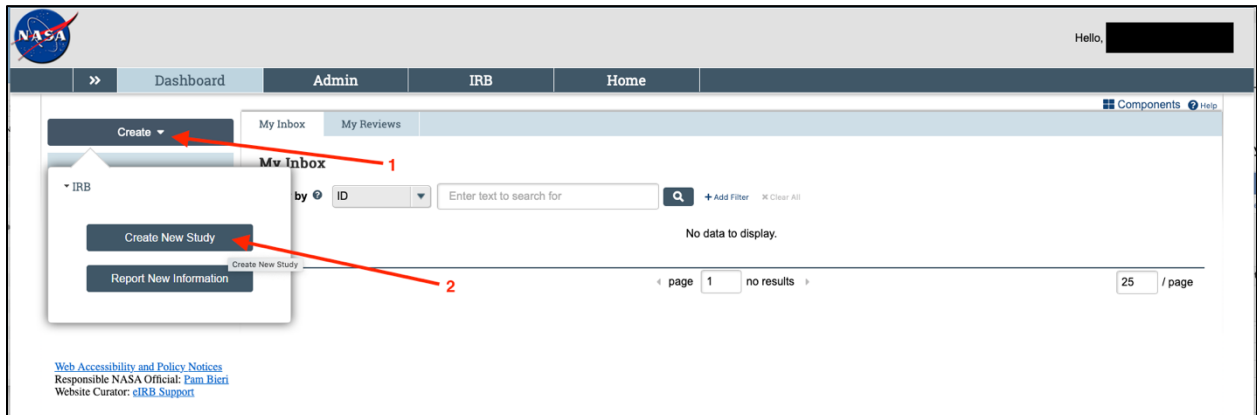
5. Basic Study Information - Complete sections 1 through 8. Note, all sections are required as indicated by a red asterisk (*). Using the relevant Center protocol template, upload a word document in section 8.
When attaching the protocol, click "+ Add". A new screen will appear. You will need to locate 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."

6. 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.**

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.
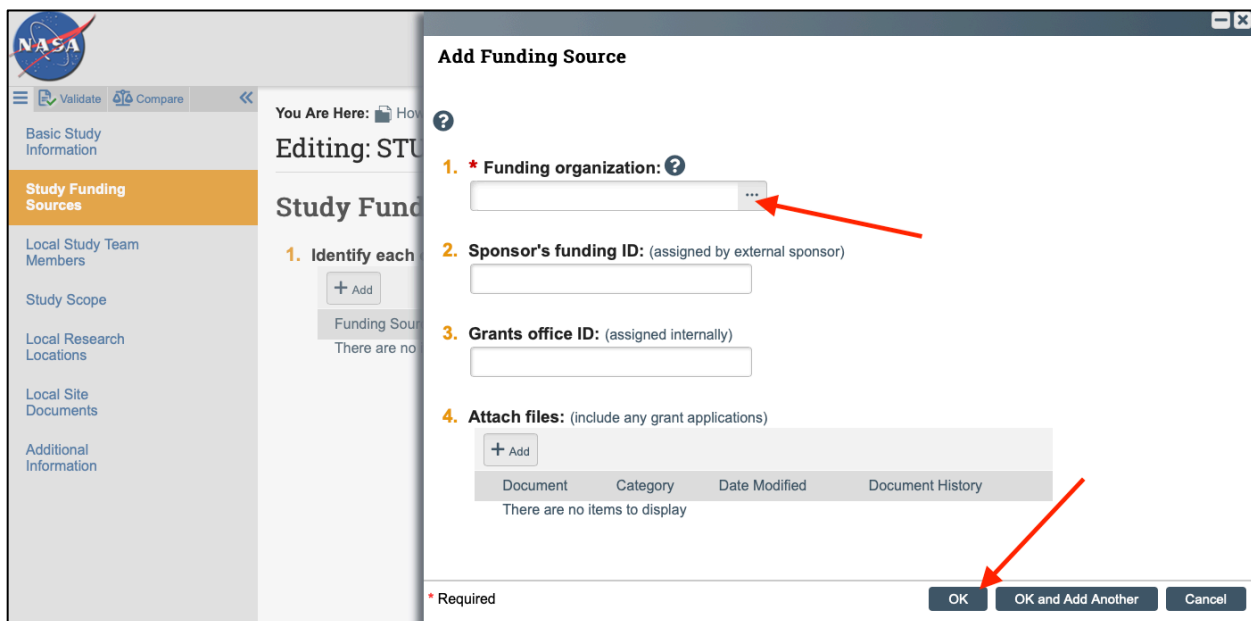
9. Local Study Team Members - Add all local study team members and external team member information if applicable by clicking on "+ Add" in the corresponding areas. **Be sure to upload CITI training certificates and Financial Conflict of Interest Disclosure forms for each individual under Local Study 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.

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.

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.

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.

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

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.

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

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

16. You will see the screen below indicating the Study is now in the "Pre-Submission" phase. **The study has <u>not</u> been submitted to the IRB.**
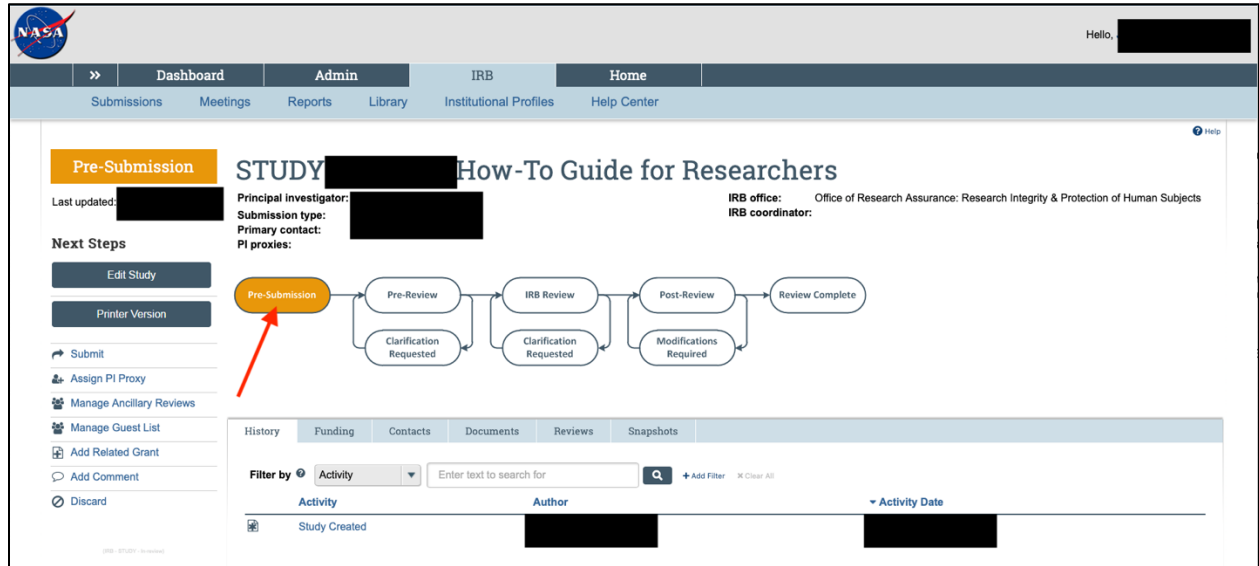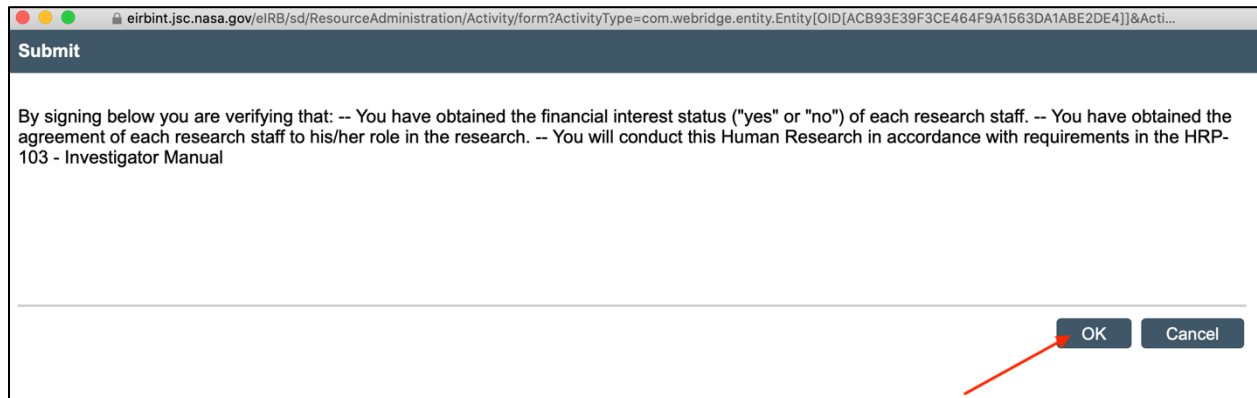
17. You may make adjustments to the protocol in this stage before submission. When ready to submit to the IRB office, click "Submit" on the left side of the screen.
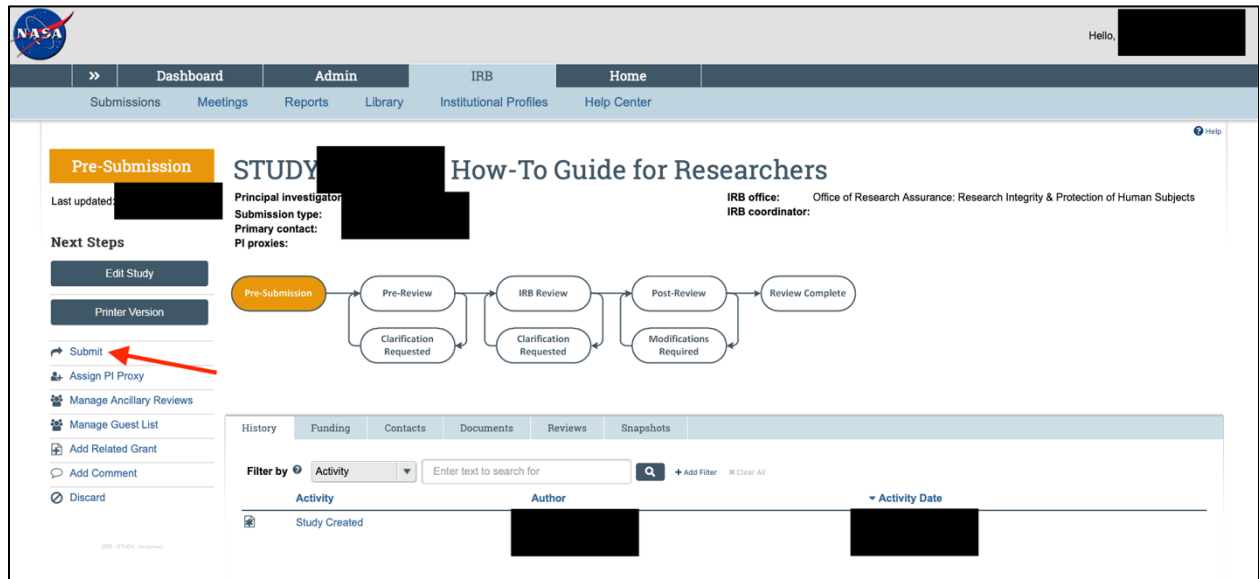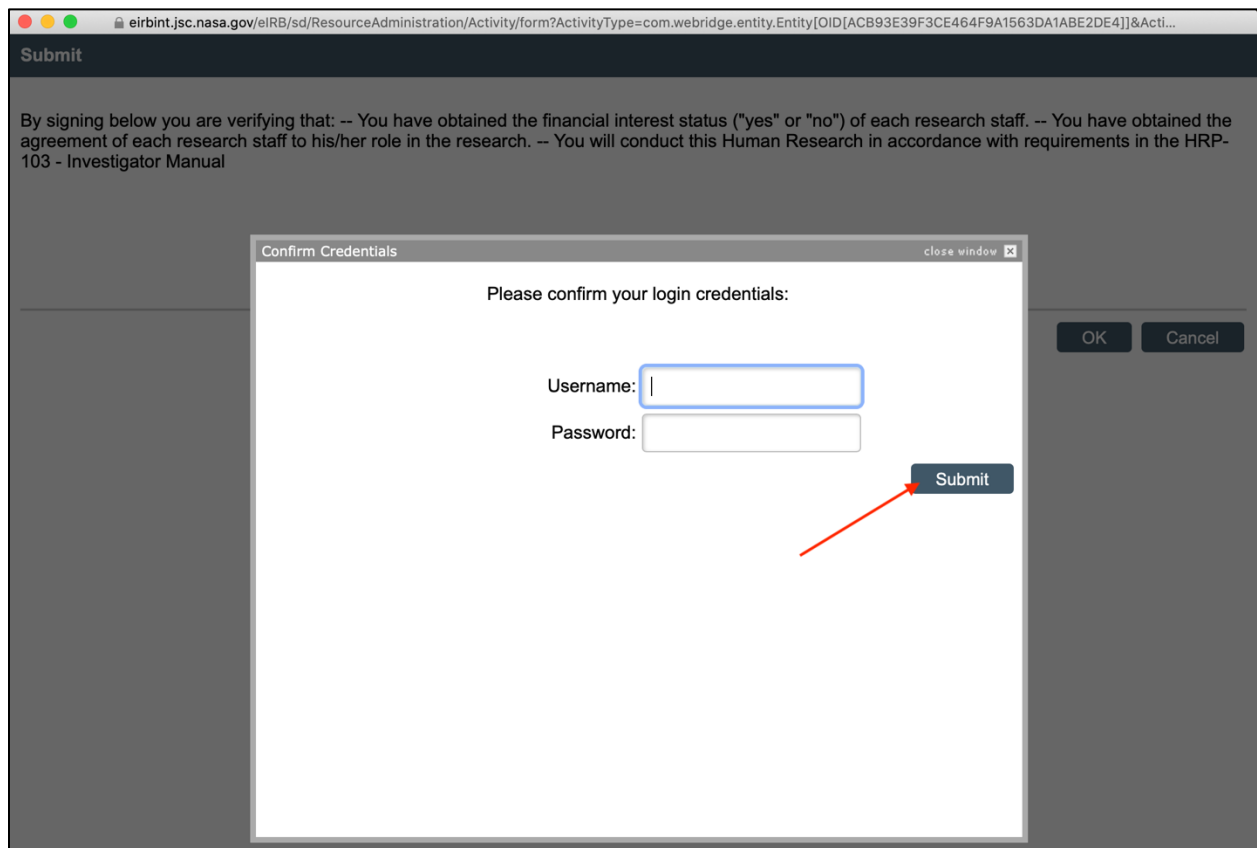
18. Once selected, a new screen will open as shown below. Click "OK" to verify.

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

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

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

- 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