PROTECT
Not Human Subjects Research (NHSR) and Not Research (NR) Submissions Guide

Create and Submit for a Determination of NHSR or Not Research

Before you begin, gather all files and information about your project. For more information and guidance about these types of projects, please go the following OHSRP webpage.

Project creation overview

What follows is a high-level overview of creating and submitting a project for consideration of a determination of Not Human Subjects Research (NHSR) or Not Research (NR), followed by the specific steps.

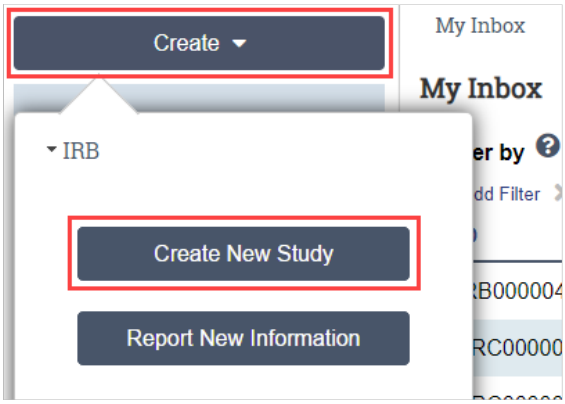
Reminder: If your project does not meet the definition of research or human subjects research, you are not required to submit a request for determination. Refer to Policy Memo - Change re: Requirement for NHSR Determinations (01/15/19)

If you require a formal determination, you may proceed by following the steps below.

Note: The IRB will not review modifications to projects that have already received a determination of NHSR or Not Research in iRIS or PROTECT. If something about your project is changing that could affect the previous determination, you will need to "Create a New Study" in PROTECT and receive a new determination.

To create a study

1. From the **Dashboard**, click the **Create** menu and then click **Create New Study**.



2. Complete each section of the Study Application. Please note that most of these questions are not relevant for these types of projects. When in doubt, you can choose **No** or **None**. Click

Continue to move to the next page.

3. Pay attention to the following pages:
   a. **Basic Study Information**
      - **Brief description** - Be sure to clarify here that you are submitting for an NHSR or a Not Research determination. This section should be used to specifically explain:
        - Whether the goal of the project is to develop generalizable knowledge for research purposes or something else
        - What activities the NIH team will be performing as part of the project
        - Whether the data or specimens will be newly collected for this project by NIH staff or another organization, or already exist at the time of the submission
        - What type of data or specimens will be collected or used
        - Whether the NIH team will have access to and retain personally identifying information that will be linked to the data or specimens
        - If another organization will have a role in the project, you should also explain their role here.
      - **What kind of study is this?** – Always select **Single-site** study because **Multi-site** is only used for studies in which NIH and at least one other non-NIH site are engaged in non-exempt human subject research.
      - **Will an external IRB act as the IRB of record for this study?** – Always select **No**.
      - **Total Accrual Ceiling (at all NIH sites)** – Provide an estimate of the number of subjects whose data or specimens you intend to obtain. If you don't know the answer or the project is not research, you can answer "0".
      - **Attach the Protocol** – Attach the completed NHSR application here.
        - You can locate the "Not Human Subjects Research Application" under the Library in the IRB tab of PROTECT or on the following OHSRP webpage.
        - When naming the NHSR Application, please make sure that you include the term "NHSR". Please note that if you want a different name to show up in PROTECT, add the title that you want to show up in the text box where it says "Name".
      - **NIH Addendum** - If you want to attach a more detailed description of the project or an actual protocol, please attach it here.
   b. **NIH Local Requirements**
      - **Is Scientific Review required for the initial submission of this study**? Select **No**.
   c. **Local Study Team Members** – For these types of projects, no team members beyond the PI must be listed in the application.
   d. **Local Site Documents** – There is no requirement to upload additional documents to

this section. If there is additional information that you think might be helpful for the IRB staff member to see and review, you can upload it here. (e.g., the data collection tool that includes all the de-identified data points you will be reviewing and analyzing).

4. On the final page, click **Finish**. You will then be taken to the study workspace. You can continue to edit the Study Application prior to submission by clicking the **Edit Study** button.

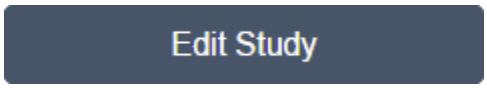
> **Important!** Clicking **Finish** does not send the project to the IRB office. It remains in the Pre-Submission state. **When the project is ready for IRB review, the PI/PI proxy must submit it using the steps in the "To submit a study for review" section below.**

Change Study Documents

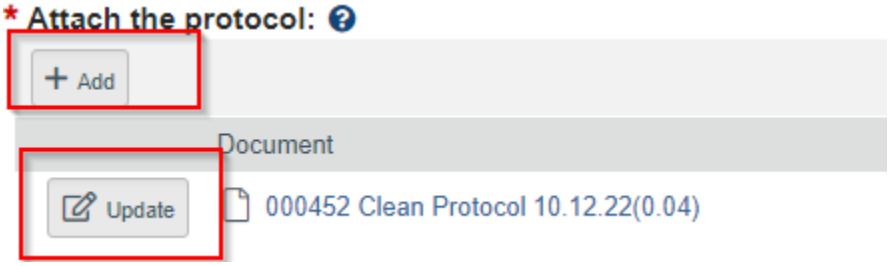
You can update your project documents any time **prior to submitting the project** to the IRB for review. Once it is in the review process, you can only update documents if an IRB staff member requests clarification.

To change study documents

1. From My Inbox, open the study you want to edit.
2. From the submission workspace, click **Edit Study**.



   a. Add and update documents in the Study Application as needed and exit the study when done. To add a new document, you can click the **+Add** button. To update an existing document, click the **Update** button.



To submit a project for IRB review

1. Open the project you would like to submit. Click **IRB** in the Top Navigator, then find the study in the **In-Review** tab. Click the project name to open it.
2. From the study workspace, click **Submit** on the left side of the screen. Then click **OK**.

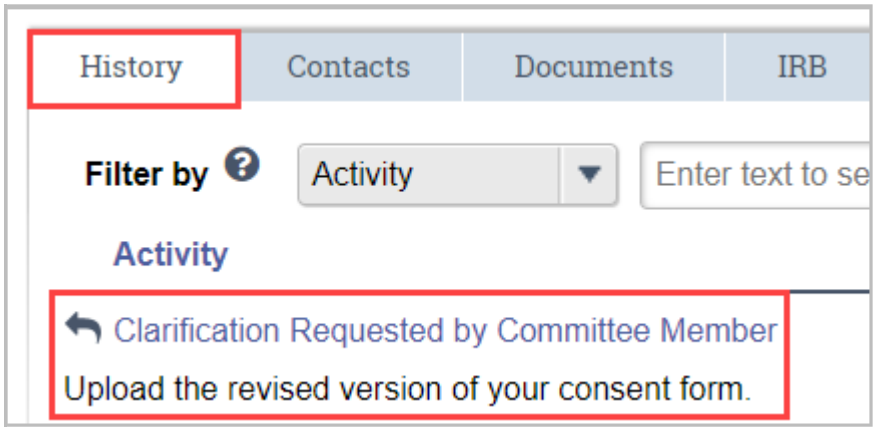
3. Type your login credentials and click **Submit**. Only the PI or PI proxy can submit to the IRB. Your project has been submitted and has moved to the Pre-Review state. You can log off the system.
4. After submitting, please click **Add a Comment** and state that you are submitting for a Determination of NHSR (or Not Research) and choose **IRB Coordinator**.

Respond to a Clarification Request

If an IRB staff member has questions or requires you to modify your submission, you will receive an email indicating that you have a Request for Clarifications. To review the request details:

1. In the email, click the submission ID link to open the Request for clarification.
2. If you no longer have the email, find the study on the **Dashboard** or in the **IRB** workspace and then click on the project name to open the project.
3. Click **Clarification Requested** in the **History** tab.

Note: If the reviewer attached a document, a link to open it appears on the **History** tab.



To submit a response to the clarification (changing the study application, uploading new documents, etc.)

1. To edit the Study Application or change the documents submitted with the study application, click **Edit Study** on the left.
2. If applicable, change any questions as instructed. To upload new documents, click the **Update** button next to the document that needs to be changed and upload the new document.
3. Once that is complete, return to the submission workspace and click **Submit Response** (PI or proxy).

4. In the Response box, explain your response to the reviewer**. Note:** If you wish to respond to the reviewer's request(s) in a document, you can add the document in the **Supporting Documents** area. **DO NOT attach the revised NHSR Application in the response form. It must be uploaded in the same section as the originally submitted NHSR Application form.** Click **Update** and choose the revised NHSR Application from your computer to stack the new one on top of the old one.
5. Click **OK**.
6. Type your login credentials and click **Submit**.

You can log off the system. The project has moved back to the reviewer's inbox so that he or she can continue their review.