PROTECT
IRB Exempt Submissions Guide

Create and Submit a Study for Determination of an Exemption or a Modification to an Exempt Study

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

Note: If the study will be carried out by a separate organization/company, e.g., under a contract, on behalf of NIH, no submission for an exemption should be made in PROTECT. The external company or organization should obtain their own exemption or IRB approval from an external IRB.

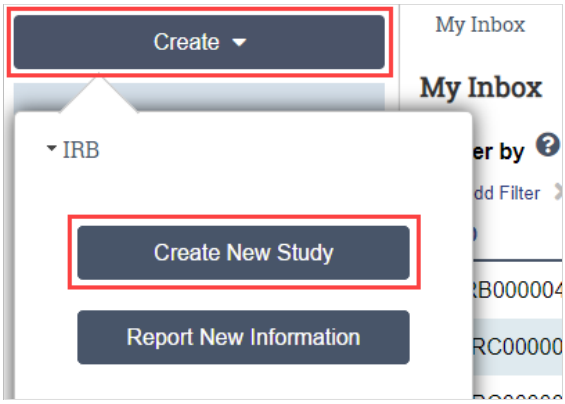
Study creation and modification overview

What follows is a high-level overview of creating and submitting a study for consideration of an exempt determination, followed by the specific steps, including submissions for modifications.

Note: Studies that previously received a determination of exempt in iRIS were not migrated. If your exempt study is changing, it will require a new submission in PROTECT. The study should be newly created in PROTECT with all the changes rather than being submitted as a new study followed by a Mod. Please see page 5 for more information.

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. 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 Exempt determination. This section should be used to specifically explain:

- The research question
- What activities the NIH team will be performing as part of the study
- Whether the data or specimens will be newly collected for this study 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 research 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 study, 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 who you intend to enroll or the number of existing subjects' data or specimens you will review. If you don't know the answer, you can write "0".
- **Attach the protocol** – Attach a clean MS Word version of the protocol here.
  - You can locate the applicable exempt protocol template to use to create your protocol on the following OHSRP webpage.
  - When naming your protocol document, please include the term "Exempt". 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".

b. **NIH Local Requirements** – Please note that most of these questions are not relevant for exempt projects. When in doubt, you can choose **No** or **None of the above.**

- **Is Scientific Review required for the initial submission of this study?** Select **No**. If your IC specifically requires SR for exempt studies, you may choose **Yes**.

c. **Local Study Team Members** – Identify all NIH study team members who are engaged in human subjects research (HSR) who are working at the NIH site(s) under this NIH PI. This section should include all personnel who are listed in NED.

- **Note:** If data will only be collected on-line and no identifiers are being collected, those team members responsible for the actual **conduct** of the study should still be added. The only exception to this is study members who will be responsible for analysis of de-identified data only do not need to be added.
- "Working at NIH sites" also includes NIH staff or trainees who are working remotely on this study.
- Protocol Navigators, although not engaged in HSR, should be listed in this section to give them read/write access to the project.

- Only assign one role per person. Choose the role with the highest level of responsibility.

d. **Study Scope** – These questions are not relevant for exempt projects. Choose **No**.

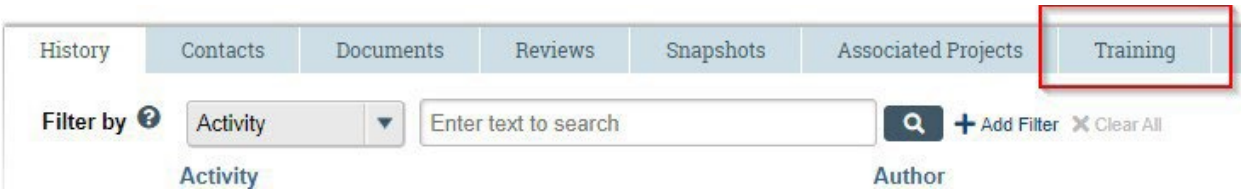
e. **Local Site Documents** – Add consent forms (e.g., written, verbal scripts), recruitment materials (e.g., e-mails, flyers, letters), study instruments (e.g., survey), focus group interview scripts, Access to CRIS form, data collection form, screen shots of content from on-line platforms, as applicable, to your study.

- Please refer to the instructions in each protocol template to determine what documents must be submitted.

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 study to the IRB office. It remains in the Pre-Submission state. **When the study 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.**

5. Check the training status of your study team members. From the study workspace, click on the **Training** tab. All people listed as Study Team members must have current training per Policy 103.



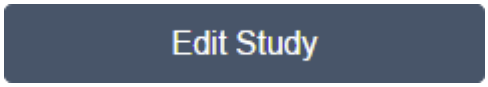
Change Study Documents

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

To change study documents

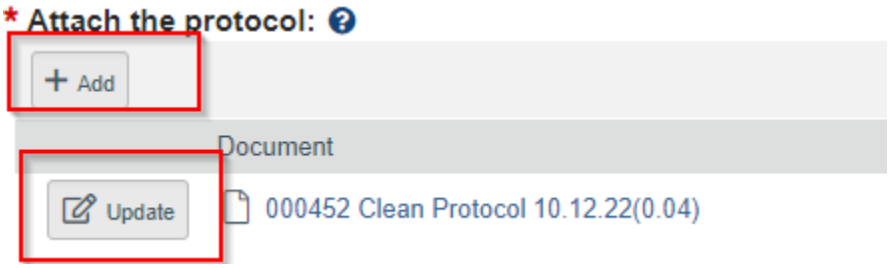
1. From My Inbox, open the study you want to edit.

2. From the submission workspace, click **Edit Study**



a. Add and update documents on study pages 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.



b. When updating a document previously submitted to the IRB, be sure to only upload a clean MS Word version. You can then use the **Compare** feature to generate an MS Word tracked changes version if needed.

To submit a study for IRB review

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

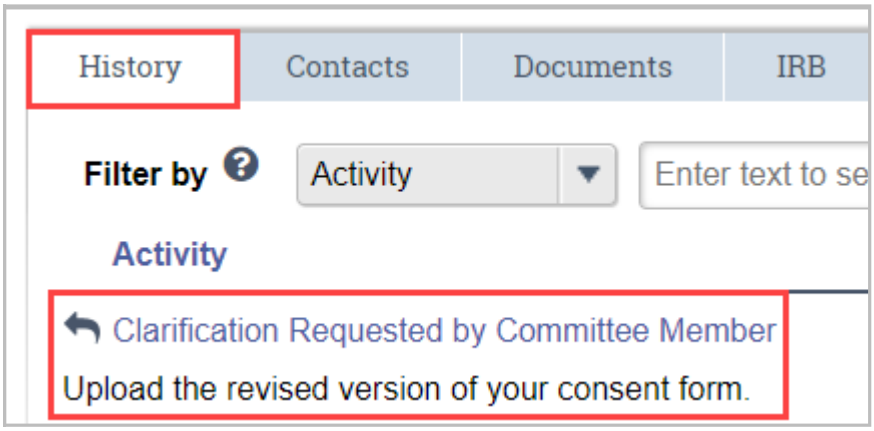
3. Type your login credentials and click **Submit**. Only the PI or PI proxy can submit to the IRB. Your study has been submitted and has moved to the Pre-Review state. You can log off the system.
4. After submitting, please click **Add a Comment** and state that you are submitting for an Exemption and 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 submission that requires 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 study name to open the study.
3. Click the **Clarification Requested** activity 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. **Do not remove the initially submitted documents as they allow us to view the tracked change versions in the system.**

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 any documents that need to be updated in the response form (such as the protocol and/or consent). These must be uploaded and attached to the actual study form.
5. Click **OK**.
6. Type your login credentials and click **Submit**.

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

Create and Submit a Modification to An Exempt Study

If needed, you can submit a modification of an existing exempt study to the IRB.

Note: Please contact your IRB Team Lead if you have a question as to whether your study requires submission of a modification.

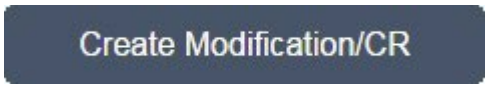
To create a Modification to an Exempt Study in iRIS

If your study was already submitted in iRIS and received an exemption and is now being revised and requires a new exemption with the changes, you will need to submit your project as a new study in PROTECT along with the revised documents and information.

1. Go to the Create a study section of this document and follow the instructions, with the exception of the following points:
    a. In the Brief description**, please refer to the former study number in iRIS**, make it clear that the project previously received an exempt determination, and briefly describe the changes.
    b. Upload the **previously approved** clean versions MS Word documents and then upload the revised clean documents on top of them. This will allow the reviewer to see the changes and allow for a more streamlined review.
    c. After submitting, please **Add a Comment** that states that you are submitting a revision to a study that was previously given an Exemption in IRIS and choose **IRB Coordinator**.

To create a Modification to an Exempt Study in PROTECT

1. In the Top Navigator, click **IRB.**
2. On the IRB page, click the **Active** tab and open the approved study.
3. Click the **Create Modification** button. You will only see this button if you are part of the study team.



4. Select that the submission is a **Modification**.
    a. **Modification scope** – To make changes to any part of the study except for study team members, select **Other parts of the study**.
    b. You can have two MODs in process at the same time ONLY if one is changing **Other parts of the study** and the other is **Study team member changes**. You cannot have two of the same types of MODs open at one time. The system will not allow you to do this.

5. Complete the pages. Click **Continue** to move through the pages and **Finish** on the last page.
6. From the workspace, click **Submit**.
7. Click **OK** to agree to the terms.
8. Type your login credentials and click **Submit**.
9. After submitting, please **Add a Comment** that states that you are submitting a MOD to an Exempt Study and choose **IRB Coordinator**.

You can log off the system. Your modification has been submitted.

NOTE: To find your modifications, from the IRB Parent Protocol, click the **Follow-on Submissions** tab.