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Create and 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.

Create a Study

1. From the My Inbox page, click Create New Study.

2. Complete the pages. Click Continue to move to the next page.

3. Pay attention to the following:
   
   a. Basic Study Information page questions: Use the questions pictured to the left to indicate whether the study is a single- or multiple-site study or will be locally or externally reviewed.
   
   b. Basic Information page protocol: The study protocol is the only mandatory document to include.
   
   c. Local Site Documents: add consent forms, recruitment materials and other documents specific to your study.
   
   d. Study Related Documents: if the study is a multi-site study for which you are serving as the sIRB, use this page to add templates for consent forms, recruitment materials, and other that participating sites will need to access.

4. On the final page, click Finish. You are taken to the study workspace. You can continue to edit the study (Edit Study button) until you submit it.

Submit a Study for Review

5. From the study workspace, click Submit.

6. Click OK to agree to the terms.

7. Type your login credentials and click Submit.

You can log off the system. Your study has been submitted to the IRB.
Create and Submit a New Single-Site External Study

External IRB study forms require less information than normal, but do require information about the external IRB.

Create an External Single-site Study

1. From the My Inbox page, click Create New Study.

2. Complete the pages. Click Continue to move to the next page.

3. Pay attention to the following:
   a. Basic Study Information page: Use the questions pictured to the left to indicate the study is a single-site and that an external IRB will act as the IRB of record (Externally reviewed MSS are covered in the MSS Quick Reference.)
   b. External IRB page: Specify which institution will serve as the external IRB.

4. On the final page, click Finish. You are taken to the study workspace. You can continue to edit the study (Edit Study button) until you submit it.

Submit the External Study for Review

5. From the study workspace, click Submit.

6. Click OK to agree to the terms.

7. Type your login credentials and click Submit.

You can log off the system. Once an IRB coordinator confirms reliance on the external IRB, your study will be submitted.
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 the IRB coordinator or a committee member requests clarification, or if you are submitting a modification to the study.

Change Study Documents

1. From your inbox, open the study you want to edit.
   If the study is not in your inbox, contact the IRB coordinator assigned to your study.

2. From the submission workspace, click Edit Study.

3. Add and update documents on study pages as needed and exit the study when done.

   Note: When updating a document previously submitted to the IRB, revise it using Word’s Track Changes feature and then replace the original document with the tracked-changes version. When the IRB finalizes documents on approved studies, all tracked changes will be accepted and comments removed.

   If responding to a clarification request, see Respond to Clarification Requests to submit the changes back to the IRB.
Respond to Clarification Requests

If a reviewer has questions or requires you to change your submission, you will receive an email indicating this. Review the request details and then respond to the request.

**Review the Request Details**

1. Click the submission ID link in the email to open it.
   If you no longer have the email, see Open a Submission and then View History to see reviewer comments.

2. Click the History tab and review the “Clarification Requested” activity.
   **Note:** If the reviewer attached a document, a link to open it appears on the History tab.

**Submit Response**

3. On the submission workspace, click Submit Response.

4. In the Notes box, explain your response to the reviewer.
   **Note:** If you responded to the reviewer’s request in a document, you can add the document in the Supporting documents area.

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 inbox to continue the review.
Create and Submit a Continuing Review or Modification

You can submit a Continuing Review (CR), a modification, or both combined:

- To close a study or extend your approval period, submit a CR.
- To change an approved study or the study team’s members, submit a modification.

Create a CR or Modification

1. From your inbox, click the Submissions shortcut.
2. On the IRB page, click the Active tab and open the approved study.
3. Click the Create CR/Modification button.
4. Select whether the submission is a CR, a modification, or a combination.
5. Pay attention to the following question:
   Modification scope. To make changes to any part of the study except for study team members, select Other parts of the study.
6. Complete the pages. Click Continue to move through the pages and Finish on the last page.
7. From the workspace, click Submit.
8. Click OK to agree to the terms.
9. Type your login credentials and click Submit.

You can log off the system. Your modification or CR has been submitted to the IRB.

To find your modifications and CRs, go to the Submissions page (click the Submissions shortcut), and then the Follow-On Submissions tab.
Update Study Details for a Single-Site External Study

Use Update Study Details to make changes to an approved, single-site external study. The resulting External Update will be found in the study’s Follow-on Submissions tab.

To Update Study Details for an External Study

1. From your inbox, click the Submissions shortcut.
2. Click the External IRB tab and open the study. Note that active external IRB studies are in the External IRB state.
3. Click the Update Study Details button.
4. Summarize the updates, click Continue, then make changes to the study.
5. From the study workspace, click Finalize Updates.
6. Click OK to agree to the terms.
7. Type your login credentials and click Submit.

You can log off the system. Your updated study details have been submitted to the IRB.

To find your External Update, go to the Submissions page (click the Submissions shortcut), and then click the External IRB tab. You can also find the External Update by clicking the Follow-on Submissions tab in the study’s workspace.
Report CR Data for a Single-Site External Study

Both the local PI and local IRB coordinator can report continuing review data for a single-site external study, so ask the IRB coordinator for help if the need arises.

1. From your inbox, click the Submissions shortcut.
2. Click the External IRB tab and open the study. Note that active external IRB studies are in the External IRB state.
5. In Supporting Documents, be sure to include an explanation for each item left unchecked in question 2 above.
6. Click OK.
Create and Submit Reportable New Information

Report any adverse events or new information about a study as soon as you become aware of it.

Create an RNI

1. From your inbox, click the Submissions shortcut.
2. Click the Report New Information button.
   (2a) Note: You can also open an active study and report new information from the study workspace.
3. Complete the Reportable New Information page. Pay attention to the following question:
   a. Related studies and modifications: Select any studies or modifications that the RNI applies to.
      Note: You cannot relate sites, external studies (unless the external study is part of a multi-site study), or follow-on submissions (except for modifications, which can be added by adding the parent study) to an RNI.
4. Click Continue when done.
5. From the RNI workspace, click Submit RNI.
6. Click OK to agree to the terms.
7. Type your login credentials and click Submit.

You can log off the system. The RNI has been submitted to the IRB. After reviewing the RNI, the IRB may require specific actions be taken and assign a responsible party to do so.
Navigation and Basic Tasks

When you first log in, you will be on the My Inbox page. This topic lists where to find submissions and the basic tasks you will perform.

Where do I find?

From the My Inbox page, you will find:

1. **Submissions** that require you to take action.
2. **Actions** you can perform, such as create a new study.
3. **Shortcuts** that provide access to other items such as all the submissions you can view.

What do I do?

4. Review the state of submissions in your inbox. The state gives a clue as to what to do next. For example, "Pre-Submission" means you haven't submitted the study. You can finish and submit it for review.

Open a Submission

5. From your inbox, or from the Submissions page, click the submission name.
6. The submission workspace opens.

View History

7. From the submission workspace, click the History tab.
8. The history tab lists the activity taken on a submission including any comments, attachments, or correspondence added.
9. Click the **Submissions** shortcut.

10. Click the tab to see submissions you can access:

- **In-Review**: Submissions undergoing IRB review.
- **Active**: All approved submissions as well external IRB, non-human research, human research not engaged, lapsed, and suspended submissions.
- **New Information Reports**: All Reportable New Information (RNI) submissions, in any state.
- **External IRB**: All studies managed by an external IRB.
- **Relying Sites**: All participating sites relying on the local IRB as the single IRB of record.

Click the ellipsis to see:

- **All Submissions**: All submissions, in any state.
- **Archived**: All closed, disapproved, discarded, and terminated submissions.

### Filter Data

Many pages contain tables that you can filter to show specific data.

11. Select the column to filter by.

12. Type the beginning characters for the items you want to find. You can also type a % symbol as a wildcard before the characters. Examples:

- 71 shows all items beginning with 71
- %71 shows all items containing 71

13. Click the Help icon for operators you can type in the text box.

14. Click **Go** to apply the filter.

15. To combine multiple filter criteria, click **Add Filter**.
# Checklist of 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)
- Investigator protocol
- Complete sponsor protocol
- Site supplement to sponsor protocol
- HHS (Department of Health and Human Services) protocol

## Funding information: (Funding Sources page, with each source)
- Grant applications

## 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 or 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:
  - Consent forms
  - HHS-approved consent document
  - For non-written consent, a script of the information provided orally to the 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:
  - Conflicts of Interest Committee's determination for each financial interest related to the research
  - Completed checklist of meeting Department of Energy requirements

## 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