Researcher's Guide

UCI IRB is the Reviewing IRB

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About this Document

This document covers tasks related to multi-site studies (MSS) under single Institutional Review Board (IRB) of record review. Tasks common to single and MSS can be found in the IRB Researcher Guide, IRB Reviewer Guide, External Reliance Researchers Guide, and IRB Staff Guide.

Multi-Site Study Process Overview

This section provides information on multi-site study, site modification, reportable new information, and continuing review.

Elements of a Multi-Site Study

A multi-site study (MSS) involves research from a single protocol carried out at multiple institutions. For a multi-site study, one institution serves as the single IRB of record (sIRB), and the other institutions serve as participating sites. The sIRB assumes review responsibility for the study at all sites, including the institution where the sIRB is located and any other participating institutions.

Note: The institution's role depends on the particular multi-site study. For example, an institution that serves as the single IRB of record for one MSS can act as a participating site for another MSS.

A multi-site study includes several parts:

- **A study submission** that describes the research and the study-related details of the institution serving as the single **IRB of record (sIRB)**.
- **Site submissions** that represent the study-related details of each **participating site (pSite**).

The multi-site study will appear differently based on whether you are in the IRB system of the sIRB institution or the IRB system of a pSite institution.

- The sIRB system is where the main multi-site study submission is housed. This includes a study submission, and all the site submissions for every pSite participating in the study. For example, if a multi- site study involves 3 pSites, the sIRB system will have 4 separate submissions: 1 study submission, and 3 site submissions (1 for each pSite). Each of these submissions has its own workspace and their own review process. Each site submission is also linked from the study workspace.
- The pSite system only includes an abbreviated version of the multi-site study, including 1 study submission and 1 site submission, which is the pSite's own site submission. The site submission is editable in the pSite system, but the study submission is read-only. A multi-site study may have more than one pSite associated with the study, but an institution that is serving as a pSite will only see the site submission for their institution.

Study Review Process

The Principal Investigator (PI) at the sIRB institution (UCI) initiates the study, specifying that the study is multi-site and that their local institution will serve as the single IRB of record for participating institutions. This is when the study submission is created.

Once the study submission is created, the PI, study team, and IRB staff can add participating

sites to the study. Site submissions can be created after the study reaches the **Pre-Review Complete** state; each newly created site corresponds to each participating site added to the study submission. At UCI the addition of a participating site is reviewed after the study is at the **Review Complete** state. New site submissions are created immediately in the sIRB's system when participating sites are added. Please get the approval of the study prior to initiating addition of a participating site.

The study submission moves through the standard review process in the same manner as a single-site study. For more details on the study review process, see the IRB Staff Guide.

sIRB Researchers (UCI is Reviewing IRB)

This section shows how to perform basic actions of a single IRB of record researcher. It provides information on creating a study, managing participating sites, submitting a study, creating and submitting a continuing review for a multi-site study.

Note: UCI IRB recommends relying sites (pSites) to be added after the main study is approved by UCI IRB.

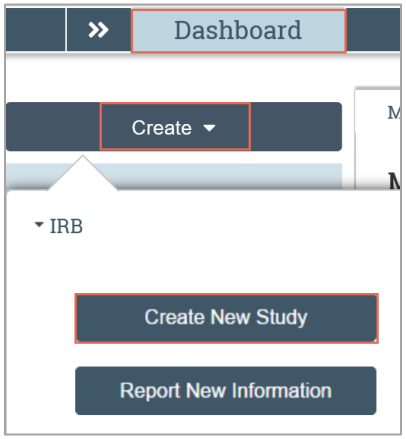
Create a Study

Before you begin, gather files and information about your study, such as supporting information (drug and device information, recruitment materials, etc.), financial interest status for each study team member, and consent forms and recruitment materials.

Who performs this activity?	When to perform this activity
▪ sIRB principal investigators	This is the first step in creating a multi-site study

To create a study

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



2. Complete the form. Pay attention to the following pages:
   a. **Basic Study Information**: Although the participating sites will be added at the Review Complete State, if your research plan is to do a multi-center study then check the multi-

site study box as “Add Participating Sites” activity is only available when the following is indicated in the Basic Study Information section:

b. Question 4 (“What kind of study is this?”): “**Multi-site or Collaborative study**” is selected

c. Question 5 (“Will an external IRB act as the IRB of record for this study?”): Answered “**no**”

d. Question 6 (“Will your IRB act as the single IRB of record for other participating sites?”): Answered “**yes**”

e. **Study-Related Documents**: add templates for consent forms, recruitment materials, and other documents that are required study-wide and that participating sites will need to access.

f. **Local Site Documents**: add consent forms, recruitment materials and other documents specific to your site.

3. Click **Continue** to move to the next page. Complete the pages.
4. On the final page, click **Finish**.

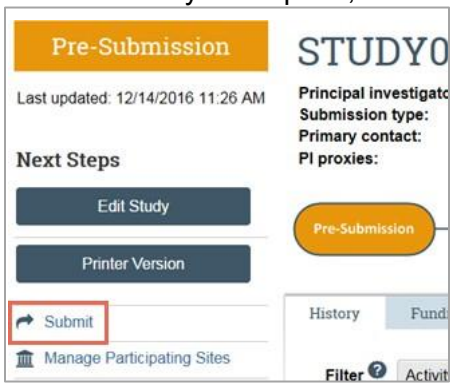
Submit a Study

Once you have finished creating a Multi-Site Study (MSS), you can submit the study for review.

Who performs this activity?	When to perform this activity
▪ sIRB Principal Investigators	After you have created a study. Once you submit a study, it moves to the Pre-Review state.

To submit a study

1. From the study workspace, click **Submit**.



2. Click **OK** to agree to the terms.
3. Type your login credentials and click **Submit**.

You can log off the system. Your study has been submitted to the IRB.

Note: The overall study must first be approved for UCI IRB site only and the standard approval process will be followed.

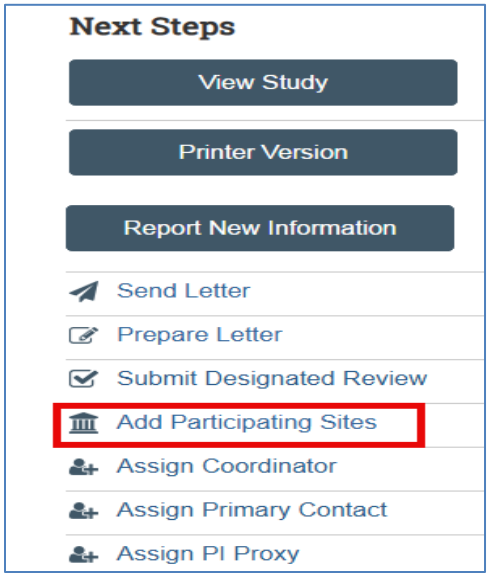
Manage Participating Sites

Although Manage sites is a feature available in ZOT IRB at the Pre-review and Pre-Submission states, UCI IRB prefers sites to be added after the review and approval of the main study by sIRB.

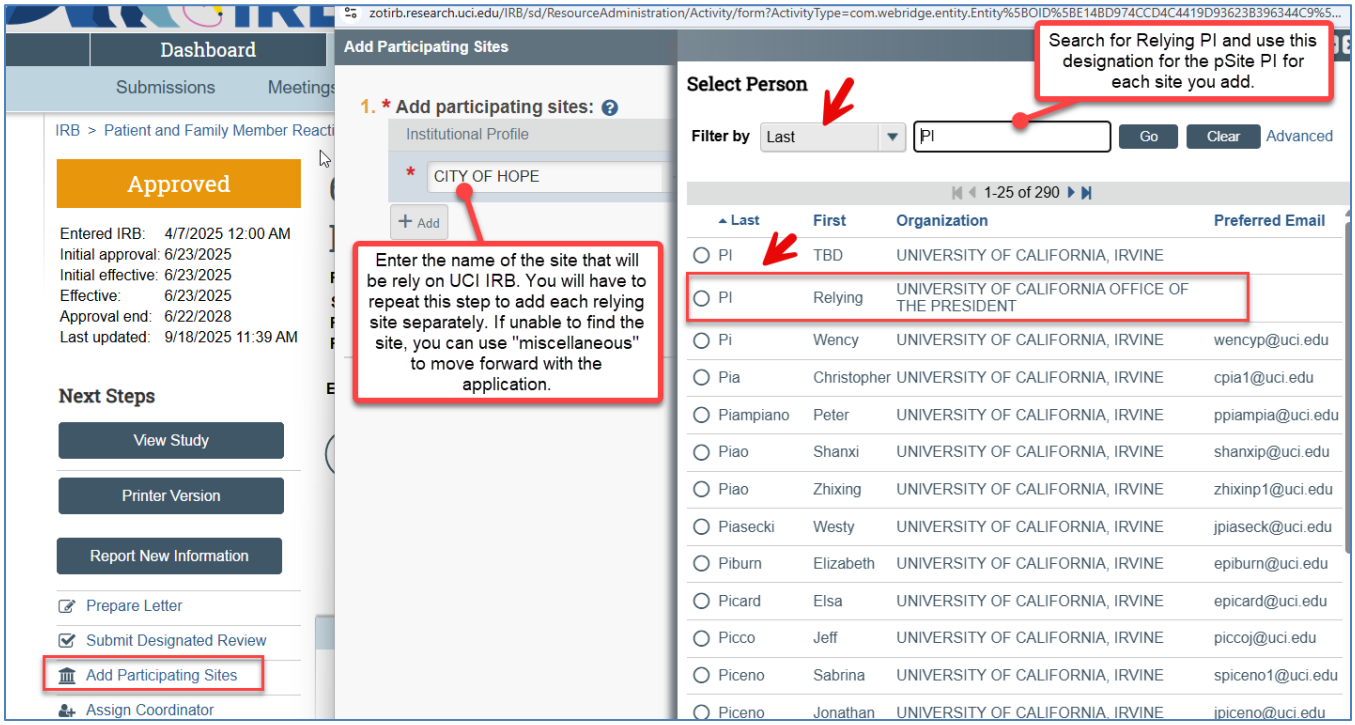
Once the main UCI site is approved you can begin the process of adding participating sites.

To add participating sites

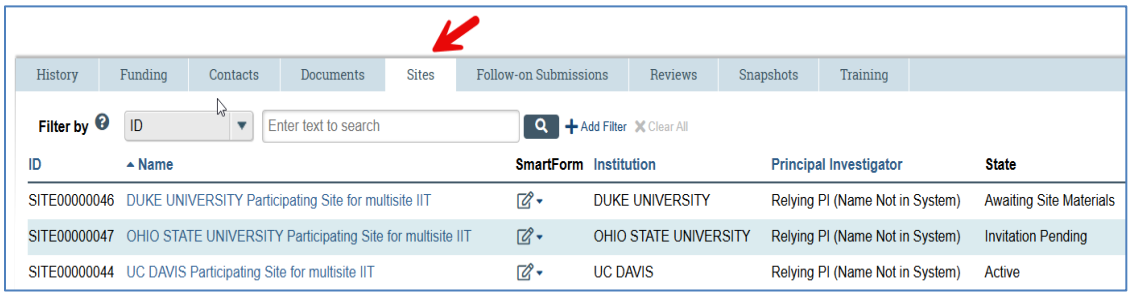
1. From the study workspace of an approved multi-site study, click **Add Participating Sites**.



2. Click the ellipses to add an institutional profile and a principal investigator. For each Relying site you must select “Relying PI”. Repeat this process to add additional institutions.

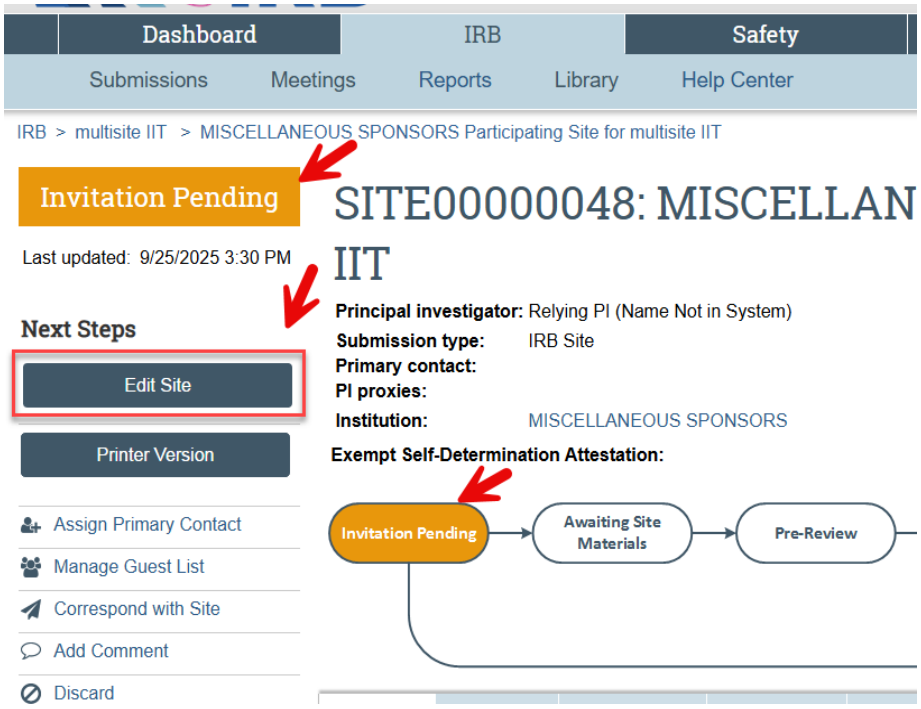


3. If you are unable to locate your Institutional Profile, please select **Miscellaneous Sponsor** under participating sites to proceed with the application and then contact the HRP staff at irbreliance@uci.edu for assistance with adding the Institutional Profile for the specific site.
4. Click **OK** when you are finished.
5. Click the **Sites** tab to view participating sites. A site is automatically created for any institutions you add. In the **Sites** tab, click the name of a site to go to the site workspace.



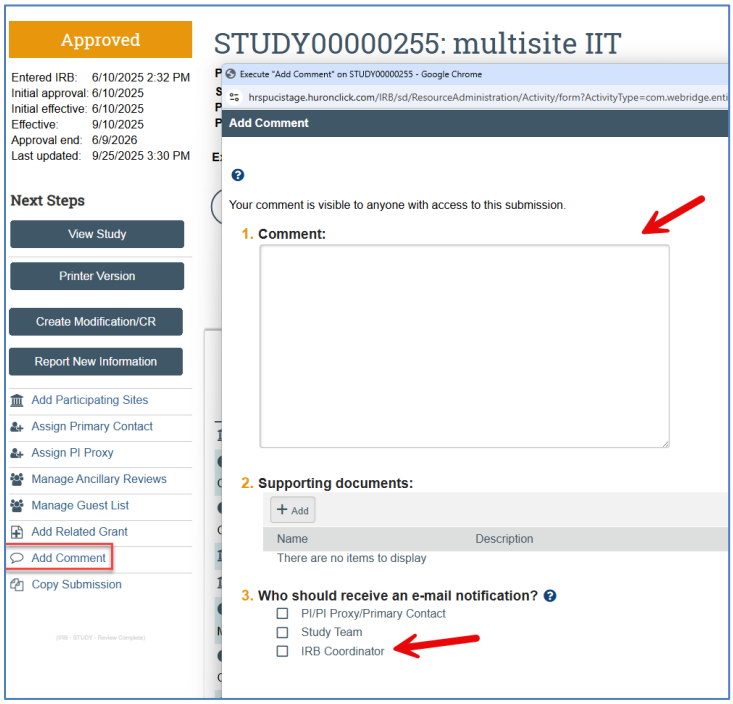
Note:

- Adding the participating sites themselves will not be processed via the "Create Modification / CR" button on the study's homepage.
- Once participating sites are added to a study, the study cannot be withdrawn until all associated sites are in an Inactive or Discarded state.



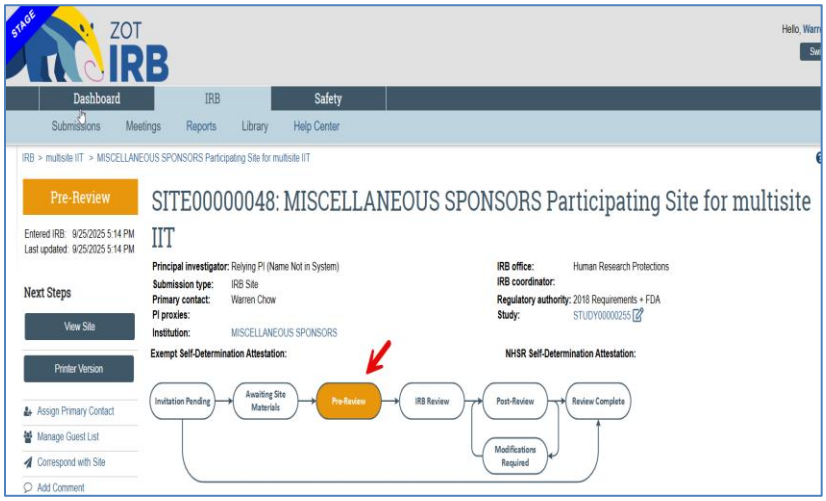
6. Click on Edit Site and complete the Basic Site Information, Additional Local Funding Sources and attach the Local Site Documents in the Local Site Documents section (if available). Remember, all this information is specific to the relying site being added.
7. Once the form is complete, click "Finish"

8. Please note that there is no submit button after ‘Finish’ so the IRB staff does not get notified.
9. Please add a comment from the main study workspace to notify the IRB staff about the invitation pending.



Note: After IRB staff submits the invitation decision, the study status will change to Awaiting Site Materials.

10. In the Awaiting Site Material state you can edit site information and add additional materials as needed.
11. The IRB staff completes the check on materials and confirms that al site-specific materials have been received and marks ‘OK”.
12. Once the Submit Site Materials activity is completed, the site addition will be in the pre-review state for IRB processing and approval.

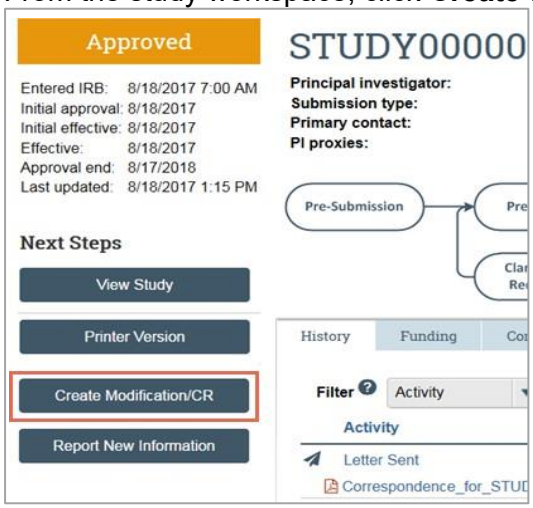


Create and Submit a Continuing Review for a Multi-Site Study

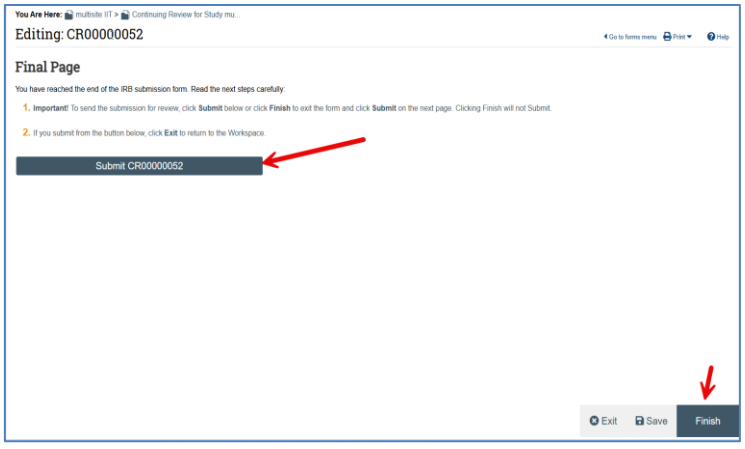
A PI at the sIRB institution can create and submit a continuing review (CR) that reports data for the sIRB institution and any pSites involved in the multi-site study.

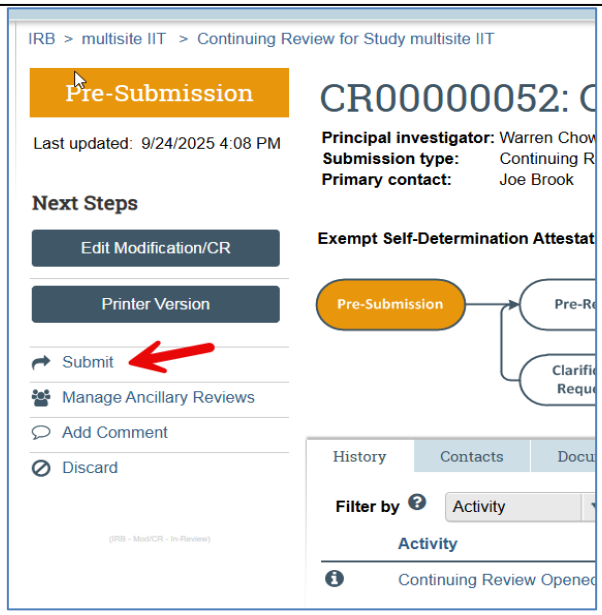
To create a continuing review

1. From the study workspace, click **Create Modification/CR**.



2. Select **Continuing Review** as the purpose of the submission.
3. Click **Continue**.
4. On the **Continuing Review / Study Closure** page, pay attention to the **Specify enrollment totals** question.
   You must specify the subjects enrolled at your local site as well as the combined enrollment totals for all sites (Study-wide).
   - If you have received all pSite CR data, you can manually enter the study-wide enrollment count.
   - If you have not yet received all pSite data, you can exit the Continuing Review form and return to the continuing review workspace. From the workspace, you can complete the To record site CR data on page 19 steps as site data becomes available.
5. Complete the questions and click **Continue**.
6. Click **Submit or** Click **Finish** on the last page. You can also submit from the study workspace.



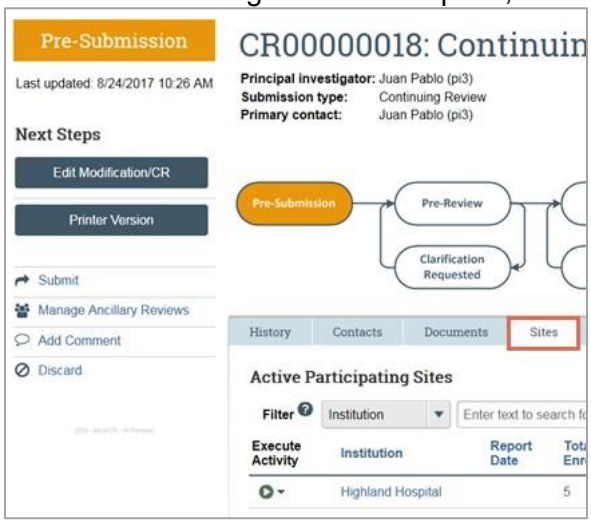


Note: If you do not have all the information you need to complete the CR, you can save your information and then click **Exit** to leave the form. To return to the CR, click **Edit Modification/CR** from the CR workspace.

To record site CR data

As continuing review data from pSites becomes available, the sIRB PI/PI Proxy/study team can enter the site data directly from the continuing review workspace without having to edit the continuing review submission multiple times.

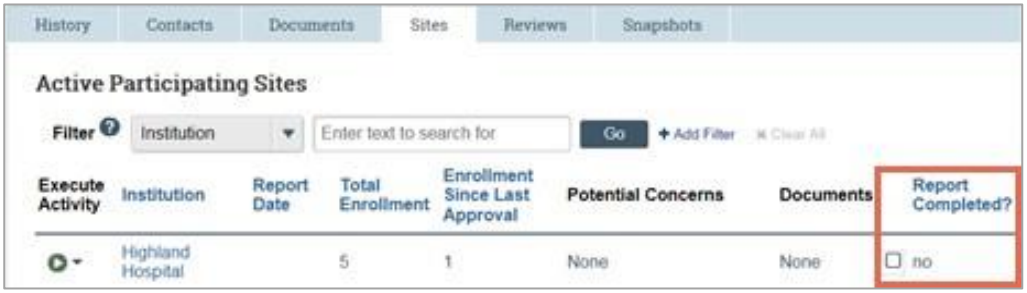
1. From the continuing review workspace, click the **Sites** tab.



2. Under **Execute Activity**, click the arrow.
3. Click **Report Continuing Review Data**.
   a. manually enter the CR data.
4. Click **OK**.
5. If you have sufficient data to complete the site's continuing review report, under **Report Completed**, select the check-box. You must select the check-box for the site's enrollment

totals to be confirmed and added to the Continuing Review form.

Note: If the CR is discarded, the Report Complete checkmarks for all sites are automatically cleared.



To submit a continuing review

1. If necessary, from the study workspace, click **Edit Modification/CR**, update the CR, and click

Finish.

2. From the study workspace, click **Submit**.
3. Click **OK** to agree to the terms.
   Type your login credentials and click **Submit**.

Site Modification Process

Modifications to active sites require additional review. Modifications fall into the following categories:

- Changes that affect the study team membership and research locations. These modifications only require local review by IRB staff. (When UCI is the IRB of record (sIRB), UCI will not review these as these will remain with pSite IRB)
- Changes that affect other parts of the site submission. These modifications require review by the sIRB of record. (UCI Reviewing IRB)
- Changes that affect both categories. These modifications also require review by the sIRB of record. (UCI Reviewing IRB)

Note: Modifications to a multi-site study submission (as opposed to a site submission) follow the regular study modification process. For more information on study modifications in the *IRB Staff Guide*.

Site modifications to other parts of the site require sIRB review:

1. The pSite PI or study team member submits the modification to pSite IRB and pSite approves the modification. The modification is then uploaded to ZOT IRB by the study team so the sIRB can access it.
2. On the sIRB side, sIRB staff take the modification through the review process. While this

happens, the modification remains in the **Pending sIRB Review** state on the pSite system.

3. Once the sIRB review is completed, pSite IRB staff record the sIRB decision, moving the modification to either **Post Review** (if a letter is required) or **Review Complete** on the pSite system.
   Note: If modifications are required for approval, the modification submission moves to **Modifications Required**. The pSite PI can then submit a response to the sIRB, which moves the modification submission back to **Pending sIRB Review** until a new determination is received by the pSite and recorded in the pSite system.

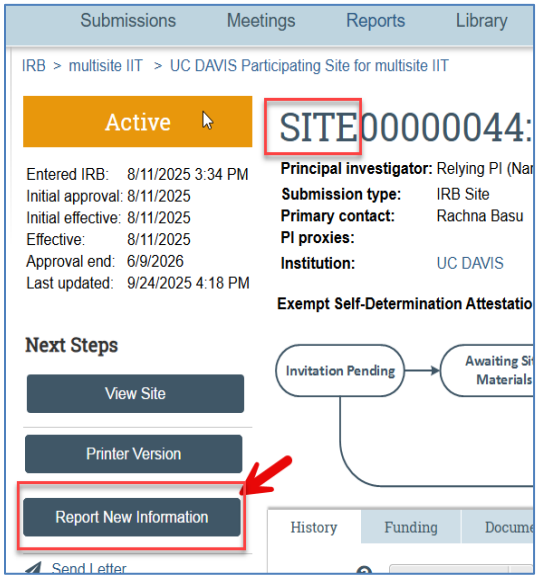
Note: A modification (of any category) that is disapproved remains active until the modification is either approved (which applies the modifications to the study) or discarded (in which case, no modifications are applied to the study).

Note: The relying site-specific approved documents will be available in the “documents” tab on the “site” workspace accessed by the “sites” tab from the overall study home page.

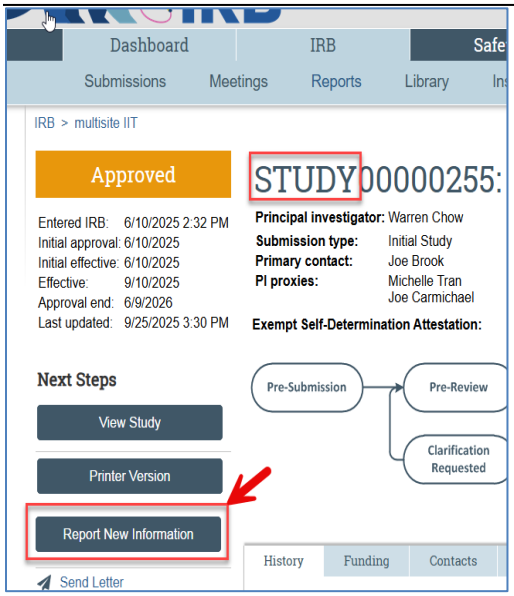
Reportable New Information Process

The review process for reportable new information (RNI) associated with a multi-site study differs depending on whether the RNI originates from the sIRB or the pSite system, and on where the RNI is routed for review. An RNI originating from the sIRB system follows a review process like that of single-site study RNIs, as described in the *IRB Staff Guide*.

If the RNI is site specific then submit it through the site workspace for that specific pSite.



If the RNI has an impact on the entire protocol then submit it via the main sIRB study workspace.



When the RNI is sent for sIRB review:

a. The RNI begins in the **Pre-Review** state.

b. The RNI moves through the **IRB Review** process (which may include local review by a designated reviewer, full committee review, or both) and is sent to **Post-Review**, where further actions may be required, and eventually to **Review Complete**.

c. On the pSite system, a staff member can record the sIRB decision and move the RNI to the **Post- Review** or **Review Complete** states.