UT Health San Antonio | Enterprise Research Management System (ERMS)

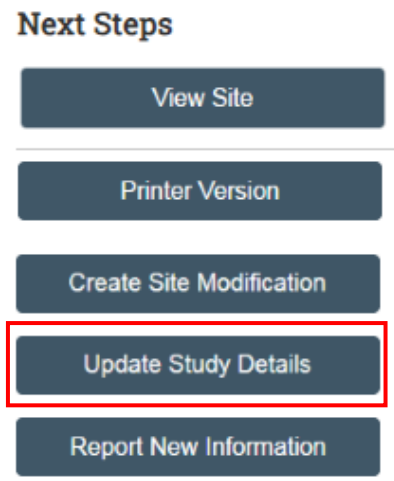
Quick Guide - External IRB Modification

Dashboard | Agreements | COI | IRB

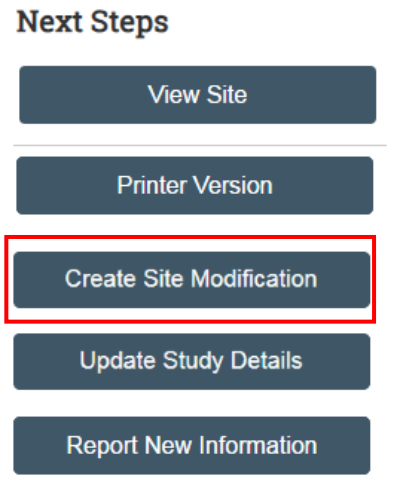
1. On the IRB page, navigate to the **External IRB** tab, and select the approved study.

2. Based on what you wish to modify, select 'Create Site Modification' OR 'Update Study Details'.

IMPORTANT: Use the tables on the next page to help identify which option to choose.



OR



After review, a letter will **not be** generated for updating study details.

After review, a letter will be generated for site modifications.

Select Update Study Details **to modify:**

Basic Study Information	• Title of Study • Short Title • Brief description • Protocol
External IRB	• External IRB name • External IRB Study ID
Study Funding Sources	• Study Funding Sources
Study Scope	• Study Scope Page: Answering 'Yes' will create forms for drugs and/or devices.
Drugs	• Drugs Page
Devices	• Devices Page
Study-Related Documents	• Consent form templates • Recruitment material templates • Other attachments

Select Create Site Modification **&** Modification scope: ☐ Study team and research location information ☑ Other parts of the site **to modify:**

Basic Site Information	• Local PI • Brief description of activities this site will perform
Additional Local Funding Sources	• Local funding sources
Local Site Documents	• Site consent forms • Site recruitment material • Other site attachments (i.e. Form A, Inst Form, Participant Payment Form)

Select Create Site Modification **&** **Modification scope:** ☑ Study team and research location information **to modify:**

Local Study Team Members	• Local study team members
Local Research Locations	• Local research locations

- When creating a site modification to add University Health as a new study site, select both options to modify team members/locations and local site documents (i.e. Inst form and consent form).

  Modification scope:
  ☑ Study team and research location information
  ☑ Other parts of the site

- Some study revisions (i.e. protocol changes) may require an update to study details and a site modification.

3. For Site Modifications: When all information has been provided, select Finish and Submit.

   For Study Updates: Edit Study Details. When all information has been provided, Save and Exit. The study update will be finalized by IRB Coordinator.