

Quick Guide - External IRB Study Closure

Dashboard

Agreements

COI

IRB

! Important! A study cannot be closed until the active Modifications have been approved or discarded.

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

In-Review

Active

New Information Reports

External IRB

- 2 Once on the study homepage, select the Create Site Modification button below:

Next Steps

View Site

Printer Version

Create Site Modification

- 3 Select **Modification / Update** and *Other parts of the site*, then **Continue** ➔ .

Modification

* What is the purpose of this submission? ?

 Modification / Update[Clear](#)

i To change the PI, choose 'Other parts of the study/site' scope

Modification scope:

 Study team and research location information Other parts of the site

Need Help?

[Create Site Modification](#) request **study closure** or approval for changes to your study that must also be reviewed by the external sIRB. A letter will be generated for site modifications.

Note: [Study Update Details](#) should be used for minor updates that do not require review by the external sIRB (e.g. personnel change). A letter will not be generated for study updates

4 Provide all relevant information to this Inactivation on the **Modification Information** page.

An image of the page is displayed below:


Modification Information

1. Study enrollment status:

- No subjects have been enrolled to date
- Subjects are currently enrolled
- Study is permanently closed to enrollment
- All subjects have completed all study-related interventions
- Collection of private identifiable information is complete

2. Notification of subjects: (check all that apply)

- Current subjects will be notified of these changes
- Former subjects will be notified of these changes

 Attach files: If notifying subjects, add a description of how they will be notified to the Other attachments section of the Local Site Documents page.

3. * Summarize the modifications:

Please indicate in this section that the study will be inactivated.

5 Select [Continue](#) 

6 Select **Local Site Documents** located on the left side of the page.




7 Upload the External IRB Inactivation letter to the “Other attachments” section. An image of the page is displayed below:


Local Site Documents

1. **Consent forms:** (include an HHS-approved sample consent document, if applicable) 

Document	Category	Date Modified	Document History
There are no items to display			

2. **Recruitment materials:** (add all material to be seen or heard by subjects, including ads) 

Document	Category	Date Modified	Document History
There are no items to display			

3. **Other attachments:** 

Document	Category	Date Modified	Document History
There are no items to display			

Please attached the External IRB Inactivation letter in the following section.


8 Select [Finish](#)

7 You may now  [Submit](#) your Inactivation request.

Next Steps

[Edit Modification/CR](#)

[Printer Version](#)

 [Submit](#)