

Updating/Closing External IRB Study Record in IRES IRB

IRES IRB contains a record of studies reviewed by external IRBs on behalf of Yale. The Yale Principal Investigators maintain responsibility to notify Yale HRPP about certain modifications to the studies under purview of external IRBs. These include:

- Personnel modifications including a change of the PI
- Change of the status of the study e.g. initial approval, suspension, termination, or closure
- Modifications that would require a review by a new ancillary committee

Submitting Updates

1. Locate the approved study in IRES IRB. To quickly locate studies under purview of an external IRB, click on **Submissions** under **My Current Actions**. In the **Active** tab, filter by **State** and type the word **External** in the text field. This action will generate a list of studies that were authorized for external IRB review. You will only see studies that you were either listed on or were named a guest.

IRB

The screenshot shows the IRES IRB interface. On the left is a navigation menu with 'Submissions' highlighted. The main area shows a tabbed interface with 'Active' selected. A search filter is applied: 'Filter by State External'. Below the filter is a table of results:

ID	Name
1606017973	The Adolescent Brain Cognitive Development (ABCD) Study (under purview of the UCSD)
2000020168	Test External IRB Study
2000020154	Testing with External IRB study

2. Open the study by clicking on its name. Under **My Current Actions**, click on **Update Study**.

The 'External IRB' window displays the following information:

- Entered local IRB: 3/15/2017 2:15 PM
- Locally confirmed: 3/15/2017
- Initial approval: 3/14/2017
- Approval end: 3/2/2018
- Last updated: 5/22/2017 4:17 PM

3. Explain the update in the **Study Update Summary Information** window that will open. Click **Continue**.

The 'My Current Actions' menu includes the following options:

- View Study
- Printer Version
- View Differences
- Update Study** (highlighted)
- Report New Information

Study Update Information

The 'Summarize the updates' section contains a text input field with the placeholder text: 'The update is to ...'

4. The study screens will open for editing. If you are modifying research staff, proceed to **Study Team Members** screen to make the appropriate updates.

- In order to update the study record with the approval and expiration dates, proceed to the **External IRB** screen. Modify the dates per instructions shown in the screenshot below.

External IRB

- * External IRB:**
WIRB
- IRB authorization agreement:** (if no existing agreement covers this study)
Name
There are no items to display
- Approval letter from external IRB:**
Outcome_Letter_3-2-16.pdf(0.01)
- Initial approval date by external IRB:**
- Last day of approval period:**
- * Specify the reason the study should be reviewed by an external IRB:**
- * Has the external IRB closed the study?** Yes No

Upload the current approval letter in question # 3.

Update question # 4 only with the initial approval date.

Update the current expiration date in question # 5.

State YES if the study has been completed and the external IRB closed it. The closure letter issued by the external IRB should be uploaded in question # 3.

- Click on **Submit** under **My Current Actions**. Notice the different submission process diagram.

Pre-Submission

MOD0000316: Study Update #3 for Study 200020154

Principal investigator: James Peters **IRB Office:**

Submission type: Modification/Update **External IRB:**

Primary contact: James Peters **External IRB /**

IRB coordinator:

Entered local IRB:
Locally confirmed: 3/15/2017
Last updated: 4/25/2017 1:53 PM

```

graph LR
    A[Pre-Submission] --> B[Pre-Review]
    B --> C[Post-Review]
    C --> D[Review Complete]
    B --> E[Clarification Requested]
    E --> B
    
```

My Current Actions

History

Filter by

No data to display.

Acknowledgement of Updates

Depending on the type of the update submitted, a different level of review may be required. For example, if the update is to change the PI of a study, in addition to the review of the proposed PI's training and COI disclosure, the submission will be sent to OSP for a verification that a sponsor contract was amended prior to acknowledgement of the update.

Updates to the initial approval/expiration dates

The PI and the PI Proxy will be notified via email when the update to the approval/expiration date is acknowledged. There will not be any official letter available for this type of acknowledgement.

Notification of Acknowledgement

To: James Peters
Link: [MOD00000329](#)
P.I.: James Peters
Title: Test External IRB Study
Description: The updates to this submission have been acknowledged.
To review additional details, click the link above to access the project workspace.
Please continue to keep the internal IRB informed of changes in the study approval status. Click the link above to access the project workspace. Then use the **Update Study** button to update related external IRB information or to close the study.

Personnel modifications and updates requiring additional reviews

In addition to a notification email, an acknowledgement letter will be available for acknowledgement of updates to the research staff, PI, and other parts of the protocol that would trigger additional review e.g. from an ancillary committee. The letter will be available in the heading area of the submission workspace as shown in the screenshot below.

Acknowledged

MOD00000325: Study Update #1 for Study 2000020168

Principal investigator: James Peters	IRB Office: Yale IRB
Submission type: Modification/Update	Local IRB Acknowledgement Letter: Correspondence_for_MOD00000325.docx(0.01)
Primary contact: James Peters	External IRB: WIRB
IRB coordinator:	External IRB Approval Letter:

Entered local IRB: 5/2/2017 1:42 PM
Locally confirmed: 5/2/2017
Update acknowledged: 5/22/2017
Last updated: 5/22/2017 4:56 PM

```
graph LR; A[Pre-Submission] --> B[Pre-Review]; B --> C[Post-Review]; C --> D[Review Complete]; B --> E[Clarification Requested]; E --> B;
```

Closures

Notification of the acknowledgement of the study closure will be sent to the PI and the PI Proxy. There will not be any official letter available for this type of acknowledgement.

Notification of Closure

To: James Peters

Link: [2000020168](#)

P.I.: James Peters

Title: Test External IRB Study

Description: The study has been closed. To review additional details, click the link above to access the project workspace.

Note: Once the closure update is acknowledged, the status of the study will change to **CLOSED**. Closed studies cannot be updated. Should new information become available that Yale HRPP must be informed about such as a serious noncompliance determination, it should be submitted as **Reportable New Information**.



Entered local IRB: 3/15/2017 2:15 PM
Locally confirmed: 3/15/2017
Initial approval: 3/14/2017
Approval end: 5/22/2017
Last updated: 5/22/2017 4:35 PM

My Current Actions

[View Study](#)

[Printer Version](#)

[View Differences](#)

[Report New Information](#)

 [Assign PI Proxy](#)

 [Copy Submission](#)

 [Add Comment](#)
