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.

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

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

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.
5. 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**

1. **External IRB:**
   - Select... | Clear

2. **IRB authorization agreement:** (if no existing agreement covers this study)
   - Add
   - Name
   - There are no items to display

3. **Approval letter from external IRB:**
   - Outcome_Letter_3-2-16.pdf(0.01)
   - Upload Revision
   - Delete

4. **Initial approval date by external IRB:**
   - 3/19/2017

5. **Last day of approval period:**
   - 3/2/2018

6. **Specify the reason the study should be reviewed by an external IRB:**
   - WIRB serves as the Central IRB for this study.

7. **Has the external IRB closed the study?**
   - Yes | No | Clear

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

![Submission Process Diagram](image-url)
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.

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.
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.

Closed  
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