



How to update a study with an “external IRB” status

If your study that was migrated and now has an “external IRB” status or if you selected “single IRB” and an external IRB is reviewing your study:

External IRB

Entered IRB: 12/20/2016 6:00 AM
Initial approval: 12/21/2016
Initial effective: 12/21/2016
Effective: 12/21/2016
Approval end: 7/10/2020
Last updated: 2/10/2020 7:51 PM

If you are seeking Emory IRB approval of study documents (for example, if changes are made to the CIRB addendum), or if the change to the study may require a new ancillary review or changes to our local context information, you need to click on “Add Comment” and send an email to the IRB staff (IRB coordinator in the system) with the tracked document and a clean copy instead.

You may update documents using the “Update Study Details” option. This does not represent Emory IRB Approval and you should use this function only after the external IRB has approved these changes you are about to submit. Make sure you include external IRB approval letters to the changes submitted. To update your study after the external IRB has approved changes to your study, follow these steps:

1. Click on “Update Study Details”

External IRB

Entered IRB: 10/30/2019 5:00 AM
Initial approval: 12/4/2019
Initial effective: 12/4/2019
Effective: 12/4/2019
Approval end: 7/17/2020
Last updated: 2/17/2020 4:00 PM

IRB00

Principal investigator: Initial Study
Submission type: Initial Study
Primary contact:
PI proxies:

IRB office: Emory IRB Office
IRB coordinator:
External IRB: NCI CIRB
External study ID:
External IRB approval letter:
Regulatory authority: 2018 Requirements

Next Steps

- View Study
- Printer Version
- Update Study Details**
- Report New Information
- Assign Primary Contact
- Add Comment
- View CITI Training

Workflow Diagram:

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graph LR
    A[Pre-Submission] --> B[Pre-Review]
    B --> C[Pending sIRB Review]
    C --> D[Post-Review]
    D --> E[Review Complete]
    C --> F[Modifications Required]
    F --> C
    B --> G[Clarification Requested]
    G --> B
  
```

History

Activity	Author	Activity Date
Snapshot generated	Administrator, System	12/13/2019 7:40 PM
Log Comment To Study Team		12/4/2019 6:29 PM



2. Describe all the changes you are submitting:

EMORY eIRB
DataLoad

You Are Here: CIRB: EAA173 > _IRBSubmission

Creating New IRB Submission

Study Update Information

1. * Summarize the updates:

3. Update the information accordingly. Please remember that if your study was migrated, you need to update the financial interest question for each of the study team members. In addition, if your submission has a drug section, please attach the IBs and FDA correspondence (if any) for each drug. Answer the questions on the last page of the submission.

NOTE: If your study was migrated, you are not required to upload the HIPAA attestation and waiver form.

Validate Compare

You Are Here: CIRB: EAA173

Editing: IRB00133020

Basic Study Information

1. * Title of study:

2. * Short title:

3. * Brief Description (Lay Summary). Please see our IRB guidelines [Guidelines](#). ?



4. After all the changes are made, click finish and you will be taken back to the current MODs window.

The screenshot displays the Emory IRB system interface. At the top, there is a navigation bar with tabs for 'My Inbox', 'Facilities', and 'IRB'. Below this, there are sub-tabs for 'Submissions', 'Meetings', 'Reports', 'Library', and 'Help Center'. The main content area is titled 'Updating Study' and shows the study ID 'MOD001-IRB00' and the update title ': Update #1 for CIRB:'. It includes fields for 'Principal investigator:', 'Submission type: Study Update', 'Primary contact:', 'IRB office: Emory IRB Office', 'IRB coordinator:', and 'Regulatory authority: 2018 Requirements'. A 'Next Steps' section contains buttons for 'Edit Study Details' and 'Printer Version'. A progress indicator shows 'Updating Study' in an orange circle followed by an arrow pointing to 'Updates Complete' in a white circle. Below this, there is a 'History' section with tabs for 'Documents', 'Reviews', and 'Snapshots'. A search bar is present with a filter set to 'Activity' and a search input field. A table of activity is shown with columns for 'Activity', 'Author', and 'Activity Date'. The table contains one entry: 'Minor Version Incremented' with an author field and a date of '2/19/2020 9:58 PM'. On the left side, there are options for 'Add Comment', 'Discard', and 'View CITI Training'.

5. Only the PI or the PI proxy will be able to click on Finalize Updates. If you missed something, click on “edit study details” to keep updating.
6. **If you do not see the option to “finalize updates”, log a comment to the study submission for our staff to do it for you.**