

Study Status Updates

Medical University of South Carolina

What is an Annual Status Update (ASU)?

- One of the changes associated with the 2018 Common Rule had to do with removing the requirement for Continuing Reviews for certain expedited studies approved on or after January 21, 2019.
- While a Continuing Review is no longer mandatory for those certain expedited studies, MUSC does require the PI to submit an Annual Status Update for the study.
- Annual Status Updates are submitted via the eIRB system and have been designed to collect a very limited amount of information from the study team.
- It is important to note that a completed annual status update must be received by the IRB 30 days prior to the annual status date of the study.
- If the researcher does not submit the MUSC required Annual Status Update, the IRB may consider this noncompliance.

Getting Started

- In your inbox, select the study that needs a Status Update.
- Under “My Activities” select “New Study Status Update”



Statuses Explained

- **Enrolling Subjects and/or Collecting Data:** use this status if actively enrolling subjects and/or collecting data on enrolled subjects
- **Enrollment Closed – Subjects continue to receive study treatment/intervention:** use this status once enrollment has been reached or closed, but are still actively treating the subjects
- **Data Analysis Only – Identifiable:** use this status when enrollment is closed and only completing data analysis with identifiable data.
- **Data Analysis Only – De-identified:** use this status when enrollment is closed and only completing data analysis with de-identified data.
- **Enrollment Temporarily Suspended:** use this status when enrollment has been suspended by the sponsor/PI
- **Permanently Closed – All study activities are completed:** use this status when closing out/terminating the study with the IRB

Changes Reviewed

- Amendments, Status Changes, and Reportable Events automatically populate for the study if any have been submitted over the past year.
- Confirmation is needed that all Reportable Events have been submitted.

Changes Reviewed - IRB reviews since last application review

1.0 Amendments:

No data to display

2.0 Status Change:

No data to display

3.0 Reportable Events:

No data to display

Do you certify that all reportable events have been submitted since the last update?

☒ Yes ☐ No

Documentation

- Upload anything from the Sponsor that supports approval, closure, or suspension of the study.
- For Reliance studies, a Continuing Review is needed from the IRB of Record in order to assign new expiration dates.

Study Status Documentation

1.0 Upload correspondence related to the study review or status, such as the current External IRB approval, closure or suspension notices, as applicable.

Name	Description	Orig. Author	Orig. Created	Last Mod
There are no items to display				

Conflict of Interest

- The statement below is a confirmation that the COI Disclosure is correct!
 - Answer YES if the COI has not been changed
 - Answer NO if the COI needs to be updated.
- If the COI needs to be updated, then submit an amendment ASAP!

Conflict of Interest

THE ITALICIZED INFORMATION REFLECTS THE CONFLICT OF INTEREST FOR THIS STUDY. PLEASE REVIEW THIS (READ-ONLY) INFORMATION AND ANSWER THE CERTIFICATION QUESTION AT THE BOTTOM OF THE PAGE.

1.0

Do any of the participating study investigators or other research personnel (or their immediate family) have a financial and/or intellectual property interest in the sponsor or products used with this research study?

No

I certify that the above disclosure statement is correct: ☒ Yes ☐ No

General Comments

- Comment and/or upload anything that will assist in the review.

General Comments

1.0

Add any additional comments to assist in the review

2.0

Add any miscellaneous documents that do not fit in other sections of the study application
Click Add to upload document(s)

Name	Description	Orig. Author	Orig.
There are no items to display			

FINISH

The PI will submit
the completed
Study Status
Update!

