#### 2018 Revised Common Rule - Reminder: Annual Status Updates

#### What is an Annual Status Update?

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 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 report 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.

#### How do I submit an Annual Status Update?

## Creating and submitting Annual Status Updates in eIRB can be confusing. Here is why:

Annual Status Update (ASU) documentation will be located within the "Continuing Review" tab on the study's home page. Because of the way eIRB works, the Annual Status Updates will be assigned a Continuing Review number rather than an ASU number.

#### Below is how to submit an Annual Status Update in the eRIB system:

1. Select "New Status Update" on the left side of your screen beneath "My Activities".



- 2. eIRB smartforms will open; complete the four forms as directed.
- 3. When the Status Update is ready for submission, the PI will still select the "SUBMIT CONTINUING REVIEW" option in the eIRB system.



#### What is the difference between an Annual Status Update and a Status Change?

It is important to note that an Annual Status Update is an abbreviated report that must be submitted to the IRB annually for review. Status Changes are only submitted to the IRB to report an immediate change in study status that is outside of normal study progression.

If the Continuing Review requirement has been removed for a study please make sure to use the status update button to report any changes in the status of the study.

### Q. How do I know if I need to submit an Annual Status Update vs a Continuing Review?

A. There are several ways to determine if you will need to submit an Annual Status Update vs. a Continuing Review such as:

- 1. If you are working on a full board study that is actively enrolling subjects, you are required to submit a Continuing Review to the IRB 30 days prior to the study's expiration date.
- 2. If you are working on a study that is funded by Department of Justice and/or is FDA-regulated you are required to submit a continuing review to the IRB 30 days prior to the study's expiration date.
- 3. Look on the study's main page look for the blue text that states "2018 Common rule", if a "No" response is listed, then you are required to submit a Continuing Review to the IRB 30 days prior to the study's expiration date.
- 4. Review the letter of approval that is located on the study's main page by selecting the "View" link next to "Letter of Approval". The approval letter will indicate either the study's expiration date or the deadline for the Annual Status Update submission.
- 5. Reminder notifications that are sent automatically from the eIRB system will specify if the study requires a status update or a Continuing Review.

### Q. Will I receive notifications that my Annual Status Updates needs to be submitted?

A. Yes. Individuals who are listed as eIRB communication coordinators will begin receiving reminder notifications from the eIRB system at 60 and 45 days prior to the due date of the Annual Status Update.

#### Q. Who can submit the Annual Status Update to the IRB?

A. The PI is the only individual who can submit the Annual Status Update for processing in the eIRB system. It is important to remember that the PI will still use the, "Submit Continuing Review" option to submit the status update to the IRB. Note: The study team can still create the application but the PI must be the one to push the submit button.

# Q. What happens if I do not submit the MUSC required Annual Status Update prior to the deadline?

A. The IRB will carefully review each situation and may consider this noncompliance per <u>HRPP 3.5.</u>