March 20, 2020

Procedures for Notifying the IRB of a Pause in Research Activities Due to COVID-19 ONLY

This represents a change in the IRB guidance from 3/13/20.

Investigators should notify the IRB when some or all of the procedures/activities for a study are being paused to minimize the risk of COVID-19 transmission within 7 days of the initiation of the pause. A simple process has been developed for this purpose. It does not require additional IRB review and approval.

1. Click on the activity “Log Public Comment” in the left hand column of the study workspace.

2. Follow the instructions in the new window that opens, being sure to check the box ONLY if study procedures/activities are being paused due to COVID-19. Specify in the Comments box: a) which procedures are being paused and b) who initiated the pause (e.g., the PI, external funding agency, etc.).

3. Supporting documents (e.g., a letter from the study sponsor regarding the pause) can be uploaded in this window. Click OK to close the window. Public comments are visible to the research team, OPHS staff, and IRB reviewers. They are logged in the study history with a date and time stamp.

4. You will receive an automated notification in Outlook from www.irbear.org acknowledging your comment.

It may be necessary to submit more than one comment if some procedures are paused at different times. You should also log a public comment when any study activities are resumed. Use the checkbox and describe the situation in the Comments box.