Status Report

January 2019

Background:

Per the preamble, “continuing review is eliminated for all studies that undergo expedited review, unless the reviewer explicitly justifies why a continuing review would enhance protection of research subjects.” Continuing review has also been eliminated for research that has progressed to the point that it involves only data analysis or “accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care.” See information on specific changes to the new section 46.109. Per the new section 46.115, the reviewer must “provide a rationale for conducting continuing review of research that otherwise would not require continuing review as described in 46.109(f)(1).”

1. Q: What is meant by a Status Report?

An IRB Status Report is simply a way for the PI of an IRB approved Expedited study to keep the IRB and the University aware of what IRB approved research is still active.

Protocols approved by the IRB under an Expedited category no longer require continuing review (CR). In lieu of CR, every 3 years, the PI and other key study staff will receive an automated notice from the myIRB software system asking for the submission of a Status Report. Status Report notices will be sent at 45 day, 30 days, and 7 days prior to the protocol’s 3 year anniversary date.

2. Q: How is a Status Report submitted?

The PI of the study simply goes to the Study Workspace in myIRB of the protocol in question, and clicks on the Status Report activity shown below.
• If you indicate the study is still active, then 3 years from that date, you will receive another automated email to provide a current Status Report.
• If you indicate the study is no longer active, then once you click “OK” the study will be automatically closed by the myIRB software.

3. **Q: What if the IRB does not receive a Status Report?**

If no status report is received by the 3 year anniversary approval date of the protocol, the IRB will consider the protocol no longer active, and the study will be automatically closed by the myIRB software.

4. **Q: How does the IRB decide which protocols will require a Status Report and not a Continuing Review?**

Reasons the IRB will require a Continuing Review and not a Status Report are:
• The protocol is governed by the FDA Human subject’s regulations 45 CFR 56
• Special circumstances such as studies involving a conflict of interest, IRB reliance, or prior compliance concerns.

5. **Q: Can an Expedited study be closed anytime between approval and the 3-year Status Report?**

Yes, by submitting a Status Report at any time. If a Status Report is submitted outside of the 45 day window of the study’s 3-year anniversary, the only displayed option is to close the study.

6. **Q: Once a protocol is closed, can it be re-opened?**

No, a new protocol will have to be submitted, reviewed and approved.