Closed Studies and Closed to Accrual

January 2017

Background:

Federal regulations require prompt reporting to the IRB of proposed changes in a research activity. The closure of a research study is considered a “change in research activities”. The UF IRB requires that Investigators submit a Study Closure Report when study activities including enrollment, interventions/interactions, and/or data analysis of personally identifiable information have been completed (including premature completion of the research). Analysis of de-identified research data may continue after study closure. Study closures are initially conducted under expedited review procedures (as a minor change in previously approved research), but the Executive Reviewer can refer the closure for consideration by the Full Board as deemed necessary.

Q: What is the difference between closed vs. closed to accrual?

When a study is “Closed to accrual” it means that no additional subjects will be enrolled in the study. In this case, study activities are still ongoing and may include intervention or interaction with subjects, continued use of a drug or device, and/or data analysis of identifiable information. A “Closed” study means that ALL study activity has ceased – whether because the sponsor has decided that it may not continue, the investigator chooses not to continue the research, or the study activity and data analysis are complete.

Q: If a study is closed to accrual, does the IRB still need to review the research protocol?

Yes. When a study is “closed to accrual”, the investigator must still inform the IRB if any study interventions that are continuing, or if only follow-up data collection, or data analysis of identifiable information is continuing. If all study interventions are completed, the IRB will approve the revision to close the study to accrual, and move it what is called “Longitudinal Review”. If the original approval for the study was “greater-than-minimal-risk”, the Board will move the approval to “minimal risk”, move the study to applicable Expedited category and future continuing reviews can be conducted via the Expedited review process.

If a “greater-than-minimal-risk” study is closed to accrual, but study interventions continue on at least one subject, the IRB will keep the original risk approval designation.

Q: How do I close a study?

To close a study, Investigators must submit a Continuing Review via myIRB. The smartform questions and branching will guide the investigator to continue or close the study. The cumulative Adverse Event Reporting table, cumulative deviation table, and the last signed copy of the informed consent (with subject name(s) redacted) will be required to be uploaded within the system and any other new findings/publications that relate to the study.

A study is not closed until the closure submission has been approved by the IRB.
Q: Can I re-open a closed study?

No, a new study will need to be submitted to the IRB.

Q: What if the Principle Investigator wants to close a study before the research study is completed?

The PI must notify the IRB if he/she closes or suspends a research project. The IRB will want to know what is happening to subjects who have been enrolled. For projects that are funded, the PI must work with the Research and Compliance office prior to the study being officially closed by the IRB.

Q: What do I need to do with the Research Records?

After a study is closed, all study documents must be kept in accordance with the University of Florida’s Record Retention policy, http://cms.uflib.ufl.edu/records/Records. You can email the UF Records Manager at: lib-recordmanagement@uflib.ufl.edu