Subject: Closure

Section: 8-9

This policy and procedure supersedes those previously drafted.

Approved by: Vice President of Research & Graduate Studies on 3-9-2008. Revision 1 approved by VP Research & Graduate Studies on 8-22-2011.

Related Sections: 4-7, 8-7

“An IRB shall conduct continuing review of research covered by [this policy, these regulations] at intervals appropriate to the degree of risk, but not less than once per year, and shall have authority to observe or have a third party observe the consent process and the research.” 45 CFR 46.109 (e), 21 CFR 56.109(f)

An application for renewed approval or closure must be submitted to the Institutional Review Board (IRB) prior to the expiration of IRB approval for non-exempt research. At any time prior to the expiration date, principal investigators (PI) may request closure if research activities are complete.

Human subject research activities are complete if:

1. Data collection is complete and there is no further contact or interaction with human subjects, and
2. Analysis of identifiable private data is complete.

After expiration of the IRB approval, all research activities, including data collection and analysis of identifiable private data, must stop. If the PI believes that it is in the best interest of the individual subjects to continue participating in research interventions or interactions, he/she should notify the IRB immediately. The IRB chair will make the decision of whether to allow continuation with consultation from other members of the IRB, if necessary. In any case, enrollment of new subjects cannot occur after the expiration of IRB approval.

Research studies that are not renewed or closed by the expiration date will be administratively closed by the IRB. An investigation into the status of the research and investigations may be initiated, including further attempts to contact the investigators, chair, director, dean, obtain a closure application, and/or auditing of the research study.

Closure Requested by the PI

If research activities involving human subjects, including data collection and analysis of identifiable private data, are complete, the PI may permanently close the research study. The PI should complete and submit the closure application.

An IRB member reviews the completed closure application. A letter confirming that the research study has been closed is made available through the MSU IRB online system and notification of the letter is sent to the researchers.
Data resulting from the research study should be stored and protected in a manner to maintain the privacy and confidentiality of the subjects. At a minimum, “records [relating to research which is conducted, 45 CFR 46.115] [required by this regulation, 21 CFR 56.115] shall be retained for at least 3 years after completion of the research.” 45 CFR 46.115(b), 21 CFR 56.115(b). See the Human Research Protection Program (HRPP) Manual 4-7 “Recordkeeping” for guidance. Investigators should be aware that other laws and requirements (e.g., funding agency) may require a longer record retention period. Whenever possible, the data should be permanently de-identified. For guidance on data storage, see Michigan State University Guidelines on Research Data: Management, Control and Access.

Closure Based on Failure to Apply for Renewed Approval
Renewal reminders are routinely sent by the IRB to investigators to assist in meeting the continuing review requirement. See HRPP Manual 8-7 “Renewed Approval” for procedures.

If the PI believes that it is in the best interest of individual subjects to continue participating in research interventions or interactions beyond the expiration date and IRB approval has not been obtained, he/she should notify the IRB immediately. The IRB chair will make the decision of whether to allow continuation with consultation from other members of the IRB as appropriate. In any case, enrollment of new subjects cannot occur after the expiration of IRB approval.

After expiration, the research study status will be changed to “Closed.” A closure letter will be made available through the MSU IRB online system and notification of the letter is sent to the researchers. An investigation into the status of the research study and investigators may be initiated including further attempts to communicate with the researchers, communicating through the chair, dean, and/or director if necessary, and auditing of the research. “When continuing review of a research protocol does not occur prior to the end of the approval period specified by the IRB, IRB approval expires automatically. Such expiration of IRB approval does not need to be reported to OHRP as a suspension of IRB approval under HHS regulations.” OHRP Guidance on Continuing Review

If the research study is federally funded, notification of the closure is sent to the MSU Office of Sponsored Programs.

To reactivate the research after this time, a new initial application will typically be required.