**GUIDANCE 5**

**GUIDANCE FOR STUDY CLOSURE OF STUDIES**

1. The RowanSOM IRB administrative office must be notified when a study is completed. This notification should be sent when enrollment of participants and data collection is complete and data analysis is to the point that participants' records will no longer be required. Please complete a Final Study Report and submit it to the IRB within 30 days of closure of the study. Notification of the closure of exempt studies is also recommended.
2. Principal investigators have the responsibility of informing the IRB when a study has been completed. A study is considered to be open and active until the investigator has submitted an electronic version of the Final Report to the IRB. When Final Reports are submitted, an administrative review will be conducted by the IRB staff. IRB Chair/IRB Director will review the form and report the closure of study to the IRB.
3. Faculty advisors for student research have the obligation to ensure that a final report to close the study is electronically filed with the IRB in a timely fashion. If protocols are not closed (Expedited and Full Board), IRB has the authority to not to review any new protocols submitted by the investigator (who has not closed the study) until the study which has been completed but not closed (not submitted final report).

4. When a principal investigator terminates employment or other association with the Institution, he or she is obligated to submit a Final Report to the IRB or formally transfer the protocol to another principal investigator via a modification, which will be reviewed and approved by the IRB. A study may be closed when all of the following apply:

A. All subject recruitment and enrollment is complete (i.e., no new subject recruitment or enrollment are ongoing);

B. All subject specimens, records, data have been obtained (i.e., no further collection of data/information from or about living individuals will be obtained);

C. No further contact with subjects is necessary (i.e., all interactions or interventions are complete and no further contact with enrolled subjects is necessary) and

D. Analysis of subject identifiable data, records, specimens are complete (i.e., use or access to subject identifiable data is no longer necessary. Note: this includes review of source documents by study sponsors.

E. In very rare cases, the IRB may grant special permission for the departing individual to remain as principal investigator on the project at another institution. Such cases are reviewed on a case by case basis. Before final approval is granted, the Principal Investigator must:

i. Complete, sign and submit the “Agreement between RowanSOM and Departing Faculty member” to his/her Department Chair. The Agreement must also be signed by the Senior Associate Dean for Research and the Dean. Once signed, the form must be submitted electronically through Cayuse IRB; and

ii. A copy of the IRB approval from the transferring Institution must be submitted electronically through Cayuse IRB if the study is continuing.