Division of Research
University Policy

SUBJECT: Closing an IRB Approved Study		**Policy Number:** 10.3.9
	Effective Date: November 20, 2015	**Renewal Date:** November 20, 2018
	Supersedes: October 21, 2011 September 10, 2010	**Page 1 of 5**
	Responsible Authorities: Vice President, Research Institutional Review Board Director, Research Integrity	

I. Background

Continuing Institutional Review Board (IRB) review and approval is required as long as study activity is ongoing, including intervention or interaction with subjects, continued use of a drug or device, and/or data analysis of identifiable data. When all study activity has ceased an investigator should close a research study. Regulations (21 CFR 56.108) require prompt reporting to the IRB of changes in a research activity; because the completion of a study is considered a change in activity, it must be reported to the IRB for processing.

II. Purpose

This policy describes when and how a study may be closed or terminated by the Principal Investigator (PI) or the IRB.

III. General Statement

A process for closing studies shall be required because of the potential risks to human subjects that may arise if study activities are terminated without final review.
Such risks may include ethically or medically indicated follow-up procedures that may otherwise not be made available.

The IRB will notify a PI that IRB approval or active IRB status has expired or that the IRB has inactivated IRB approval due to non-response from the PI to IRB requests. The IRB and/ or the Institutional Official may also suspend or terminate IRB approval. Study closure requires IRB review and acceptance. Regardless of the category for study closure, the expiration date for IRB approval falls on the last day before the approval period end date.

Study closure falls into the following four categories:

1. Closure request initiated by the PI;
2. Non-response from PI to IRB requests for revisions;
3. Closure due to non-enrollment of subjects;
4. Lapse of approval due to PI's non-response to requests for continuing review.

IV. Policy

- If a study has been open for a period of three or more years and the PI has not enrolled subjects in the study, the IRB may require study closure unless there are extenuating circumstances for keeping the project open (e.g., the study is about a rarely seen condition).

- A study should be terminated by the PI when no further contact with human subjects or their individually identifiable information is planned, no subjects are or will be treated or followed, and all identifiable data are gathered and analyzed. Investigators are expected to continue to honor confidentiality protections for data after studies are officially closed.

- Studies may be closed when individually-identifiable data are no longer being collected or analyzed on subjects. Multi-site studies, such as clinical investigations, may be closed when the sponsor has completed all data queries on the FAU site's study records, has "locked" the site data, and remaining data analysis will not be completed by FAU.

- Studies may be closed by PI if all of the following conditions are met:
  a) All subject enrollment is complete; ***AND***
  b) All data (including study follow-up data) pertaining to human subjects have been collected; ***AND***
  c) No further human subject interaction is planned for the purpose of research; ***AND***
  d) No further analysis of identifiable private information is to be conducted.

- Studies may be closed by the IRB without PI approval in the following circumstances:
  a) If it is determined that the investigator is no longer affiliated with FAU;
  b) If the study expires because the PI has not provided a continuing review;
  c) In response to unanticipated problems involving risk to subjects or others, serious or continuing non-compliance, findings presented during an IRB review, or problems identified in a monitoring process;
  d) If the investigator has not responded to the IRB's requests for revisions and/or clarifications within the timeframe determined by the IRB, based upon the vulnerability of the subject population and the risk of the research;
  e) If a study is not accruing participants.

- Closing an expired study is not considered termination of approval of research per 45 CFR 46.113 and is not reportable to OHRP.

V. Definitions

Closed to Enrollment: Enrollment of new subjects is stopped either permanently or temporarily.

Temporary Closure to Enrollment: A study may be temporarily closed or closed to enrollment when there is a pause in the conduct of research or recruitment. (e.g. when conducting an interim analysis.)

Permanent Closure to Enrollment: A study is closed permanently when no further enrollment will occur and individually-identifiable follow-up data are no longer being collected on subjects.

Suspension: An action taken by the IRB or other body with such authority. It is a temporary or permanent halt to some or all research procedures short of a termination until the IRB (or other body with such authority) determines whether the research may re-commence (with or without modifications to the research) or whether the research must be terminated.

Termination: An action to permanently end a study with the guarantee that no further contact with human subjects or their individually identifiable information is planned; no subjects are or will be treated or followed; all data are gathered and analyzed; and any final reports or publications, if applicable, are complete. A PI may request to terminate a study when it no longer constitutes human subject research, which can be done by de-identifying the data. The IRB may also terminate a study, therefore halting further research.

VI. Accountability

A. The principal investigator (PI) will be responsible for closing out an IRB approved study if any of the following conditions exist:

1. All research activities including data analysis and reporting are complete;
2. The PI never initiated the study;
3. Subject accrual is finished, all data collection is complete and the only remaining activity is analysis of the data, the data are de-identified, and there are no identifying links or codes to the de-identified data;
4. The PI plans to leave the University and intends to continue the research activities at another institution;
5. The study has been open for a period of three or more years and the PI has enrolled no subjects in the study.

B. The Research Integrity office will be responsible for:

1. Providing for automated expiration alerts through electronic protocol management system at multiple intervals prior to expiration.
2. If a principal investigator fails to respond to IRB requests within the given timeframe, and the study expires, closing the study on behalf of the IRB.
3. Providing principal investigators with written notice detailing the IRB's action regarding the study.
4. Providing for administrative final review and closure of submission unless concerns warrant Chair involvement.

C. The Institutional Review Board (IRB) will be responsible for:

1. Reviewing and acknowledging the request for closure.
2. Ensuring the rationale presented by the PI for closure is acceptable for the protection of human subjects.

VII. Procedures

- The Principal Investigator (PI) submits a written request to close an IRB approved study to the Research Integrity office within the Division of Research. When closing a study, the PI completes a continuing review / final report form unless: 1) he/she never initiated the study or; 2) the study received initial/continuation review within the last six months and the PI has enrolled no subjects in the last six months. PIs do not have to wait for the end of the study approval period to request study closure.

- When a PI terminates employment or other association with FAU, he or she is obligated to either:
  i. Submit the continuing review / final report form with request to close the study, *or*
  ii. Submit an "IRB Amendment form" to transfer the study to another FAU PI. (Note: change of key personnel in federally funded or FDA-regulated research requires prior approval of the funding agency and/or FDA.)

- If an investigator wants to use identifiable data from a closed research study, whether by the original investigator or other investigators, this may be considered human subjects research requiring separate IRB approval.
  PIs are advised to consult with Research Integrity for further guidance in these circumstances.

- Under some circumstances, PIs must fulfill stated commitments to the participant, such as communicating research results or following through on compensation to subjects, even if the study is closed. These can be done with permission of the IRB Chair.

- In the event that a PI wishes to keep a study open and there is a lack of enrollment activity, the PI must justify the rationale for keeping the study open as part of the continuing review process. The IRB will make a determination and notify the PI of its decision.

- PIs must retain all records relating to an IRB approved research study for at least 3 years after completion of the research. All records shall be accessible for inspection and copying by persons authorized through the appropriate university, state or federal agency requesting such documents, at reasonable times and in a reasonable manner. [45 CFR 46.115(b)]

- A PI may re-initiate research previously closed by the IRB by following the procedures for initial full review, initial expedited review, or continuing review, as determined by the IRB Chair, Vice Chair, IRB members, or RI staff.

VIII. Policy Renewal Date
11/20/2018

IX. References
45 CFR 46.109
45 CFR 46.115(b)
21 CFR 56.108

POLICY APPROVAL

Initiating Authority

Signature: Date:

Name: Daniel C. Flynn, Ph.D., Vice President for Research

Executed signature pages are available in the Initiating Authority Office(s)