

SUBJECT:

Closing an IRB Approved Study

Policy Number:

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-

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

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)