

Closure of Research (HRPP 2.9)

Description:

This policy describes the criteria for, and process of, closing an on-going human subject research study, and to describe UNMC's requirements of investigators when studies are closed.

Definitions:

Closure of a study: all research interventions, including analysis of identifiable data, have ceased, or must be ceased.

Expiration of a study: the approval is no longer valid because the required continuing review has not received full approval by the IRB by the expiration date.

Low accrual: less than 1/2 of expected accrual based on the total accrual divided by the estimated time to accrue subjects in initial IRB application.

When Closure May Occur:

- When the aims of the study are satisfied.
- As a decision by the investigator before the study aims are met (ex. Lack of funds, poor accrual, departure of the investigator, etc.).
- As a decision by the sponsor or granting agency.
- By the IRB if subject accrual is judged to be inadequate to achieve scientific goals of the study or if resources are deemed inadequate to complete the study in a timely fashion.
- By the IRB/ORAs if an investigator fails to respond (via a continuing review or demographic form, as appropriate) to the "Approval Expired" email notifications.

Procedures:

- All research activities must stop.
- Investigators must inform the IRB:
 - **For studies that require continuing review**, this is done by submitting a continuing review application or a completion report.
 - **For studies that do not require continuing review**, submit a message in the message portal in RSS or complete the annual demographic form.

If a study is closed and you want it reactivated:

If a study is closed by the IRB or ORA:

- **For studies that do not require continuing review**, the investigator may request reactivation, with adequate justification, within 30 days from date of completion.
 - Reactivation after 30 days requires submission of a new application.
- **For studies that involve continuing review**, a new application **MUST** be submitted. The study may not be reactivated.

If a study is closed by the IRB or ORA for failure to respond to the “Approval Expired” notification:

- Investigator must submit a new application.

Closures for Inadequate Accrual:

- The IRB or ORA can close a study for low accrual in:
 - Single site studies where UNMC/UNO/CHMC is the sole participant or
 - Multi-site studies where UNMC/UNO/CHMC is a participant but there is no external funding.
- Studies with low or no accrual after 2 review cycles are required to provide an explanation and a detailed plan to increase accrual. Plans might include the following:
 - Additional sites
 - Additional investigators
 - Additional study personnel
 - Expanded study populations or less restrictive inclusion/exclusion criteria
 - Augmented education/training of referring physicians
 - New advertising
 - Extension of expected time to achieve target accrual
- Failure to accrue a minimum number of subjects by the next review cycle (without acceptable justification) may lead to closure of the study.
- The IRB may allow certain studies involving rare conditions to continue despite low or no accrual.

Closures for Standard Follow-Up:

- Studies may remain in standard follow-up for no more than 3 review cycles unless:
 - The organization is contractually required to keep the study open.
 - The study includes a tissue bank at the organization.
 - The investigator can provide adequate justification for the study to remain open.