2.9 Closure of On-Going Research

Last Revised: 08/10/2023

1.0 Purpose

The purpose of this policy is to describe the criteria for, and process of, closing an on-going human research study, and to describe the Organization's requirements of investigators when studies are closed.

2.0 Policy

It is the policy of the Organization that

- 2.1. All research activities, including analysis of identifiable data, must cease when a research study has closed.
- 2.2. Studies may be closed by the PI or sponsor at any time, or by the IRB if subject accrual has been judged to be inadequate to achieve the scientific goals of the study, or by the ORA if the study remains in standard follow-up without additional research interventions or protocol dictated assessments, or by the IRB or ORA if the investigator has failed to respond to the "Approval Expired" notification from the ORA that IRB approval for a study has expired
- 2.3. The investigator is responsible for notifying the IRB when a study is closed, and for making appropriate updates on ClinicalTrials.gov as appropriate, and for posting the consent forms on ClinicalTrials.gov as required.
- 2.4. Studies closed by the ORA or IRB due to inadequate accrual or closed in standard follow-up, may be reactivated under certain circumstances; studies closed by the IRB or ORA for failure to respond to "approval expired" notification require submission of a new application.

3.0. Definitions

- 3.1. Closure of a study means that all research interventions, including analysis of identifiable data, have been or must be ceased. Closure may occur:
  - 3.1.1. When the aims of the study have been satisfied.
  - 3.1.2. As a decision by the investigator before study aims have been met (for example, due to lack of funds, poor accrual, departure of an investigator, demonstration of lack or efficacy or futility).

    - 3.1.3. As a decision by the sponsor or the granting agency.
    - 3.1.4. By the IRB if subject accrual has been judged to be inadequate to achieve the scientific goals of the study.
    - 3.1.5. By the ORA if the study remains in standard follow-up without additional research interventions or protocol dictated assessments.
    - 3.1.6. By the IRB or ORA if the investigator has failed to respond to the “Approval Expired” notification from the ORA that IRB approval for a study has expired, as per HRPP policy 2.7 (Continuing Review of Research).
- 3.2. Expiration means that approval is no longer valid because required continuing review has not received full approval by the IRB by the expiration date, per HRPP policy 2.7 (Continuing Review of Research). Approval expiration is not study suspension (see HRPP policy 8.6 (IRB Study Hold, Suspension and Termination)).

4.0. Closure for Inadequate Accrual

- 4.1. Single site studies where UNMC/UNO/CHMC is the sole participant, or multi-institution studies where UNMC/UNO/CHMC is a participant but there is no external funding, may be closed by the IRB or ORA for low or no accrual.
    - 4.1.1. Low accrual is defined as less than 1/2 of expected accrual based on the total accrual divided by the estimated time to accrue subjects in initial IRB application.
- 4.2. Studies with low or no accrual after two review cycles will be required to provide an explanation and a detailed plan to increase accrual. Plans to increase accrual might include, but are not limited to:
    - 4.2.1. additional sites
    - 4.2.2. additional investigators
    - 4.2.3. additional study personnel, such as coordinators
    - 4.2.4. expanded study populations or less restrictive inclusion or exclusion criteria
    - 4.2.5. augmented education/training of referring practitioners, as applicable
    - 4.2.6. new advertising
    - 4.2.7. extension of the expected time to achieve target accrual
- 4.3. Failure to accrue a minimum number of subjects by the next review cycle, without acceptable justification by the investigator may lead to closure of the study.
- 4.4. The IRB may allow certain studies involving rare conditions to continue despite poor or no accrual.

5.0. Closure of Studies in Standard Follow-Up

- 5.1. Studies may remain in standard follow-up for no more than three review cycles, and then may be closed, unless:
    - 5.1.1. the study is collecting data in any form (such as survival); or
    - 5.1.2. the organization is contractually required to keep the study open; or
    - 5.1.3. the study includes a tissue bank at the organization (UNMC, UNO, CHMC or BMC); or
    - 5.1.4. the investigator can provide adequate justification for the study to remain open.

- 5.2. If later access to study data is needed by investigators or sponsors, a Medical Records application should be submitted to access existing data.

6.0 Closure Procedures

- 6.1. When a study is closed, all research activities must cease. The investigator may not conduct any further research activities (including collection of existing or additional identifiable private information, or new analysis of existing identifiable private information), or allow any other person or organization to conduct any further research activities.
- 6.2. The investigator is responsible for notifying the IRB when a study is closed.
  - 6.2.1. For studies that require continuing review, this is done by submitting a Continuing Review application or a Completion Report.
  - 6.2.2. For studies that do not require continuing review, such as Central IRB applications or expedited research approved under the 2018 New Common Rule, by submitting a message using the message portal in RSS or by completing the annual demographic recruiting numbers form.
- 6.3. When a study is closed, the investigator is responsible for revising the study status on ClinicalTrials.gov, and posting study results as appropriate, as per HRPP policy 1.29 (ClinicalTrials.gov Reporting).
- 6.4. When a study is closed, the investigator is responsible for posting the consent forms on ClinicalTrials.gov as required.
- 6.5. If a study is closed by the IRB or ORA (per section 3.1.4 or 3.1.5. above), the investigator may request reactivation, with adequate justification, within 30 calendar days from the date of completion. Reactivation after the 30 calendar days grace period requires submission of a new IRB application.
- 6.6. If a study is closed by the IRB or ORA for failure to respond to “approval expired” notification (per section 3.1.6 above), investigators wishing to continue the research must submit a new application.

DOCUMENT HISTORY:

? Written: 1/12/2018 (Approved: 1/12/2018) - original author not recorded

? Revised: 1/29/2021 - Added inadequate accrual as reason for closure by IRB (section 3.1.4) and criteria and process for closure (section 4); added prolonged time in standard follow-up as reason for closure by ORA (section 3.1.5) and criteria and process for closure (section 5).

? Revised: 08/10/2023 – clarified that “closure” includes cessation of analysis of identifiable data; deleted definitions of suspension and termination as irrelevant to this policy; clarified possible options for improving accrual; clarified that closure for inadequate accrual, or of studies in prolonged follow-up may (not “must”) occur; clarified investigator responsibilities regarding study closure by the investigator; added that studies closed for failure to respond to “approval expired” notification may not be reactivated, but will require submission of a new application.

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