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-related activities, including interventions and analysis of identifiable data, must stop. ***Expiration of a study:*** IRB approval is no longer valid because the study did not receive full continuing review approval before the expiration date. ***Low accrual:*** less than 50% of expected accrual based on the ratio of enrolled subjects to projected timeline (as stated in the original IRB application).

When Closure May Occur:

- When the study aims have been achieved
- At the investigator's discretion, even if the aims are not achieved. This may be due to:
  - Lack of funding
  - Low participant enrollment
  - PI leaving institution
  - Futility or inefficacy of intervention
- When the sponsor or granting agency ends the study
- If the IRB determines that subject accrual is insufficient to meet the scientific goals
- When the ORA determines that the study is in standard follow-up only *(i.e. no further research-specific interventions or assessments)*
- If the PI fails to respond to an "Approval Expired" notice from the ORA

Closure for Inadequate Accrual:

- **Closure Criteria:**
  - The IRB or ORA may close studies for low or no accrual, specifically:
    - Single-site studies where UNMC/UNO/CN is the sole participant
    - Multi-site studies where UNMC/UNO/CN is a participant but there is no external funding
- **Required Action After 2 Review Cycles with Low Accrual:**
  - The PI must submit:
    - A justification for low/no accrual
    - A detailed plan to improve accrual, which may include:
      - Adding more sites
      - Adding investigators
      - Adding study personnel
      - Broadening eligibility criteria
      - Educating referring physicians
      - New recruitment/advertising
      - Extending recruitment timeline
- **Closure if Accrual Still Inadequate:**
  - If minimum accrual isn't met by the next review and no acceptable justification is given, the study may be closed
  - The IRB may allow low-accruing studies to continue if the study targets a rare condition

Closure of Studies in Standard Follow-Up:

- **Time Limit:**
  - Studies in standard follow-up (no active interventions) **may remain open for up to 3 review cycles** unless:
    - Data (e.g. survival) is still being collected
    - A contract requires the study remain open
    - A tissue bank is associated with the study at the site
    - The investigator provides a valid justification
- **Accessing Data After Closure:**
  - If future access to study data is needed post-closure:
    - A **medical records IRB application** must be submitted

Closure Procedures:

- **All research activities must stop**
- **Investigator Notification to the IRB**
    - PI must inform the IRB of study closure:
        - If **continuing review was required-** submit a Continuing Review application or Completion Report
        - If **continuing review wasn't required-** use the RSS message portal or submit the annual demographic form
- **ClinicalTrials.gov Requirements:**
    - The PI must:
        - Update study status
        - Post results, if applicable
        - Post consent forms, if required

If the study is closed and you want it reactivated:

- 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 **require continuing review:**
    - The study **may not be reactivated**; a new application must be submitted