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## **KNH- UoN ERC STUDY CLOSURE POLICY**

This policy shall apply for the closure of KNH-UoN ERC approved studies.

### **SCOPE**

Describes levels and procedures of closure:

- Temporary closure due to:
  - Delayed onset
  - Lapsed approval
  - Researcher non-response to issues raised by the KNH-UoN ERC within stipulated period
  - Funding or accrual constraints
- Permanent closure due to:
  - Accrual
  - After completion of research activities

### **RESPONSIBILITIES**

Responsible persons for study closure are:

- Chair KNH-UoN ERC
- KNH-UoN ERC members and staff
- Researcher (PI & research team)
- Study sponsor

### **PROCEDURES FOR CLOSURE**

- i. The PI shall initiate study closure when the study was never carried out and there are no plans to initiate it.
- ii. The PI shall initiate the closure procedures if the study has been completed including the data collection, verification and analysis has been completed.
- iii. The KNH-UoN ERC shall initiate the closure procedures if the study PI has had no contact with the KNH-UoN ERC or has been non-responsive.
- iv. The KNH-UoN ERC can initiate the closure procedures if the approval has lapsed and request for renewal has not been done after 2 months.
- v. In single site studies :
  - a. Closure can be initiated when contact with human participants and the data has been verified and analysed.
  - b. When there are confidentiality agreements for the use of research data in participants consent, closure shall be initiated upon completion of the study by PI and sponsor after destruction of identifiers and links to identifiers in health records data.

- vi. In multisite studies: Closure shall be done when:
  - a. All participants enrolled at the KNH-UoN ERC approved and over sighted site have completed all their research activities
  - b. The sponsor has concluded the study close out visit and no additional identifiable private information is being obtained by research team.
- vii. For retrospective studies or reviews, unless otherwise indicated by the investigators, the KNH-UoN ERC shall close study on the annual closure date.
- viii. A study can be closed if the sponsor receives an unsatisfactory report from the DSMB indicating unacceptable risk to study participants.
- ix. Additional information regarding suspension or termination by the KNH-UoN ERC refer to standard operating procedures (SOP).

### **STUDY CLOSURE REPORTS**

- i. When the study has met the closure criteria, the PI must submit a closure report to the KNH-UoN ERC in addition to completion of closure application form. (KNH-UoN-ERC/FORM/SC/1B).
- ii. If the research qualifies for permanent closure, the PI shall submit the study closure report to the KNH-UoN ERC for verification and approval.
- iii. The ERC shall ensure the closure report includes all the necessary documentation required.
- iv. The KNH-UoN ERC chair or appointee shall review the study closure report and issue an approval to indicate the permanent study closure.
- v. The KNH-UoN ERC administrator shall coordinate the storage of closed study data for archiving in keeping with relevant regulations and guidelines.

### **ADDITIONAL RESEARCH PROJECT CLOSURE ACTIVITIES**

- i. The PI shall be responsible for commitments made to the participants in terms of care after research and dissemination of study outcomes.
- ii. The PI shall ensure the safety and storage of all original records e.g. questionnaires, audio interviews records, research authorisation documents for anonymity and completion.
- iii. The final database, on which data analysis and publication is based, shall be properly labelled ready for archiving.
- iv. The PI shall be responsible for the final reporting procedures including reporting to the funders, sponsors and KNH-UoN ERC at the end of the research project including publications and results dissemination plan.