

Appendix 9: MIRERC Annual Progress Report

Complete the form in NO smaller than 12 point font; handwritten submissions are NOT acceptable

Use this form only if data are being collected or participants are still being followed. If all data collection and participant follow-up has ended and the study is either completed or cancelled, submit a Study Completion Report.

A. IDENTIFYING INFORMATION

1. Name of Local Principal Investigator and contact information:
2. Research Project Title:
3. MIRERC Project number:

B. CURRENT STATUS OF THE STUDY

Actively enrolling participants
 Enrolment completed, but participants being followed
 Other (Attach explanation)
 See **Progress to Date**

Check [✓]
 (one only)

[]
 []
 []

Number of participants currently enrolled at **THIS** site.
 Number of participants who have completed the study to-date at **THIS** site.
 Number of participants who have been withdrawn at **THIS** site. (Attach explanation)
 Number of participants who have been enrolled to-date at **ALL** sites (for multi-centre studies).

Specify #
 (where appropriate)

[] []
 [] []
 [] []
 [] []

NB: Where not applicable indicate N/A.

C. STUDENT'S RESEARCH AND THESIS PROGRESS TO-DATE

1. Please give a brief summary of the progress of the study to date, including any difficulties encountered.

1. What were your main research objectives for this past year?

Main objectives:

2. To what extent did you achieve the objectives mentioned in (1)?

Results:

3. What are your objectives for this year?

4. What are the next steps?

Next Steps

2. Has an interim data analysis been done? YES NO
If YES, attach a summary.
3. Have any articles been published or presentations given using the results of the study? YES NO
If YES, please submit a copy of the abstract(s) or a list of references. ATTACHED

D: THESIS SUPERVISOR'S REPORT

4. Taking into account last year's objectives and the thesis advisory committee report (if applicable), is the student progress satisfactory?

1. Were last year's research objectives appropriate and realistic? Have they been met?
2. Will these objectives enable the student to complete the programme in a timely fashion?
3. How often do you meet with the student? 1=Weekly, 2=Monthly, 3=Every two months 4=Rarely or never
4. When do you expected the thesis to be submitted for examination? day/month/year
4. What is your general assessment of the student's progress during the past year? 5=Excellent, 4=Very good, 3=Good, 2=Fair, 1=Inadequate

D. CHANGES IN THE STUDY PROTOCOL OR CONSENT FORM

Have there been changes in the study protocol or consent form since the last Annual Report? [] YES [] NO
If YES, have these changes been approved by the MIRERC? [] YES [] NO
If NO, attach completed Amendment Form. [] Attached

Please attach a copy of the Consent Form/Information Sheet currently in use. [] Attached

E. SAFETY ISSUES

1. If this is a **multi-centre study**? [] YES [] NO
2. Have there been any serious adverse events in the study population in the past year? [] YES [] NO
If YES, have these been reported to the MIRERC? [] YES [] NO
If NO, attach completed MIRERC Adverse Event Report Form. [] Attached
3. Has there been any new literature which would change your assessment of risk/benefit for participants? [] YES [] NO
If YES, and your assessment of risk has increased, have all participants been informed? [] YES [] NO
If NO, indicate when and how this will happen. [] Attached

F. CHANGES IN THE INVESTIGATORS

Have there been any changes in investigators since the last approval? [] YES [] NO
If YES, has the MIRERC been notified? [] YES [] NO
If NO, submit changes now. [] Attached

G. INSTITUTIONAL RESOURCES REQUIRED

Have there been increases in the institutional resources required to support the study? [] YES [] NO
If YES, indicate who has been notified. [] Attached

H. CHANGES IN THE FUNDING STATUS

What is the current funding for the project? **Ksh.** _____
Have there been any changes in funding status since the last approval? [] YES [] NO
If YES, has the MIRERC been notified? [] YES [] NO
If NO, attach description of changes. [] Attached

I. CONFLICT OF INTEREST

- Does the principal investigator(s) or any co-investigators involved in this research study:
- (a) Function as an advisor, employee, officer, director or consultant for the sponsor? [] YES [] NO
 - (b) Have direct or indirect financial interest in the drug, device or technology employed (including patents or stocks) in this research study? [] YES [] NO
 - (c) Receive an honorarium or other benefits from the sponsor (apart from fees for service)? [] YES [] NO
 - (d) If YES to any of the above, was the conflict reported when the study was first reviewed and approved by the MIRERC? [] YES [] NO
If NO, please describe the conflict and explain how it is being managed to ensure that participant rights and welfare are not affected. [] Attached

SIGNATURE

Signature of Principal Investigator

Date

**Send signed original to the MIRERC Office at the Innovation & Entrepreneurship Centre.
Do not fax or email.**

ANNUAL PROGRESS REPORT

*MIRERC Review of an Active Study
(to be completed by MIRERC Chair only)*

MIRERC Project #: _____ **Principal Investigator:** _____

Project Title: _____

Approved for Continuation

Approved conditional on changes noted in “Conditions” section below

Type of Approval:

Full MIRERC Meeting

Expedited

MIRERC Approval Period: _____ to _____
(from date) (to date)

New Enrolment Suspended

Suspended pending further review

Conditions:

The MIRERC operates in compliance with the NACOSTI and CIOMS Ethical Conduct for Research Involving Human Subjects and the ICH Good Clinical Practice.

Signature of MIRERC Chairperson

Print or type name of MIRERC Chairperson

Date