

Form 17

CLOSE-OUT FORM

ZANZIBAR HEALTH RESEARCH INSTITUTE



Instructions for Closure of a Research Study

Send to the ZAHREC:

1. This completed Close-out Form only.

Complete and submit this form before the expiration date for your study. If ZAHREC Approval is not granted by the expiration date, all study participants' activities will Be suspended until approval is regained.

Date of this Submission:

Study Title:

Proposal Number:

Sponsor/Funding Agency:

Date of last Continuing Review Approval:

Section A. Study Status

1. Summary of research activities to date.

2. Number of subjects involved in the study **to date** (cumulative) either through direct contact or through use of their data. (Complete all blanks)
 - a. Number of people screened:

 - b. Number of subjects enrolled (i.e., the number who consented/assented and took part in any part of the study intervention or data collection, for randomized trials list those who were randomized) in the study to date:

 - c. Project number of enrolled subject, as approved by ZAHREC in the proposal. Number must match the listed in the initial approval for the study. If amendments have been submitted to increase sample size after initial approval, list both original approved sample size and note the approved amended.

Original approved Sample size:

Approved Amended sample size:

If (b) is greater than (c) above, please explain:

3. Since subject enrollment began, have any subjects withdrawn from the study (e.g. voluntarily withdrawn or lost to follow-up) or been withdrawn from the study by the investigator?(NOTE: Do not include refusals.)

Yes –provide cumulative number and reasons for withdrawal

No

4. Did any un anticipated problems, protocol violations, adverse events (AEs), or serious adverse events (SAEs) occur since the initial review or last continuing renewal? (NOTE: If study has been renewed one or more times, please only list problems or events from the current approval period.)

Yes –provide a list of these problems, protocols violations, AEs, and SAEs, and indicate which ones were previously reported to the ZAHREC

No

5. Were any complaints received about the research since the initial review or last renewal by the ZAHREC? (NOTE: If study has been renewed one or more times, please only list complaints from the current approval period.)

Yes –provide a list of these complaints and indicate which ones were previously reported to the ZAHREC

No

6. Were any amendments approved by the ZAHREC for this study since the initial review or last renewal by the ZAHREC? (NOTE: If study has been renewed one or more times, please only list amendments from the current approval period.)

Yes –provide a list of amendments (including amendment #) by date of approval with the description of the amendment. For example:
Amendment 03: 5/2/09--Revised consent forms

No

6a. Were any additional changes made to the study procedures or materials since the initial review or last renewal by the ZAHREC that were not submitted for approval? (NOTE: If study has been renewed one or more times, please only list changes from the current approval period)

Yes –provide a list of these changes

No

7. Summary of any remaining activities.

8. Does your institution currently maintain any identifiable subject data or specimens from this study? (Select one)

Yes, still maintain identifiable data or specimens from this study.

No, no longer maintain any identifiable data or specimens from this study.

Specify the Material Transfer Agreements (MTAs):

Section B. REASON FOR CLOSING THE STUDY:

Research completed and no identifiable data or specimens are maintained. Data analysis of de-identified data and report writing can continue.

NOTE: Documentation of informed consent of subjects -either Signed informed consent forms or short forms and written

Research summary-must be retained by the research team for at least 5 years after completion of the research (per regulations), unless ZAHREC waived the requirement for informed consent or documentation of informed consent.

Research was never done (lack of funding, etc.)

Other reason to close the study, specify_____

Name of Principal Investigator

Signature

Date

