

In case of reply the number  
And the date of this  
Letter should be quoted

My Ref. No.....

Your Ref. No.....



**KORLE BU TEACHING HOSPITAL**  
P. O. BOX KB 77,  
KORLE BU, ACCRA.

Tel: +233 302 667759/673034-6  
Fax: +233 302 667759  
Email: [Info@kbth.gov.gh](mailto:Info@kbth.gov.gh)  
[pr@kbth.gov.gh](mailto:pr@kbth.gov.gh)  
Website: [www.kbth.gov.gh](http://www.kbth.gov.gh)

## FORM E – Final Report/ Study Closure Form

### **Instructions:**

1. Please complete all sections and a two page detailed report should accompany the study closure form. The report should have an introduction, materials and methods, preliminary results, discussion, further studies to be done, etc.
2. Under Section C, check boxes with X and attach a memorandum explaining any “yes” answers.
3. Submit 14 hardcopies and send a soft copy of all documents [rdo@kbth.gov.gh](mailto:rdo@kbth.gov.gh) to facilitate the review process.
4. Use very clear font size such as Times New Roman 12pt, Arial 11 pt, Calibri 12pt.

### **Section A – Background Information**

Title of study:

Certified Protocol Number (CPN):

Principal Investigator:

Co- Investigators:

Initial Date of Approval:

Duration of Project:

### **Section B – Enrollment**

1. Total number of participants enrolled:
2. Number of participants discontinued:
  - By investigator: \_\_\_\_\_
  - Voluntarily: \_\_\_\_\_
  - Due to SAE: \_\_\_\_\_
  - Other reasons (Please specify): \_\_\_\_\_
3. Total number of participants who completed the study: \_\_\_\_\_

**Section C – Study Assessment**

- |   | NO                       | YES                      |
|---|--------------------------|--------------------------|
| 1. Have there been any complaints received from anyone about the study?<br>(Participants, Parents/Guardians, Community Members, Staff, etc)   | <input type="checkbox"/> | <input type="checkbox"/> |
| 2. Did the anticipated risks or benefits change during the study?   | <input type="checkbox"/> | <input type="checkbox"/> |
| 3. Did this study have a Data Safety and Monitoring Board?<br>If yes, attach the most recent report from the board.   | <input type="checkbox"/> | <input type="checkbox"/> |
| 4. Was your study audited or monitored by the NMIMRIRB or any other agency?<br>If yes, please attach a copy of the findings and any corrective actions that have<br>been implemented as a result of this audit or monitoring. | <input type="checkbox"/> | <input type="checkbox"/> |
| 6. Are there any publication regarding this study?<br>If yes, please attach an abstract, quoting the reference publication.   | <input type="checkbox"/> | <input type="checkbox"/> |

**Section D – Reason For Study Closure**

- 1. Data analysis complete
  - 2. Interim analysis determined study is not safe or efficacious
  - 3. No funding, time constraints or personnel to do the study
  - 4. Others (Please explain)
- 

**Section E – Signature**

As the **Principal Investigator / Co-investigator** on this project, my signature confirms that:

- 1. The study was conducted in accordance with all relevant policies and regulations that govern research involving human participants.
- 2. I agree that the study should be closed.

Name & Signature of Principal Investigator: \_\_\_\_\_ Date: \_\_\_\_\_