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| **GHANA HEALTH SERVICE**  **DODOWA HEALTH RESEARCH CENTRE INSTITUTIONAL REVIEW BOARD (DHRCIRB)**  **APPLICATION FORM FORPROTOCOL SUBMISSION**  **!cid_001601c2c2d8$38b13fe0$0100007f@SORY**E:\LOGOS\dodowa.jpg  **(Please complete in BLOCK letters and submit together with full Protocol for IRB Consideration )** | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | |
| * 1. Title of study:............................................................................................................................................................................................................   .……………………………………………………………………………………………………………………………………………………………………….. | | | | | | | | | | | | | | | |
| **PART I: ADMINISTRATIVE INFORMATION OF PRINCIPAL INVESTIGATOR (S)** | | | | | | | | | | | | | | | |
| * 1. Details of Principal Investigator | | | | | | | | | | | | | | | |
| Surname: .................................................................................................................................................................................... | | | | | | | | | | | | | | | |
| First Name: ................................................................................................................................................................................. | | | | | | | | | | | | | | | |
| Others: .......................................................................................................................................................................................... | | | | | | | | | | | | | | | |
| Institutional Affiliation(s): | | | | | | | | | | | | | | | |
| Full Postal Address: | | | | | | | | | | | | | | | |
| Telephone/ Mobile: | | | | | | | | | | | | | | | |
| Email | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | |
| * 1. Details of Co-Principal Investigator***(if applicable)*** | | | | | | | | | | | | | | | |
| Surname: .................................................................................................................................................................................... | | | | | | | | | | | | | | | |
| First Name: ................................................................................................................................................................................. | | | | | | | | | | | | | | | |
| Others: .......................................................................................................................................................................................... | | | | | | | | | | | | | | | |
| Institutional Affiliation(s): | | | | | | | | | | | | | | | |
| Full Postal Address: | | | | | | | | | | | | | | | |
| Telephone/Mobile: | | | | | | | | | | | | | | | |
| Email | | | | | | | | | | | | | | | |
| **PART II: INFORMATION ON COLLABORATOR (S)** | | | | | | | | | | | | | | | |
| 1.4(a) Names of First Collaborator**:** | | | | | | | | | | | | | | | |
| Institutional Affiliation (s): | | | | | | | | | | | | | | | |
| Full Address: | | | | | | | | | | | | | | | |
| Telephone/ Mobile: | | | | | | | | | | | | | | | |
| Email: | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | |
| 1.4(b) Names of Second Collaborator***(if applicable)*:** | | | | | | | | | | | | | | | |
| Institutional Affiliation (s): | | | | | | | | | | | | | | | |
| Full Address: | | | | | | | | | | | | | | | |
| Telephone/Mobile: | | | | | | | | | | | | | | | |
| Email: | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | |
| **PART III: INFORMATION ON SPONSOR (S)** | | | | | | | | | | | | | | | |
| 1.7 Names of Sponsoring Agency ***(please specify name of lead person)*** | | | | | | | | | | | | | | | |
| Institutional Affiliation (s): | | | | | | | | | | | | | | | |
| Full Address: | | | | | | | | | | | | | | | |
| Telephone:/Mobile: | | | | | | | | | | | | | | | |
| Email: | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | |
| **PART IV: INFORMATION ON PROPOSED STUDY** | | | | | | | | | | | | | | | |
| **1. Nature of Protocol *(Please tick appropriate column)*** | | | | | | | | | | | | | | | |
| Institutional Protocol€ | | Academic Protocols€ | | | | | | | | | | | Individual € | | Others(specify)  € |
|  | | PhD  € | | MSc  € | MPhil  € | | | MPH  € | | | MA  € | Undergraduate  € | Fellowship € | |  |
| **2. Type of Study *(Please tick which of the below is applicable to your study)*** | | | | | | | | | | | | | | | |
| **Type A** | | | | | | | | | **B. Type B** | | | | | **Type C** | |
| i) Clinical Trial € | | | | | | | | | iv. Social Science € | | | | | v. Implementation Research € | |
| ii) Biomedical Study/Epidemiological Study € | | | | | | | | | a. Economic studies € | | | | |  | |
| iii) Others (specify): € | | | | | | | | | b. Policy Studies € | | | | |  | |
|  | | | | | | | | | c. Exploratory studies € | | | | |  | |
|  | | | | | | | | | d. Monitoring and Evaluation studies € | | | | |  | |
|  | | | | | | | | | h. Other (Specify) €  ........................................................................................................................................ | | | | | | |
| **3. Study Site(s)** | | | | | | | | | | | | | | | |
| 1. Name of Study Site: | | | | | | | Region: | | | | | | | | |
|  | | | | | | | District: | | | | | | | | |
|  | | | | | | | Sub-District: | | | | | | | | |
| 1. Name of Study Site: | | | | | | | Region: | | | | | | | | |
|  | | | | | | | District: | | | | | | | | |
|  | | | | | | | Sub-District: | | | | | | | | |
| 1. Name of Study Site: | | | | | | | Region: | | | | | | | | |
|  | | | | | | | District: | | | | | | | | |
|  | | | | | | | Sub-District: | | | | | | | | |
| **4. Date of Initial Submission to DHRCIRB: ....................................................................................** | | | | | | | | | | | | | | | |
| **5. Duration of Study:**  .......................................................... | | | | | | Start of Study:  ...................................................... | | | | | | | End of Study:  ................................................... | | |
| **PART V:TYPE OF REQUEST (please tick appropriate column)** | | | | | | | | | | | | | | | |
| A) New Submission: 1. Yes € 2. No € | | | | | | | | | | | | | | | |
| B) Request for Amendment: 1. Yes € 2. No € | | | | | | | | | | | | | | | |
| C). Type of Amendment:  i. Additional information to protocol€  ii. Change of study site €  iii. Additional study site€   1. Additional PI(s)€ 2. Change of PI(s) € 3. Amendment of Informed Consent€ 4. Amendment of Data collection tools (Questionnaires, Interview Guides)€ 5. Others (please specify)€ | | | | | | | | | | | | | | | |
| *As the* ***Principal Investigator / Co-investigator / Researcher/ Student Investigator*** *on this project, your signature on the proposal confirms that:*   1. *You will ensure that all procedures performed under the study will be conducted in accordance with all relevant policies and regulations that govern research involving human participants.* 2. *You understand that if there is any change from the project as originally approved you must submit an amendment to the IRB for review and approval prior to its implementation. Where you fail to do so, the amended aspect of the study is invalid.* 3. *You understand that you will report all serious adverse events associated with the study within seven days verbally and fourteen days in writing.* 4. *You understand that you will submit progress reports each year for review and renewal. Where you fail to do so, the IRB is mandated to terminate the study upon expiry.* 5. *You agree that you will submit a final report to the IRB at the end of the study.*   Name of person completing the form: ……………………………………………………………………………………………………………………  Role on the study: …………………………………………………………………………………………………………………………………………………  Signature: …………………………………………………………………………………………………………………………………………………………….  Date: ………………………………………………………………………………………………………………………………………………………………  **For Student’s Supervisor(s)**  I have thoroughly read through the proposal and all the accompanying research instruments.  *First Supervisor*  …………………………………………………………….…………………………………………………. ………………………………  Name in Full Signature Date  *Second Supervisor*  ……………………………………………………………. …………………………………………………. ………………………………  Name in Full Signature Date  *Third Supervisor*  ……………………………………………………………. …………………………………………………. ………………………………  Name in Full Signature Date | | | | | | | | | | | | | | | |
| **PART VI: FOR DHRCIRB OFFICIAL USE ONLY** | | | | | | | | | | | | | | | |
| 1. Protocol ID No: ............................. Date Received: ......................... Month received: .................Year received:............... | | | | | | | | | | | | | | | |
| 2. Process of Protocol Consideration:  i. Full Board Review €ii Recommended for Expedited Review € | | | | | | | | | | | | | | | |
| 3. Date of Initial Review: ......................................................................................... | | | | | | | | | | | | | | | |
| 4. Outcome of Initial Review: | | | | | | | | | | | | | | | |
| i. Outright approval € | ii. Conditional approval€ | | | | | | | iii. Redesign document € | | | | | iv. Pending € | | Other (specify): € |
| 5. Date of Re-submission: ........................................................ | | | | | | | | | | | | | | | |
| 6. Outcome of Resubmission Review: | | | | | | | | | | | | | | | |
| 1. Approved € | | | ii. Conditional € | | | | | | | iii. Pending € | | | Others (specify): € | | |
| 7. Date of Final Approval: ...................................................... | | | | | | | | | | | | | | | |
| 8. Status of Approved Study:   1. Started € ii. Ongoing € iii. Completed € iv. Yet to Start € 2. Suspended € vi. Discontinued € vii. Others (specify) € | | | | | | | | | | | | | | | |
| 9. Request for Presentation of Study by PI (s) (1) Yes € (2) No € | | | | | | | | | | | | | | | |
| 10.Submission of Reports:  A. Submitted € B. Not Submitted €  Type of Report Submitted:  i. Initial/ Inception report €  ii. Interim Report €  iii. Progress report €  iv. Adverse Report/Serious Adverse report €  v. Final /Completion report € | | | | | | | | | | | | | | | |