GHANA HEALTH SERVICE

DODOWA HEALTH RESEARCH CENTRE INSTITUTIONAL REVIEW BOARD

P.O. BOX DD1, Dodowa
Email : irbdodowa@gmail.com

GUIDELINES FOR PROTOCOL SUBMISSION

SECTION A: KEY POINTS FOR RESEARCH PROTOCOL SUBMISSION

- Applications received after deadlines, will not be processed but kept for the next meeting.
- **Bound protocols** should be delivered to Dodowa Health Research Centre Institutional Review Board (DHRCIRB) and soft copies **(as a single pdf file)** sent to irbdodowa@gmail.com
- Applications should follow DHRCIRB recommended format
- The application letter should be signed by the Principal Investigator (PI)
- In cases where the PI and co-PIs are all either foreign nationals or not resident in Ghana, a Ghanaian researcher must be included in the team, and should include support letters and Curriculum Vitae (CVs).
- Support letters from all collaborators and collaborating institutions should be attached to the research protocol for submission.
- A PI applying for ethical clearance is directly responsible for the ethical and scientific conduct of the research and as such must be qualified to undertake the research.

SECTION B: STUDENT'S APPLICATION

All student's applications are required to be submitted under the responsibility of a supervisor involved in the oversight of the student's research work with supervisor(s) signature(s) appended.

SECTION C: PROTOCOL PRESENTATION FORMAT

Font should be either 'Times New Roman' or 'Arial' with font size **12**, **1.5 spacing**, and pages printed on **one side only.** All pages of the protocol should be **sequentially numbered including appendixes.**

The PI should submit all documents required for ethical review of the proposed research and contents arranged in **this order**. The documents may include but not limited to the underlisted:

1. Principal Investigator's Application for submission

2. Co-Investigator(s)' Support letter(s)
3. Cover letter from head of the PI's Institutions i.e. (Institutional Support letter for the study (where applicable)
4. Permission letter to the study site (s)
5. Confirmation letter from participating/collaborating institution involved in the study
6. Material Transfer Agreement (MTA) for shipment of specimen/biological materials (where applicable)
7. Administrative Information on the sponsors of the study
8. Signed agreement between the sponsor and the PI (where applicable)
9. Signatory page of key persons of the collaborating institutions involved in the study i.e. Sponsor Signatory Approval Page duly signed, with date (where applicable)
10. Completed DHRCIRB Application form (copy can be accessed from Dodowa Health Research Centre's website)
11. Completed DHRCIRB checklist (copy can be accessed from Dodowa Health Research Centre's website)
12. Full Protocol (refer to recommended format for research protocol **below**)
13. The following included as Appendix:
    a) Detailed budget
    b) Prior Scientific/Ethical Review: (Name any other Ethical and Protocol review board/committee this proposal has been submitted to and attach approval letter if applicable. In case of rejection, state reasons)
    c) Written Informed Consent form and Information sheet (with translations into the local language (where necessary)
    d) Written Parental Consent form & Assent form for children/ participants **less than 18 years** (if study involves Minors & Adolescents)
    e) All data collection forms to be used in the research including but not limited to case report forms, diary cards, questionnaires, interview schedules.
    f) Referral forms for treatment (where applicable)
    g) All forms, documents, advertisements to be used in the recruitment of potential participants.
    h) Any other information deemed necessary to facilitate the review process.
    i) CV(s) of Principal Investigator and Co-Investigator(s) (Abridged, not exceeding 3 pages but relating to current work)

SECTION D: DHRCIRB RECOMMENDED FORMAT FOR FULL PROTOCOL

1. COVER PAGE
2. TABLE OF CONTENT
3. LIST OF ABBREVIATIONS
4. ABSTRACT *(1 page maximum and must not have references)*
5. BACKGROUND *(1-3 pages maximum)*

- Introduction
- Problem statement
- Justification/Relevance
- Hypothesis (if applicable)
- Aim (s)
- Specific Objectives

6. LITERATURE REVIEW *(5 pages maximum)*

7. METHODOLOGY *(8 pages maximum*)

- Study Design
- Study Site
- Subject/Study Population
- Inclusion/Exclusion Criteria
- Sample Size Determination
- Procedures to be used (Data Collection methods and instruments, personnel of the study team) & Data handling (May include coding, quality control, data security and confidentiality)
- Statistical Analysis

8. DISSEMINATION OF RESULTS

9. ETHICAL ISSUES
    - Recruitment and sampling procedures, Potential risks and benefits, confidentiality, how participants' protection will be ensured.

10. SUMMARISED BUDGET

11. TIMELINES/WORK SCHEDULE/WORK PLAN
    - This is usually in the form of a Gantt chart (to show different activities versus time frames for expected completion).

12. REFERENCES
    - Referencing style used must be consistent

13. APPENDIX

SECTION E: ADDITIONAL REQUIREMENTS FOR CLINICAL TRIALS

- Summary of previous study i.e. Phase 1 & Phase II studies (where applicable)
- Investigator Agreement (PI's responsibility), Page duly signed, with name and date.
- Current Certificate of Training in Good Clinical Practice (GCP) for PI(s) and researchers
- Investigational Product Brochure for the study
- Data Safety Monitoring Board (DSMB) membership and Charter of Work/Current Curriculum Vitae of members.

- Insurance cover for study participants
- Scientific review approval
- Food and Drugs Authority approval letter for use of the Investigational Product/ Devices and clinical trial approval Current CVs of PI & Co-Investigators (Abridged – Three pages relating to current work)
- Clinical trial registration with Pan African Clinical Trial Registry (PACTR)
- For multi-country studies, Ghana specific addendum/proposal is required.

SECTION F: ADDITIONAL REQUIREMENTS FOR UNDERGRADUATE AND POSTGRADUATE STUDENTS

- Covering letter and CV of supervisor
- Covering letter from school/college confirming student status
- Students not taking their academic programme in Ghana are required to identify a local supervisor and submit his/her covering letter and CV
- Ethics Approval letter from the student's foreign university (where applicable)

SECTION G: NUMBER OF COPIES OF PROTOCOL FOR SUBMISSION

- **Institutional/PhD & Fellowship Students**:

Applicant shall submit **nine (9) comb-bounded copies** of the full research protocol with the items indicated above.

- **Master/Undergraduate Student Protocols:**

  Applicant shall submit two **(2) comb-bounded copies** of the full research protocol with the items indicated above.

It is recommended that *one hard copy of the full protocol together with all supporting documents is first submitted to the DHRCIRB office for administrative check before final submission.* ***This is optional.***

A protocol submitted ***after the deadline*** *of a particular month will be processed for review in the* ***subsequent month.***

Contact for Further Clarification

For Further enquiries, kindly contact the IRB Administrator **8:00am-4:30pm (Mondays- Fridays)** OR by email: irbdodowa@gmail.com

SIGNED: DHRCIRB ADMINISTRATOR