**DODOWA HEALTH RESEARCH CENTRE INSTITUTIONAL REVIEW BOARD**

**CONTINUING REVIEW SUBMISSION REQUIREMENTS**

*Tel: +233-0208719996/ 0501336172 Email: irbdodowa@gmail.com*

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| *!cid_001601c2c2d8$38b13fe0$0100007f@SORY* |  |

As stated in the Standard Operating Procedure of DHRCIRB, a continuing review shall be conducted on all research protocols submitted to the Committee. In the initial approval letter of the Committee, it shall be stated when investigators are expected to submit progress reports to the Committee. The progress report submission shall include copies of the following documents:

Completed Continuing Review form (this form is available at the DHRCIRB secretariat)

A summary of the protocol

Copies of any changes/ amendments made to the protocol/consent forms since the last approval

A status report on the progress of the research that includes any new information on the research that could alter the IRB’s previous determinations with respect to risks to subjects or regarding any unanticipated problems involving risks on the study

Progress reports not received by the submission date risk a lapse in IRB approval. This means that all research must stop after the project expiration date.

The DHRCIRB Administrator

Dodowa Health Research Centre

Ghana Health Service

P. O. Box DD1

Dodowa

Email: irbdodowa@gmail.com

**A. Principal Investigator**

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| --- | --- |
| 1. Principal Investigator |  |
| 2. Address of PI |  |
| 3. Email Address |  |
| 7. Fax Number |  |
| Name of Person completing this form  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Contact Address  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Email  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Phone  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Signature  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Date | |

**B. Protocol Information**

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| --- | --- |
| 1. Title of protocol: |  |
| 2. Protocol number: |  |
| 3. Funding agency and grant number: |  |
| 4. Please indicate grant status: active / pending |  |
| 5. Location of research activity: |  |
| 6. \*DHRCIRB approval dates from additional institutions:  *\*Please note that copies of current DHRCIRB approvals from additional institutions are required.* |  |

**C. Protocol Status**

|  |  |
| --- | --- |
| 1. Pending:  If yes, please indicate the reason why the study has not yet  begun: | Yes/No |
| 2. Active:  If yes, please indicate the month and year the study began:  Please indicate remaining duration of the study: | Yes/No  (mm/yy) |
| 3. Closed:  If yes, please indicate date the study closed:  *Please note that if the study is closed, a Request for File Closure must be submitted to the DHRCIRB.* | Yes/No |

**D. Participant Information:**

|  |  |
| --- | --- |
| 1. Is the study closed to enrollment? | Yes/No |
| 2. Total number of participants who consented for the study |  |
| 3. Number of participants enrolled since study begun |  |
| 4. Number of participants who dropped out of study.  Please state the reason(s) for drop out |  |
| 5. Number of participants still to be enrolled |  |
| 6. Number of participants scheduled for follow-up |  |

**E. Data Sources**

|  |  |
| --- | --- |
| Check all categories that apply to your protocol: | |
| Human subject intervention with use of informed consent form |  |
| Genetic analysis |  |
| Interviews, questionnaires, tests |  |
| Medical records or other human data |  |
| Other *please specify***:** |  |

**F. Adverse Events or Unexpected Problems**

|  |  |
| --- | --- |
| 1. Have there been any ***adverse events*** or unexpected problems in the past approval period?  If yes, please explain in detail and indicate when the DHRCIRB was notified of the event or problem. If the DHRCIRB was not notified, please explain why this was not done. | Yes/No |
| *2.* Does the study have a Data Safety Monitoring Board  (DSMB)?  If yes, please indicate the date of the last DSMB review:  *Please note that investigators are required to submit DSMB reports to the DHRCIRB at the time they are made available to the investigator.* | Yes/No  N/A |

**G. Protocol Amendments or Revisions**

|  |  |
| --- | --- |
| 1. Have there been any amendments or revisions to the protocol?  If yes, please indicate the date of the approval from the DHRCIRB for the amendment or revision*.* | Yes/No |
| 2. Do you wish to submit an amendment at this time?  If yes, please describe the amendment request and rationale for the changes: | Yes/No |
| 3. Are there new personnel working on this study?  If yes, please list new personnel | Yes/No |

**H. Current Consent Form**

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| 1. Please attach a copy of your current consent form for renewal.  2. Is this the original consent form or a revised form? Original Revised |
| If revised, please provide date of DHRCIRB approval for the revision: |

**I. Protocol Progress Report**

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| **1.** Please submit a ***detailed*** progress report. The progress report must be substantive and complete,  and include the goal(s) of the study, findings to-date, and plans for the next year/review period: |

**J. Publications, Presentations and Recent Findings**

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| --- |
| **a)** Have there been any presentations or publications resulting from this study during the past approval period? Yes/No  If yes, please submit a copy of the abstract, or the publication, with this application.  **b)** Have there been any recent findings either from this study, or from a related study, that would have an effect on this study’s risk/benefit analysis? Yes/No  If yes, please describe and cite references: |

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| --- |
| **Additional Comments:** |

**…………………………………………………. ……………………….**

Principal Investigator Date

**Please do not fill below this line (For DHRCIRB use only)**

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| Reviewed By:  Date reviewed:  Comments:  Action: |

**Updated Version 2 dated March 29, 2021 - Property of DHRCIRB Secretariat only**