**DODOWA HEALTH RESEARCH CENTRE INSTITUTIONAL REVIEW BOARD**

**PROTOCOL AMENDMENT SUBMISSION REQUIREMENT**

*Tel: +233- 208719996/ 0501336172 Email: irbdodowa@gmail.com*

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Requests for protocol amendment or modifications to consent forms should include the following:

1. Cover letter from PI requesting for protocol amendment
2. Completed protocol amendment and continuing review forms (forms are available at the DHRCIRB office)
3. Summary of the request with a justification table (principal investigators must justify why the change is necessary)
4. Copies of the DHRCIRB approval letter(s)for the study
5. Progress report
6. Copies of the revised documents should clearly indicating the amendments effected in track changes
7. Clean copies of the revised documents should also be attached
8. All revised consent forms with their translation(s) if any
9. Revised documents should be version controlled (also as footnotes in the protocol)

***Please note that the administrative fees for review of amendment protocol is the same as that of the initial submission***

**Submit 2 copies of the application for social science, epidemiological, biological and 3 copies for clinical trial protocols to:**

The DHRCIRB Administrator

Dodowa Health Research Centre

Ghana Health Service

P. O. Box DD1

Dodowa

Email: irbdodowa@gmail.com

Please complete all sections of this form electronically

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| 1. Project Title |  |
| 2. DHRCIRB Protocol Number |  |
| 3. Protocol Version Number & Date |  |
| DHRCIRB Expiration Date |  |
| 4. Principal Investigator |  |
| 5. Address of PIPhone Number | Email: |
| 6. Type of Amendment (circle allthat apply) | a. Protocol amendmentsb. Modifications to consent formc. Other (specify) |
| 7. Request(s) (summary ofrequest) |  |
| Name of Person completing this form\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Contact Address\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Email\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Phone\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Signature\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date |

**SECTION A: Change of Principal Investigator. (If no other changes, skip to C.) For other changes to co-investigators, student investigators or study personnel, please use the Administrative Amendment for change to Study Personnel Form, and the Investigator/Study Personnel Agreement. Attach Ethics Training Certificate as needed.**

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| Explain reason for change below. Please attach an investigator/ study personnel agreement signed by the new PI.Note: If the study has a certificate of Confidentiality in the name of the PI, you must amend it to substitute the new name. |

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| **SECTION B: Amendment to Research Study (Choose all that apply)** |
| * Change (s) to study title
* Change(s) to research plan (attach clean and tracked versions of research plan)
* Change(s) to consent form/scripts (attach clean and tracked versions of document(s))
* Change to study population
* Change of study site
* Addition of study site
* Change to sample size
* Initiation of new study phase
* Change to funding
* Changes to recruitment materials, data collection forms, instruments, questionnaires/surveys (attach clean and tracked version of revised documents with new version numbers and Protocol number.)
* Change to drug or device information for FDA regulated study
* Change in conflict of interest
* Other change (describe below)
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| 1. Provide a detailed description of the proposed changes noted above with an explanation of why you are making the changes. Itemize each change that you are making to the study. |
| 2. If you are submitting a new or revised study documents, please provide a list of all documents including titles, identifiable versions and revision dates. |
| 3. Does the proposed amendment affect the risks to subjects? If yes, please explain whether the change affects subjects already enrolled, or just subjects to be enrolled in the future. Describe whether and how subjects will be notified about the change. |

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| **SECTION C** |
| Signature of Principal Investigator Date(signature of co-investigator or study staff is not acceptable) |
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**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**