******RESEARCH OPERATIONS OFFICE**

**INSTITUTE OF HEALTH RESEARCH**

**UNIVERSITY OF HEALTH AND ALLIED SCIENCES**

**RESEARCH ETHICS COMMITTEE (REC)**

**PROTOCOL CONSENT FORM**

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| Section A- **BACKGROUND INFORMATION** |

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| Title of Study:  |  |
| Principal Investigator: |  |
| Certified Protocol Number |  |

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| Section B– **CONSENT TO PARTICIPATE IN RESEARCH** |

**General Information about Research**

* State clearly the purpose of the study in easily-understood words (avoid the use of jargons and technical language) and why the person has been selected to partake in the study.
* Indicate the expected duration that will be required of participants in the study.
* Give a description of the procedures/methods to be followed and the identification of any procedures which are experimental and what the participant(s) is (are) supposed to do.

**Benefits/Risks of the study**

* Indicate specifically the benefits and risks associated with the study. Include all physical, social and psychological risks and benefits anticipated.
* Indicate any hazards to participants and what steps to be taken to minimise the risks

**Confidentiality**

* Describe the extent to which confidentiality of records identifying the participants will be maintained.
* Indicate all groups that may have direct access to the research records at any particular time; thus by signing or thumb-printing a written consent form, the participant or their representative is authorizing such access.
* Indicate that participants have the right to access information about them collected as part of the study

**Compensation**

* State clearly if there are any compensation packages either in cash or kind available for participants who participate in the study.
* The exact amount or gift to be given must be clearly spelt out.
* The conditions for receiving the package and when it will be made should also be indicated (where compensation is to be, it should be given at the end of the study)
* Indicate clearly how adverse or serious adverse effects resulting from a treatment given as part of the study will be treated.

**Withdrawal from Study**

* State that participation is voluntary and participants may withdraw at any time without penalty.
* More specifically, state that the participant will not be adversely affected if he/she declines to participate or later stops participating.
* Provide assurance that the participant or the participant's legal representative will be informed in a timely manner if information becomes available that may be relevant to the participant's willingness to continue participation or withdraw.
* Any circumstances and/or reasons under which the participant’s participation may be terminated should be stated clearly.

**What happens after study or when the participant changes his/her mind**

* State whether any study intervention will be available to participants after the study and, if so, under what conditions (including any cost to them)
* Indicate how study data will be stored and for how long, whether the data will be retained for possible future use, who will be responsible for their secure storage and how they will be destroyed
* Explain whether any biological specimens collected during the research will be destroyed at its conclusion and, if not, details of their storage and possible future use
* Indicate how the study findings will be communicated on completion of the study, including to participants, and in what expected time frame.

**Contact for Additional Information**

* This statement should indicate whom to contact for answers to any questions about the research and whom to contact in case of research-related injury.
* Names, Institutional affiliation, addresses, email and telephone numbers (including mobile numbers) should be made accessible to all participants.
* If you have any questions about your rights as a research participant in this study you may contact the Administrator of the Research Ethics Committee, IHR, University of Health and Allied Sciences at **rec@uhas.edu.gh****or +233- 362-196-193**.

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| Section C- **PARTICIPANT AGREEMENT** |

**"I have read or have had someone read all of the above, asked questions, received answers regarding participation in this study, and am willing to give consent for me, my child/ward to participate in this study. I will not have waived any of my rights by signing this consent form. Upon signing this consent form, I will receive a copy for my personal records."**

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Name of Participant

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Signature or mark of Participant Date

**If participant cannot read and or understand the form themselves, a witness must sign here:**

I was present while the benefits, risks and procedures were read to the volunteer. All questions were answered and the volunteer has agreed to take part in the research.

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Name of witness

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Signature of witness / Mark Date

I certify that the nature and purpose, the potential benefits, and possible risks associated with participating in this research have been explained to the above individual.

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Name of Person who Obtained Consent

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Signature of Person Who Obtained Consent Date