University of Ghana Medical Centre
Medical and Scientific Research Centre (MSRC)
Standard Operating Procedure and Policy on Informed consent

Informed Consent

A. General Consent Requirements: In order to approve the research, the IRB must determine the following:

- The PI will obtain the legally effective informed consent of the participant or the participant's legally authorized representative unless a waiver of consent has been approved by the IRB in accordance with Section (B) of this SOP.
- Consent is sought under circumstances that:
  - provide the prospective participant or the representative sufficient opportunity to discuss and consider whether or not to participate; and
  - minimize the possibility of coercion or undue influence.

- The consent process is appropriate taking into consideration where the consent process will take place, timing of the consent process and the individual who will be obtaining consent (e.g. the PI, collaborator, or qualified designee). Enough information should be given for a reasonable person to make an informed decision with opportunities for discussions and questions.

- The information that is given to the participant or the representative is in language understandable to the participant or the representative. When the participant cannot read a translator must be present throughout the process of consent.

- The information communicated to the participant does not include exculpatory/disclaimer language through which the participant or the representative is made to:
  - Waive or appear to waive any of the participant's legal rights; or
  - Release or appear to release to the PI, the Sponsor, UGMC or its agents from liability or negligence.

- The basic elements of informed consent (as stated in ICH-GCP guidelines) must be provided to each participant unless the IRB has approved an alteration of the basic elements (see section (B) of this SOP).

- One or more of the following additional elements of consent may be provided to participants:
  - statement that a particular treatment or procedure may involve risks to the participant that are unknown to be investigators.

- circumstances under which the participant may be terminated by the PI without their consent as approved by the IRB.
- The consent form should outline any additional costs to the participant.
- The consent form should state the consequences of a participant's decision to withdraw from the research and procedures for orderly termination of participation by the participant when withdrawal from the research might place a participant at risk of harm.
- The consent form should include a statement that significant new findings developed during the course of the research, which may relate to the participant's willingness to continue participation will be provided to the participant.
- The consent form should state the approximate number of participants involved in the study.
- When the research involves the collection or use of biospecimens or associated information, the consent form should include a statement that the participant's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit.
- When the research involves the collection or analysis of clinical information or biospecimens, the consent form should include a statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions.
- Where applicable, the consent form should include whether whole genome sequencing will be performed on participant's specimen.

- The consent form for FDA -regulated research will:
  - Identify the test article as investigational and will inform participants that the FDA may inspect research records.
  - Include a statement that there is a description of the clinical trial available required by the FDA. This will not include information that can identify the participant. At most the information will include a summary of the results.

- Informed consent is documented by the use of a written consent form approved by the IRB and signed and dated by the participant or the participant's legally authorized representative. The short form requires the following:
    - The elements of consent have been presented orally
    - An IRB-approved written summary of what is to be said to the participant or the representative. This summary must include the basic and any required additional elements of consent

- The form must be signed and dated by the participant or their legally authorized representative;
- The person obtaining consent must sign and date a copy of the form; and
- A copy of the signed form must be given to the participant or their legally authorized representative.

- The IRB may approve a process that allows the consent document to be delivered and signed electronically. All other applicable conditions for documentation of informed consent must also be met when using this procedure.

- Current IRB approval is documented by a stamp that indicates the dates of IRB approval and expiration of IRB approval.

B. Waiver or alteration of the requirement to obtain informed consent

- A waiver of informed consent may be granted only when the IRB finds that the research meets the conditions of "No More Than Minimal Risk to Human Subjects"

- When approving a waiver of informed consent, the IRB minutes must justify the reasons.

- The IRB under exceptional circumstance may approve waiver of informed consent if the meet the study criteria for "Waiver of Informed Consent Requirements in Certain Emergency Research." See SOP on Special Categories of Research for a description of the specific requirements for these special circumstances.

C. Additional considerations for studies involving Protected Health Information (PHI)

- Studies that involve access to or collection of PHI of a covered entity require consideration of additional items. In these instances, the IRB must find that:
  - Appropriate authorization is obtained from research participants or their effective representative for the use or disclosure of their PHI.
  - The IRB has approved a waiver of such authorization.
  - The PHI will be contained in a limited data set with appropriate safeguards to maintain privacy.
  - The PHI will be de-identified.