UNIVERSITY OF GHANA MEDICAL CENTRE

CLINICAL TRIALS UNIT

STANDARD OPERATING PROCEDURES

Version 1,

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Introduction

Glossary

AE	Adverse Events
CAPA	Corrective and Preventive Actions
CIOMS	International, non-governmental, non-profit organization representing the biomedical scientific community
CRF	Case Report Forms
CRO	Contract Research Organizations
CTE	Clinical Trial Exemption
CTN	Clinical Trial Notification
CTU	Clinical Trials Unit
EDC	Electronic Data Capture
FDA	Food and Drugs Authority
GCP	Good Clinical Practice
HUD	Humanitarian Use Device
ICF	Informed Consent Form
ICH	International Council for Harmonization for Technical Requirements for Registration of Pharmaceuticals for Human Use
IVD	In Vitro Diagnostics
IRB	Institutional Review Board
NHREC	National Health Research Ethics Committee
NSR	Non-Significant Risk
PI	Principal Investigator
SAE	Severe Adverse Events
SDV	Source Data Verification
SOP	Standard Operating Procedures
SR	Significant Risk
UGMC	University of Ghana Medical Center

Terms

Adverse Device Effect (ADE): Adverse event related to the use of an investigational medical device Note: This definition includes adverse events resulting from insufficient or inadequate Instructions for use, deployment, implantation, installation, or operation, or any malfunction of the investigational medical device. This definition includes any event resulting from use error or from intentional misuse of the investigational medical device.

Adverse Event (AE): Any untoward medical occurrence in a participant administered an investigational medicinal product or device and which does not necessarily have a causal relationship with this treatment. An adverse event can therefore be any unfavorable and unintended sign (for example, an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal product or device, whether or not considered related to this medicinal product or device.

Clinical Research Associate (CRA): An individual designated by a sponsor or Contract Research organization to monitor the sites conduct in a clinical trial

Coordinating Principal Investigator (CPI): The health professional, whether or not they are an investigator at any particular site, who is assigned the responsibility for the conduct of the study and coordination of investigators

Contract Research Organization (CRO): An organization contracted by the sponsor to oversee the conduct of the clinical trial

Curriculum Vitae (CV): A résumé of academic and professional training, work history and other qualifications

Data and Safety Monitoring Board (DSMB): or **Independent Data Monitoring Committee (IDMC**) or Monitoring Committee or Data Monitoring Committee An independent data-monitoring committee that may be established by the sponsor to assess at intervals the progress of a clinical trial, the safety data, and the critical efficacy endpoints, and to recommend to the sponsor whether to continue, modify, or stop a trial

Essential Documents: which individually and collectively permit evaluation of the conduct of a study and the quality of the data produced. These documents serve to demonstrate the compliance of the investigator, sponsor and monitor with the standards of Good Clinical Practice (GCP) and with all applicable regulatory requirements. They may be subject to, and should be available for, audit by the sponsor's auditor and inspection by the regulatory authority(ies).

Good Clinical Practice (GCP) ICH GCP E6 (R2): An international ethical and scientific quality standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that involve participation of humans. GCP provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial participants are protected. Compliance with this standard provides public assurance that the rights, safety and well-being of trial subjects are protected, consistent with the principles that have their origin in the Declaration of Helsinki, and that the clinical trial data are credible.

Informed Consent: A process by which a participant voluntarily confirms his or her willingness to participate in a particular trial, after having been informed of all aspects of the trial that are relevant to the participant's decision to participate. Informed consent is documented by means of a written, signed and dated informed consent form.

International organization for Standardization (ISO): 14155:2011 Clinical Investigation of Medical Devices for Human Subjects The international standard which addresses good clinical practice for the design, conduct, recording and reporting of clinical investigations carried out in human subjects to assess the safety or performance of medical devices for regulatory purposes

Investigational Medical Device (IMD): Medical device is any instrument, apparatus, implement, machine, appliance, implant, software, material or other similar or related article that is being assessed for safety or performance in a clinical investigation. This includes medical devices already on the market that are being evaluated for new intended uses, new populations, new materials or design changes

Investigator: An individual responsible for the conduct of a clinical trial research study at a study site and ensures that the study complies with ICH GCP E6 (R2) guidelines. An Investigator can be either a Coordinating Principal Investigator, Principal Investigator or a Sub-Investigator

Investigator Brochure (IB) Medicine: A compilation of the clinical and non-clinical data on the investigational product that is relevant to the study of the product in human participants. For marketed products it may be acceptable to use the Product Information

Institutional Review Board (IRB): An independent ethics committee

Monitoring Plan A: document developed by the sponsor that is tailored to the specific human subject protection and data integrity risks of the trial. The plan should describe the monitoring strategy, the monitoring responsibilities of all the parties involved, the various monitoring methods to be used, and the rationale for their use. The plan should also emphasize the monitoring of critical data and processes. Particular attention should be given to those aspects that are not routine clinical practice and that require additional training. The monitoring plan should reference the applicable policies and procedures.

Participant screening log: To document identification of participants who entered pre-trial screening.

Participant Information and Consent Form (PICF): The ethically approved document used for providing written patient information about a specific clinical trial and the documentation of Informed Consent in the form of the patient and the investigator signatures and date

Protocol Deviation: A deviation is any breach, divergence or departure from the requirements of Good Clinical Practice (GCP) or the protocol that does not have a significant impact on the continued safety or rights of participants or the reliability and robustness of the data generated in the research project. GCP requires all deviations to be reported to the trial sponsor

A description of the methods, roles and responsibilities and requirements for monitoring the safety data of the trial.

Serious Adverse Event (SAE): – drug Any untoward medical occurrence that, at any dose:

- results in death
- is life-threatening
- requires inpatient hospitalization or prolongation of existing hospitalization
- results in persistent or significant disability / capacity
- is a congenital anomaly / birth defect

Serious Adverse Event (SAE): – device Serious Adverse Event for medical devices: any adverse medical occurrence that causes:

- results in death
- lead to a serious deterioration in health of a study participant user or other. o
- a life-threatening illness or injury o
- a permanent impairment of body function or permanent damage to a body structure o
- a condition requiring hospitalization or increased length of existing hospitalization
- a condition requiring unnecessary medical or surgical intervention
- foetal distress, foetal death or a congenital abnormality/birth defect

Sub Investigator (SI) or Associate Investigator (AI): Any individual member of the clinical trial team designated and supervised by the investigator at a trial site to perform critical trial-related procedures and/or to make important trial-related decisions e.g. associates, residents, research fellows

Supervision Plan: A plan that outlines processes for a Principal Investigator in the supervision of any individual or party to whom he/she delegates study-related duties and functions conducted at a study site, which includes, but is not limited to, details on joint consultations using telehealth, collation and monitoring of documents, frequency of joint trial meetings across a cluster (with minutes of these meetings) and clarification of activities performed by the PI and the Sub Investigator, other study staff and independent third party i.e. external service providers.

Standard Operating Procedure (SOP) Creation, Implementation and Revision

1. Purpose

To document the procedure for the creation and implementation of new Standard Operating Procedures (SOPs) and review of existing SOPs according to the principles of ICH GCP E6 (R2) and the NHMRC National Statement on Ethical Conduct in Human Research (2007) - Updated 2018.

2. Scope

This standard applies to all health employees but not limited to visiting health professionals, contractors, consultants and volunteers who propose to undertake, administrate, review and/or govern human research involving patients, facilities and or staff. All study personnel involved in the clinical study must operate within their scope of practice.
This applies to all SOPs when a need is identified to either create a new SOP or modify an existing one.

3. Procedure

Review date is two years after the effective date. The time between SOP authorization and the effective date may be reduced in special circumstances (e.g. urgent situations where procedures must be implemented immediately).
An earlier review date is permitted where necessary (e.g. changes to legislation, changes to NMA policy and procedures).

3.1 Initiating the creation of a new SOP or revision of an existing SOP

All researchers may:

- Identify the need for a new SOP or a deficiency or an improvement in an existing SOP and suggest appropriate modification
- Notify the jurisdiction health department (or equivalent) and discuss this need with the SOP number and title in the subject header

NMA members will delegate a responsible jurisdiction to coordinate the following:

- Assess and verify the need
- Use the provided template in Appendix 1 and assign a document ID number and Version date for all new SOPs or to modify an existing SOP
- Draft the new or modify existing SOP and distribute to relevant stakeholders for review and comment
- Maintain a record of the review process either on a document tracking review log (including at a minimum the SOP ID, version number, reviewer name, and review date, changes and comments noted by reviewer, action by owner, date of action, new version) or electronically by using the tracked changes feature with a file naming paradigm and save files on central drive.
- Incorporate relevant comments and if required redistribute to relevant stakeholder for second review.
- If necessary, repeat above 2 steps until a final version is ready for approval.
- Update the front-page identifier box and / or amendment history box as necessary, ensuring the ‘SOP effective date’ and ‘SOP review date’ is in alignment with the timeframe identified in this SOP.
- Arrange for final review and incorporate any relevant comments.

3.2 Approval and Authorization of the SOP

NMA members will:

- Print the final SOP and arrange for approval and authorization and final sign off by the NMA jurisdictional working group.
- Ensure the original signature field and / or amendment history field is completed by the delegated coordinating jurisdictions.
- File the final approved (in writing) new/amended SOP electronically as a pdf file and distribute to all jurisdiction members to post on a website.
- Securely store the final, approved, new/amended master SOP.
- Once the authorized Generic Standard Operating Procedures for Clinical Trials, including Tele-trials, in Australia has been approved any changes can only be made by following the steps outlined in this SOP.

3.3 Training, Implementation, Distribution of the new or revised SOP

- All relevant jurisdiction stakeholders should be notified of the new/updated SOP between the authorization and the effective date. This would include Ghana Health Service Ethics Review Committee (GHSERC) and Research Governance Officers (RGOs).

3.4 Superseded SOPs

- NMA jurisdictions will notify relevant stakeholders including all GHSERC and RGOs of superseded SOPs.
- The superseded SOP will be watermarked with SUPERCEDED and filed.
- The superseded hard copy master SOP shall be clearly marked as superseded and be securely stored as a record of previously used SOPs.
- The superseded SOP shall be removed from the relevant websites.

Standard Operating Procedure (SOP) for Clinical Trials at the University of Ghana Medical Centre

1. Purpose:

The purpose of this Standard Operating Procedure (SOP) is to establish standardized procedures and guidelines for the operations of the Clinical Trials Unit (CTU) at the University of Ghana Medical Centre (UGMC). This SOP aims to ensure the efficient and ethical conduct of clinical trials in accordance with applicable regulations and guidelines, locally and internationally.

2. Scope:

This SOP applies to all personnel involved in the conduct of clinical trials at UGMC, including researchers, principal investigators, coordinators, clinical staff, participants and any other individuals directly or indirectly involved in clinical trial activities.

3. Regulatory Compliance:

3.1. The CTU shall adhere to all applicable laws, regulations, and guidelines governing clinical trials, including but not limited to the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) Good Clinical Practice (GCP) guidelines, the local regulatory authority (FDA) requirements, and the UGMC policies and procedures.
3.2. The CTU shall maintain up-to-date knowledge of regulatory requirements and ensure compliance with any updates or changes.

4. Study Protocol and Documentation:

4.1. All clinical trials conducted within the CTU shall have an approved study protocol that complies with relevant regulatory requirements.
4.2. The CTU shall maintain accurate and complete documentation related to each clinical trial, including the study protocol, informed consent forms, case report forms, and other essential documents as required.
4.3. Any amendments or modifications to the study protocol shall be properly reviewed, approved, and documented.

5. Study Initiation and Management:

5.1 Prior to initiating a clinical trial, the CTU shall ensure that all necessary approvals, including ethical clearance and regulatory authorization, have been obtained.
5.2. Adequate resources, including personnel, facilities and equipment shall be allocated for the successful execution of each clinical trial.
5.3 The CTU shall appoint a designated principal investigator and study coordinator responsible for the overall management and coordination of each trial.
5.4 Every personnel involved in the clinical research shall be qualified by education, training and experience.
5.5 Proper training and education shall be provided to all personnel involved in the clinical trial to ensure their competency in conducting study procedures and adhering to the protocol requirements.

6. Approval and Implementation:

This SOP shall be approved by the relevant regulatory body for the Clinical Trials Unit and communicated to all personnel involved in clinical trial activities. The SOP shall become effective upon approval.

7. Training and Continuous Professional Development:

7.1 The CTU shall provide ongoing training and educational opportunities to its personnel to enhance their knowledge and skills related to clinical trial conduct and regulatory compliance.
7.2 Training records shall be maintained for each individual, documenting their participation in relevant training programs.

8. Participant Recruitment and Informed Consent:

8.1. Participant recruitment shall be conducted in an ethical and transparent manner, ensuring that all eligible participants receive adequate information about the trial and provide informed consent.
8.2. Informed consent shall be obtained from each participant before their inclusion in the trial, following applicable regulatory and ethical guidelines.
8.3. The CTU shall maintain accurate and confidential participant records and ensure the privacy and protection of participants' personal information.

9. Data Collection and Management:

9.1. The CTU shall establish robust systems for the collection, recording, and management of trial data, ensuring accuracy, completeness, and confidentiality.
9.2. All data collected shall be captured in case report forms or electronic data capture systems, following the protocol-specific procedures and timelines.
9.3. The CTU shall implement quality control measures to ensure the accuracy and integrity of the collected data.

10. Safety Monitoring and Reporting:

10.1 The CTU shall establish mechanisms for the monitoring of participant safety during the trial, including regular safety assessments and reporting of adverse events.
10.2 Serious adverse events and unexpected safety concerns shall be promptly reported to the appropriate authorities and ethics committee as per regulatory requirements.

11. Quality Assurance and Auditing:

11.1. The CTU shall conduct regular internal quality assurance activities to ensure compliance with SOPs, regulations, and guidelines.
11.2. External audits or inspections may be conducted by regulatory authorities or sponsors, and the CTU shall cooperate and provide necessary support during these audits.

12. Revision and Review of SOPs:

12.1 This SOP and associated procedures shall be reviewed periodically to ensure their continued relevance, compliance with regulations, and effectiveness.
12.2 The updated SOP will be approved by the appropriate IRB and regulatory body.
12.2. Any updates or revisions to this SOP shall be communicated to relevant personnel, and training on the revised procedures shall be provided as necessary.

13. Documentation and Record Keeping:

13.1. The CTU shall maintain accurate and complete records of all clinical trial-related activities, including documentation of approvals, participant consent forms, study data, and any other essential documents.
13.2. Records shall be securely stored, appropriately archived, and retained for the required period as per applicable regulations and institutional policies.

14. Non-compliance and Deviations:

14.1. Any instances of non-compliance with this SOP or deviations from the study protocol shall be

documented, investigated, and appropriately addressed.
14.2. Corrective and preventive actions shall be implemented to rectify non-compliance or deviations and prevent their recurrence.

15. Study Closeout and Reporting:

15.1. Upon completion or termination of a clinical trial, the CTU shall ensure proper study closeout procedures, including documentation, archiving, and reporting requirements.
15.2. Study results shall be disseminated appropriately, adhering to publication guidelines, and ensuring transparency and integrity in reporting.

Note: This SOP is intended as a general guideline to the specific requirements and regulations of the University of Ghana Medical Centre's Clinical Trials Unit.

Study Start-Up in a Clinical Trials Unit at the University of Ghana Medical Centre

1. Purpose:

The purpose of this Standard Operating Procedure (SOP) is to provide guidelines for the initiation and start-up of clinical trials in the Clinical Trials Unit (CTU) at the University of Ghana Medical Centre (UGMC). This SOP outlines the procedures for site selection, feasibility assessment, study initiation activities, and obtaining necessary approvals.

2. Scope:

This SOP applies to all personnel involved in the study start-up process at the CTU, including principal investigators, study coordinators, regulatory affairs personnel, and any other individuals responsible for initiating and setting up clinical trials.

3. Site Selection:

3.1. The CTU shall establish criteria for site selection based on study requirements, infrastructure, expertise, patient population, and regulatory considerations.
3.2. Potential study sites shall be evaluated against the defined criteria to identify suitable sites for conducting the clinical trial.

4. Feasibility Assessment:

4.1. A feasibility assessment shall be conducted for each potential study site to evaluate its capability to meet study requirements and timelines.
4.2. The feasibility assessment shall consider factors such as patient recruitment potential, availability of resources, site personnel expertise, and potential challenges.

5. Regulatory and Ethical Considerations:

5.1. The CTU shall identify and obtain necessary approvals from regulatory authorities, such as the Food and Drugs Authority (FDA) and any other regulatory and review body.
5.2. Ethical considerations shall be addressed by obtaining approval from the relevant ethics committee or institutional review board (IRB).

6. Study Initiation Activities:

6.1. Once regulatory and ethical approvals are obtained, study initiation activities shall be conducted, including the development of study-specific documents, such as the protocol, informed consent form, and case report forms.
6.2. A kick-off meeting shall be conducted to communicate study objectives, roles and responsibilities, study procedures, and timelines to the study team members.
6.3. Investigator and study staff training shall be organized to ensure proper understanding of the study protocol, procedures, and regulatory requirements.

7. Investigational Product Management:

7.1. Procedures for handling investigational products, including storage, accountability, dispensing and reconstitution shall be established in compliance with Good Clinical Practice (GCP) guidelines.
7.2. Adequate facilities and equipment for investigational product storage shall be provided, ensuring adherence to temperature control requirements.

8. Contracts and Budget Negotiation:

8.1. Contractual agreements shall be established with involved parties, such as sponsors, contract research organizations (CROs), and third-party vendors.
8.2. Budget negotiation and financial arrangements shall be conducted to ensure adequate funding for the study.

9. Site Initiation Visit:

9.1. A site initiation visit shall be conducted by the study sponsor or representative to ensure that the site is ready to initiate the study.
9.2. During the site initiation visit, study-specific procedures, documentation, and regulatory requirements shall be reviewed, and any outstanding issues shall be addressed.

10. Document Control:

10.1. All essential study documents, including the protocol, informed consent form, and study-specific SOPs, shall be properly managed, version-controlled, and accessible to authorized personnel.
10.2. A document control system shall be implemented to track and archive study-related documents.

11. Review and Revision:

11.1. This SOP shall be reviewed periodically to ensure compliance with applicable regulations, best practices, and institutional policies.
11.2. Any revisions to this SOP shall be communicated to all relevant personnel, and training on the revised procedures shall be provided as necessary.

12. Approval and Implementation:

This SOP shall be approved by the appropriate authority for the CTU and implemented as part of the standard procedures for study start-up activities.

13. References:

List any relevant regulations, guidelines, or reference documents applicable to study start-up processes in clinical trials.

Note: This SOP is a general guideline tailored to the specific requirements and regulations of the University of Ghana Medical Centre's Clinical Trials Unit.

General Administration and Operation in a Clinical Trials Unit at the University of Ghana Medical Centre

1. Purpose:

The purpose of this Standard Operating Procedure (SOP) is to provide guidelines for the general administration and operation of a Clinical Trials Unit (CTU) at the University of Ghana Medical Centre (UGMC). This SOP aims to ensure efficient and effective management of clinical trial activities, adherence to applicable regulations, and coordination among personnel involved in clinical trial operations.

2. Scope:

This SOP applies to all personnel involved in the administration and operation of the CTU at UGMC, including principal investigators, research coordinators, study coordinators, regulatory affairs personnel, data managers, and any other individuals responsible for clinical trial management.

3. Roles and Responsibilities:

3.1. Roles and responsibilities of key personnel involved in the CTU shall be defined and documented, including the study team, investigators, coordinators, regulatory affairs personnel, and administrative staff.
3.2. Clear communication channels and reporting structures shall be established to facilitate effective collaboration and decision-making.

4. Regulatory Compliance:

4.1. The CTU shall adhere to all applicable regulations, guidelines, and ethical standards, including local regulatory requirements, Good Clinical Practice (GCP), and institutional policies.
4.2. Regulatory affairs personnel shall be responsible for maintaining up-to-date knowledge of relevant regulations and ensuring compliance throughout the clinical trial process.

5. Study Documentation and Recordkeeping:

5.1. The CTU shall establish and maintain a system for the proper documentation, storage, and retention of study-related documents and records, including study protocols, informed consent forms, investigator brochures, ethics committee approvals, and regulatory submissions.
5.2. Document version control, file organization, and record retention periods shall be clearly defined and documented.
5.3. Access to study documents shall be restricted to authorized personnel only.

6. Study Budget and Financial Management:

6.1. The CTU shall establish a budgeting and financial management process for each clinical trial, including the identification of study-related costs, funding sources, invoicing, and financial reporting.
6.2. Financial transactions and records shall be accurately documented and maintained in accordance with institutional policies and sponsor requirements.

7. Training and Education:

7.1. Training programs shall be implemented to ensure that all personnel involved in clinical trial operations receive appropriate training on their roles, responsibilities, and the relevant procedures.
7.2. Training records shall be maintained to demonstrate compliance with training requirements.

8. Communication and Collaboration:

8.1. Effective communication channels and mechanisms shall be established to facilitate communication within the CTU, with study sponsors, ethics committees, regulatory authorities, and other stakeholders.
8.2. Regular team meetings, email communications, and document sharing platforms may be utilized to ensure timely and accurate information exchange.

9. Quality Assurance and Quality Control:

9.1. The CTU shall establish a quality assurance program to monitor and assess the quality of clinical trial operations, data collection, and compliance with protocols, regulations, and GCP.
9.2. Quality control measures, such as regular monitoring visits, source data verification, and internal audits, shall be conducted to ensure adherence to study protocols and quality standards.

10. Facility and Equipment Management:

10.1. The CTU shall maintain appropriate facilities and equipment necessary for conducting clinical trials.
10.2. Facilities shall be clean, well-maintained, and meet the required standards for participant safety and privacy.
10.3. Equipment used for data collection, sample storage, and study procedures shall be regularly calibrated, maintained, and monitored for performance.

11. Review and Revision:

11.1. This SOP shall be reviewed periodically to ensure compliance with applicable regulations, industry best practices, and institutional policies.
11.2. Any revisions to this SOP shall be communicated to all relevant personnel, and training on the revised procedures shall be provided as necessary.

12. Approval and Implementation:

This SOP shall be approved by the responsible authority within the CTU at UGMC and communicated to all personnel involved in clinical trial administration and operation. The SOP shall become effective upon approval.

Note: This SOP is intended as a general guideline tailored to the specific requirements and regulations of the University of Ghana Medical Centre's Clinical Trials Unit.

Protocol Development in A Clinical Trials Unit at The University of Ghana Medical Centre

1. Purpose:

The purpose of this Standard Operating Procedure (SOP) is to provide guidelines for the development and finalization of study protocols in the Clinical Trials Unit (CTU) at the University of Ghana Medical Centre (UGMC). This SOP outlines the process for ensuring that study protocols are well-designed, scientifically rigorous, and compliant with applicable regulatory requirements.

2. Scope:

This SOP applies to all personnel involved in the development of study protocols within the CTU, including principal investigators, study coordinators, research scientists, biostatisticians, and any other individuals responsible for protocol development activities.

3. Protocol Development Process:

3.1. Study Objectives:

3.1.1. Clearly define the research question(s) and study objectives, ensuring they are feasible, relevant, and aligned with the study's purpose.
3.1.2. Review existing literature and consult with subject matter experts to inform the development of study objectives.

3.2. Study Design:

3.2.1. Select an appropriate study design based on the research question(s) and objectives, considering factors such as population, interventions, comparators, outcomes, and feasibility.
3.2.2. Provide a rationale for the chosen study design and justify why it is most suitable to address the research question(s).

3.3. Methodology:

3.3.1. Clearly describe the study population, including eligibility criteria and recruitment strategies.
3.3.2. Define the study interventions, procedures, assessments, and data collection methods in detail.
3.3.3. Include information on sample size calculation, randomization (if applicable), and statistical analysis plan.

3.4. Ethical Considerations:

3.4.1. Ensure that the study protocol adheres to ethical principles and guidelines, protecting the rights, safety, and well-being of study participants.
3.4.2. Include a comprehensive section on informed consent procedures, risk-benefit assessment, data confidentiality, and privacy protection.

3.5. Regulatory Requirements:

3.5.1. Comply with all applicable regulatory requirements, including local laws, international guidelines, and institutional policies.
3.5.2. Obtain necessary approvals from relevant ethics committees and regulatory authorities.

3.6. Protocol Writing and Review:

3.6.1. Prepare a clear and concise protocol document, organizing the information in a logical and structured manner.
3.6.2. Involve relevant stakeholders, such as co-investigators, study coordinators, and biostatisticians, in the review process to ensure accuracy and scientific rigor.
3.6.3. Incorporate feedback from reviewers and make necessary revisions to the protocol.

3.7. Finalization and Version Control:
3.7.1. Obtain final approval from the principal investigator and other key stakeholders.
3.7.2. Implement a version control system to manage changes and revisions to the protocol.
3.7.3. Clearly document the version number, revision date, and changes made in each protocol version.

4. Revision and Approval:

4.1. This SOP shall be periodically reviewed and updated as necessary to align with evolving regulations, guidelines, and best practices.
4.2. Any changes or updates to this SOP shall be communicated to all relevant personnel, and training on the revised procedures shall be provided as necessary.

5. References:

List any relevant regulations, guidelines, or reference documents applicable to protocol development in clinical trials.

Note: This SOP is a general guideline tailored to the specific requirements and regulations of the University of Ghana Medical Centre's Clinical Trials Unit.

Participant Recruitment in a Clinical Trials Unit at the University of Ghana Medical Centre

1. Purpose:

The purpose of this Standard Operating Procedure (SOP) is to outline the strategies and procedures for participant recruitment in the Clinical Trials Unit (CTU) at the University of Ghana Medical Centre (UGMC). This SOP ensures the identification, screening, and enrollment of eligible participants into clinical trials while maintaining compliance with recruitment criteria.

2. Scope:

This SOP applies to all personnel involved in participant recruitment at the CTU, including principal investigators, study coordinators, recruitment staff, and any other individuals responsible for the recruitment process.

3. Recruitment Strategy:

3.1. The CTU shall develop a comprehensive recruitment strategy for each clinical trial, considering the target population, recruitment goals, timelines, and available resources.
3.2. The recruitment strategy shall be designed to reach the target population through various channels, such as medical centers, community organizations, online platforms, and advertisements.

4. Screening and Assessment:

4.1. Eligibility criteria shall be clearly defined and documented for each clinical trial.
4.2. Screening procedures shall be established to assess potential participants' eligibility based on the defined criteria.
4.3. Screening may involve pre-screening questionnaires, medical record reviews, physical examinations, laboratory tests, or other necessary assessments.

5. Informed Consent and Participant Education:

5.1. Once potential participants meet the initial eligibility criteria, the informed consent process shall be conducted following the Informed Consent SOP.
5.2. Participants shall receive detailed information about the study objectives, procedures, risks, benefits, and their rights as participants to make an informed decision.
5.3. Participants shall be provided with sufficient time to review the informed consent document, ask questions, and seek additional information before providing consent.

6. Enrollment and Randomization:

6.1. If potential participants meet all eligibility criteria and provide informed consent, they can be enrolled in the clinical trial.
6.2. Enrollment may involve the use of randomization procedures as defined in the study protocol, ensuring fair and unbiased participant allocation to treatment groups.

7. Tracking and Follow-up:

7.1. The CTU shall establish a system to track enrolled participants, including their contact information, study visits, and any relevant follow-up procedures.
7.2. Study coordinators or designated personnel shall conduct regular follow-up with participants, ensuring compliance with study procedures and addressing any participant concerns or questions.

8. Documentation and Record Keeping:

8.1. The recruitment process and outcomes shall be accurately and comprehensively documented,

including participant screening results, enrollment numbers, and reasons for ineligibility or withdrawal.
8.2. Participant records shall be securely stored and accessible only to authorized personnel.
8.3. Any recruitment-related documentation, such as advertisements or recruitment materials, shall be retained as part of the trial documentation according to regulatory requirements.

9. Review and Revision:

9.1. This SOP shall be reviewed periodically to ensure compliance with applicable regulations, best practices, and institutional policies.
9.2. Any revisions to this SOP shall be communicated to all relevant personnel, and training on the revised procedures shall be provided as necessary.

10. Approval and Implementation:

This SOP shall be approved by the appropriate authority within the CTU and implemented as part of the standard procedures for participant recruitment in clinical trials.

11. References:

List any relevant regulations, guidelines, or reference documents applicable to participant recruitment in clinical trials.

Note: This SOP is a general guideline tailored to the specific requirements and regulations of the University of Ghana Medical Centre's Clinical Trials Unit.

Informed Consent in a Clinical Trials Unit at the University of Ghana Medical Centre

1. Purpose:

The purpose of this Standard Operating Procedure (SOP) is to establish standardized procedures and guidelines for obtaining informed consent from participants enrolled in clinical trials within the Clinical Trials Unit (CTU) at the University of Ghana Medical Centre (UGMC). This SOP aims to ensure that participants provide voluntary, informed, and documented consent to participate in clinical trials in compliance with applicable regulations and ethical principles.

2. Scope:

This SOP applies to all personnel involved in the conduct and oversight of clinical trials within the CTU at UGMC, including principal investigators, clinical staff, research coordinators, and any other individuals responsible for obtaining informed consent.

3. Definitions:

3.1. Informed Consent: A voluntary and autonomous decision made by a competent individual to participate in a clinical trial, based on a comprehensive understanding of the purpose, procedures, risks, benefits, and alternatives involved in the study.
3.2. Informed Consent Process: The ongoing dialogue between the investigator and the participant, including the provision of information, discussion, and opportunity for questions, leading to the participant's understanding and voluntary agreement to participate.

4. Informed Consent Procedures:

4.1. The informed consent process shall be conducted in a private, comfortable, and confidential setting that allows for effective communication between the investigator and the participant.
4.2. The investigator or designated personnel shall explain the purpose, nature, duration, and procedures of the clinical trial in a clear, understandable language, tailored to the participant's level of comprehension.
4.3. All information provided during the informed consent process shall be consistent with the approved protocol, relevant regulatory requirements, and ethical principles.
4.4. The participant shall be given sufficient time to consider participation, and the opportunity to ask questions, seek additional information, and consult with family members, healthcare providers, or other advisors.
4.5. The informed consent form (ICF) shall be provided to the participant, and its content shall be thoroughly explained, including the purpose, risks, benefits, confidentiality, compensation, and any potential conflicts of interest.
4.6. The participant's voluntary agreement to participate shall be documented by signing and dating the ICF or providing an alternative method of documented consent, if applicable.

5. Vulnerable Populations:

5.1. Informed consent for participants belonging to vulnerable populations (e.g., minors, individuals with cognitive impairments, pregnant women) shall involve additional considerations and safeguards in accordance with applicable laws and regulations.
5.2. In cases where proxy consent is required, the procedures for obtaining informed consent from legally authorized representatives shall be followed, ensuring their understanding and agreement to act in the best interest of the participant.

6. Ongoing Consent Process:

6.1. The investigator shall ensure ongoing communication with participants throughout the study, addressing any changes in the research plan, new findings, or potential risks that may affect the participant's willingness to continue participation.
6.2. Participants shall be informed of their right to withdraw from the study at any time without penalty or loss of benefits, and the procedures for withdrawal shall be clearly explained.

7. Documentation and Confidentiality:

7.1. The signed or documented consent forms shall be retained securely as part of the participant's study record.
7.2. The confidentiality of participant information and consent-related documents shall be maintained in accordance with applicable privacy laws and regulations.

8. Training and Documentation:

8.1. Training programs shall be conducted to educate personnel involved in the informed consent process on the proper implementation of this SOP, including effective communication techniques, participant-centered approaches, and documentation requirements.
8.2. Documentation of the informed consent process, including the ICF, participant questions, and any modifications, shall be maintained in the participant's study file.

9. Review and Revision:

9.1. This SOP shall be reviewed periodically to ensure compliance with applicable regulations and ethical guidelines, and to incorporate any necessary updates or changes.
9.2. Any revisions to this SOP shall be communicated to all relevant personnel, and training on the revised procedures shall be provided as necessary.

10. Approval and Implementation:

This SOP shall be approved by the responsible authority within the CTU at UGMC and communicated to all personnel involved in the informed consent process. The SOP shall become effective upon approval.

Note: This SOP is intended as a general guideline tailored to the specific requirements and regulations of the University of Ghana Medical Centre's Clinical Trials Unit.

Randomization and Blinding in a Clinical Trials at the University of Ghana Medical Centre

1. Purpose:

The purpose of this Standard Operating Procedure (SOP) is to establish guidelines for randomization procedures and maintaining blinding (if applicable) in clinical trials conducted at the Clinical Trials Unit (CTU) at the University of Ghana Medical Centre (UGMC). This SOP ensures the unbiased allocation of participants to study groups, minimizing potential biases and maintaining the integrity of the study.

2. Scope:

This SOP applies to all personnel involved in the randomization and blinding processes within the CTU, including principal investigators, study coordinators, data managers, and any other individuals responsible for implementing randomization and blinding procedures.

3. Randomization Procedures:

3.1. The study protocol shall clearly define the randomization method to be used, such as block randomization, stratified randomization, or other appropriate methods.
3.2. The randomization process shall be conducted using a validated and secure randomization system, software, or an independent statistician.
3.3. Randomization lists shall be generated and securely stored by authorized personnel who are not involved in participant enrollment or data collection.
3.4. The randomization process shall ensure that participants have an equal chance of being assigned to each study group, maintaining balance and reducing selection bias.

4. Blinding Procedures:

4.1. If blinding is applicable to the study design, the protocol shall clearly define the blinding method, such as single-blind, double-blind, or triple-blind.
4.2. Blinding procedures shall be implemented to ensure that participants, investigators, study personnel, and outcome assessors remain unaware of the assigned treatment group.
4.3. Procedures for blinding shall be established to prevent inadvertent unblinding or bias during the study conduct, data collection, and analysis.
4.4. The study medication or intervention shall be appropriately packaged, labeled, and administered to maintain blinding.

5. Unblinding:

5.1. Unblinding procedures shall be established in case of emergencies or situations where knowledge of the assigned treatment group becomes necessary for participant safety or ethical reasons.
5.2. Unblinding should only be conducted by authorized personnel and documented in accordance with the study protocol and applicable regulations.

6. Documentation and Record Keeping:

6.1. All randomization and blinding-related activities shall be accurately documented, including randomization lists, blinding codes, and any unblinding occurrences.
6.2. Participant records shall indicate the assigned treatment group (if applicable) without compromising blinding integrity.
6.3. Data management procedures shall ensure that the blinding status is maintained during data collection, entry, and analysis.

7. Review and Revision:

7.1. This SOP shall be periodically reviewed to ensure compliance with applicable regulations, best practices, and institutional policies.
7.2. Any revisions to this SOP shall be communicated to all relevant personnel, and training on the revised procedures shall be provided as necessary.

8. Approval and Implementation:

This SOP shall be approved by the appropriate authority within the CTU and implemented as part of the standard procedures for randomization and blinding in clinical trials.

9. References:

List any relevant regulations, guidelines, or reference documents applicable to randomization and blinding in clinical trials.

Note: This SOP is a general guideline tailored to the specific requirements and regulations of the University of Ghana Medical Centre's Clinical Trials Unit.

Monitoring and Quality Assurance in a Clinical Trials at the University of Ghana Medical Centre

1. Purpose:

The purpose of this Standard Operating Procedure (SOP) is to establish guidelines for monitoring the conduct of clinical trials conducted at the Clinical Trials Unit (CTU) at the University of Ghana Medical Centre (UGMC). This SOP ensures that the study procedures are conducted in compliance with the approved protocol, applicable regulations, and Good Clinical Practice (GCP) guidelines. It outlines the processes for monitoring visits, source data verification, and quality assurance to ensure data integrity and participant safety.

2. Scope:

This SOP applies to all personnel involved in the monitoring and quality assurance processes within the CTU, including principal investigators, study coordinators, monitors, auditors, and any other individuals responsible for monitoring and ensuring quality control in clinical trials.

3. Monitoring Visits:

3.1. Monitoring visits shall be conducted by qualified monitors who are independent of the study team and have appropriate knowledge and training in GCP.
3.2. The monitoring plan, including the frequency and scope of visits, shall be defined in the study protocol and approved by the sponsor and relevant ethics committees.
3.3. Monitors shall conduct on-site visits to assess protocol compliance, source data verification, and adherence to GCP guidelines.
3.4. Monitoring visits shall be scheduled in advance and documented in monitoring visit reports, which include findings, observations, and recommendations for corrective actions.

4. Source Data Verification:

4.1. Monitors shall perform source data verification (SDV) to ensure that the data collected and reported in the case report forms (CRFs) accurately reflect the source documents.
4.2. SDV shall be conducted according to the monitoring plan and may include review of medical records, laboratory results, informed consent forms, and other relevant source documents.
4.3. SDV findings shall be documented, and any discrepancies or errors shall be resolved through discussion with the site staff and appropriate documentation.

5. Protocol Compliance and Regulatory Requirements:

5.1. Monitors shall verify that the study procedures are conducted in accordance with the approved protocol, applicable regulations, and institutional policies.
5.2. Monitors shall review the completeness, accuracy, and timeliness of regulatory documents, such as informed consent forms, ethics committee approvals, and investigator's brochures.
5.3. Monitors shall assess the implementation of the study protocol, adherence to inclusion and exclusion criteria, and proper documentation of adverse events and serious adverse events.
5.4. Any protocol deviations, violations, or non-compliance shall be documented, reported, and addressed promptly.

6. Quality Assurance:

6.1. The CTU shall establish a quality assurance program to ensure the overall integrity and quality of the clinical trial.
6.2. Quality assurance activities may include internal audits, process evaluations, and compliance assessments to identify areas for improvement and ensure adherence to GCP guidelines.

6.3. Corrective and preventive actions (CAPAs) shall be implemented to address any identified deficiencies or non-compliance.
6.4. The CTU shall maintain a quality management plan, which outlines the responsibilities, processes, and procedures for quality assurance activities.

7. Training and Documentation:

7.1. Personnel involved in monitoring and quality assurance activities shall receive appropriate training on GCP guidelines, study protocols, and monitoring procedures.
7.2. All monitoring and quality assurance activities shall be thoroughly documented, including monitoring visit reports, SDV findings, and CAPAs.
7.3. Documentation shall be retained as per institutional policies and regulatory requirements.

8. Review and Revision:

8.1. This SOP shall be periodically reviewed to ensure compliance with applicable regulations, best practices, and institutional policies.
8.2. Any revisions to this SOP shall be communicated to all relevant personnel, and training on the revised procedures shall be provided as necessary.

9. References:

List any relevant regulations, guidelines, or reference documents applicable to monitoring and quality assurance in clinical trials.

Note: This SOP is a general guideline tailored to the specific requirements and regulations of the University of Ghana Medical Centre's Clinical Trials Unit.

Data Management in a Clinical Trials at the University of Ghana Medical Centre

1. Purpose:

The purpose of this Standard Operating Procedure (SOP) is to establish standardized procedures and guidelines for the data management process within the Clinical Trials Unit (CTU) at the University of Ghana Medical Centre (UGMC). This SOP aims to ensure the efficient, accurate, and secure management of clinical trial data in compliance with applicable regulations and guidelines.

2. Scope:

This SOP applies to all personnel involved in data management activities within the CTU at UGMC, including data managers, coordinators, clinical staff, and any other individuals responsible for data collection, storage, and analysis in clinical trials.

3. Data Management Plan:

3.1. A data management plan shall be developed for each clinical trial, outlining the specific procedures and processes for data collection, data entry, data validation, data quality control, and data security.
3.2. The data management plan shall be created in collaboration with the study team, principal investigator, and relevant stakeholders, and shall be approved prior to the initiation of data management activities.

4. Data Collection:

4.1. Data collection forms, case report forms (CRFs), or electronic data capture (EDC) systems shall be designed and implemented in accordance with the study protocol, ensuring that all required data elements are captured accurately and completely.
4.2. Data collection tools shall be standardized, and clear instructions shall be provided to the clinical staff for consistent and reliable data collection.
4.3. Data collection forms or CRFs shall be assigned unique identifiers and version numbers for proper tracking and documentation.

5. Data Entry and Validation:

5.1. Data entry shall be performed by trained personnel using validated data entry systems, such as EDC systems or dedicated data entry software.
5.2. Double data entry or other data validation procedures shall be implemented to ensure accuracy and minimize data entry errors.
5.3. Range checks, data consistency checks, and validation rules shall be defined and applied during data entry to identify and resolve data discrepancies.

6. Data Quality Control:

6.1. Data quality control checks shall be conducted regularly to identify and address any data quality issues, including missing data, outliers, inconsistencies, or other data anomalies.
6.2. Queries and data clarification requests shall be generated and resolved through effective communication with clinical staff and investigators.
6.3. Any changes made to the original data shall be documented, justified, and properly authorized.

7. Data Security and Confidentiality:

7.1. Adequate measures shall be implemented to ensure the security and confidentiality of clinical trial data, including participant information and study-related documents.
7.2. Access to data shall be restricted to authorized personnel only, and appropriate data protection mechanisms, such as password protection, encryption, and secure file storage, shall be employed.

7.3. Data backup procedures shall be established to prevent data loss or corruption.

8. Data Monitoring and Auditing:
8.1. Data monitoring activities, including source data verification, shall be conducted periodically to ensure the accuracy, completeness, and reliability of the data.
8.2. External audits or inspections may be performed by regulatory authorities or sponsors, and the CTU shall cooperate and provide necessary support during these audits.

9. Data Archiving and Retention:
9.1. Proper data archiving procedures shall be followed to ensure the long-term preservation and accessibility of clinical trial data.
9.2. Study data and related documents shall be retained for the required period as per applicable regulations and institutional policies.
9.3. Data archiving methods shall comply with relevant standards and guidelines for data integrity and preservation.

10. Training and Documentation:
10.1. Training programs shall be conducted to educate personnel involved in data management activities on the proper implementation of this SOP and relevant data management processes.
10.2. Documentation of data management activities, including data management plans, data cleaning procedures, and data quality control reports, shall be maintained as part of the trial documentation.

11. Revision and Review:
11.1. This SOP and associated procedures shall be reviewed periodically to ensure their continued relevance, compliance with regulations, and effectiveness.
11.2. Any updates or revisions to this SOP shall be communicated to relevant personnel, and training on the revised procedures shall be provided as necessary.

12. Approval and Implementation:
This SOP shall be approved by the relevant authority within the Clinical Trials Unit and communicated to all personnel involved in data management activities. The SOP shall become effective upon approval.

Note: This SOP is intended as a general guideline tailored to the specific requirements and regulations of the University of Ghana Medical Centre's Clinical Trials Unit.

Sample Handling in a Clinical Trials at the University of Ghana Medical Centre

1. Purpose:

The purpose of this Standard Operating Procedure (SOP) is to provide guidelines for the proper handling, storage, and transportation of samples collected during clinical trials within the Clinical Trials Unit (CTU) at the University of Ghana Medical Centre (UGMC). This SOP aims to ensure the integrity, traceability, and compliance of samples throughout the study process.

2. Scope:

This SOP applies to all personnel involved in the collection, handling, storage, and transportation of samples within the CTU at UGMC, including principal investigators, clinical staff, research coordinators, laboratory personnel, and any other individuals responsible for sample management.

3. Sample Collection:

3.1. Sample collection procedures shall be conducted in accordance with the study protocol and any specific guidelines provided by the study sponsor or regulatory authorities.
3.2. Personnel involved in sample collection shall be appropriately trained and qualified to perform the procedures.
3.3. Samples shall be collected using standardized techniques, and relevant documentation, including sample collection forms, labels, and requisition forms, shall be completed accurately and legibly.

4. Sample Identification and Labeling:

4.1. Each sample container shall be properly labeled with a unique identifier that corresponds to the participant and study visit.
4.2. Labels shall include essential information such as participant identification number, study visit number, sample type, date and time of collection, and initials of the person collecting the sample.
4.3. Labels shall be affixed securely to the sample container and be resistant to smudging or fading.

5. Sample Handling and Storage:

5.1. Samples shall be handled with care to prevent contamination, degradation, or loss of integrity.
5.2. Proper techniques, including aseptic procedures and use of appropriate personal protective equipment (PPE), shall be followed during sample handling.
5.3. Samples shall be stored under appropriate conditions, as specified in the study protocol or laboratory manual, to maintain sample stability and integrity.
5.4. Storage conditions, such as temperature, light exposure, and humidity, shall be monitored and documented regularly.

6. Sample Transportation:

6.1. If samples need to be transported to external laboratories or storage facilities, transportation procedures shall be established and documented.
6.2. Transport containers shall be suitable for the sample type and ensure sample stability during transit.
6.3. Samples shall be packaged and labeled in accordance with applicable regulations and transport guidelines to ensure compliance and safety.
6.4. Proper documentation, including chain of custody forms, temperature logs (if applicable), and any required customs or shipping documentation, shall accompany the samples during transportation.

7. Quality Control and Documentation:

7.1. Quality control measures, including regular calibration and maintenance of equipment, monitoring

of storage conditions, and proficiency testing of laboratory personnel, shall be implemented and documented.
7.2. All sample handling activities, including collection, labeling, storage, and transportation, shall be documented accurately and promptly in the study records and relevant laboratory documentation.

8. Training and Documentation:

8.1. Training programs shall be conducted to educate personnel involved in sample handling on the proper implementation of this SOP, including sample collection techniques, labeling requirements, storage conditions, and transportation procedures.
8.2. Documentation of sample handling activities, including sample logs, storage temperature records, and any modifications, shall be maintained as part of the study records.

9. Review and Revision:

9.1. This SOP shall be reviewed periodically to ensure compliance with applicable regulations and best practices, and to incorporate any necessary updates or changes.
9.2. Any revisions to this SOP shall be communicated to all relevant personnel, and training on the revised procedures shall be provided as necessary.

10. Approval and Implementation:

This SOP shall be approved by the responsible authority within the CTU at UGMC and communicated to all personnel involved in sample handling. The SOP shall become effective upon approval.

Note: This SOP is a general guideline tailored to the specific requirements and regulations of the University of Ghana Medical Centre's Clinical Trials Unit.

Safety Reporting in a Clinical Trials at the University of Ghana Medical Centre

1. Purpose:

The purpose of this Standard Operating Procedure (SOP) is to provide guidelines for reporting safety-related information during the conduct of clinical trials at the Clinical Trials Unit (CTU) at the University of Ghana Medical Centre (UGMC). This SOP ensures that safety data, protocol deviations, safety monitoring, and updates are appropriately reported to the ethics committee and regulatory authorities in compliance with applicable regulations and guidelines.

2. Scope:

This SOP applies to all personnel involved in the conduct of clinical trials within the CTU, including principal investigators, co-investigators, study coordinators, research nurses, data managers, and any other individuals responsible for the collection, monitoring, and reporting of safety-related information.

3. Safety Reporting Responsibilities:

3.1. Principal Investigator (PI):

3.1.1. The PI is responsible for overseeing safety reporting in the clinical trial and ensuring compliance with regulatory requirements.
3.1.2. The PI shall promptly report all adverse events (AEs), serious adverse events (SAEs), and unanticipated problems to the ethics committee and regulatory authorities as per the specified timelines.
3.1.3. The PI shall review and assess the clinical significance and causality of reported AEs and SAEs in collaboration with the study team and medical experts.
3.1.4. The PI shall ensure that protocol deviations related to participant safety are reported and documented appropriately.

3.2. Study Team Members:

3.2.1. All study team members shall promptly report any observed or reported AEs, SAEs, or unanticipated problems to the PI or designated safety officer.
3.2.2. Study team members shall maintain accurate and complete records of safety-related information and ensure its timely communication to the PI.

4. Safety Reporting Procedures:

4.1. Adverse Event Reporting:

4.1.1. All AEs and SAEs occurring during the clinical trial shall be reported following the established reporting procedures outlined in the protocol and applicable regulations.
4.1.2. AEs shall be recorded, assessed for seriousness and causality, and documented in the case report form (CRF) or other designated safety report forms.
4.1.3. SAEs shall be reported to the ethics committee and regulatory authorities within the specified timelines using the approved reporting templates.
4.1.4. Follow-up information on AEs and SAEs shall be collected and reported as per the requirements of the ethics committee and regulatory authorities.

4.2 Safety Monitoring:

4.2.1. Safety monitoring activities shall be conducted as per the protocol and the monitoring plan.
4.2.2. Data on safety parameters, including laboratory results, vital signs, and other safety assessments, shall be collected, reviewed, and appropriately documented.
4.2.3. The study team shall perform regular safety reviews and assessments, addressing any safety concerns or emerging risks.

4.3. Protocol Deviations:
4.3.1. Protocol deviations related to participant safety, including deviations from the study drug administration, safety assessments, or study procedures, shall be documented and reported as per the protocol and applicable regulations.

4.4. Updates to Ethics Committee and Regulatory Authorities:
4.4.1. Any significant changes to the safety profile of the study drug, protocol, or study procedures shall be promptly reported to the ethics committee and regulatory authorities as per the specified reporting requirements.

5. Documentation and Record-Keeping:

5.1. All safety-related information, including AEs, SAEs, protocol deviations, safety monitoring reports, and communication with ethics committee and regulatory authorities, shall be accurately documented, securely stored, and maintained in accordance with Good Clinical Practice (GCP) guidelines and applicable regulations.
5.2. Records of safety reporting shall be readily accessible for audit and inspection purposes.

6. Training and Education:

6.1. All personnel involved in safety reporting shall receive appropriate training on their roles, responsibilities, and the procedures outlined in this SOP.
6.2. Training records shall be maintained to demonstrate compliance with training requirements.

7. Revision and Approval:

7.1. This SOP shall be periodically reviewed and updated as necessary to ensure compliance with evolving regulations, guidelines, and best practices.
7.2. Any changes or updates to this SOP shall be communicated to all relevant personnel, and training on the revised procedures shall be provided as necessary.

8. References:

List any relevant regulations, guidelines, or reference documents applicable to safety reporting in clinical trials.

Note: This SOP is a general guideline tailored to the specific requirements and regulations of the University of Ghana Medical Centre's Clinical Trials Unit.

Site Staff Qualifications, Training Records and Capability

1. Purpose:

The purpose of this Standard Operating Procedure is to ensure the appropriate documentation of clinical research site staff qualifications and training records are completed and maintained up to date during the course of the study, and to ensure the provision of resources to perform clinical research at all clinical research sites, according to the principles of ICH GCP and the NHMRC National Statement on Ethical Conduct in Human Research (2007) - Updated 2018.

2. Scope:

This Standard Operating Procedure applies to all relevant employees but not limited to visiting health professionals, contractors, consultants and volunteers who propose to undertake, administrate, review and/or govern human research involving patients and staff. All study personnel involved in the clinical study must operate within their scope of practice.

3. Procedure:

3.1 Site Staff Qualifications

The Investigator must:

3.1.1 Be qualified by education, training and experience, including GCP training, to assume ultimate responsibility for the proper conduct of the research.
3.1.2 If required by the local site RGO submit a current Curriculum Vitae (CV) to the RGO if not submitted previously and at any time the CV changes including:

- other relevant documentation requested by the sponsor, the GHSERC, and/or the regulatory authority (e.g. current GCP training).
- Current workplace name and address

3.1.3 Ensure all investigational site staff, at both Primary and Satellite Sites, or Independent Third Party, and External Service Providers are qualified by education, training and experience, including GCP training, to assume responsibilities to perform the delegated study-related duties and functions.
3.1.4 Ensure all investigational site staff, at both Primary and Satellite Sites, or Independent Third Party, who has been delegated significant responsibilities has a current CV in the research office/SMF for sighting by sponsor and / or regulatory authority.
3.1.5 Implement procedures to ensure the delegated study-related duties and functions performed are carried out safely.
3.1.6 Implement procedures to ensure integrity of any data generated.

3.2 Site Staff Training Records

The Principal Investigator must:

3.2.1 Ensure all required staff, including new staff involved during the course of a study, who assist with the clinical trial are informed about and trained on the protocol, any Investigational Product, and their research-related duties and functions. This can be in the form of an Initiation meeting held by any communication means e.g. via face-to-face, skype, videoconference, telehealth means etc.
3.2.2 Record the study specific training given, documents and tools used, to whom and when e.g. on a training record or log.
3.2.3 Ensure that all required training is completed, and the training record are kept up to date and a copy is kept at the Primary Site and/or Satellite Sites (when applicable) and available for review on request throughout the entire duration of the clinical research trial.

3.3 Capability

The Principal Investigator must:

3.3.1 Demonstrate a potential for recruiting the required number of suitable participants, either from the Primary Site only or from associated Satellite Sites, within the specified recruitment period. This may be in the form of de-identified participant recruitment listings or other documented written or printed evidence.

3.3.2 Have sufficient time to properly conduct and complete the research within the specified period.

3.3.3 Have an adequate number of qualified staff and adequate facilities for the foreseen duration of the research.

3.3.4 Maintain a record identifying appropriately qualified persons to whom they have delegated significant research-related duties (on a 'per person' basis) such as a Delegation Log.

3.3.5 Where applicable ensure each Satellite Site maintains their own site Delegation Log separate to the Primary Site. The Sub-Investigator will delegate duties appropriately, sign and date the log and send a copy to the Primary Site, when requested.

3.3.6 Develop and complete a Supervision Plan before the commencement of a clinical research study that documents the manner and frequency of supervision to be undertaken between Primary Site and Satellite Site and other study staff, especially sub-investigators and other team members new to the role. The Supervision Plan must include cover for planned leave. See Appendix 5 Supervision Plan.

3.3.7 Provide oversight, as outlined in the Supervision Plan, to any third party to whom any study- related duty or function is outsourced and take responsibility for any study-related duty or function performed and any data generated by the third party.

Protocol and Investigational Brochure (IB) Requirements

1. Purpose:

To describe the procedures related to the development of a research protocol, an investigational brochure, and amendments to these documents ensuring compliance to ICH GCP E6 (R2).

2. Scope:

This Standard Operating Procedure applies to all relevant employees but not limited to visiting health professionals, contractors, consultants and volunteers who propose to undertake, administrate, review and/or govern human research involving patients and staff. All study personnel involved in the clinical study must operate within their scope of practice.

3. Procedure:

3.1 Protocol content and development

Specific content of a protocol will vary depending on the subject of the research, the level of risk to participants, the phase of research and study design, whether a medicinal product is being researched or a device or a therapeutic intervention. Consequently, the terminology will be different and should be adapted appropriately.

Where the investigator is responsible for the protocol development, they must ensure the protocol follows the outline as per ICH GCP E6 (R2) Section 6 CLINICAL TRIAL PROTOCOL AND PROTOCOL AMENDMENT(S). This protocol table of contents is not mandated but it is recommended a trial protocol should generally include the topics detailed in the section. However, site specific information may be provided on separate protocol page(s), or addressed in a separate agreement, and some of the information listed may be contained in other protocol referenced documents, such as an Investigator's Brochure.

Where Satellite Sites will be involved in the study, no specific wording will be required in the protocol, as the following considerations will be addressed in other study-specific documents which may be annexed to the protocol e.g. the site selection report, ethics application, Supervision Plan, the monitoring manual, laboratory manual, pharmacy manual, safety monitoring manual or a trial specific working guideline. Nevertheless, the following considerations are to be addressed such that protocol deviations are not created.

The manner in which Informed Consent will be taken is to be clearly described i.e. face-to-face, videoconference, via telehealth, skype, phone etc.

- Description of how study procedures will be undertaken, e.g. how visits, assessments, collection of data and medical consultations will be conducted i.e. face-to-face or via telehealth or a combination of both.
- Description of storage and handling of Investigational Product, e.g. will the Investigational Product be stored at the Primary Site and shipped to the Satellite Site via appropriate handling and shipping method when a participant is deemed eligible or will Satellite Sites with appropriate facilities store the Investigational Product?
- Description of storage and handling of laboratory samples at Satellite Sites if involved and if relevant e.g. frequency of and timelines between transport of samples to Primary Site or direct to a Central or Local laboratory.
- Description of the handling of other study related non-IMP materials
- Description of the roles and responsibilities of investigators and other staff who will be involved

in the study at both the Primary and Satellite Sites.

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3.2 Investigational Brochure (IB) content and development

Where the investigator contributes to the content and development of the Investigator Brochure, they must ensure the Investigator Brochure follows the outline as per ICH GCP E6 (R2) Section 7 INVESTIGATOR'S BROCHURE.

An example of an IB Table of Contents is found in Section 7.5 Appendix 2 section in the above link is not mandated but is recommended for use as it ensures adherence to ICH GCP E6 (R2). The IB should remain up to date via annual revision at a minimum, depending on the type of product and its stage of development.

In some situations, for investigational medicinal products, where a product is registered, and has a well-understood pharmacology, a Product Information document may be substituted for an IB, provided that current and comprehensive information about the product under study is available to the investigators. If a product is registered, but is being trialled for a new indication, or in a different population to the approved indication, an IB must be collated with reference to this new indication/population.

3.3 Amendment/s to the Protocol and IB

The Investigator must inform the GHSERC:

3.3.1 and obtain acknowledgement of receipt of the updated IB

3.3.2 and obtain approval of all amendments to the protocol including amendments that:

- are proposed or undertaken without prior GHSERC approval in order to eliminate immediate risks to participants.
- may increase the risks to participants; or
- significantly affect the conduct of the trial (including changes to the Inclusion / Exclusion criteria).

3.3.3 as soon as possible any new safety information from other published or unpublished studies that may have an impact on the continued ethical acceptability of the project or may indicate the need for amendments to the research protocol.

Notification to the GHSERC is GHSERC specific and the investigator should be familiar with the terms of reference of their ethics committee. Refer to SOP 05 Communication with **Ghana Health Service Ethics Review Committee (GHSERC)**, Research Governance (RGO), Sponsor and Institution's Insurer, regarding communication with the GHSERC.

The Investigator must provide to the RGO the GHSERC approval letter for the amendment(s) a copy (if required by the RGO) of all GHSERC approved amended documents. and obtain authorization from the RGO to continue the project where a governance aspect has been affected (if required) including protocol amendments that:

- are proposed or undertaken without prior GHSERC approval in order to eliminate immediate risks to participants.
- may increase the risks to participants
- significantly affect the conduct of the trial (including changes to the Inclusion / Exclusion criteria)
- pose a risk to the Institution.

Notification to the RGO is site specific and the investigator should be familiar with the processes of their RGO.

Communication with Ghana Health Service Ethics Review Committee (GHSERC), Research Governance (RGO), Sponsor and Institution's Insurer

1. Purpose:

To describe the procedures relating to communication with the GHSERC, RGO, Sponsor and Insurer.

2. Scope:

Applies to all relevant employees but not limited to visiting health professionals, contractors, consultants and volunteers who propose to undertake, administrate, review and/or govern human research involving patients, facilities and or staff. All study personnel involved in the clinical study must operate within their scope of practice. This SOP takes into consideration the Single Ethical Review Processes.

3. Procedure:

Communication with the GHSERC and RGO is illustrated in a tabular form in the National Mutual Acceptance Single Ethical Review of Multi-center Human Research Projects. MONITORING AND REPORTING TABLES.

3.1 Communication with Reviewing GHSERC

When communication regarding key decision points is verbal, the initiating party should follow up verbal communication with written correspondence/e-mail and send to the call recipient. The title of the letter / e-mail should include the term "FILE NOTE" followed by a text string which should include the decision topic. Such documentation must be filed in the Study Master File (SMF) and where applicable in the Satellite Site Study File (SSSF).

3.1.1 Prior to study commencement, the Investigator (CPI/PI/SI) must:

- Choose a reviewing GHSERC whose approval is acceptable to the institution/s where the clinical study is being undertaken.
- Understand the reviewing GHSERC requirements, submission processes and be aware of their meeting and submission dates to better liaise with sponsors.
- Be familiar with the relationships between GHSERC review and approval, governance authorization and any other processes/approvals that need to be in place e.g. does the GHSERC have subcommittees, before any study startup activities can commence. This process and approval flow will be required by Sponsors, auditors and inspectors.
- Submit an ethics application as per the reviewing GHSERC submission process
- Include in the relevant section of the ethics application that the trial may be undertaken using Telehealth with Satellite Sites, if applicable, and that the informed consent process and/or some or all study assessments will be undertaken using Telehealth, face to face consultation or a combination of both.
- Submit any other application as per that process found on the relevant website.
- Ensure all documentation and correspondence pertaining to the submission and approval processes is filed in the SMF e.g. correspondence to and from the GHSERC, RGO or other body.

3.1.2 During the study, the Investigator (CPI/PI/SI) must:

- No longer submit individual reports of AEs, SAEs, SUSARs, USADEs and six-monthly line listings to the reviewing GHSERC unless otherwise advised.
- Submit all documents/reports/summaries according to the requirements and timelines as stipulated on the respective reviewing GHSERC approval letter including but not limited to: sponsor reports of accumulated safety data outcome analyses; proposed changes to the protocol;

major violations; annual progress reports; and unforeseen events that might affect continued ethical acceptability of the trial.
- Immediately notify the reviewing GHSERC of any notification received from a participant in a trial that they intend to initiate a claim against either the Sponsor and/or the Institution.
- File all documentation in the SMF/SSSF.

3.1.3 At the end of the study, the Investigator (CPI/PI/SI) must:
- Submit a trial termination/closeout report according to the requirements and timelines as required by the respective reviewing GHSERC. This may be stipulated in the approval letter and/or on their website.
- File all documentation in the SMF/SSSF.

3.2 Communication with the Research Governance Office (RGO)
For the purpose of this SOP the Clinical Trial Research Agreement (CTRA), other site-specific trial-related documentation and the Site-Specific Assessment (SSA) Form constitute a research governance application for the Primary Site. Similarly, for the Satellite Site, a site-specific assessment/research governance application consists of the sub-contract, the SSA form and other site-specific trial-related documentation. This application may be submitted to the RGO in parallel to the GHSERC submission if all governance related documentation is available and completed correctly. In this case the final document to be provided to the RGO is the GHSERC approval. This has the advantage of enabling an RGO review in parallel to the GHSERC review and allows a timelier RGO authorization which may lead to expedited study start up. It is important to note, that GHSERC approval must be obtained and submitted to the RGO, prior to the final RGO authorization being granted.

3.2.1 Prior to study commencement, the Investigator (CPI/PI/SI) must:
- Submit the CTRA, the SSA Form and any other required documentation to the RGO.
- Ensure all documentation and correspondence pertaining to the submission and approval processes is filed in the SMF.
- Ensure each Satellite Site in the cluster (whether in a different Hospital and Health Service (HHS) to the Principal Investigator or the same HHS) completes a clinical trial sub-contract and a SSA Form which is a subsection of the main SSA and submits to their RGO.
- Await site specific RGO authorization before any study related activity can occur at that site.
- Ensure the Satellite Site files all documentation in the SSSF.

3.2.2 During the trial, the Investigator (CPI/PI/SI) must:
- Submit all governance related documents/reports/summaries to the relevant RGO according to the requirements and timelines as stipulated by the respective RGO including but not limited to: changes to the CTRA/sub-contract; budget; any change that might affect continued financial acceptability of the trial; any change that may increase institution risk.
- Immediately notify the RGO of any notification received from a participant in a trial that they intend to initiate a claim against either the Sponsor and/or the Institution.
- Ensure the Satellite Site files all documentation in the SSSF.

3.2.3 At the end of the trial, the Investigator (CPI/PI/SI) must:
- Notify the RGO the trial has terminated/closed.
- File all documentation in the SMF/SSSF.

3.3 Communication with the Sponsor
3.3.1 notify the sponsor within 24 hours of discovery of any Serious Adverse Events (SAE) involving trial participants under the care of the investigator and where relevant notify the PI in parallel

3.3.2 notify the sponsor promptly regarding any changes significantly affecting the conduct of the trial, and/or increasing the risk to participants and where relevant notify the CPI/PI/SI. Communication must be followed up with written report/email and filed in the SMF/SSSF
3.3.3 notify the sponsor of any Protocol Violation (which may include significant deviation from the protocol) and where relevant notify the CPI/PI/SI.
3.3.4 be available to meet with the sponsor to discuss study progress, issues and safety
3.3.5 provide the sponsor with copies of all correspondence from the reviewing GHSERC and / or RGO
3.3.6 immediately notify the sponsor of any notification received from a trial participant that they intend to initiate a claim against either the sponsor and/or the Institution.

3.4 Communication with Institution's Insurer

If the Institution is notified or becomes aware that a trial participant intends to make a claim against the Institution or Sponsor for injuries arising as a result of participating in a clinical trial undertaken at the Institution or any of the Satellite Sites under supervision by the Institution, the Institution must promptly notify the Institution's insurer in writing that such an action is intended.

3.4.1 Communication with Solicitor, Sponsor and CPI/PI/SI

If the Investigator is notified or becomes aware that a trial participant intends to make a claim against the Institution or Sponsor for injuries arising as a result of participating in a clinical trial undertaken at the Institution or any of the Satellite Sites under supervision by the Institution, the Investigator must promptly notify the following in writing that such an action is intended:

- the relevant Solicitor
- the CPI/PI/SI as relevant, and
- the Sponsor.

Site Initiation

1. Purpose:

To describe the procedures related to site initiation of a clinical trial at all sites.

2. Scope:

This standard applies to all relevant employees but not limited to visiting health professionals, contractors, consultants and volunteers who propose to undertake, administrate, review and/or govern human research involving patients and staff. All study personnel involved in the clinical study must operate within their scope of practice.

3. Procedure:

3.1 Prior to initiation of the study, the Investigator must:

3.1.1 mutually agree with the Sponsor a scheduled date, time and location for the Study Initiation Visit at the participating site or the Primary Site in the case of a tele-trial.
3.1.2 review all study related documentation and be familiar with the Investigational Product and protocol.
3.1.3 ensure that all relevant staff involved with the study, (Sub-Investigator, pharmacist, Clinical Research Coordinator and others as appropriate including trial related staff at a Satellite Site), have been advised of the meeting and are able to attend either in person or via videoconference.
3.1.4 be in possession of all required approvals and authorizations to conduct the research project.
3.1.5 ensure a Supervision Plan is in place, that documents the manner and frequency of supervision to be undertaken with other trial staff, especially those new to the role, and, where relevant, trial related staff at a Satellite Site. A Supervision Plan is to be created for each Satellite Site.
3.1.6 under the tele-trials model a Satellite Site is not initiated until such time a potentially eligible participant is identified.

3.2 During the Initiation Visit the Investigator must ensure the following are available and/or addressed:

3.2.1 Study Master File containing all required essential documents and review arrangements for organizing and maintaining study files. (Satellite Site Study File in the case of the PI initiating a Satellite Site)
3.2.2 a list of all study personnel attending the initiation meeting on an attendance log/training log with full name, signature, date and the method attended i.e. in person or via video conference.
3.2.3 original, signed and dated curricula vitae of all study personnel involved in the study at the site and any Satellite Sites for which the Investigator has responsibility.
3.2.4 other documents such as, financial disclosures, training logs, medical licenses, and other essential documents as per Sponsor requirements.
3.2.5 a contact list with names and contact details of all study personnel from all sites including Satellite Sites, Sponsor and Independent Third-Party service providers is available.
3.2.6 timeline for shipment, delivery and receipt of Investigational Product and other study related supplies to site
3.2.7 a laboratory manual, where applicable, clearly defining sample handling instructions and processes, shipping procedures, documentation handling, contact list of all laboratories involved and any other laboratory activity to be undertaken during the course of the trial.
3.2.8 a pharmacy manual clearly defining any activity linked to the handling or the IMP/IMD
3.2.9 any specialized equipment required will be available throughout the period of the trial, e.g. centrifuge, freezer, etc.
3.2.10 the eCRF, completion guidelines and that they are accessible by all sites.
3.2.11 training in all aspects required by the protocol is recorded on Training Log
3.2.12 archiving of study records at the end of the study

3.2.13 subsequent training for staff not in attendance at the Initiation Visit. Such initiation training can be conducted remotely where feasible. It is critical however that this training is undertaken and documented before they commence activities in the study.
3.2.14 Supervision Plan
3.2.15 Under the tele-trials model when a Satellite Site is initiated, the Satellite Site Study File is set up and all above steps apply at that time.

3.3 At the conclusion of the initiation the Investigator must:
3.3.1 File the sponsor's initiation visit report/letter in the SMF.
3.3.2 Ensure that the staff at the Satellite Site files all communication and documentation in the SSS

The Study Master File

1. Purpose:

To describe the procedures related to the maintenance of the Study Master File (SMF) held at all clinical research Sites/units, according to ICH GCP E6 (R2) Section 8 to ensure it is current at all times for the duration of the clinical study.

2. Scope:

Applies to all relevant employees but not limited to visiting health professionals, contractors, consultants and volunteers who propose to undertake, administrate, review and/or govern human research involving patients, facilities and or staff. All study personnel involved in the clinical study must operate within their scope of practice.

3. Procedure:

3.1 The Principal Investigator must:

3.1.1 Ensure an SMF is created, if not provided by the Sponsor, prior to study commencement and it must contain at a minimum the Essential Documents listed in Appendix 8 Example of Study Master File Index and Contents. The SMF is stored at the Primary Site.
3.1.2 Establish the maintenance rules of the SMF and relationship between Primary Site Study Master File (SMF) and Satellite Site Study File (SSSF). For example, the contents of the SSSF, how and which documents generated at the Satellite Site will be sent to the Primary Site and filed in the SMF and archiving of Satellite Site study file after study close out. When establishing the maintenance rules, it will be important to ensure that key documents from the SSSF are present in the SMF and vice-versa after the close out of the study but prior to archiving, so that a full record of all study activities under the control of the Principal Investigator is contained in the SMF.
3.1.3 Establish prior to the commencement of the trial and maintain a current record of the location of all Essential Documents including Source Documents and where relevant, study related Essential Documents from Satellite Site. The storage system used during the study and for archiving (irrespective of the type of media used) should provide for document identification and location, version history, search ability and retrieval for the length of the archiving retention time.
3.1.4 File Essential Documents in a timely manner.
3.1.5 Ensure Satellite Sites also maintain SSSF and file study related essential documents in a timely manner, with focus on version control.
3.1.6 Maintain a current contact list of all Study Personnel including staff at all Satellite Site/s within the Cluster involved in the clinical trial, clearly identifying the Primary Site, the Satellite Site and any External Service Provider.
3.1.7 Ensure study documentation is kept and archived as specified in SOP 13 Site Close Out and Archiving.

3.2 The Study Master File (SMF)

3.2.1 Study related Essential and Source Documents generated for/by the Primary Site, as per Appendix 8 at a minimum, will be filed in the SMF.
3.2.2 Certified copies of study related Essential and Source Documents generated for/by the Satellite Site, the identity of which will be established prior to the commencement of the trial, will be sent to the Primary Site and filed in the SMF, on request by either, the Sponsor, monitor or Primary Site staff as per rules established prior to the commencement of the trial and documented in the Supervision Plan

3.2.3 Where financial documentation, such as the Clinical Trial Agreement and sub-contract, invoicing and remittances etc. may be filed in a separate location to the SMF, the location is to be recorded on the SMF index. See Appendix 9 for example of Study Master File Index. A copy may be filed in the SMF if requested by the Sponsor.
3.2.4 Investigational Product handling documentation e.g. shipping, receipt, IVRS, IWRS, codes, randomization list and accountability and destruction documents etc. may be kept in a separate file e.g. at the site pharmacy. In this case the location to be recorded on the SMF index. However, the records must be made available to Sponsors, monitors, auditors and regulatory agencies at any time. The Investigational Product documentation will be archived with the SMF after completion of the study.
3.2.5 Sample handling procedures are to be clearly documented if performed e.g. in a laboratory manual. Sample management records at both Primary and Satellite Site/s including the storage, processing and transportation of samples between Satellite and Primary Sites are filed in the SMF/SSSF as agreed.
3.2.6 Other study related materials handling documentation are filed in the SMF/SSSF as agreed.

3.3 The Satellite Site Study File
3.3.1 All the relevant site-specific essential documentation pertinent to the activities that have been and that are to be performed at the Satellite Site, similar to Appendix 8.
3.3.2 All Source Documents generated at the Satellite Site.
3.3.3 Relevant GHSERC approval and governance authorization documentation.
3.3.4 Sub-contract with the clinical trial agreement in annexure.
3.3.5 Study specific supervision plan.
3.3.6 Satellite Site Delegation Log
3.3.7 Satellite Site Training Records
3.3.8Satellite Site, Site Specific Assessment form.
3.3.9 Investigational product shipping, receipt and accountability documents
3.3.10 Details of the processing, storage of samples at both Sites and transportation between Satellite and Primary Sites and related documentation (if performed)
3.3.11 Files notes indicating if the original document is found in another location e.g. pharmacy folder with the pharmacy, a document will be found in the SMF.

Handling and Shipping of Biological Substances (Cat B) and/or Dangerous Goods in Clinical Trials

1. Purpose:

To outline the procedures to follow when handling and shipping Biological Substances (Cat B) and/or Dangerous Goods in clinical trials to ensure the safety of all staff when carrying out this activity. To also outline the regulations that govern this activity in clinical trials.

2. Scope

This standard applies to all relevant employees but not limited to visiting health professionals, contractors, consultants and volunteers who propose to undertake, administrate, review and/or govern human research involving patients, facilities and or staff. All study personnel involved in the clinical study must operate within their scope of practice.
This SOP covers the handling and shipment of biological substances category B and dangerous goods (dry ice) only.
When biological samples/specimen/substances are written, category B is implied.

3. Procedure:

3.1 Handling and Shipping of Biological Substances and Dry Ice in Clinical Trials

This activity may be delegated to another staff member or third-party service provider, provided they hold a current certificate to do so. This duty is delegated as per Site Staff Qualifications, Training records and Capability. It is still the Investigator's responsibility to ensure all procedures and regulations are adhered to.

The Investigator must:

3.1.1 Ensure all study staff, who have cause to handle or ship biological substances, hold a current certificate in the IATA Approved, Ghana Aviation Safety Directives (GCAD) Certified Dangerous Goods Packaging Course.
3.1.2 Ensure specimens are handled in accordance with local and Sponsor requirements as written in the protocol and laboratory manual.
3.1.3 Ensure specimens are packed and shipped in accordance with local and Sponsor requirements as written in the protocol and laboratory manual and according to
International Air Transport Association (IATA) requirements, including that a valid export permit is in place, if required.
3.1.4 Ensure that in situations where research personnel do NOT hold current certification, arrangements for biological substance / dry ice shipment are made with IATA certified Pathology Laboratory staff or External Third Party.
3.1.5 Ensure that the National Pathology Accreditation Advisory Council (NPAAC) Requirements for the Packaging and Transport of Pathology Specimens and Associated Materials are followed by relevant certified staff.
3.1.6 Ensure any training is recorded on the training log as per SOP 03 Site Staff Qualifications, Training Records and Capability and copies of certificates are kept in the respective site file (SMF/ SSSF)
3.1.7 Ensure that documentation (e.g. receipts, shipping records, order forms, proformas etc.) related to handling and shipment of biological specimens is maintained and filed in the respective site file (SMF/ SSSF).

3.2 Notes regarding Certification to handle and transport biological substances and dry ice

3.2.1 Organise training for handling and shipping of biological substances and dry ice, staff should contact their Pathology Service/Laboratory. The Ghana Aviation Safety Directives (GCAD) Certified Dangerous Goods Packaging Course can be done by any media and must be recorded on the respective training log as per Site Staff Qualifications, Training Records and Capability.

3.2.2 GCAD Regulations have defined categories of personnel who should attend training and the subject matter in which they must be qualified. These regulations are mandatory and legally binding, consequently must be adhered to in full.

3.2.3 Re-certification is required every two years. Certificates and any training records must be kept for a minimum period of 36 months from the most recent training completion date, and must be made available, upon request to sponsor, regulatory authority, and GCAD

Research Involving Investigational Devices and HUDs

1. Purpose:

This SOP describes the requirements for research involving medical devices, including the responsibilities of Principal Investigators (PIs), IRBs, and sponsors.

2. Scope

PIs and IRBs must ensure that research (i.e., clinical investigation) involving medical devices is conducted in accordance with applicable federal regulations. These regulations describe, among other things, requirements for Investigational Device Exemptions (IDEs), use of custom devices and accountability and record retention, and responsibilities of PIs, IRBs, and sponsors when research is conducted with medical devices.

3. General Information

3.1. When human subjects research involves the use of medical devices, FDA regulations apply. Investigators must provide sufficient information about the device for the IRB to evaluate its associated risks and benefits, including the FDA approval status of the product (i.e., approved for marketing or investigational).

3.2. Medical devices can receive FDA approval or clearance for marketing in several different ways. Examples include pre-market approval, which is given following clinical trials to determine the safety and efficacy of a new device, and marketing clearance (pre-market notification), granted by FDA when a device is determined to be "substantially equivalent" to a device already on the market. Investigational devices include medical devices under clinical investigation to test their safety and efficacy, as well as investigation of certain modifications, or new intended uses of already marketed devices.

3.3. The FDA requirements for studies involving investigational devices are proportional to the potential risk level. Studies presenting a significant risk to subjects must be conducted under an IDE. Non-significant risk studies do not require an IDE but must meet the abbreviated IDE requirements. Certain investigational device studies are exempt from the IDE requirements.

3.4. When an IDE is required for the proposed use of an investigational device in research, investigators must submit an application to FDA. An IDE number will be assigned by FDA upon receipt of the application, and studies shall be initiated upon receipt of the IDE number. Final IRB approval will not be given until a valid IDE number is provided.

3.5. An investigator obtaining an IDE for the proposed use of an investigational device in research becomes a "sponsor-investigator" and additional institutional resources are available to assist investigators in complying with applicable FDA regulations.

3.6. FDA regulations allow sponsors to charge for an investigational device. The charge should not exceed an amount "necessary to recover the costs of manufacture, research, development, and handling of the investigational device." Proposed charges are included in the IDE application. The IRBs should ensure that charges for investigational devices appear appropriate and equitable and that any additional costs to subjects are disclosed during the consent process.

3.7. In certain non-emergency situations, an investigational device intended to treat a serious or immediately life-threatening condition may be used under a Treatment IDE. Such "treatment use" of an investigational device requires IRB review and approval.

3.8. The "compassionate use" of an investigational device allows access for a patient (or small group of patients), who does not meet the requirements for inclusion in a research protocol for the device, but for whom a physician believes the device may provide benefit in treating and/or diagnosing the disease or condition. Such use of an investigational device is considered a protocol "deviation" for which prior FDA approval and reporting to the IRB is required.

3.9. Additional requirements apply to the emergency use of an investigational device or biologic and planned emergency research involving investigational devices subject to FDA regulations.

3.10. Although custom devices and humanitarian use devices are not investigational, additional FDA requirements apply to their use, including IRB notification or review as described below (see "Custom Devices" and "Humanitarian Use Devices").

4. Submission and Pre-Review Procedures

4.1. To describe proposed uses of medical devices in human subject research, PIs will indicate in their UGMC protocol submission that they will be using devices in their proposed research.

4.2. During the pre-review process, UGMC grants administration staff are responsible for making an initial determination about the FDA requirements applicable to the device's use. For investigational devices, one of the following determinations must be made:

- The device requires an IDE (i.e., significant risk (SR) device research);
- The device fulfils the requirements for an abbreviated IDE (i.e., non-significant risk (NSR) device research); or
- The device meets one of the FDA exemptions from the IDE requirements.

4.3. When the research involves a device with an IDE, UGMC grants administration staff will verify that the IDE number provided by the PI is valid. Protocol-specific confirmation (e.g., sponsor's protocol cover sheet, FDA or sponsor correspondence, etc.) will be obtained.

5. IRB Review

5.1. The convened IRBs will review proposed research involving investigational devices considering the criteria for approval.

Note: Research involving a device for which an IDE (including an abbreviated IDE) is required is not eligible for expedited review.

5.2. When research involves the use of a device, to approve the research the IRBs will also require the following:

- Available clinical and non-clinical information on the investigational product that is adequate to support the proposed research and to make the SR/NSR determination (when applicable).
- Documentation of a valid IDE, unless the proposed use of the device fulfils the requirements for an abbreviated IDE (NSR device) or meets one of the FDA exemptions from IDE requirements.

- An adequate plan for monitoring data to ensure the safety of subjects and for reporting adverse events and unanticipated problems involving risks to subjects or others.
- A plan for control, accountability, and storage of the investigational device that ensures that the product will be used only in the approved research under the direction of the approved investigator(s); and
- For sponsor-investigators, that they are knowledgeable about and will comply with additional FDA requirements associated with conducting research for which an IDE has been obtained.

6. Significant and Non-Significant Risk Devices

6.1. Significant risk (SR) device studies pose the potential for serious risk to the health, safety, and/or welfare of research subjects. Examples include studies involving surgical sutures, cardiac pacemakers, intravascular stents, and orthopedic implants. An IDE is required for SR device studies.

6.2. Non-significant risk (NSR) device studies do not present potential serious risks to subjects. Examples include studies involving most daily-wear contact lenses and lens solutions, ultrasonic dental scalers, and foley catheters. NSR studies do not require an IDE but must follow the abbreviated IDE requirements.

6.3. Sponsors are responsible for making the initial risk determination for a proposed investigational device research project. The IRB must review the sponsor's SR or NSR assessment and may modify the determination if the IRB disagrees. If the FDA has made the SR or NSR determination prior to IRB review, the IRB is not required to make this determination (FDA's determination is final).

6.4. The IRB will make the SR or NSR determination for a protocol by convened review. A description of the device, reports of prior studies conducted with the device, proposed investigational plan, risk assessment, and subject selection criteria should be considered. The sponsor's rationale for its SR or NSR determination (unless already determined by FDA) should also be reviewed. The SR/NSR determination must be documented in the IRB minutes, including a description of the reason(s) for the IRB's decision.

6.5. The IRB is not required to make a SR/NSR determination for studies involving devices that meet the criteria for exemption from the IDE regulations.

7. Expanded Access

7.1. Expanded access, sometimes called "compassionate use," is the use outside of a clinical trial of an investigational medical product (i.e., one that has not been approved by the FDA). Expanded access refers to the use of a medical device when the primary purpose is to diagnose, monitor, or treat a patient's disease or condition rather than to obtain the kind of information about the device that is generally derived from clinical trials. Except for emergency expanded access use, when there is not sufficient time to secure prospective IRB review, an investigator treating a patient with an investigational device under expanded access is responsible for obtaining IRB review and approval before treatment with the investigational device may begin.

7.2. Under FDA's current regulations, there are three categories of expanded access:

- Expanded access for individual patients, including for emergency use.
- Expanded access for intermediate-size patient populations (smaller than those typical of a treatment IDE or treatment protocol – a treatment protocol is submitted as a protocol to an existing IDE by the sponsor of the existing IDE); and
- Expanded access for widespread treatment use through a treatment IDE or treatment protocol (designed for use in larger patient populations).

8. Investigational Device Control, Accountability, and Record Retention

8.1. Investigational devices used in UGMC clinical trial research must be appropriately controlled and stored in compliance with IRB and FDA requirements and applicable policies. Such requirements include processes to ensure that investigational products are manufactured, handled, and stored in compliance with applicable good manufacturing practices; inventory and accountability records are maintained for investigational device receipt, dispensing, and disposition; and investigational devices are used only in accordance with available information regarding their design, physical and chemical composition, performance, safety, biocompatibility, labeling, and the approved protocol.

9. Additional Responsibilities of Sponsor-Investigators

9.1. Investigators obtaining an IDE to initiate and conduct research must also fulfill the federal requirements of sponsors. These requirements include (but are not limited to) additional FDA reporting (e.g., annual progress reports, data monitoring, and recordkeeping obligations). Additional institutional assistance may be available when an investigator wishes to obtain an IDE to perform human subjects research. Sponsor-investigators may be referred to any number of institutional groups who can assist with IDE requirements related to being a sponsor-investigator.

9.2. In addition to FDA regulations for the protection of human subjects, (21 CFR Parts 50 and 56), additional regulations may apply to sponsor-investigators, depending on the nature of the research. It is the responsibility of the investigator to become familiar with these regulations and requirements if they become a sponsor-investigator for FDA-regulated research. These regulations could include:

- Electronic Records/Signatures (21 CFR 11).
- Financial Disclosure by Clinical Investigators (21 CFR 54).
- Medical Device Reporting (21 CFR 803).
- Establishment Registration and Device Listing for Manufacturers and Initial Importers of Devices (21 CFR 807).
- In Vitro Diagnostic Products for Human Use (21 CFR 809).
- Pre-market Approval of Medical Devices (21 CFR 814).
- Medical Devices: Quality System Regulation (21 CFR 820).
- Medical Device Classification Procedures (21 CFR 860); or
- Laboratory Requirements (42 CFR 493).

9.3. Additional Human Subject Protection training (CITI GCP Course for Clinical Trials Involving Investigational Devices or GCP Course for Clinical Trials with Investigational Drugs or Biologics) for first-time sponsor-investigators will be required prior to protocol approval and activation of the FDA-regulated research.

10. In Vitro Diagnostics (IVD)

Leftover specimens are frequently used in feasibility studies and studies to characterize the performance of new in vitro diagnostic devices. Routine clinical care testing can provide information about the laboratory characteristics of the specimen that allow investigators to quickly ascertain whether the specimen will meet the research protocol inclusion criteria. The remnants of these specimens therefore become valuable to the research at a point when they are of no value to the patient and are ready to be discarded. It is possible, in certain circumstances, for IVD devices to be conducted using leftover specimens obtained without informed consent while protecting the human subjects who are the sources of such specimens. FDA can exercise enforcement discretion as to the informed consent requirements if the following are true:

- The research protocol meets IDE exemption criteria.
- The research protocol uses leftover specimens;
- The specimens are not individually identifiable.
- The clinical information accompanying the specimens does not make the specimen identifiable.
- The individuals caring for the patients are different from, and do not share information about, the patient with those conducting the research;
- The specimens are provided to the investigator(s) without identifiers and the supplier of the specimens has established policies and procedures to prevent the release of personal information; and
- The research protocol has been approved by an IRB.

11. Humanitarian Use Devices

11.1. An approved humanitarian device exemption (HDE), containing sufficient information for FDA to determine that the probable benefits outweigh the risks of a device's use, is required for marketing a humanitarian use device. **Note:** Results from scientifically valid clinical investigations demonstrating efficacy are not required for HDEs.

11.2. Humanitarian use devices (HUDs) are marketed products; therefore, their use does not constitute research when used according to the approved labeling. However, IRB approval is required before the HUD is initially used at an institution. FDA regulations require that initial IRB review and approval of the HUD occur at a convened meeting. Continuing review must be performed at least annually but may be conducted by expedited review procedures.

11.3. IRB review of HUDs should consider the criteria for approval (as applicable) described by regulations and UGMC IRB Full Board Review. The following materials should be reviewed:

- HDE approval order.
- Description of the device.
- Product labeling.
- Patient information packet.
- Consent form; and
- Summary of the proposed use of the device, including a description of any screening procedures, HUD procedure, and any follow-up visits, tests, or procedures for patients.

Patient information packets are available for most HUDs and contain a description of the potential risks and benefits of the HUD and any procedures associated with its use. The HDE approval order, product labeling, and patient information packet for a HUD can be obtained from the FDA.

11.4 Informed consent should be obtained orally or in writing before HUD use. Minimally, the consent process should contain a discussion of the potential risks and benefits of the HUD, description of the procedures associated with its use, and a statement that the device is a "humanitarian use device" that has not undergone clinical testing for effectiveness. Use of the HUD should not be referred to as "research" or a "clinical investigation." The IRBs will approve the consent process, its content, and any associated documents (i.e., consent form, information packet, etc.) that will be distributed to recipients of the HUD.

11.5 FDA regulations require the institution and/or device manufacturer to report to FDA, and the IRB, deaths or serious injuries that may have been caused by a HUD or malfunctions that would, "be likely to cause or contribute to a death or serious injury if the malfunction were to recur."

11.6 Investigational use of a HUD (i.e., for broader or different indication than approved by FDA) requires an approved IDE in addition to IRB approval when the HUD is a significant risk device. For more information on HUDs, including investigational and emergency uses, see FDA Guidance on HDE Program.

Management of Investigational Product

1. Purpose:

To describe the procedures related to managing all aspects of Investigational Product, either medicinal product or device. Management includes but is not limited to the receipt, storage, accountability, preparation and administration, shipment and destruction of investigational product. Note: Re-labelling of investigational product is not covered here as it will follow the procedures sent to the sites by the sponsor or follow the institution's pharmacy procedures for re-labelling.

2. Scope

This standard applies to all relevant employees but not limited to visiting health professionals, contractors, consultants and volunteers who propose to undertake, administrate, review and/or govern human research involving patients and staff. All study personnel involved in the clinical study must operate within their scope of practice.

3. Procedure

3.1 Management of Investigational Product (Medicinal Product or Device)

Responsibility for Investigational Product (IP) management and accountability at the trial site rests with the Principal Investigator (PI). However, the PI may delegate responsibility for IP management to the site pharmacist or, where a pharmacist is not available or involved, to an appropriately qualified person (as per Site Staff Qualifications, Training Records and Capability).

The site pharmacist or the appropriately qualified person will undertake management of the Investigational Product at the Primary Site and / or the Satellite Site. Where the delegation of this activity requires supervision (e.g. pharmacist or appropriately qualified person new to the role), the delegated activity is to be clearly documented on the Supervision Plan, the Delegation and Training Logs. (see Site Staff Qualifications, Training Records and Capability).

The Investigator, Pharmacist or appropriately qualified non-pharmacist must:

3.1.1 Ensure the Investigational Product is used only in accordance with the approved protocol.

3.1.2 Maintain records of all aspects of the management of the Investigational Product. These records at a minimum should include: shipping documents; date of each transaction; quantities; batch/serial numbers; expiration dates/retest dates (if applicable); temperature logs showing the storage conditions of investigational product throughout the trial period; the set of unique code numbers assigned to the Investigational Product and to the trial participant; and record of destruction/return.

3.1.3 Provide maintenance and calibration records for storage equipment (e.g. refrigerators, thermometers) in accordance with sponsor requirements.

3.1.4 Ensure that the Investigational Product is received, stored respecting correct temperature control, prepared, administered, shipped and destroyed as specified by the sponsor in accordance with the Protocol, pharmacy manual and applicable regulatory requirement. Consideration must be given to security of the Investigational Product, with restricted access to approved personnel.

3.1.5 Ensure any deviation to required temperature, storage conditions, potential defect / issue with IP is notified to sponsor in a timely manner and in accordance with study Protocol. Follow study site quarantine process as applicable.

3.1.6 Explain the correct use of the Investigational Product to each participant and should check, at intervals appropriate for the trial, that each participant is following the instructions

properly. Instruct participant where relevant to return empty and partially used medication containers at their next visit. Extra counselling by the investigator or delegate, for study participants regarding poor medication compliance may be required.

3.1.7 Follow the trial's randomization procedures, if any, and ensure, for blinded studies, the blind is broken only in accordance with the protocol. For a blinded study, the investigator must promptly document and explain to the sponsor any premature unblinding (e.g., accidental unblinding, unblinding due to a serious adverse event) of the Investigational Product.

3.1.8 Where the Investigational Product is shipped to, and/or returned from, a Satellite Site, a written working instruction or procedure documenting the manner in which this process is to occur must be in place at the Primary Site pharmacy. The sponsor will require evidence of this document for the Primary Site to manage the Satellite Site stock. The document must address, at a minimum, aspects of IP shipment such as: the appropriate transfer method, respecting temperature control and monitoring thereof; clear identification of what is being shipped; that the IP is to be used according to the sponsor's guidelines; relevant documentation to accompany the shipment; acknowledgement of receipt by Satellite Site or Primary Site; delivery information of IP from or to the Primary Site; filing of relevant documentation at both sending and receiving sites.

3.1.9 File all relevant trial-related documentation in the SMF/SSSF as per Study Site Master File.

Study Closure and Archiving in a Clinical Trials at the University of Ghana Medical Centre

1. Purpose:

The purpose of this Standard Operating Procedure (SOP) is to provide guidelines for the closure of a clinical trial conducted at the Clinical Trials Unit (CTU) at the University of Ghana Medical Centre (UGMC). This SOP outlines the procedures for ensuring the completion of all study-related activities, including data lock, final data analysis, study report preparation, and archiving of study documents in compliance with applicable regulations and guidelines.

2. Scope:

This SOP applies to all personnel involved in the conduct of clinical trials within the CTU, including principal investigators, co-investigators, study coordinators, research nurses, data managers, and any other individuals responsible for study closure activities.

3. Study Closure Responsibilities:

3.1. Principal Investigator (PI):

3.1.1. The PI is responsible for overseeing the study closure process and ensuring compliance with regulatory requirements.
3.1.2. The PI shall coordinate the activities of the study team members involved in study closure.
3.1.3. The PI shall ensure that all study-related activities are completed in a timely manner and according to the protocol and applicable regulations.

3.2 Study Team Members:

3.2.1. All study team members shall actively participate in the study closure process and fulfill their assigned responsibilities.
3.2.2. Study team members shall ensure that all study-related data, documents, and materials are appropriately collected, organized, and prepared for study closure.

4. Study Closure Procedures:

4.1. Data Lock:

4.1.1. The data lock process involves the completion of all data collection, data entry, and data cleaning activities.
4.1.2. The data lock shall be initiated by the data management team upon completion of the final data entry and verification.
4.1.3. Once the data lock is implemented, no further changes or modifications should be made to the study database unless justified and documented.

4.2. Final Data Analysis:

4.2.1. The data management and biostatistics teams shall perform the final data analysis using the locked database.
4.2.2. The analysis shall be conducted according to the statistical analysis plan (SAP) specified in the study protocol.

4.3. Study Report Preparation:

4.3.1. The study report shall be prepared by the study team in collaboration with the PI.

4.3.2. The study report should include a summary of study objectives, methodology, results, and conclusions.

4.3.3. The report should follow the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) guidelines and other applicable regulatory requirements.

4.4. Archiving of Study Documents:

4.4.1. All study-related documents, including the protocol, informed consent forms, CRFs, monitoring reports, and correspondence, shall be archived in accordance with Good Clinical Practice (GCP) guidelines and applicable regulations.

4.4.2. The study documents shall be securely stored and retained for the specified period as per regulatory requirements.

5. Study Closure Checklist:

5.1. A study closure checklist shall be developed and utilized to ensure that all study-related activities are completed before finalizing the closure process.

5.2. The checklist should include items such as data lock confirmation, completion of final data analysis, preparation of the study report, and archiving of study documents.

6. Revision and Approval:

6.1. This SOP shall be periodically reviewed and updated as necessary to ensure compliance with evolving regulations, guidelines, and best practices.

6.2. Any changes or updates to this SOP shall be communicated to all relevant personnel, and training on the revised procedures shall be provided as necessary.

7. References:

List any relevant regulations, guidelines, or reference documents applicable to study closure in clinical trials.

Note: This SOP is a general guideline tailored to the specific requirements and regulations of the University of Ghana Medical Centre's Clinical Trials Unit.