102.1A INVESTIGATOR INITIATED RESEARCH STUDIES

I. PURPOSE:
This Standard Operating Procedure (SOP) describes the standards for conducting Investigator-Initiated Research at the University of Tennessee Graduate School of Medicine (GSM) and the requirements for ensuring the necessary oversight and compliance measures.

II. DEFINITION:

Investigator Initiated Research is research developed, initiated, and managed by a non-pharmaceutical company researcher, like an individual investigator or institution in which they have written and plan to execute the protocol. Essentially, the investigator serves as the Sponsor-Investigator for this type of research.

Sponsored Research is research developed, initiated, and managed by a pharmaceutical company, and compensation is provided to an individual investigator or institution to execute the protocol at the site level.

III. SCOPE:
This SOP provides instruction and sets minimum standards regarding the process for an investigator who is implementing an investigator-initiated research protocol at GSM. This SOP is not intended to supersede regulations set forth by the Federal Code but is intended to set a minimum standard for all investigators who wish to conduct investigator-initiated research.

IV. RESPONSIBLE INDIVIDUALS:
This SOP applies to all investigators engaging in investigator-initiated research including those studies that are regulated by the Food and Drug Administration Code of Federal Regulations (FDA CFR) under an Investigational New Drug (IND- 21 CFR Part 312) or Investigational Device Exemption (IDE- 21 CFR Part 812). The Dean of the GSM, Department Chairs, and Director of Research are charged with ensuring that this review is complete and thorough. It is encouraged that other senior research members within the department be available as mentors for anyone conducting investigator-initiated research within a particular department.

V. PROCEDURES

i. Mentoring Young Investigators
If the investigator is not experienced in the conduct of clinical research at GSM, the Director of Research or designee will identify a mentor in the applicable field, preferably during the study design phase.

ii. Project Feasibility Assessment
Before beginning a new research proposal at the GSM, investigators are strongly encouraged to complete a protocol feasibility assessment to ensure there are adequate
resources, including potential participants, to successfully conduct and complete the study. This will include an evaluation from the Director of Research and/or the GSM Assistant Director of Research, Biostatistician, and if needed, the Clinical Director of the Office of Clinical Trials at UHS.

iii. Protocol Oversight/Sponsorship
The Investigator of an Investigator-Initiated Study that is regulated by the FDA under an IND (21 CFR Part 312) or IDE (21 CFR Part 812) must have a GSM faculty member (MD/PhD; MD; DO; OD) as the PI. The FDA regulated trial must be within the sponsor-investigator’s scope of practice. In addition, the acting Sponsor-Investigator must not delegate the primary responsibly of oversight, project implementation, and treatment oversight to a trainee or anyone else who is not qualified. However, the PI will, at all times, maintain total responsibility for the conduct and execution of any clinical research project regardless of who has been delegated the responsibility of study management.

The oversight of a clinical study is critical to the successful outcome of a research project. Active engagement of the principal investigator is necessary to ensure data collection methods are completed ethically in accordance with all federal state and local regulations.

iv. Project Design/Protocol Creation
The creation of a protocol includes:
1. A project design that will meet scientific and ethical review
2. Informed consent form describing potential research volunteer risks and benefits
3. Corresponding study budget and coverage analysis to ensure adequate funding to complete the study if applicable.
4. The retention and management of Essential Trial Documents
5. The PI will provide the Assistant Director of Research with a signed copy of the GSM Investigator Statement of Responsibility for Conducting Clinical Research.

Templates, including protocol and consent forms, are available for all GSM Researchers via the Director of Research, Assistant Director of Research, or the IRB office.

v. Investigational Products
If the investigator-initiated research proposal includes the use of a drug, device, and/or biologic and the investigator is unsure if it is approved for use by the FDA for the study’s therapeutic target, the investigator should contact the Regulatory & FDA Guidance Core https://www.fda.gov/regulatory-information/search-fda-guidance-documents for assistance in helping to determine if the protocol needs to be reviewed by the FDA.

vi. Study Funding
The Investigator must identify external funding or sufficient non-operating internal funding to support the research plan, or provide detailed documentation of how trial procedures will be conducted without funding to the GSM Dean, Director of Research, or their designee (Assistant Director of Research).
vii. Data Management
The FDA mandates that any study regulated under the Code of Federal Regulations must adhere to FDA 21 CFR Part 11 Compliance (link below), or the electronic storage and entry of clinical research information. Research that is not regulated by the FDA is not held to this standard, however, every measure should be taken to ensure all research information and data is stored in a secure location to minimize risk. 
https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm

viii. Study Implementation and Oversight
Investigator-Initiated Research requires an increased level of regulatory and clinical coordination support and knowledge. Each investigator should ensure that they have experienced regulatory and clinical support (GCP train and CITI certified) to help conduct the research study and maintain compliance throughout the course of the study.

If experienced personnel are not available within a department to assist with an investigator-initiated research study, the investigator must provide details as to who will be completing all necessary regulatory and clinical coordination. The GSM Dean, Director of Research, Assistant Director of Research, and Biostatistician can help facilitate identification of the appropriate support.

VI. FEDERAL AND LOCAL COMPLIANCE
The Code of Federal Regulations (21 CFR Part 312 and 812) mandates that the sponsor of a drug, device, or biologic research trial provide independent monitoring of the information relating to their research trial (this is independent from the function of a Data Safety Monitoring Board, IRB or a Medical Monitor). The FDA acknowledges the responsibility of the placement of a monitor to be with the sponsor-investigator. Investigators must create a monitoring plan that describes how the trial will be reviewed for regulatory compliance. The GSM Dean, Director of Research or Assistant Director of Research facilitates this regulatory requirement with the investigator, and in some cases, in coordination with the UHS Office of Clinical Trials and IRB.

VII. TRANSFERRING INVESTIGATOR-INITIATED TRIALS TO THE OFFICE OF CLINICAL TRIALS
If an investigator-initiated trial will be conducted with the OCT resources, investigators will follow the OCT SOPs for conducting research. The GSM Assistant Director of Research will provide these SOPs and OCT contact information.

VIII. REFERENCES
FDA 21 CFR Part 312 Investigational New Drug Application
FDA 21 CFR Part 812 Investigational Device Exemption
FDA 21 CFR Part 11 Electronic Records; Electronic Signatures – Scope
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