# 102.1B QUALITY ASSURANCE AND MONITORING PLAN

## I. PURPOSE:

This Standard Operating Procedure (SOP) describes the process for identifying the Quality Assurance Pathway and Monitoring Plan for Investigator-Initiated Research projects conducted at the University of Tennessee Graduate School of Medicine (GSM) and on the University of Tennessee Medical Center campus that requires the informed consent of patients.

## II. SCOPE:

Per GSM institutional guidelines, and in coordination with UTMC research compliance-requirements, this SOP provides instruction and sets minimum standards regarding the process for implementing an Investigator-Initiated Research protocol Quality Assurance Pathway. This SOP is not intended to supersede l 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.

## III. RESPONSIBLE INDIVIDUALS:

This SOP applies to all GSM 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), Investigational Device Exemption (IDE- 21 CFR Part 812), or studies requiring the Informed Consent of Patients. The GSM Dean, Department Chair, and/or Director of Research or designee is charged with ensuring that this review is complete and thorough.

## IV. PROCEDURES

Investigator-Initiated Research that requires the use of a written Informed Consent Form (ICF) will require Routine Monitoring for Quality Assurance and Compliance.

A Quality Assurance and Monitoring Plan Strategy *IS NOT REQUIRED* for low risk studies that do not require the informed consent of patients. However, GSM SOPs and Good Clinical Practice will still be applicable and monitored via investigator oversight.

The IRB will include the GSM Assistant Director of Research and UHS Executive Director of Research in IRB approval notifications via email for any GSM clinician conducting Investigator-Initiated Research that requires the written consent of participants.

The GSM Assistant Director of Research and UHS Office of Clinical Trials (OCT) Director will review IRB approved protocols that meet the previously stated criteria and determine which GSM-UHS approved pathway for Quality Assurance and Monitoring will be required.

Once the appropriate pathway is identified, the Quality Assurance designee (UHS or GSM) will then notify the PI and work with them to ensure appropriate Standard Operating Procedures are reviewed, the Investigator Statement of Responsibility has been signed, and other Essential Trial Documents needed to facilitate their compliance pathway are reviewed/initiated prior to the enrollment of any study subjects.

## V. 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). In addition to CFR regulations, GSM recognizes the need for independent monitoring of any research study in which an Informed Consent is required from patients.

APPROVED:

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