

106.1 STEPS TO CONDUCT A CLINICAL RESEARCH STUDY

Additionally: For OCT/Sponsored Trials, Please Refer to Office of Clinical Trials SOPs

I. PURPOSE

To define the steps and procedures needed to conduct a clinical research study involving the use of an investigational drug or device from initiation to closure.

II. SCOPE

This SOP applies to the activities involved in conducting clinical trials at the investigator's site. The following members of the research team should be familiar with this SOP:

- Principal Investigator
- Sub or Co Investigators
- Clinical Trials personnel
- Study Pharmacist
- Any support staff significantly involved in the study

III. REGULATIONS/GUIDELINES

- 45 CFR 46: e.g. 46.101 Research that is neither conducted nor supported by a federal department or agency but is subject to regulation as defined in 46.102(e) must be reviewed and approved, in compliance with 46.101, 46.102, and 46.107 through 46.117 of this policy by an institutional review board (IRB) that operates in accordance with the pertinent requirements of this policy.
- 21 CFR 50: e.g. 50.20 No investigator may involve a human being as a subject in research covered by these regulations unless the investigator has obtained the legally effective informed consent.
- 21 CFR 54: e.g. 54.6 Record keeping and Record retention of Financial Disclosure by Clinical Investigators.
- 21 CFR 56: e.g. 56.103 Circumstances in which IRB review is required.
- ICH Good Clinical Practice

IV. DEFINITIONS:

- The Glossary of definitions presented in ICH E6 Good Clinical Practice: Consolidated Guidance sections 1.1-1.62 apply to this SOP

V. ROLES/PROCEDURES FOR TRIALS CONDUCTED BY THE OFFICE OF CLINICAL TRIALS (OCT)

Please refer to OCT SOP 203 Version 1.3 Dated June 1, 2017

VI. ROLES/PROCEDURES FOR STUDIES CONDUCTED AT THE GSM

1. Pre-Trial Phase:

The University of Tennessee Knoxville Graduate School of Medicine

- a. PI in collaboration with GSM Research Leadership will complete feasibility of the protocol. Feasibility of protocol, procedures, and site resources should be completed prior to IRB submissions. Please refer to GSM SOP 102.1-102.2.

This should include a *risk assessment* of trial procedures, time availability, support resources, and patient recruitment strategies.

- b. Team members are trained on applicable aspects of the protocol, GSM SOPs for conducting research activities, IRB / FDA regulations, and Good Clinical Practice.
- c. Final Protocol and Consent forms are submitted to the IRB for approval
- d. UHS Application to conduct research is submitted (GSM Assistant Director of Research can provide the one-page application)
- e. Source documents and electronic databases should be created and tested for any errors.
- f. Clinicaltrial.gov Registration if applicable. (The GSM Assistant Director of Research can facilitate this)
- g. Regulatory binders, depending on the nature of the study may include:
 - i. IRB submissions/approvals
 - ii. Fully executed CTA if applicable
 - iii. FDA 1572 if applicable
 - iv. Protocol
 - v. Investigational Brochure if applicable
 - vi. Informed Consent
 - vii. Training logs
 - viii. Delegation of Authority logs
 - ix. Master subject log/Patient Identification Log
 - x. Drug Accountability log (may be retained by pharmacy)
 - xi. Source documents
 - xii. Case Report Form copies
 - xiii. Study correspondence

** GSM Research Support Staff can assist with the construction of the study regulatory binders if needed. **

- h. Study supplies are received, and documentation of receipt filed within regulatory binders.
- i. Investigational drug/device(s) are received (if applicable) and stored properly within the pharmacy or other appropriate designated investigational drug accountability binders/documents.

2. Trial Phase:

Research team under the direction of the PI will:

- i. Recruit subjects
- ii. Obtain Informed Consent from subjects
- iii. Enroll subjects
- iv. Monitor for adverse events and serious adverse events
- v. Report AE/SAE appropriately to regulating institutions (IRB, Sponsor, and FDA: CFR Title 21 part 312 -- investigational new drug application

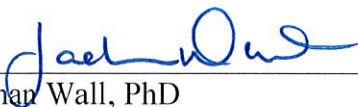
- subpart B--Investigational New Drug Application (IND) Sec. 312.32 IND safety reporting).
- vi. Comply with applicable federal, local laws, regulations, and/or guidelines
 - vii. Ensure proper reporting of protocol deviations/violations to the IRB and other appropriate regulating entities if applicable.
 - viii. Perform measures to facilitate subject retention
 - ix. Maintain records/essential documents
 - x. Perform subject visits and procedures per protocol
 - xi. Manage, collect, and process/ship specimens per protocol
 - xii. Complete paperwork necessary for subject payments
 - xiii. During the course of a trial, any protocol amendment approved by the IRB, and documentation of protocol amendment training, will be filed within the regulatory binder.
 - xiv. Any protocol amendment that results in a change to the ICF, will require any active subjects to be re-consented at their next scheduled visit, or sooner if applicable.
 - xv. Dispense/return and maintain study drug accountability
 - xvi. Reconcile all queries as required
 - xvii. If applicable, follow the GSM/UHS Monitoring Pathway for Quality Assurance and Compliance. Please refer to GSM SOP 102.1B.

3. Trial Closure:

Research team under the direction of the PI will:

- i. Reconcile queries as required in any electronic database
- ii. Provide accountability, return, and/or destruction of study product per institutional guidelines
- iii. Provide notification of study termination to the IRB
- iv. Complete Clinicaltrials.gov study outcome and data information
- v. Archive and store any study materials appropriately per GSM Policy

APPROVED:



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9/23/21
Date



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09/23/2021
Date