107.1 ACCRUAL, ORGANIZATION, REVISION, AND STORAGE OF ESSENTIAL DOCUMENTS AND SUPPLIES FOR INVESTIGATOR INITIATED STUDIES

I. PURPOSE

To describe the accrual, organization, revision, and storage of essential regulatory study documents. Essential documents are generated throughout various stages of a clinical study, from study start-up to completion, and maintained for a period of time thereafter. This SOP is intended to assist research personnel conducting GSM clinical research comply with FDA regulations, ICH GCP, IRB, and GSM guidelines concerning essential study documents.

II. SCOPE

This SOP applies to the activities involved in creating and maintaining essential documents for all clinical studies conducted by GSM investigators. The PI and his/her study team are responsible for the collection, storage, timely submission, and quality of study data collected during study activities. In addition, the PI and study team are responsible for maintaining all administrative and regulatory documents critical to the conduct of the study. This body of information is known as the 'Essential Documents' or "Trial Master File". The PI may deem study team members qualified to assist in the accrual, collection, management, and storage of essential documents for their clinical study. Study team members who assist in this responsibility may include the following:

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

Responsible team members will be identified for each individual clinical study on the "Delegation of Authority" (DOA) log. This log can be drafted by the investigator or provided to the investigator for completion by the Assistant Director of Research if requested.

III. BACKGROUND

Federal regulations require documentation of all study-related activities. The sponsor, IRB, clinical study team, and regulatory entities review regulatory files and research documents. These records serve as the site's proof of compliance with good clinical practice, local, and federal regulations.

IV. REGULATIONS/GUIDELINES

- 45 CFR 46: e.g. 46.115 (a) (1) "Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent documents, progress reports submitted by investigators, and reports of injuries to subjects." 21 CFR 11; e.g. 11.1 (b) "This part applies to records in electronic form that are created,

modified, maintained, archived, retrieved, or transmitted, under any records requirements set forth in agency regulations."

- 21 CFR 54: e.g. 54.6 Record keeping and Record retention of Financial Disclosure by Clinical Investigators. 21 CFR 312.62: Investigator record keeping and record retention (addressing IND study requirements re: disposition of drugs, case histories, and record retention).
- 21 CFR 312.64: Investigator reports (addressing IND study requirements re: progress reports, safety reports, final reports, and financial disclosure reports).
- 21 CFR 812.140, .145, and .150: Addressing IDE study requirements re: records, inspections, and reports.
- ICH Good Clinical Practice: Consolidated Guidelines: e.g. 4.9.1 The Investigator should ensure the accuracy, completeness…of the data reported…

V. ROLES/PROCEDURES

1. PI/designee will allocate specific short term (while study is active) and long term (after study completion) storage space for study documents prior to study initiation.
2. Study/Regulatory documents will be organized in a manner that is easily accessible and preferably in a ringed binder with appropriate tabs. Study documents will be maintained in a secure location with access restricted to authorized personnel. All of the documents addressed in this SOP must be available for audits/inspections.
3. The PI/designee will maintain a regulatory file for each study and should include the following documents if applicable: * GSM Research Support Staff can assist with the construction of the study regulatory binders if needed. *
    a. GSM SOP's
    b. IRB submissions/approvals
    c. FDA 1572 if applicable
    d. Investigational Brochure if applicable
    e. Protocol and amendments
    f. Informed Consent (all versions)
    g. Training logs
    h. Delegation of Authority logs
    i. Master Subject Log/Patient Identification Log
    j. Drug Accountability log (may be kept with pharmacy until study closure)
    k. Subject Source Documents
    l. Case Report Form copies
    m. Study specific correspondence
    n. Advertising material if applicable
    o. Patient dairies and questionnaires if applicable
    p. Study supplies (lab kits and any equipment that might need calibrations)
4. The PI/designee will update the regulatory/study file(s) as necessary to keep documents current. A study document will be created and/or filed as soon as possible after the correspondence and/or event has occurred.

5. The PI/designee will keep study documents organized and complete. If any study documents are filed separately from the regulatory file, a note-to-file will be placed in the study/regulatory file detailing where the document is stored and can be located.
6. The PI/designee will review essential documents for completeness at regular intervals and prior to inspections and/or audits.
7. Discrepancies in any essential document must be noted by creating a note-to-file describing the discrepancy, its origin(s) and resolution(s).
8. After study closure, the PI/designee will archive regulatory and all other study files in a secure location with limited access. Retention or destruction of essential documents should be in accordance with the institutional regulations.
9. Electronic versions of the above files, when available, will be stored on secure computers with password protection. Electronic record storage must comply with FDA regulations 21 CFR 11.

APPROVED:

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