

EFFECTIVE DATE: May 2023

The documentation required for clinical trials is dictated by regulatory agencies and by the ICH Good Clinical Practice Guidelines. The purpose of this Standard Operating Procedure is to define the preferred method for the set-up and use of the study files, including the regulatory documents

records.

PurposeH1 &MCI3ATE:

The formalized compilation of study records dealing with the conduct of the study as a whole will visit notes and patient information, should be kept separate from the Req. Binder.

The following procedures apply to all of the study files.

- 1. Good Clinical Practice (GCP) requires that all study related activities be documented.
  - 1.1. The regulatory binder checklist provided for this SOP includes the documents expected to fully capture regulatory activities.
  - 1.2. Specific studies may require additional documents.
- 2. Essential documents shall be stored in files (electronic or paper) and maintained for the required duration specified by regulations and the clinical trial agreement.
  - 2.1. Study files must be stored in a secure location.
  - 2.2. Files or file room shall be locked to prevent unauthorized access.
- 3. The filing system shall be segmented so that individual trials remain separate, in particular when sponsored by different entities.
- 4. A complete record must be maintained of all approved documents. When required documents are modified or updated, the original and all modified or updated versions must be maintained. Some workable ways to control use of the correct version include:
  - 4.1. Documents that have been superseded may be moved from the active bi binder or can be kept electronically. Although all required documentation must be available for inspection at any time, all documents need not be stored together in one location. The historical binder should maintain the same contents format as the active binder.
  - 4.2. All version copies may be kept together, with the most recent version to the front of the binder. If kept electronically, most recent versions should be separate from previous versions and easily identifiable.
- 5. A Study File should be prepared as soon as is practical after the first contact with a potential Sponsor (or Contract Research Organization).
  - 5.1. All correspondence regarding a potential study should be kept.
  - 5.2. If the Principal Investigator (PI) decides not to participate in the study then confidential materials should be returned or destroyed, as agreed between the two parties. Verification of destruction (include method, date, responsible party) should be sent to the Sponsor, with the PI retaining a copy of the notification.
  - 5.3. Keeping the information as to why a study was declined may help with future decisions.

6.	When the regulatory binder is supplied by the Sponsor, the initial departmental Study File should