**Storage of Records**

1. **PURPOSE**

To outline the procedure(s) for storage of Research Records or files.

1. **SCOPE**

Applies to all site personnel involved in the coordination of protocols for investigational drugs, devices, in vitro diagnostics, biologics or other such studies.

Personnel responsible: Investigator/Co‑investigator(s) and, *when delegated by the investigator,* sub‑investigator(s) and clinical research coordinators, administrative personnel.

1. **BACKGROUND**

The principal investigator along with other administrative personnel must provide secure storage for all research records according to the contract and CFR.

**In accordance with**:

Study Contract.

21 CFR 56.115 IRB Records

21 CFR 312.62 Investigator Recordkeeping and Record Retention

21 CFR 312.68 Inspections of investigator’s records and reports

21 CFR 812.140 Records

1. **PROCEDURE**
   1. The principal investigator, research manager or designee(s) will obtain secure storage facilities for all records pertaining to the participation in a research project.
   2. A Note to File will be placed in the Regulatory Notebook at study closure or whenever any study records are sent to storage.
   3. The Note to File will contain the following information: name, address, phone number and other contact numbers (ie. fax number) of the facility where research records are stored, the name of contact person(s), and any identifying numbers (box numbers) specific to the research records.
   4. A copy of the note to file will be provided to the Sponsor at study close out.
   5. Anytime storage facilities are changed, the Sponsor must be notified of the location of study records in writing; a copy of the notice will be filed in the study regulatory notebook(s).
   6. The length of time research study records will be kept in secure storage will be dictated by the CFR requirements or study contract (whichever is longer).
   7. If the investigator is going to transfer custody of the records to the Sponsor at study closure, this will be done per instructions received from the Sponsor at the close out visit.
   8. The investigator, site manager or their designee shall contact the Sponsor prior to releasing from storage any research records to determine if sufficient time has passed to allow for discontinuation of storage requirements.
   9. Final disposition of study documents will be decided upon by the Sponsor and communicated to the site in writing. A copy of this correspondence will be kept in the regulatory files.