DM-504–Record Retention, Archive, and Storage

1. **PURPOSE:**
   To manage the retention, archive, and storage of UTRGV research records properly and effectively.

2. **SCOPE:**
   This SOP applies to all research records, including subject records and regulatory records.

3. **RESPONSIBLE INDIVIDUALS:**
   The Principal Investigator (PI) or any research personnel designated by the PI to collect, organize, store, or archive research records. This includes ancillary services, as applicable (i.e., Investigational Drug Services).

4. **RELATED TERMS AND DEFINITIONS:**

   Close Out Visit (COV)
   Electronic Investigator Site File (eISF)
   Email Communications
   Florence
   Note to File (NTF)
   PHI (Protected Health Information)
   Research Records

   Please reference the Standard Operating Procedures Glossary of Terms for complete definitions of terms in this SOP.

5. **POLICY STATEMENT**
   The PI is responsible for determining which guideline(s) apply to their study for proper storage, retention, and archive of research records (See Appendix 1: Record Retention Table)

6. **PROCEDURES**
   The PI must determine which regulatory bodies have oversight of their study (DHHS, FDA, NIH, IRB, GCP, Industry Sponsor, etc.) and follow the corresponding guidelines on record retention. Some tools can be referenced below. No specific guidelines overrule

any of the others. A best practice is to compare the requirements of any/all regulatory body(ies) that have oversight of the study, then retain records for the longest period of time.

6.1 The archiving method will depend on the nature of the study documentation.

6.1.1 Studies using physical/paper records. The PI or designated staff must ensure the following:

- The entire study record is present within the archived files.
- The archived files are clearly labelled so they may be easily identified.
- Each folder/binder/box/storage vessel should be labelled so it is clear how many make up the complete record. For example, if the study record is being kept in binders and there are 4 binders, the first binder should be labelled "Binder 1 of 4," the second binder should be labelled "Binder 2 of 4," and so on.
- The archive location should be secure, dry, dark, and temperature controlled.
- If the archive location is off site, the process to retrieve the archives should be determined prior to archival.
- If a third-party vendor will be used for archival, ensure a contract is in place and verify the process for invoicing and payments prior to archival.
- An archive log must be kept on site. The archive log must include:
    - Full Study Title
    - Study Funding Source
    - PI
    - Brief description of archived material
    - Any unique identifiers assigned to the archived material
    - Name and address of archive location (including suite numbers, storage unit numbers, etc.)
    - Contact information for archive retrieval
    - Date sent to archive
    - Date of planned destruction, if applicable
    - Name of person archiving the files
    - Signature of person archiving the file

- The complete physical address of the archived material must be provided to sponsors and regulatory bodies upon request.

6.1.2 Studies Using Florence eISF. PI or designated staff must ensure the following:

- The entire study record is present within the archived files.

- The archived files are clearly labelled so they may be easily identified.
- The staff member responsible for archiving in Florence must be notified via email. If the PI is not sending the email, the PI must be copied.
- The email requesting study archival must include the following:
    - Study Department
    - Full Study Title
    - Short Study Title/Study Number
    - PI
    - Reason for archival
    - IRB Closure Letter and Sponsor COV letter, if applicable
    - Date study should be sent to archive

- If unsure who has the authority to archive within Florence, contact clinicalresearch@utrgv.edu.
- Records archived in Florence will remain there in perpetuity, with no plan for destruction.
- No archive log is necessary because Florence has a built-in audit-trail.
- Study sponsors and regulatory bodies may be referred to clinicalresearch@utrgv.edu for more information on archival records within Florence.
- If there comes a time when UTRGV no longer uses or has access to Florence, the archived records will be downloaded from the system and archived in accordance with section 6.1.1.

6.1.3 Studies using a combination of paper/physical records and Florence.

- The PI or study designee will create a Note to File (NTF) outlining which parts of the study records are physically kept and which parts are kept within Florence.
- The NTF may be signed by either the PI or the regulatory coordinator for the study.
- The NTF must be filed with the physical records and a copy uploaded into Florence. In both cases, the NTF will be filed in the NTF section. A copy may also be filed in the Closeout section.
- The Note to File will be provided to sponsors and auditors upon request.
- The physical records will then be archived in accordance with 6.1.1.
- The Florence records will be archived in accordance with 6.1.2.

7. REFERENCES

- DHHS 45 CFR 46.115, 45 CFR 75.361, and 45 CFR 75.364
- FDA 21 CFR 56.115, 21 CFR 812.140, and 21 CFR 312.62
- ICH GCP E6R2 3.4, 4.9.0, 4.9.4, 4.9.5, and 8.1
- NIH Grants Policy Statement 8.4.2
- UTRGV RA-201
- UTRGV RA-205

8. FORMS OR ATTACHMENTS:

None