Clinical Research
STANDARD OPERATING PROCEDURE

RA-201 - Regulatory Documentation

1. **PURPOSE:**
   This SOP is intended to meet Federal regulations requiring documentation of all study-related activities. The regulatory files, which are periodically reviewed by the sponsor and upon request by the FDA, serve as the site's record of compliance with Good Clinical Practice (GCP).

2. **SCOPE:**
   This SOP applies to all clinical studies conducted at UTRGV.

3. **RESPONSIBLE INDIVIDUALS:**
   The Principal Investigator (PI) is ultimately responsible for maintaining all required documentation for clinical studies conducted at UTRGV. This task can be delegated to appropriate study personnel for each study.

4. **RELATED TERMS AND DEFINITIONS:**
   Audit
   Confidentiality
   Direct Access
   Documentation
   eISF – electronic investigator site file
   Essential Documents
   Florence™
   Inspection
   Investigator's Brochure
   Note-to-File
   Quality Assurance (QA)
   Regulatory Binder: Referred to synonymously as the Study Files, Investigator Site Files, Trial Master File or Investigator Binder
   Source Documents

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

5. POLICY STATEMENT

All clinical research regulatory documents must be maintained per this outlined procedure.

6. PROCEDURES:

6.1 When a study is planned, the study or regulatory coordinator will contact the Office of Clinical Research (OCR) for a determination on whether their regulatory will be stored within Florence or on paper.

6.2 If OCR determines the study belongs in Florence, a representative from OCR will assemble an electronic binder within Florence to file all regulatory documentation.

6.3 If OCR determines the study does not belong in Florence, the regulatory or study coordinator for the department will need to assemble a paper regulatory binder. The coordinator should reach out to OCR for examples of regulatory binder structure for each study.

6.4 Copies of regulatory documents should be provided to the study sponsor or appropriate regulatory binder upon request in a timely manner. Research documents are often proprietary, contain Personal Identifiable Information (PII), Protected Health Information (PHI) or other information of a sensitive nature, so make sure to only send to the document requestor, and include only appropriate study staff in the correspondence.

6.5 No original, wet ink documents should be sent to a sponsor or regulatory body without notifying the local study PI. Prior to sending, copies should be made of the original. The copies should be marked as copies and a note-to-file (NTF) created that includes the following:

- Name of person who requested the original
- Justification the person provided for obtaining the original
- Date PI was notified of the request
- Date the original was sent
- Address to which the original was sent (email or physical)
- If email, a read receipt should be requested.
- If physical, the original should be sent via certified mail
- The read receipt or certified mail receipt should be filed along with the NTF

The NTF and any corresponding documentation should be filed with the copy of the original document in the regulatory binder.

6.6 Regulatory documents should be well-organized in a readily available format. Paper regulatory should be in reverse chronological order in a ringed binder with the appropriate tabs clearly labeled. All studies using Florence should have documents filed in the appropriate location within the system. A regulatory log is recommended to track most current study related documentation such as protocol amendments and changes in informed consent documents.

6.7 Paper documents may be stored in a single binder or several binders in a secure, locked area. If possible, in a location accessible to only study staff.

6.8 As the study progresses, the study or regulatory coordinator is responsible for the retention of documents received in the appropriate sections of the regulatory file whether paper or electronic.

6.9 Prior to scheduled monitor and/or auditor visits, the study or regulatory coordinator should review content of regulatory files for completeness.

6.10 Regulatory requirements will differ for different types of research, however, at a **minimum** a regulatory binder should include the following:

- Current Protocol
- Any previous versions of the protocol (if applicable)
- Current Informed Consent and HIPAA Templates
- Any previous versions of the Informed Consent and HIPAA Templates (if applicable)
- All IRB and other applicable approval committee(s) correspondence
- Study Specific Training Log for all research staff
- Delegation Log
- Any Applicable Manuals and Guidance Documents
- Any study communication

6.11 At the end of the study, the regulatory file should be reviewed for accuracy. Missing documents should be retrieved and inserted, and discrepancies should be noted by creating a note-to-file. If a document cannot be found or replaced, a NTF explaining why the document is missing should be placed in the regulatory file. In the event that a document is temporarily stored outside of the regulatory binder, a note-to-file should be created indicating the document's location.

6.12 After a study is completed and the file is reviewed completely, the regulatory file can be archived. The physical address of archived paper regulatory files must be recorded and provided to sponsors and/or regulatory bodies upon request. They also must be made available in the event of a regulatory audit. Studies archived within Florence can be downloaded at any time by staff with the appropriate permissions.

6.13 Record Retention

- UTRGV Clinical Research and Federal Regulations require the retention of regulatory files for a minimum of three (3) years after the research is completed.
- If the research records contain HIPAA Authorizations, these records must be maintained as outlined in the HIPAA Authorization language.
- If the research records contain original medical records, these records must be maintained for a minimum of seven (7) years after the completion of the last date of treatment. If the patient is under 18 years of age at the time of treatment, the records must be retained until the patient is 21 years of age.

- Refer to the sponsor/funding agency's contract/agreement to determine if the required regulatory document retention guidelines are different than those required by UTRGV. If there is a difference, the longer timeline must be observed.
- **In all cases – the longest applicable timeline for record retention is the one that must be observed.**

6.14 Investigational Test Article Record Requirements- See Investigational Pharmacy SOPs

7. REFERENCES:

- FDA 21 CFR 312.60 - General responsibilities of investigators
- 21 CFR 312.62 - Investigator recordkeeping and record retention
- 21 CFR 312.68 - Inspection of investigator's records and reports
- 21 CFR 812.140(a) - Investigator records
- ICH E6: Harmonized Tripartite Guideline for GCP
- 2.10, 2.11 - The Principles of ICH GCP
- www.utrgv.edu/recordsmanagement

8. FORMS OR ATTACHMENTS:

None