

**LOUIS STOKES CLEVELAND VA MEDICAL CENTER**  
**Medical Research Service**  
**Standard Operating Policy and Procedure (SOP)**

**Effective Date:** October 3, 2019

**SOP Title:** Collection of Regulatory Documentation

**SOP Number:** HSP-006

**SOP Version:** .06

**1. PURPOSE.** To describe the steps for fulfilling regulatory and clinical requirements for collecting, filing and storing study-related documents for each clinical study conducted. The regulatory files serve as the site's record of compliance with good clinical practice (GCP). They are subject to audit by the sponsor, by the Louis Stokes Cleveland VA Medical Center, the FDA and other federal agencies.

**2. RESPONSIBILITIES.** The Principal Investigator is responsible and accountable for collecting, filing and storing all study-related documents for each VA approved human study as required by federal and state law and LSCVAMC policy. The PI may delegate responsibility for maintaining accurate and complete records to another member of the research team, but may not delegate accountability.

**3. PROCEDURES:** A regulatory file labeled with sponsor name, investigator name, protocol number and title will be prepared for the study prior to enrolling subjects or collecting any data by PI or designated staff. The sponsor should be contacted by the PI or designated staff at the start of the study to determine the sponsor required documentation in addition to local required documentation. The regulatory file should be kept in chronological order and maintenance delegated to key personnel on the study.

**4. REGULATORY FILES CONTENTS**

- a. R&D Approval Letter approving the research study
- b. SRS Approval Letter(s)
- c. IRB documents including:
  - i. Initial IRB Approval Letter
  - ii. Initial IRB approved stamped research plan and all attachments
  - iii. IRB correspondence (to and from PI/site)
  - iv. Investigator's Brochure (if applicable)
  - v. IRB approvals for all study advertisements
  - vi. IRB notification of SAEs, Unanticipated Problems, safety reports, protocol deviations
  - vii. IRB approval letter (s) for all modifications, revisions, and personnel changes including revised research plan (if applicable)
  - viii. IRB modification forms, study staff change forms

- ix. HIPAA waivers and consent waivers
  - x. IRB continuing review report(s) and approval letter(s).
  - xi. IRB notification of study closure and final report
  - xii. IRB acknowledgments of any submission
  - xiii. Other IRB correspondence
  - xiv. IRB approved stamped informed consent (all versions) and reviewed HIPAA authorization/waiver (all versions)
  - xv. Copy of any regulatory application (IND/IDE) to FDA and all supplements, notices and correspondence
- d. Screening/enrollment logs indicating reasons for screen failure (if applicable)
  - e. A master list of all subjects for when informed consent has been obtained along with all re-consents and HIPAA's (if applicable)
  - f. Drug/Device accountability records (shipping records and individual device accountability logs.)
  - g. Subject Files
    - Completed Case Report Forms (CRF)
    - Original signed informed consent/HIPAA
    - Durable Power of Attorney (if applicable)
    - Data clarification forms
    - Copies of source documents
    - SAE/Unanticipated problem reporting to sponsor
    - Subject correspondence
  - h. Notes-to-file
  - i. Data Monitoring Committee Correspondence
  - j. Signed and dated FDA Form 1572 / Investigator Agreement (if applicable)
  - k. Personnel required information:
    - i. Delegation of Responsibility/Site Personnel Signature Log
    - ii. Department of Transportation Training (if applicable)
    - iii. Safety Training (if applicable)
  - l. The regulatory file should be maintained and updated as necessary by the PI, adding appropriate documents as they are generated or received. The sponsor should be contacted by the PI to determine which study documents should be forwarded, whether the sponsor requires original documents or photocopies. **The study sponsor should also be contacted by the PI at the start of the study to determine the sponsor required documentation in addition to local required documentation.**
  - m. All subject records and regulatory files must be kept confidential and must be stored in a secure location. Access to files will be limited to those who create, work with, or rely on the files.
  - n. The contents of the regulatory files and subject records should be reviewed for completeness, prior to scheduled study monitor and auditor visits.

**5. RECORD RETENTION.** The required records, including the investigator's research records, must be adhere to disposition instructions as approved by the National Archives and Records Administration and are published in VHA's Records Control Schedule (RCS 10- 1). All records must be accessible for inspection and copying by authorized

representatives of VA, OHRP, FDA, and other authorized entities at reasonable times and in a reasonable manner in accordance with 38 CFR 16.115(b). Records are the property and the responsibility of the local research office. The local VA facility must designate where the records will be maintained or stored.

**6. RESCISSION:** Medical Research Service SOP HSP-006 dated August 1, 2013 was rescinded. The review date for this SOP is March 1, 2020.

**7. FOLLOW-UP RESPONSIBILITY:** Research Compliance Office