VA Northeast Ohio Healthcare System
Medical Research Service
Standard Operating Policy and Procedure (SOP)

Effective Date: June 2, 2022

SOP Title: Sponsor Study File Management - Device

SOP Number: Human Researchers – HSP- 026

SOP Version: .02

1. Purpose.

To define procedures to be followed in the organization and management of clinical trial documents generated in the conduct of clinical trials under the sponsorship of VA Northeast Ohio Healthcare System (and/or its designee).

2. Policy.

This SOP is required for all clinical studies involving human subjects conducted or sponsored by the VA Northeast Ohio Healthcare System and/or its designee.

3. Definition/Background.

Sponsors are required to maintain records required under Sec. 312. 57 & 812.140(b) (4) and (5) and make the reports required under Sec. 312.57 & 812.150(b) (1) through (3) and (5) through (10); and (vi) ensure that participating investigators maintain the records required by Sec. 312.62 & 812.140(a)(3)(i) and make the reports required under Sec. 812.150(a) (1), (2), (5), and (7), (b)(4) and (b)(5) – Records. 'Records' are itemized under Section 5.0 – Procedures, of this Standard Operating Policy and Procedure (SOP)

4. Responsibility.

As Sponsor, the VA Northeast Ohio Healthcare System and/or its designee, and designated research staff (i.e., principal investigator, co-investigator(s), regulatory specialists, research nurse(s), and/or study coordinator(s)) for a given study are responsible for the collection and retention of that study's Sponsor files. Site principal investigators, if applicable, and their designee (if any) are responsible for the content and maintenance of the site study files.

Sponsor's designated monitor is responsible for auditing proper content and maintenance of site study files created by the principal investigator/coordinator and

research staff and for obtaining required copies, if applicable, of associated files for inclusion in Sponsor files. Sponsor's designated monitor will also be responsible for creating monitoring reports.

5. Procedure.

1. VA Northeast Ohio Healthcare System and/or its designee is responsible for training all appropriate personnel on this SOP and on their responsibilities. Such training will be documented on a training log.
2. Sponsor study files will be initiated and maintained by the Sponsor VA Northeast Ohio Healthcare System and/or its designee and will include the required essential documents for the lead site and each study site (assuming a multi-site trial). These files are subject to inspection by internal GCP auditors and regulatory authorities per Federal guidelines.
3. Files under the authority of the Sponsor consist of three types of files: general regulatory files, site specific regulatory files and site-specific data files (which may be electronic or paper).
4. General regulatory files (if applicable for a particular study) may contain the following and are maintained by the Sponsor and/or its Regulatory designee(s):
    a. Copy of any regulatory application to FDA and / or funding agency (in date order).
    b. All supplements, notices and correspondence to FDA and / or funding agency related to application.
    c. Copy of the investigational plan (protocol) and all versions, amendments (tracked and clean)
    d. Blank CRFs (all versions (tracked and clean) and version history)
    e. CRF manual or instructions (all versions - tracked and clean) and version history)
    f. IRB documentation (possibly central or local)
    g. Central laboratory documentation / certifications / licenses / normal Ranges for each year of the study / CV of lab director (if applicable) and all updates (see also Site-Specific Files).
    h. Investigational supply documentation and correspondence
    i. General study correspondence to investigators, if applicable
    j. Study newsletters, updates, etc. used for study
    k. Medical advisory board reports and associated correspondence
    l. Research manual, user manual and product labeling
    m. Safety reports
    n. Randomization code (if applicable)
    o. Study progress reports
    p. 6-Month investigator list to FDA in date order, if applicable
    q. Sponsor annual report(s) in date order
    r. Final study report
    s. Study specific forms
    t. Regulatory agency audit reports

u. IRB audit reports
v. Quality Control documents and correspondence.

5. Site specific files (if applicable for a particular study) may contain the following and are maintained by the Sponsor and/or its regulatory designee:
   a. Signed protocol signature pages (signed by the principal investigator of each site if applicable). All versions / amendments require a signature page.
   b. Manual of use or research manual at site (version tracking).
   c. Study personnel signature form(s).
   d. Delegation of Responsibility form (if used for specific study).
   e. Investigator required information:
   i. CV (signed and dated within the last 3 years) and all updates.
   ii. Copy of current medical license.
   iii. Copy of training records (Sponsor specific, IRB required, and GCP training if completed).
   iv. HIPAA training.
   v. Signed / dated confidentiality / non-disclosure agreement(s). (Note: this may be a part of the clinical trial agreement or contract and may be kept with the legal files).
   vi. Signed / dated investigator agreement (all versions / updates).
   vii. E-Signature certificate (if applicable).
   viii. Signed / dated financial disclosure forms collected at specified intervals.
   ix. Copy of previous regulatory audits (FDA or HHS) 483, warning letters or other reports for any investigator at the site.
   f. IRB approved ICF (all versions) and HIPAA authorization.
   g. IRB (possibly central or local) documents including:
   i. Initial IRB application and all site-specific attachments.
   ii. IRB correspondence (to and from PI/site).
   iii. IRB approvals for protocol, amendments and ICFs.
   iv. IRB approvals for all study advertisements, recruiting materials, addition of investigators, etc.
   v. IRB notification of AE/SAE/UADE, protocol deviations and other required reports.
   vi. IRB continuing review report / approval(s).
   vii. IRB notification of study closure and final report.
   viii. IRB acknowledgment of any submission.
   ix. Other IRB correspondence.
   x. IRB roster or FWA for each year of the study. Note, if the IRB does not give out a roster, the Sponsor must have the IRB chairperson's name and address for all IRBs reviewing the study for the required annual reports to FDA.
   xi. Copy of IRB accreditation (if applicable).
   xii. Copy of any IRB regulatory audit by FDA/HHS (past or if occurs during study).
   h. Safety reports
   i. Laboratory (central and/or local) documentation (if applicable)

j. Site specific approvals / licenses (for example, electrical safety sign-off, radiation license, MQSA certification, bio-safety committee approvals/ correspondence) for the study.
k. Monitors' visitor signature log.
l. Monitor / CRA correspondence.
m. Monitoring reports.
n. Device accountability records (shipping records and site-specific individual device accountability logs).
o. Screening / enrollment logs.
p. Investigator / site specific correspondence.
q. Deviation reports / investigation / follow-up or corrective action plan.
r. Quality Control documents and correspondence.
s. Completed CRF's and source documents including pathology reports; laboratory reports; surgical reports; medication orders; physician/nurses' reports; medical records; radiological images; participant's diaries; questionnaires, surveys; and letters from referring physician's.
t. Device accountability records including shipping and receipt records; maintenance and storage records; dispensing records; final disposition records; and documentation of compliance with the Attestation Form
u. Contracts and budgets

6. Exclusions to the content and / or additional study specific documents required for study files are to be described and listed in the study plan or monitoring plan for each specific investigational plan (protocol). The designated monitor is responsible for collecting copies of the above documents at each monitoring visit to update Sponsor files, or is responsible for ensuring that copies are adequately and securely maintained within research offices.
7. Each site's files will be maintained and organized, by study, and will be identified by the protocol number/name, PI's name and site number (when appropriate). Site files may be kept securely in notebooks, binders, hanging file folders, and/or in locking cabinets or offices and may be modified as necessary and as allowed, for secure maintenance.
8. Electronic files will be securely maintained on password protected computers. In addition to password protection, the sponsor VA Northeast Ohio Healthcare System maintains networks and drives that are protected by firewalls for added security.
9. Site specific data files are established, maintained, and updated by Sponsor and/or its designee named to oversee data management. These files include:
    a. Completed CRFs.
    b. Data clarification forms (queries).
    c. Copies of source documentation.
    d. AE/SAE/UADE reports and supporting documentation.

6. Reference:

Clinical Trials Guidance Documents | FDA

Frequently Asked Questions About Medical Devices (fda.gov)

7. Rescission:

Sponsor Study File Management - Device HSP-026 dated January 1, 2011 was rescinded. Review date for this policy is by June 1, 2025

8. Follow up Responsibility:

Investigator(s)/co-investigator(s) and, when delegated by the investigator(s) with permission of the sponsor, also sub-investigator(s) and clinical research staff. Designated individuals who monitor sites and those named as responsible for performing data management and regulatory affairs by the sponsor, VA Northeast Ohio Healthcare System.