Collection of Regulatory Documentation

SOP HSP-006

VA Northeast Ohio Healthcare System
Cleveland, Ohio 44106

Service Line(s):
Research Service

Signatory Authority:
Neal Peachey, Ph.D. ACOS/Research

Effective Date:
January 5, 2023

Responsible Owner:
Education and Policy Specialist

Recertification Date:
January 5, 2028

1. PURPOSE AND AUTHORITY

a. 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 Cleveland VA Medical Center, the FDA, and other federal agencies.

2. PROCEDURES

a. Documentation may be maintained in physical binders or electronically on the VA research drive in the designated folder for the study and/or in VAIRRS/IRBnet. VAIRRS/IRBnet is only appropriate for documents generated in VAIRRS/IRBnet. Documents should be kept in chronological order and maintenance delegated to key personnel on the study. 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.

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.

3. ASSIGNMENT OF RESPONSIBILITIES

a. 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 VANEOHS policy. The PI may delegate responsibility for maintaining accurate and complete records to another member of the research team but may not delegate accountability.

4. REFERENCES

a. 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) https://www.va.gov/vhapublications/rcs10/rcs10-1.pdf

b. . 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.

5. REVIEW

At certification or when there are changes to the governing documents.

6. RECERTIFICATION

This SOP is scheduled for recertification on or before the last working day of January 5, 2028. In the event of contradiction with national policy, the national policy supersedes and controls.

7. SIGNATORY AUTHORITY

Neal Peachey 411157

Digitally signed by Neal Peachey 411157
Date: 2023.01.11 15:13:26 -05'00'

Neal Peachey, Ph.D.
Associate Chief of Staff/Research
Date Approved: January 5, 2023

NOTE: *The signature remains valid until rescinded by an appropriate administrative action.*

DISTRIBUTION: This will be posted on the Research website: https://www.clevelandvaresearch.org/