Essential Documents

The Principal Investigator is required to maintain written documentation on file that the protocol is being implemented as approved by IRB and in accordance with other required approvals. ICH GCP guidance defines *essential documents* as "those documents which individually and collectively permit evaluation of the conduct of the clinical trial and the quality of the data produced. These documents serve to demonstrate the compliance of the investigator, sponsor, and monitor with the standards of Good Clinical Practice and with all applicable regulatory requirements."

Here is an example of how study records can be organized to ensure compliance; additional regulatory documents may be required by a study sponsor.

REGULATORY BINDERS OR FOLDERS FOR:

1. Study Protocol and Protocol Revisions
2. Investigator Brochure and Updates
3. Initial IRB Review documents
    a. Initial IRB Application packet
    b. IRB (and SRS) Approval letter(s)
    c. Authorization to Conduct Research (ACR) - signed by RDC Chair and ACOS/Research
    d. Approved Waivers
    e. Approved Informed Consent and HIPAA Authorization forms
4. All Continuing Review documents
    a. Continuing Review submission packet
    b. IRB (and SRS) Approval letter(s)
    c. Authorization to Conduct Research (ACR) - signed by RDC Chair and ACOS/Research
    d. Approved Informed Consent and HIPAA Authorization forms
5. All Amendment Requests - with IRB approval signatures
6. All Internal Serious Adverse Event Reports - with IRB Chair signature
7. All Unanticipated Problem Reports - with IRB Chair signature
8. Request for Closure documents
9. Correspondence to/from:
    a. Study sponsor/funding source
    b. Applicable oversight entities (e.g., IRB, ACOS/R, RDC, ORO, FDA)
    c. Study partners, service providers and other applicable entities

PARTICIPANT FILES

1. Signed Informed Consent Forms & HIPAA Authorizations *(all in one binder/folder or in individual subject files)*
2. Completed questionnaires, surveys, case report forms, and supporting data
3. Master Subject Log (See template under *"Guidance, FAQs, & How To"* on the IRB SharePoint.) *(Ideally, this log should be maintained electronically rather than in a study binder/folder.)*

ACCOUNTING OF DISCLOSURE

For every disclosure of information from this study to a non-VA entity *[NOTE: The facility Privacy Officer can assist in providing a mechanism to account for this disclosure.]*

Research records – especially those containing personally identifiable information - must be stored securely. The VA requires that hard copies be secured by a double-lock system; best practice is in a locked cabinet within a locked office. Electronic records should be maintained in a shared folder on a secure MVAMC server with restricted access.

Original research records must be kept throughout the study and archived for the records retention period. Some of these records will be in hard copy and some electronic. An original research record is the item in its original format. Information originally collected and retained electronically does not need to be printed out.

References:

1. VHA Handbook 1200.05 (May 2, 2012)
2. VHA Records Control Schedule 10-1
3. VA Handbook 6500