Log Requirements

Regulatory Binder Requirements

Additional Logs and Information

Site Visit (Monitoring) Log

The Monitoring Log provides documentation at the site that the study was monitored and the frequency of monitoring. The monitor and designated site staff both sign the log to verify the date the monitor was present. For consecutive days, each day is entered separately.

Delegation of Authority (Responsibilities) Log

The Delegation of Authority Log documents responsibilities assigned to research team members and their dates of involvement in the project. It helps ensure the appropriate delegation of study related tasks.

Site Personnel Signature Log

The Site Personnel Signature Log documents the names and provides handwriting samples of all personnel involved in the conduct of the study

Study Personnel Education

All personnel involved in research with human subjects are required to complete the following:

- CITI Course in the Protection of Human Research Subjects
- HIPAA Training

When adding personnel to the study, they must complete all of the above and their addition must be IRB approved prior to participating in the study.

Training Log

The Training Log is a record of training provided, e.g. protocol training or other study-specific training of staff. This should include a site initiation visit (SIV) attendance log.

CVs/COIs/FDA Forms 1572/1571

This section should include:

- Curriculum Vitae (signed & dated within the last 2 years) for all investigators and site staff professional licensure (including DEA if applicable).
- FDA Form 1572 (if applicable): Date and sign all versions
- FDA Form 1571 (if applicable): for Investigator initiated INDs
- FDA Forms and instructions are available online.

Note: Any time information is kept in a master binder, place a note to file (in the section of the Binder) referencing the

location of the separate binder.

Public Registration of Research Studies (PRS) (If applicable)

All research studies that meet the definition of a clinical trial must be publicly registered as per the International Committee of Medical Journal Editors (ICMJE), the FDA Amendment Act of 2007, and Health System policy.

Contact the UCLA PRS Administrator, Elaine Cooperstein to set up a ClinicalTrials.Gov PRS user account. Note: For commercially funded, multi-center studies, public registration is typically handled by the study sponsor or CRO. Place the registration receipt in this section for initial registration and for any updates.

Screening / Enrollment Log

The Screening/Enrollment Log should include a log of subjects who were screened (and reason for screen failure) and enrolled. Some studies allow for re-screening of subjects.

Subject Visit Tracking Log

The Subject Visit Tracking Log tracks all enrolled subjects' visits, reason for early termination and keeps visits scheduled as per protocol.

Consent Forms

The Consent Forms section should include consent form document(s) (all IRB approved and stamped versions) stored in reverse chronological order with the current approved version first. Place the most currently approved consent form in a plastic sleeve Note: Any changes to the consent form must be submitted to and approved by the IRB prior to use. Recommendations for consent of Non-English speaking subjects can be found within the OHRPP Consent Guidance.

HIPAA Forms for Authorization, Waiver, and/or Research Preparation Purposes

The HIPAA Forms section includes all IRB approved and stamped versions of any of the HIPAA forms (as applicable).

Research Protocol

The Protocol Template should include the protocol (and protocol signature page) and all amendments (and amendment signature page or pages), stored in reverse chronological order with the current approved version first. Any changes to the protocol must be submitted to and approved by the IRB prior to implementation.

IRB Federal Wide Assurance Letter

The IRB Federal-Wide Assurance Letter should contain the most current IRB assurance letter.

IRB Approval(s) / Communication

This section should include copies of the original IRB application/submission, IRB approval letters (contingent and final approval), and all correspondence with the IRB (including emails). It includes IRB Membership Rosters, Continuation Review Submissions, protocol modifications and DSMB reports and close-out (final study) reports.

Investigational Product Information (as applicable)

- Investigator's Brochure (IB) - This section must include all versions of the IB (may be maintained separately with note in section explaining location of IB) and receipt forms.

- Evidence of IRB submission and review of all versions must be maintained.
- Package Insert - For FDA approved agents, file a copy of the package insert.
- Device Manual - For device studies this section should have a device information sheet/manual.

Study Termination

If your research study is being terminated or if the PI is leaving and the study will no longer be continued, complete and submit an IRB Termination Report to the IRB.

Protocol Deviations / Protocol Exceptions

The Protocol Deviations / Protocol Exceptions section should include correspondence relevant to the issue and copies of the documents stored in reverse chronological order with the most current documents first. Certain Sponsor-approved waivers may need to be approved by the IRB prior to implementation.

Serious Adverse Events

The Serious Adverse Events section should include correspondence, copies and acknowledgements of reports for internal SAEs reported to the IRB and Sponsor and FDA as applicable. Use an AE/SAE log for each subject enrolled in studies that involve drug intervention. Unanticipated Problem Log

IND Safety Reports

The IND Safety Reports section should include correspondence (including IRB acknowledgement) and copies of Safety Reports for external SAE reported to the IRB. .

Advertising/Educational Materials (if applicable)

The Advertising/Educational Materials section should include: Any IRB approved advertisements, recruitment flyers, written educational, or other materials provided to study participants, stored in reverse chronological order with the most current documents first. Marketing materials used to recruit through mass media (e.g. newspaper, TV, radio, some internet postings, & etc.) must be approved by the UCLA Communications Office to ensure logo/branding is appropriate

Sample Tracking and Shipping (if applicable)

The Sample Tracking and Shipping section should include a master log that allows tracking of research specimen sample collection, shipment (or transport), and storage, and packing and shipping training certification. Shippers or receipts can be placed in this section or in individual subject files. All biological materials must be handled, stored and shipped in compliance with FAA and IATA regulations as well as UCLA policies on hazardous materials.

Temperature Logs for Refrigerator/Freezer

Refrigerator/Freezer Temperature Logs must be kept in compliance with Protocol /Study Procedures requirements and GCP.

Investigational/Test Article

The Investigational/Test Article section includes:

- Shipment records (usually requires site signature of receipt and Sponsor notification of receipt)
- Site Accountability Records (inventory of overall supply of drug/device, promps reordering of supply)
- Subject Drug Accountability Records / Device Log (documents the date and quantity of drug/device dispensed to subject and return of drug/device from subject

- Blind Break Instructions (instructions for revealing the identity of the treatment, if blinded)
- **Maintain drug accountability in the Research Pharmacy over the course of the study; at the trial completion file all records here.

Local Lab Certificates/Reference Ranges

For every lab listed on FDA Form 1572, place a copy of (maintain current certifications for duration of study):

- Lab certificate(s) and reference ranges (for the duration of study)
- Lab director's CV

Note: The above is not required for research labs that perform testing where results will not be shared with subjects or their treatment providers.

Correspondence

Please document and maintain all relevant, significant communication from the sponsor, the CRO or monitor in this section. Study related Newsletters may be placed in this section.

Blank Set of Case Report Forms

Include a blank CRF in your Regulatory Binder.

Notes To File (NTF)

The Notes To File may include site generated and/or sponsor generated notes to file. Sponsor generated NTF may be global or site specific.

Record Retention Matrix

The Record Retention Matrix contains retention guidance and disposition requirements for administrative records relating to research.

Other Documents

Place other important study documents in this section. This can include:

- Other necessary approvals (e.g.Radiation Safety Committee)
- Certificates of Confidentiality
- literature or publications
- Correspondence from the FDA, NIH, & etc.
- Other general correspondence

Additional Tools are available for your convenience.

Essential Documents

The ICH GCP Guidelines define Essential Documents as those documents which individually and collectively permit evaluation of the conduct of a trial and the quality of data produced. These documents serve to demonstrate compliance with standards of Good Clinical Practice and with all applicable regulatory requirements. Filing essential documents in a timely manner can greatly assist in the successful management of a clinical trial.

The Regulatory Binder is often the first document reviewed during audits and inspections. Not all the essential

documents are available at the start of the study. Documents can be grouped into those that are generated before study initiation, those that are generated during trial conduct and those that are generated after study completion.

Not all documents have to be filed in one single binder. The Regulatory Binder may sometimes consist of several binders that are stored in the same or different locations. It is important to know where all these documents are located to be able to pull them out when needed in a timely manner. The Regulatory Binder is referred to synonymously as the Study Files, Investigator Files or Investigator Binder.

Organizing Your Regulatory Binder

Create tabs for each section listed below and place the appropriate documents in each corresponding section in a binder. Be sure to label the outside of the binder (cover and spine) with the protocol number, PI name, and study site. Use multiple binders or master binders to maintain documentation if needed. A sample Regulatory Binder Table of Contents is provided for your convenience. All sections are required unless otherwise indicated.

Last updated: 6 Nov 2023

Source URL:https://www.researchgo.ucla.edu/regulatory-binder-log-requirements

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