Regulatory Binder

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Introduction

Congratulations! You have successfully accessed the ResearchGo Virtual Regulatory Binder sponsored by the UCLA CTSI Office of Regulatory Affairs. We thank Partners Healthcare for providing this invaluable resource so it could be modified for use at UCLA. This binder is applicable for behavioral, FDA, and non-FDA regulatory compliance.

Purposes of the Binder

The ResearchGo Virtual Regulatory Binder assists sites in achieving and maintaining regulatory compliance and ensuring the highest standards of human subject research. The binder also provides:

1. Guidance for organization and record keeping.
2. Assistance with proper study documentation and successful study management, including guidance on electronically stored records.
3. Links to on-line resources, such as the UCLA Institutional Review Board (IRB) policies, guidelines, and forms, the Clinical Research Resource ResearchGo, institutional policies, good clinical practices, and Federal Regulations.

Whom to Contact for Help

UCLA CTSI Regulatory Affairs provides individual consultation and educational offerings to both new and experienced members of the research community, including investigators and study staff. To schedule a binder consultation for **FDA and non-FDA** regulated research, please contact Uma Ganapati.

Florence eBinders

Florence eBinders, an electronic regulatory binder system designed to streamline management of study regulatory binders and enhance efficiency. Available for use as of April 22, 2024.

Last updated: 9 May 2024

Instruction Manual

How to Use the Binder

The Virtual Regulatory Binder is comprised of sections that apply to the range of human research studies. To access, click on the tabs at the left of each page.

Each section outlines the regulatory requirements, institutional policies and Good Clinical Practice (GCP) guidelines for organization, recordkeeping, QIU tips, and links to additional resources (e.g., federal regulations, IRB policies and forms, Research Go tools).

Whom to Contact for Help

UCLA CTSI Regulatory Affairs provides individual consultation and educational offerings to both new and experienced members of the research community, including investigators and study staff. To schedule a binder consultation, please contact Uma Ganapati.

Useful Links

- Printable Virtual Binder Tabs and Section Content
- UCLA Records Management Best Practices and Cost Analysis Guidance
- UCOP Record Keeping and Record Retention Requirement
- Source documentation

Last updated: 26 Aug 2022

Consent Forms

Requirements

Current version of Institutional Review Board IRB approved consent form and the dated and stamped IRB approval letter.

Tips / Additional Information

If consent forms are maintained electronically or filed in the IRB section of the Binder, include a signed and dated note-

to-file indicating the location.

Once the IRB approves a new version of the consent form, the previous version expires. Previously approved versions can be kept in the IRB section of the Regulatory Binder.

The IRB website provides guidance on the following:

- Staff Requirements for Obtaining Informed Consent
- Obtaining Consent from Non-English Speaking Subjects
- Obtaining Surrogate Consent
- The Clinical Trial Consent Development section of ResearchGo assists sites with properly documenting informed consent according to federal regulations, institutional policies and good clinical practices.

Applicable GCP sections:

- 8.2.7
- 8.2.3
- 8.3.2
- 8.3.12

Last updated: 26 Aug 2022

CV's

Requirements

- Signed and dated CVs for all IRB approved key personnel (investigators and sub-investigators)

Tips / Additional Information

- CVs should be signed, dated, and updated every 2 years to verify that information is accurate and current.
- If CVs are filed collectively for the department, include a signed and dated note-to-file indicating the location.
- If CVs are maintained electronically, include the “date prepared” and where they are electronically stored.
- For NIH funded studies, investigators can use their NIH Bio Sketch.

Applicable GCP sections:

- 8.2.10
- 8.3.5
- 4.1.1

Last updated: 26 Aug 2022

Data Collection

Requirements

Blank set of case report forms (CRFs), data collection sheets and or study questionnaires (Case Report Form (CRF) resource from NINDS)

Refer to attached guidance to ensure appropriate source documentation

Tips / Additional Information

- Source documents are original recordings of subject or study data.
- Data collection sheets can act as source documentation. For instance, during study visits, subject information is written directly onto worksheets.
- If documents are filed electronically, write a signed and dated note to file indicating the location.
- An industry sponsor will usually provide CRFs to sites. All protocol-required information is transferred from source documents onto CRFs.
- Annotated CRFs or data collection sheets should be monitored.
- Regulations/Guidelines: 21 CFR 312

Applicable GCP sections:

- 8.3.14
- 8.3.15
- 4.9.3

Last updated: 26 Aug 2022

DSMB

Requirements

- Copy of all Data Safety Monitoring Board (DSMB) reports
- Additional correspondences with DSMB (e.g. meeting minutes, information provided to the DSMB, emails)

Tips / Additional Information

Submit a copy of the most recent DSMB report to the IRB at the time of continuing review.

Refer to ResearchGo for Data and Safety Monitoring guidance and templates to assist sites in developing a monitoring plan to ensure subject safety and data integrity:

- IRB Guidance and Procedure: Data Safety Monitoring Plan
- NIH Policy and IC Guidance for Data and safety Monitoring of Clinical Trials
- FDA Guidance-Establishment and Operation of Clinical Trial Data Monitoring Committees
- DSMP Checklist

Applicable GCP sections:

- 8.3.10
- 5.19.3

Last updated: 26 Aug 2022

Drug / Device Accountability

Requirements

- Drug/Device Shipment and Receipt Records
- Drug/Device Accountability Log
- Most recent version of Investigator Brochure or Device Manual

Tips / Additional Information

If the drug/device shipment, receipt, and accountability are managed by research pharmacy, indicate this in a note-to-file.

Refer to ResearchGo for drug and device accountability logs.

The Investigator's Brochure or Device Manual provides clinical and non-clinical data on an investigational new drug or device. Updated versions of the Investigator's Brochure or Device Manual should be submitted to the IRB.

If the drug is marketed, a package insert is an appropriate alternative for the Investigator's Brochure. For marketed devices, basic product information is an appropriate alternative for the Device Manual.

Please click here for more information about the Investigational Pharmacy.

Last updated: 26 Aug 2022

Requirements

Clinical Investigator (individual who conducts the study)

- FDA 1572 (drug)
- Investigator Agreement (device)
- Investigator Responsibilities - Safety Reporting for Investigational Drugs and Devices

Sponsor-Investigator (individual who initiates and conducts the study)

- Clinician Investigator Requirements
- Original applications and all subsequent submissions to the FDA:
  - IND Application (drug)
  - IDE Application (device)
- Amendments to the Application-IDE
- Adverse Event Reports
- Annual Reports - IND and IDE
- Form 3674, Certification of Registration to ClinicalTrials.gov

Tips / Additional Information

- The form FDA 1572/Investigator Agreement identifies the facilities where the research will take place, the reviewing/approving IRB and sub-investigators participating in the study. The 1572 should be updated if changes are made during the course of the investigation.
- An IND Application must be filed when a sponsor wishes to test a newly developed drug or the use of a drug that is not yet approved by the FDA for marketing (21 CFR 312).
- The Form FDA 1571 is the cover sheet for the Investigational New Drug Application and should be included in all subsequent submissions to the FDA. Instructions can be found here.
- An IDE Application must be filed for any device that poses significant risk (21 CFR 812).

Last updated: 28 Jan 2026

Financial Disclosure

Requirements

Signed and dated FDA Financial Disclosures for all clinical investigators listed on the form FDA 1572 (drug) or IDE application (device).

Tips / Additional Information

If FDA Financial Disclosures are filed separately and/or electronically, include a signed and dated note indicating the location.

Any applicant (usually a pharmaceutical/device company) who submits a marketing application for a human drug, biological product, or device is required to submit a completed Form FDA 3455 to the FDA for each clinical investigator who participates in a covered study. This form attests to the absence of financial interests, or discloses the nature of any financial arrangements.

Everyone listed on the Form FDA 1572 (drug) or IDE application (device) shall provide to the sponsor sufficient accurate financial information on Form FDA 3455. The investigator should promptly update this information if any relevant changes occur in the course of the study, or for one year following completion of the study.

Some studies may also require a Financial Disclosure form. Refer to the UCLA Financial Conflicts of Interest in Research policy for guidance.

Last updated: 29 Oct 2026

Florence eBinders

Florence eBinders, an electronic regulatory binder system designed to streamline management of study regulatory binders and enhance efficiency. Available for use as of April 22, 2024.

Benefits of Florence eBinders for Clinical Research:

1. **Enhanced Accessibility:** Access regulatory documents anytime, anywhere, with secure cloud-based storage, ensuring seamless collaboration among research study team members and external monitors.

2. **Improved Efficiency:** Say goodbye to manual paperwork and tedious document searches. Florence eBinders automates document management and workflows, saving time and reducing errors.
3. **Real-Time Tracking:** Track document status, assigned tasks & signatures, and changes in real-time, empowering you to stay informed and in control of your regulatory compliance efforts.
4. **Advanced Security:** Rest assured knowing your sensitive regulatory documents are protected by robust security features, access controls, and audit trails.
5. **On Demand Support:** Get help when needed. In addition to accessing online reference materials and videos, you can engage in instant messaging with the vendor support team.

Take a sneak peek at Florence eBinders in action! Click on the following link to watch a video demonstration:

- Florence eBinders Overview

How to obtain eBinders Access:

- Study Team users can obtain eBinders access once they are authorized for access by their department authorizer, have taken applicable access specific training, and are listed as active staff under applicable roles for the study.
    - eBinders Access Levels & Training
- External Monitors can obtain eBinders access once they have taken applicable training, have submitted all required forms to the CTSI-ORA team, and have had their access window set by the Regulatory Coordinator in eBinders.
    - Sponsor Monitoring and Auditing for Clinical Research Studies
    - Remote and On-Site Monitoring FAQs
- Please review the eBinders FAQs linked below for additional information.

What to expect starting April 22nd, 2024:

- eBinders training will become available for study team users to complete in Cornerstone.
- Departments can work with their department authorizers to submit eBinders access authorization for approved users.
    - Department Authorizer Lookup
    - For Department Authorizers: Research Authorization Forms for OnCore & eBinders Access
- Regulatory Coordinators and Program Managers who are provisioned with Level – 4 access in eBinders can begin to interface their studies from OnCore into eBinders and manage their department central folders, assign eISF structure templates to their study folder, and start managing their regulatory binder in eBinders for their assigned studies.
    - Regulatory Coordinator Tasks & Responsibilities for eBinders
- Study team users who are provisioned for eBinders access can begin to reference and perform role specific tasks on their applicable studies in the application.

Questions?

A list of Frequently Asked Questions (FAQs) is available and linked below, to provide more information about Florence eBinders and how it can benefit study teams.

- Florence eBinders FAQs

For additional assistance with eBinders, please email CRIShelpdesk@mednet.ucla.edu.

Last updated: 24 Apr 2024

IRB

Requirements

- IRB Submissions (application, consent forms, supporting documents)
- IRB Approval Letters
- Continuing Review(s)
- Amendments
- Adverse Events
- Violations/Deviations
- Reporting Forms (DSMB reports, Investigator drug/device brochure updates)
- Close out Information
- Investigator response(s) to IRB notification (if applicable)

IRB Decisions

- Approval letters and/or notification of IRB decisions
- Approved recruitment materials
- Approved educational materials/additional study information distributed to subjects (e.g. subject diary)
- Info regarding Federalwide Assurance (FWA); IRB registration and IRB membership
- Letter to Sponsors
- Any additional correspondence relating to the study (e.g. e-mails)

Tips / Additional Information

- Copies of all signed and dated IRB submissions and correspondence between the study site and IRB should be kept on file.
- It is recommended to arrange documents in reverse chronological order to ensure that documentation provides an accurate history/timeline of study activity from approval to completion. Only one copy of each correspondence is needed.
- Request a copy of any missing documents from your protocol administrator or print them to include in the binder.
- If documents are filed electronically, write a signed and dated note to file indicating the location.
- If signed and dated correspondences cannot be maintained electronically (e.g. pdf version), keep a hard copy on file.
- Regulations/Guidelines-45 CFR 46
- 21 CFR 50
- 21 CFR 56

Applicable GCP sections:

- 8.2.7
- 8.2.9
- 8.3.2
- 8.3.3
- 8.3.4

Last updated: 29 Jul 2025

Lab Documents

Requirements

- Current Lab Certification (e.g. CLIA, CAP)
- Normal Lab/Reference Values

Tips / Additional Information

- Keep updated lab documents to document the competency of all lab facilities being utilized, and to support the reliability of test results.
- If lab documents are filed electronically or separately, include a signed and dated note to file indicating the location.
- Research laboratories typically do not have lab certifications (e.g. CLIA, CAP). In the case of research laboratories, ensure that the research lab reference values are on file.
- CLIA and all other licensure for all UCLA labs can be found here: UCLA Clinical Laboratories Licensing & Accreditation Documents
- You will also need the CV of the lab manager for your regulatory binder. Please contact UCLA Pathology & Laboratory Medicine to obtain a copy.
- Reference values: UCLA Health Laboratory Test Directory

Applicable GCP Sections:

- 8.2.11
- 8.2.12
- 8.2.14
- 8.3.6
- 8.3.7

Last updated: 30 Nov 2022

Licensure

Requirements

- Valid medical licenses and professional certifications for investigators and sub-investigators.

Tips / Additional Information

- Monitor licensure expiration dates so that those nearing expiration may be updated promptly.
- Include any professional certifications that verify staff eligibility to perform clinical procedures (e.g. phlebotomy, vital signs, ECG).
- If medical licenses /certifications are filed collectively for the department, include a signed and dated note-to-file indicating the location.
- General information regarding medical licenses is available at The Medical Board of California

Applicable GCP sections:

- 8.2.10
- 4.1.1

Last updated: 26 Aug 2022

Logs

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.

Screening / Enrollment / Withdrawal Log: Captures subjects who have been screened to determine initial eligibility for enrollment, and all subjects who sign a consent form. Review the IRB Recruitment Guidelines for additional information

Subject Visit Tracking Log: Tracks all enrolled subjects' visits, reason for early termination and keeps visits scheduled as per protocol. If a subject is found to be ineligible, withdraws consent, or is lost to follow-up, s/he is still counted as enrolled and should be included when reporting enrollment numbers to the IRB.

Staff Signature/Delegation of Responsibility Log: Documents the study-related procedures delegated to staff. The PI should initial, sign and date this list, and update it as new staff or study procedures are added to the protocol.

Monitoring Log: Documents any form of study oversight/monitoring as defined in the IRB approved protocol summary.The monitor and designated site staff both sign the log to verify the date the monitor was present. For consecutive days, enter each day separately.

Adverse Event (AE/SAE) Tracking Log: Tracks and ensures timely reporting of all applicable adverse events to the IRB. Includes correspondence, copies and acknowledgements of reports for internal SAEs reported to the IRB and Sponsor and FDA as applicable. Use the AE/SAE log for each subject enrolled in studies that involve drug intervention. UCLA adverse event guidance can be found here.

Minor Deviations/ Violations Tracking: Includes a record of all minor deviations from the approved protocol and facilitates reporting at continuing review per IRB Protocol Deviation/Exception/Violation Guidance.

Tissue Log: Tracks tissue samples collected during research and subjects' tissue consent options. Describes the requirements for sharing and/or transferring tissue samples from tissue repository banks.

Tips / Additional Information

Logs should be updated as soon as possible after a recordable event occurs, preferably on the same day.

Templates can be customized to fit a specific study or added to existing electronic versions currently maintained on

site.

Applicable GCP sections:

- 8.3.20 – 8.3.25

Last updated: 26 Aug 2022

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

Protocols

Requirements

- Current protocol and all previously approved versions
- When applicable, include a copy of the fully executed protocol signature page for original protocol and all approved versions

Tips / Additional Information

- All protocol versions can be kept in a separate location or stored electronically. Include a signed and dated note-to-file indicating where previous versions are kept.
- Version should be dated and/or numbered

Applicable GCP Sections:

- 8.2.2
- 8.3.2

Last updated: 26 Aug 2022

Sponsor

Requirements

Copy of all significant correspondence to and from the study sponsor(s) (e.g., letters, e-mails, meeting notes, and notes of telephone calls)

Tips / Additional Information

If documents are filed electronically, write a signed and dated note to file indicating the location.

Signed Agreements

- Copy of all signed agreements, including financial agreements, between involved parties, including:
- Investigator/institution and sponsor
- Investigator/institution and Contract Research Organization (CRO)
- Investigator/institution and other authorities

FAQs

Q: Some of our e-mails and phone calls with the study sponsor concern minor issues or clarifications. Is it really necessary to document and save all such communication with the study sponsor(s) when we are already so pressed for time?
A: Yes. A complete record of correspondence contributes to a well-documented audit trail. What seems minor now may assume much greater importance in the future if a problem arises. It also helps the investigator to track all decisions and changes that may be important to confirm later. As always, all notes should be signed and dated.

Q: What should I do if the Principal Investigator (PI) keeps a copy of all agreements in a locked file in their office?
A: Include a signed and dated note-to-file indicating the location of these documents.

Applicable GCP sections:

- 8.3.11
- 8.2.5

Last updated: 26 Aug 2022

Last updated: 26 Aug 2022

Source URL:https://www.researchgo.ucla.edu/regulatory-binder?qt-view__vertical_tab_section__block_3=11

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