



The University of Vermont

LARNER COLLEGE OF MEDICINE

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**Regulatory Essential Documents Binder:  
Set-up and Maintenance**



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## Introduction

Federal and state regulations, institutional policy, and good clinical and research practices require investigators to maintain documents related to human subjects research. This tool was developed to assist researchers in organizing research-related documents. It details what documents may be stored in each section of a study-specific regulatory binder. Some of the sections or documents are not applicable to certain studies. Additionally, researchers may choose to store certain documents in places other than the regulatory binder. Finally, some sponsors or federal agencies may require that investigators keep documents that are not specifically referenced in this guidance.

Some general hints for maintaining a regulatory binder

- If it is not documented, it never happened!
- Signed and dated notes-to-file can be utilized in all of the sections:
  - To note an error in record keeping
  - To note that certain documents are stored in places other than the regulatory binder (i.e. a note to file indicating where outdated versions of the protocol are kept, a note to file indicating that signed case report forms are kept in study subject files, etc.)
  - To record missing documentation or incomplete data
  - To explain how information was obtained
  - To detail who obtained information
  - To clarify any discrepancies
- All forms submitted to any federal agency pertaining to human subject research should be retained (even if not specified in any of the sections in this document).
- All authorizations, approvals, and/or notifications of protocols, protocol modifications, or other documents should be retained, even if not specified in this document. This includes the authorizations, approvals, and/or notifications of protocols, modifications or other documents from any regulatory authority (i.e. any governmental agency, authorities that review submitted clinical data and authorities that conduct inspections).
- All communications with regulatory authorities (i.e. any governmental agency, authorities that review submitted clinical data, and authorities that conduct inspections) regarding the study should be retained.
- All signed agreements should be retained, even if not specified in this document.



1. **Protocol**

- ALL IRB approved study protocol versions and modifications/amendments (all versions of the protocol and modifications/amendments should be dated)
- Protocol signature page, signed and dated by PI for all protocol versions (if applicable)
- Log of IRB approved protocol versions and modifications/amendments

2. **IRB**

All submissions to the IRB, IRB approvals/acknowledgements, and copies of the IRB approved documents, and any revisions to the documents should be retained in the regulatory binder.

Examples of documents requiring IRB approval and documents that must be retained include:

- Grant application (without financial information)
- UVMClick SmartForm
  - After you complete the initial protocol SmartForm in UVMClick (requires UVM NetID), hit "Submit" to submit it to the IRB, then click "Printer Version" on the left. Print it out (or save a PDF version).
- Initial IRB approval letter
- Written information provided to subjects (i.e., diaries, pain scales, questionnaires, educational booklets)
- Advertisements for recruiting purposes
- Retention materials
- Safety Reports
- Investigational Drug/Device Brochures (all versions)
- Documentation of submission of the following:
  - Safety Letters
  - Toxicity Letters
  - Data Safety Monitoring Board (DSMB) Reports
  - FDA Letters
- Continuing Review reports (Printer version from UVMClick)
- IRB modification/amendment approvals and supporting documents (Printer version from UVMClick)
- Reportable New Information (RNI) (Printer version from UVMClick)
  - Protocol deviations
  - Unanticipated problems
  - Reportable Adverse Events (AE's) and Serious Adverse Events (SAE's)
- All other documents submitted to the IRB
- All correspondences with the IRB
  - The retained communications should include all required reports, e-mails, memoranda, and letters. In addition, logging phone conversations is encouraged to track when conversations take place and the substance of the communications.
  - To print correspondence with IRB staff within the UVMClick system, click on the correspondence title on your study home page. The correspondence will open in its own window. To print (or save as a pdf) click the "Menu" button for your *internet*



*browser* and then select “Print”

- All other correspondences involving human research protections, including correspondences with other researchers
  - The retained communications should include all required reports, e-mails, memoranda, and letters.
  - In addition, logging phone conversations is encouraged to track when conversations take place and the substance of the communications.
- Copy of the current and older versions (dating back to the study start date) IRB member roster. This can be requested from the IRB
- IRB Federal Assurance Number
- Log of IRB approvals

For additional guidance please visit [IRB/RPO website](#)

### 3. **Consent and HIPAA Authorization Forms**

- All IRB approved versions of the consent forms (marked by the IRB approval date) or a waiver of consent and authorization
- Information sheets
- Documentation of where signed consent forms are kept
- Log of IRB approved consent versions

### 4. **Key Personnel**

- Delegation of responsibility/duties/authority log
- Curriculum vitae (CV) for all investigator(s) and key study personnel
  - CVs should be signed, dated, and updated every 2 years
- Licenses
  - Valid licenses for all professional study staff
  - Current professional certification (may be indicated on CVs)
- Training records and certifications for investigators and key study personnel, for example;
  - Human Subjects Research Training
  - Good Clinical Practice Training
  - Study Specific Training
    - Protocol
    - Electronic Data Capture (EDC)
    - Interactive Web Response System (IWRS)
  - HIPAA Training (if applicable)
  - Laboratory training (BSL2)
  - IATA (shipping dangerous goods)
- Log of key personnel with dates added and removed from the study, and training



5. **Other Reviewing/Reporting Agencies (FDA, NIH, DOD/OHRP, local scientific committees)**

▪ **FDA**

- Copies of all versions of FDA Form 1572 for all involved investigators
- IND safety reports
- Investigational New Drug Application FDA Form 1571 if the PI is a Sponsor- Investigator
- FDA Financial Disclosure Form (FDA Form 3455) for PI and all sub-investigators
- Investigational device exemption information
- Investigator-initiated IND or IDE application
- Annual Reports
- All forms submitted to FDA pertaining to human subjects research
- All correspondences with FDA
  - The retained communications should include all required reports, e-mails, faxes, memoranda, and letters. In addition, logging phone conversations is encouraged to track when conversations take place and the substance of the communications.

For additional guidance please visit the [FDA website](#)

▪ **NIH, DOD/OHRP, etc**

- Copy of the approved grant application
- All Progress Reports submitted
- All forms submitted to Agency(s) pertaining to human subjects research
- All correspondences with Agency(s)
  - The retained communications should include all required reports, e-mails, faxes, memoranda, and letters. In addition, logging phone conversations is encouraged to track when conversations take place and the substance of the communications.

For additional guidance please visit [NIH website](#) or Agency specific website.

6. **Sponsor**

Documentation of where the clinical trial agreement and study budget between the investigator/institution and the sponsor for the trial is kept. It is recommended that such financial information be maintained in a separate area.

- Newsletters
- Safety information from sponsor
- Notification to the sponsor of adverse events and related reports
- All correspondences with the Sponsor and/or Contract Research Organization
  - The retained communications should include all required reports, e-mails, faxes, memoranda, and letters. In addition, logging phone conversations is encouraged to track when conversations take place and the substance of the communications.

For additional guidance please contact your Sponsor



7. **Monitoring/DSMB (sponsor, third party, or internal)**

- Adverse Event Reports
- DSMB reports
- Audit reports
- All correspondences with the monitor
  - The retained communications should include all required reports, e-mails, faxes, memoranda, and letters. In addition, logging phone conversations is encouraged to track when conversations take place and the substance of the communications.
- Trial monitoring reports
  - Pre-trial visit
  - Initiation visit
  - Periodic monitoring
  - Closeout visit
- Monitoring visit log

8. **Product Information**

- Investigator brochure (all versions)
- Package insert (all version)
- Device manual (all version)
- Sample of product label (all versions)
- Instructions for handling investigational product(s) and trial-related materials (all versions)

9. **Laboratory Documentation**

- Laboratory certifications (e.g. CLIA) and updates of laboratory certifications
- Updates to normal value(s)/range(s) for medical lab technical procedure(s), test(s) included in the protocol
- Temperature Logs
- Medical/laboratory/technical procedures/tests and updates including:
  - Certification
  - Accreditation
  - Established quality controls/external quality assessment
  - Other validations
- Copy of the laboratory director's CV (signed and dated)
- Lab manual
- Lab shipment Log
- Record of retained body fluids/tissue samples



10. **Drug/Device Accountability**

- Shipment and receipt records for investigational products and study related supplies, including documented shipment dates, batch numbers, and methods of shipping the investigational product
- Dates, quantities received, batch/serial numbers, and expiration dates
- Inventory of the investigational product at the study site
- Documentation of investigational product return, disposal, or destruction as specified by the sponsor
- Certificates of analysis of investigational products shipped
- Documentation of investigational product accountability at study site
- Verification that dosing/device use was in accordance with the approved protocol including records regarding when the subjects received the drug/device and the specific dosage/device the subjects received
- Temperature Logs
- Drug/Device Accountability Log
- Drug/Device Dispensing Log

11. **Data Collection**

- Master randomization list (instructions on how to randomize)
- Decoding procedures in blinded trials for emergency situations
- Sample of the Case Report Forms (CRF)
- Patient Reported Outcomes
- Patient Diaries

12. **Study Logs**

Examples of other study logs include

- Subject screening log
- Subject identification code list
- Subject enrollment log
- Deviation log

This document is intended as guidance. Not all sections may be applicable to your research study. If you have questions, please contact us. [Research.Navigators@med.uvm.edu](mailto:Research.Navigators@med.uvm.edu) or call 656-9404 or 656-9407.