University Hospitals
Clinical Research Center

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Regulatory Binder Template and Section Tabs

POLICY STATEMENT:

University Hospitals (UH) requires investigators to maintain records of their research activities. Regulatory documents should be maintained and kept up to date for all research studies conducted at UH. The PI or designated member of the research team is responsible for the collection, review and maintenance of regulatory documents as required. Refer to **Research SOP SS-301 - Maintenance of Research Regulatory Documents** for further details.

INSTRUCTIONS:

1. Use the Table of Contents and Section Tab dividers included in this document as a template to organize your regulatory binder.
2. Electronic (e-Reg) systems or a mix of paper and electronic systems may be used
   - **Refer to the e-regulatory solutions that are available in the UH Research Toolbox and Digitizing your Research resources on the UH Intranet for further guidance**
3. Financial documentation (i.e., agreements, contracts, budgets, W-9s, participant compensation-voucher or gift card logs) should not be included in the regulatory binder, but they should be maintained elsewhere and made available upon request.
4. Electronic documents should be kept in a secure location with limited access and password protection, when appropriate.
5. All electronic information should be saved or backed-up to an UH encrypted thumb drive, zip drive, or other secure electronic media for long-term storage.
6. Documents containing PHI should not be kept in the same location as the regulatory documents unless they have limited access and are password-protected.
7. **Central binders** can be used for storing and organizing essential regulatory documents that apply to multiple studies. Those items can include, but are not limited to:
   - *CV*
   - *Clinical Licensure*
   - *Lab Certifications and Normal Range (CLIA/CAP)*
   - *IRB Membership Lists*
   - *Training Records*
   - *Documentation of professional certifications*
   - *etc.*
8. Consistency in filing is key so that documents can be found easily when needed.
9. Keep regulatory binder contents up-to-date. As amendments or revisions are made and reports are received, file the new information as soon as possible.
   - Maintain version numbers on all documents to identify relevance.
10. If a particular tab is not applicable, simply remove the tab and Table of Contents entry from the binder or insert a piece of paper indicating that the section is not applicable.

Regulatory Binder Relevance Grid

	Interventional	Observational	Chart Review / Repository	FDA Regulated
Contact Information	X	X	X	X
Protocol	X	X	X	X
Informed Consent / Assent	X	X	X*	X
IB/Package Insert / Device Manual	X			X
Screening / Enrollment Logs/List	X	X	X	X
Safety Reports	X	X		X
Investigational Products / Devices	X			X
Laboratory/Specimens	X			X
Data Management / Collection	X	X	X	X
IRB / IEC	X	X	X	X
FDA	X*	X*		X*
Correspondence	X	X	X	X
Monitoring	X			X
DSMB / DSMC	X	X		X
Institutional Approvals	X	X	X	X

***as applicable**

FDA Requirements:

- 21 CFR Part 50 — Protection of Human Subjects and Informed Consent
- 21 CFR Part 54 — Financial Disclosure by Clinical Investigators
- 21 CFR Part 56 — Institutional Review Boards
- 21 CFR Part 312 — Investigational New Drug Application
- 21 CFR Part 314 — Applications for FDA Approval to Market a New Drug
- 21 CFR Part 812 — Investigational Device Exemptions
- 21 CFR Part 814 — Pre-market Approval of Medical Devices
- 21 CFR Part 11 — Electronic Records; Electronic Signatures

E6 (R2) ICH Good Clinical Practice (GCP) Guidance for Industry

Regulatory Binder Table of Contents

1.	**Contact Information**	1.1 Site Staff 1.2 Sponsor
2.	**Protocol**	
3.	**Informed Consent / Assent / Information Sheet**	
4.	**Investigator Brochure / Package Insert / Device Manual**	
5.	**Essential Documents**	5.1 Delegation Logs / Site Signature Log 5.2 Training Documentation 5.3 CV / Resume / Biosketch 5.4 Professional Licenses 5.5 Certifications e.g. CREC, GCP, Credentialing
6.	**Screening / Enrollment Logs / Study Participant Identification Log / Listing of the Number of Participants EMR Records Assessed**	
7.	**Recruitment Materials** (e.g. Pamphlets, Posters, Flyers, Brochures, Phone and Email Scripts, Landing Pages)	
8.	**Safety Reports**	8.1 Adverse Events 8.2 Serious Adverse Events 8.3 Unanticipated Problems 8.4 Protocol Deviations 8.5 Safety Reports (INDSRs)
9.	**Investigational Products / Devices**	9.1 Randomization / Blinding Plans 9.2 Packing slips / Shipment Records 9.3 Preparation / Dispensation / Administration (Accountability) 9.4 Return / Destruction 9.5 Temperature Monitoring Logs / Reports
10.	**Laboratory / Specimens**	10.1 Reference Ranges / Normal Ranges / Manuals 10.2 IATA Certifications 10.3 Handling/ Storage/ Destruction 10.4 CLIA / CAP / Lab Director CV 10.5 Inventory / Shipments 10.6 Collection Logs
11.	**Data Management / Data Collection**	11.1 Source Documents 11.2 Case Report Forms 11.3 Electronic Data Capture (EDC) / Remote Data Capture (RDC) including Operating Guidelines
12.	**IRB of Record**	12.1 Approval letters 12.2 Correspondence 12.3 Roster or IEC Committee Composition 12.4 FWA Certificate
13.	**FDA, as applicable**	13.1 FDA Approval Letter 13.2 FDA 1571 13.3 FDA 1572 / Investigator Agreements 13.4 Financial Disclosures / FDA 3455 13.5 Annual report(s)
14.	**Correspondence**	14.1 Staff 14.2 Sponsor 14.3 Other
15.	**Monitoring**	15.1 Site Visit Signature Log 15.2 Reports / Letters
16.	**Data and Safety Monitoring Board / Committee / Plans**	16.1 Approved Charter 16.2 Reports / Minutes / Recommendations
17.	**Institutional Approvals, as applicable**	17.1 Feasibility 17.2 Credentialing 17.3 Department Approval / PRMC 17.4 Investigational Drug Services 17.5 Radiology 17.6 Electrical Safety

1 - CONTACT INFORMATION

Guidance:

- Develop a study team communication plan, phone tree, organizational chart, etc.
- Contact Lists should include all site/facility; staff; sponsor email address; work phone numbers, mobile/cell numbers, and applicable mailing addresses

2 - PROTOCOL(s)

Guidance:

- Documents should be filed in reverse chronological order
- All documents should contain a version date and/or version number
- If documents are maintained electronically, include a note to file indicating the location and who maintains the electronic files.
- Separate past versions and label all prior versions with their dates of relevance.

3 - INFORMED CONSENT / ASSENT / INFORMATION SHEET

Guidance:

- Documents should be filed in reverse chronological order
- All documents should contain a version date and/or version number
- If documents are maintained electronically, include a note to file indicating the location and who maintains the electronic files.
- Separate past versions and label all prior versions with their dates of relevance.

Informed consents that have been signed by study participants should always be kept in a separate location/binder than the regulatory binder

4 - INVESTIGATOR BROCHURE/PACKAGE INSERT/DEVICE MANUAL

Guidance:

- Documents should be filed in reverse chronological order
- All documents should contain a version date and/or version number
- If documents are maintained electronically, include a note to file indicating the location and who maintains the electronic files.
- Separate past versions and label all prior versions with their dates of relevance.
- If investigational product in marketed, a basic product information brochure or package insert is an appropriate alternative

5 - ESSENTIAL DOCUMENTS

Guidance:

Delegation Logs / Site Signature Log

- The Principal Investigator (PI) indicates to whom they have delegated specific study tasks and who is authorized to do work on the study. It is important to document when key study personnel transition on aw well as off a study

- It is the PIs responsibility to delegate tasks within an individual's scope of practice

Training Documentation

- Documents that the investigator and study staff have been adequately trained to conduct the study procedures that have been delegated to them

- Maintain protocol-specific training documentation in the regulatory binder. Include a copy of the training material provided (for example, handout of PowerPoint slides) and the sign-in sheet showing the date and those in attendance

CVs / Resumes / Biosketches

- CVs should be signed, dated, and updated every 2 years per UH policy

Professional Licenses

- Licensed study staff delegated responsibility for the study by the PI should maintain evidence of current licensure (i.e., medical, nursing)
- Verify all licensed staff listed on the delegation log (and Form FDA 1572, if applicable) have a license on file

- File current copies with every renewal or update.

Certifications e.g. CREC, GCP, NIH, Credentialing

- Non-UH personnel engaged in research at UH are responsible for keeping all the required credentialing documentation on file.

- All study team members conducting research with human subjects must earn their 12 CREC credits every 3 years. Maintain current CREC certificate on file.

6 - Screening / Enrollment Logs / Study Participant Identification Log / Listing of the Number of Participants EMR Records Assessed

Guidance:

- If screening and enrollment logs are stored in a separate location from your regulatory binder include a directional note for the location.

- The Screening Log captures all potential study participants who have been contacted about the research study and is used to demonstrate compliant recruitment practices. The log should indicate who agreed or declined participation and the reason when possible. was eligible to continue in the study and who were ineligible, along with the reason for screen failures.

- The Enrollment Logs contain a list of participants who signed the informed consent document, if they screen failed or ultimately enrolled in the study as well as associated dates.

7 - RECRUITMENT MATERIALS

Guidance:

This section should contain all IRB approved participant facing materials. These can include:

- Posters, Brochures, Flyers
- Scripts (phone) for screening / consenting)
- Diary Cards / Tracking Logs, etc.
- Newsletters
- Text messages
- Emails message templates
- Social media post templates
- UH website landing page mockups
- Google or Facebook advertiements

8 - SAFETY REPORTS

Guidance:

- This section should contain copies of all documentation relating to the reporting of protocol deviations, protocol violations, adverse events (AEs), serious adverse events (SAEs), and Unanticipated Problems.
    - Includes Investigational New Drug (IND) Safety Reports and Investigational Device Exemption (IDE) Reports

- It is recommended to file documents by specific event (with the most current event on top), then in reverse chronological order by acknowledgement date.

9 - INVESTIGATIONAL PRODUCTS / DEVICES

Guidance:

The PI is responsible for the following in regards to investigational drugs an/or devices:

- Maintain records of investigational product delivery to the study site.
    - Including dates, quantities received, batch/serial numbers, and expiration dates
- Maintain inventory of the investigational product at any site.
    - Inventory control records should be updated, signed, and dated by the PI
- Record/track use of investigational product by each participant
- Return and dispose of unused investigational product as specified by sponsor.
- Maintain documentation of returned/disposed items
- Store the investigational product.
    - The storage area should be locked/secured with access limited to approve study staff only.
- Drugs/devices should not be stored with standard clinical inventory.

Note: May be maintained by Investigational Drug Services.

10 - LABORATORY / SPECIMENS

Guidance:

- Laboratory certification (e.g., CLIA, CAP) and normal laboratory/reference values, the lab director's CV.
    - Documents the competency of lab facilities being used in the study
    - Supports the consistency and reliability of test results
    - Indicates the "normal" reference values for each test being conducted by the lab for the study

11 - DATA MANAGEMENT / DATA COLLECTION

Guidance:

- Blank set of Case report forms (CRFs), data collection sheets, and study questionnaires and all amended versions- include version number, version date

- If documents are maintained electronically, include a note to file indicating the location and who maintains the electronic files

- If questionnaires are conducted via electronic tablet, smart phone, smart device, include a note to file indicating the location of that device and storage/security measures

Note: Data collection sheets typically act as source documents and Case Report Forms are generally provided by industry sponsors or created by the research team; all protocol-required information is transferred to CRFs from data collection sheets.

12 - IRB OF RECORD

Guidance*:*

- All approval letter(s), FWA information; IRB membership roster/composition , meeting dates should be on file
- All documents should contain a version date and/or version number
- If documents are maintained electronically, include a note to file indicating the location and who maintains the electronic files.
- Study Relevant IRB Correspondence

13 - FDA

Guidance:

- FDA required forms (1571 and / or 1572, investigator agreement) and correspondence (if applicable)
- Annual Progress Reports
- Form 3674, certification of registration to ClinicalTrials.gov

14 - CORRESPONDENCE

Guidance:

- This section should contain all relevant study correspondence including email correspondence
- File like correspondence together with the most recent date on top.
- Note to file documents should be reserved for notable issues or discrepancies or a pattern of notable issues or discrepancies that require explanation due to a potential impact on the study data or study outcome.
    - An individual and participant specific issue or discrepancy should be documented directly in the participant source record at the place the discrepancy exists or is observed.
    - Protocol deviations requiring reporting to the IRB or Sponsor should be completed per IRB requirements, Sponsor directive and per protocol. Protocol deviations and associated documentation should be filed accordingly in the appropriate Regulatory Binder sections per the Regulatory Binder Index.

15 - MONITORING

Guidance:

This section includes a log of Monitoring Visits, Quality Assurance (QA) reviews, FDA audits, etc., including:

- Documentation from monitoring visits and reviews (for example, site visits or FDA audits)
    - Includes any study related activity performed to monitor study progress, compliance, and to verify accuracy and completeness of study records; Completed each time the study is monitored

- **Note: Records of internal self-reviews, research compliance reviews or other internal monitoring report should not be filed within the regulatory binder. Maintain records in a secure and confidential location. It is not necessary to make these reports accessible, although they may be requested.**

16 - Data and Safety Monitoring Board / Committee / Plans

Guidance:

- DSMB Plans are required for all research being conducted at UH for interventional studies to ensure there is monitoring of participant safety.

- Maintain documentation of the following:
  - Members and affiliations
  - Charter
  - Monitoring plan
  - Meeting minutes
  - Reports/recommendations
  - Correspondence

17 - INSTITUTIONAL APPROVALS

***Guidance**:*

This section should contain:

- Feasibility Assessment
- Scientific / Department
- PRMC
- Investigational Drug Services
- Radiology
- Electrical Safety
- Other relevant approvals

FORMS OR ATTACHMENTS:

- UH Clinical Research Toolbox
- Adverse Event Reporting:
  - Internal Adverse Event Summary Log
  - External Adverse Event Summary Log
- Clinical Research Regulatory Binder Index
- Delegation of Authority Log/Staff Signature Log
- Device Accountability Log
- Drug Accountability Log
- Monitoring Log
- Screening/Enrollment Log