

## Office of Clinical Research (OCR)

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### STUDY DOCUMENTATION STANDARDS AND DATA MANAGEMENT PRACTICES POLICY AND PROCEDURE

#### 1. PURPOSE

- 1.1. To establish human subject research documentation standards to effectively maintain complete, accurate, and current human subject research records by supplementing federal or state regulations with local policy.
- 1.2. The policy applies to all personnel who are responsible for collection and maintenance of human subject research documents and data (regardless of format).

#### 2. STUDY DOCUMENTATION STANDARDS

##### 2.1. General Principles:

- 2.1.1. Investigators oversee and delegate responsibilities to research team members to ensure records include a reasonable and suitable guarantee of authenticity and reliability.
- 2.1.2. Investigators ensure documentation practices protect the privacy of the research subject, maintain confidentiality of study documentation (records) and preserve business continuity.
- 2.1.3. Investigators or designated personnel ensure records are easily accessible for inspection by authorized institutional officials, and as applicable, the Food and Drug Administration (FDA) or other federal agencies, sponsors and sponsor agents, or funding entities.
- 2.1.4. Manuals, SOPs, and/or Work Instructions (WIs) must be detailed enough for uniform treatment in executing the protocol and administration of the study.
- 2.1.5. If the research is investigator-initiated, then the Principal Investigator establishes documentation forms and processes, including revision control methods to record the history of changes and to ensure removal of the superseded versions of procedures and data collection tools.
- 2.1.6. If the research is a Local Sponsor Investigator study, where the Principal Investigator (PI) holds the IND or IDE, the PI is responsible for annual and adverse event reporting to the FDA.
- 2.1.7. Research teams generate key documents either to guide study activities or as a result of the conduct of the study.

##### 2.2. Procedures:

- 2.2.1. Determine the method for how study records will be stored and how to organize paper records in binders with indexes or if digital records, on a secure server with clearly designated folders or indexing. If records are filed separately, place a note (or electronic link) in the primary study file to identify where the separated information is stored.
- 2.2.2. Maintain confidentiality of research data by replacing direct identifiers with codes. Maintain the key to the codes in a secure in locked storage cabinet or on a secure server.
- 2.2.3. Do not leave private identifiable or proprietary information exposed on a desk or viewable on a computer screen when leaving one's workspace unattended.
- 2.2.4. When transporting private identifiable research data, ensure measures are taken to reduce the risk of unintended loss of confidentiality.
- 2.2.5. Investigators conducting FDA Regulated research and storing documents electronically, refer to [Guidance for Industry: Electronic Source Data in Clinical Investigations](#)
- 2.2.6. Develop written SOPs for handling documents and train staff on creating, revising, and filing or archiving documents. Document staff training when revisions occur.

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2.2.7. Investigators ensure that study documents are not accidentally or prematurely destroyed before the expiration of prescribed retention periods per institution or sponsor, whichever is longer. ([Research and Grants Retention Schedule](#)).

2.2.8. Some sponsors may require investigators to maintain documents not specifically referenced in this policy.

### 2.3. Evaluation:

2.3.1. Create and use a checklist to efficiently review documents at every filing change to maintain current, complete study records.

2.3.2. Analyze documents and filing at sufficient intervals based on the complexity of the study. The larger the volume of documents, the smaller the frequency of review.

2.3.3. Investigators designate specific staff to manage documents clearly defined in the job description and with tasks delineated in SOPs.

2.3.4. Review SOPs regularly and revise as needed.

2.3.5. Investigators read monitoring reports upon receipt and meet with staff to discuss documentation requirements and needed changes.

## 3. DATA MANAGEMENT PRACTICES

### 3.1. General Principles:

3.1.1. Sponsors typically require a specified organization for data and often provide procedures, binders, and forms or web-hosted applications to manage data consistently and, if applicable, across multiple sites.

3.1.2. Investigators understand the vital nature of research records, which must stand alone for each study subject and as a whole for the study to illustrate the conduct and progress of a study.

3.1.3. Study-specific procedures define data collection, e.g., who will collect it, how it will be collected, and where it will be recorded.

3.1.4. Study data may be transcribed from source documents.

3.1.5. Investigators authorize who is allowed to make changes to data and who reviews the changes.

3.1.6. Sharing data that have been published is a tenet of the scientific community. Standards of data sharing are published by national scientific organizations and by federal funding agencies. (See Part 5., References)

3.1.7. Consistent with federal policy and prevailing higher education practices, research data are the property of the Health Science Center (HSC). Refer to [HOP 12.1.1., Intellectual Property Policy](#) and [HOP 7.6.1., Research Misconduct](#).

3.1.8. The HSC has the right to access research data and records for all research, performed at HSC, supported by HSC-administered funds, or conducted using HSC facilities and equipment, provided that such access shall be for reasonable cause, at reasonable times and after reasonable notice, except in the event of a bona fide emergency. The HSC right of access continues regardless of the location of the Principal Investigator or of the research data. Refer to [HOP 7.10.1 Research Data Ownership, Retention and Access](#). A written agreement on Disposition of Research Data shall be negotiated between the PI and the department chair or dean prior to an investigator leaving the HSC. These agreements serve to ensure fulfillment of HSC obligations to funding agencies and ensure appropriate access for compliance purposes.

### 3.2. Electronic data systems housing study data must comply with federal and state regulations.

3.2.1. If FDA regulated - [Guidance on Electronic Source Data in Clinical Investigations](#)

3.2.2. If VA research – Refer to VA Handbook 6500

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- 3.2.3. If HSC research – Refer to [HOP 5.8 Information Security](#)
- 3.2.4. Implement written procedures for maintaining and for using electronic systems, including adequate backup procedures. Train all research team (RT) members who are required to use the system.
- 3.2.5. Access to electronic records may require [transfer](#) to central retention server(s), should the PI or other key team member leave the institution during the execution of or after the close-out of the study.

### 3.3. Procedures:

- 3.3.1. Before initiating a study, sponsors and investigators train RT members on data filing procedures.
- 3.3.2. Investigators provide adequate supplies to ensure filing systems are maintained.
- 3.3.3. Coordinators prepare files in advance of monitoring visits.
- 3.3.4. RTs record source data at the time of observation or test result, and initial and date all entries by the person recording the entry. (See Table 1.)
  - 3.3.4.1. Write all handwritten entries in ink only, legibly, and explain all blanks.
  - 3.3.4.2. Make corrections using a single line strike out with date, time, and initials to maintain auditable changes without obscuring the original entry. Correction tape or liquid is strictly prohibited.

<b>Table 1: Example Source Documents (see also Appendix A, Section SD)</b>
Original Study Documents – Completed Informed Consent Forms (ICF) and Case Report Forms (CRF)
Records from trial execution or supporting documents on medical history including the following: <ul style="list-style-type: none"><li>• Medical records</li><li>• Hospital, clinic, &amp; office charts</li><li>• Progress notes, patient visit notes, physician's notes/orders</li><li>• Records: laboratory, radiology, cardiology, medico-technical departments</li><li>• Pharmacy dispensing records</li><li>• X-Rays, Scans (bone, brain, MRI)</li><li>• Video (angiography, endoscopy)</li><li>• Instrumentation printout: EKG, ECG, Spirometry, etc.</li><li>• Memos to record concerning the study</li><li>• Subjects' diaries, evaluation checklists, or Quality of Life questionnaires</li><li>• Recorded data from automated instruments</li><li>• Certified transcription of recorded results including dictation (i.e., verified as accurate and complete)</li><li>• Photographs, negatives, microfilm or magnetic media</li></ul>

- 3.3.5. Set up quality control checks of the transcription as routine practice or practice dual data entry for comparison.
  - 3.3.5.1. Explain any discrepancies between transcribed data and source data.
  - 3.3.5.2. Review data on a scheduled basis to identify adverse events, protocol deviations, and data recording errors.
- 3.3.6. Archive study data in a secure manner at the institution or at an off-site storage area with limited access and a sign-in/out log. See [HOP 5.8: Information Security](#).

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### 4. REFERENCES:

- 4.1.1. [Sharing Publication-Related Data and Materials: Responsibilities of Authorship in the Life Sciences](#) (The National Academies Press)
- 4.1.2. [National Institutes of Health \(NIH\) Data Sharing Policy](#)
- 4.1.3. [National Science Foundation \(NSF\) Dissemination and Sharing of Research Results](#). See Award & Administration Guide (AAG) Chapter VI.D.4.
- 4.1.4. [HOP 12.1.1., Intellectual Property Policy](#) and [HOP 7.6.1, Research Misconduct](#).
- 4.1.5. UTHSCSA Records Retention Schedule at the following link:  
<https://cdm16941.contentdm.oclc.org/digital/collection/rrs>

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[https://nccih.nih.gov/sites/nccam.nih.gov/files/CR-Toolbox/Regulatory\\_Binder\\_Checklist\\_ver3\\_07-17-2015.docx](https://nccih.nih.gov/sites/nccam.nih.gov/files/CR-Toolbox/Regulatory_Binder_Checklist_ver3_07-17-2015.docx)



### Tool Summary Sheet

**Tool:** Regulatory Binder Checklist

**Purpose:** To provide an organizational framework for filing paper versions of essential study documents (or referencing location of an electronically stored file)

**Audience/User:** Study coordinators or individuals responsible for establishing the Essential Document Binder (synonyms: Investigator Binder, Regulatory Binder, Investigational Site File (ISF), or Study Binder)

- Details:**
- This document clarifies the standard content of the Binder.
  - It is the responsibility of the investigator to ensure compliance with Good Clinical Practice (GCP), institutional review board (IRB), and applicable regulatory requirements.
  - This document serves as a template and may be modified for study-specific needs/requirements.

- Best Practice Recommendations:**
- Store items in reverse chronological order, with the newest items within a section placed at the front of the section.
  - Multi-site studies: The lead site may choose to customize the checklist for the study and provide to all participating sites.

**References:** Good Clinical Practice (E6) Section 8.1, 8.2, 8.3, 8.4

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### Regulatory Binder Checklist For Clinical Trials

The following documents (all versions) should be collected and filed in the regulatory binder, if applicable to the clinical study (ref: ICH/GCP).

#### Protocol and Amendments

- Log of protocol changes
- Institutional Review Board (IRB)-approved protocol, with signed principal investigator (PI) signature page
- IRB-approved blank Case Report Forms
- IRB-approved advertisements
- IRB-approved Participant Information Sheets
- IRB-approved protocol amendments

#### Informed Consent Documents

- Log of Informed Consent versions
- IRB-approved Informed Consents

#### IRB Documentation

- IRB Federal Assurance Number
- Updated IRB Roster
- IRB registration (optional)

#### IRB Approvals and Correspondence

- IRB approval letters (e.g., protocol, protocol amendments, consent/assent documents, continuing review, advertisement or recruitment materials, investigator's brochure, package insert)
- Original IRB application/submission
- Correspondence related to contingent approvals or stipulations
- IRB correspondence
- IRB annual renewals
- Interim/annual progress reports to the IRB

#### Investigator Qualification Documentation

- Updated investigator and sub-investigator CVs (signed/dated within 2 years)
- A clinical (dental, medical, etc.) license for the PI and co-investigators, if licensed

#### Clinical Investigator's Brochure

- Clinical investigator's brochure or
- Package insert; include labeling for approved medications

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### FDA Documents (if applicable)

- FDA Forms 1571 and 1572
- Sample of labels attached to investigational product containers
- Regulatory approval or authorization
- FDA Correspondence Log

### Financial Disclosure Forms

- Signed Financial Disclosure Forms for the PI and co-investigators

### Study Communication

- Letter of Understanding/Confidentiality Agreement
- Data Sharing Agreement
- Material Transfer Agreement
- Signed agreements between parties (i.e., sponsors/investigators)
- Important decisions regarding study conduct, such as notes to the Study File
  - Notes to File

### Delegation of Authority Log

- Delegation of Authority Log

### Clinical Research and Study Training

- Documentation of human subject protection training and Good Clinical Practice training (for all staff members)
- Documentation of Dangerous Goods Training (if applicable)

### Screening/Enrollment Log

- Screening/Enrollment Log
  - A log without identifying information that lists all screened subjects
  - Subject Identification Code list (which should be kept separately)

### Signed Consent Documents (may be kept in a separate binder)

- Study Product Records (documentation of study product and accountability forms/logs)

### Study Product Records (may be kept in the research pharmacy to protect the blind)

- Documentation of study product (e.g., botanicals, probiotics, or other natural products) disposition and accountability, or memo as to where records are located (e.g., research pharmacy) and who is maintaining accountability logs

### Laboratory Certification (Clinical Laboratory Improvement Amendments [CLIA], College of American Pathologists [CAP], etc.)

- Updated normal-range values for each reference laboratory
- A copy of certifications or accreditations (CAP, CLIA, or state certificate)

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**Specimen Tracking Log**

**Serious Adverse Events (SAE)/Unanticipated Problem Documents**

- SAE Report Forms
- Unanticipated Problem Forms
- IND Safety Reports

**Protocol Deviation Form or Memo**

**Clinical Site Monitoring Visits**

- Site visit log
- Site visit reports
- Site visit correspondence

**Sponsor Correspondence**

**Data and Safety Monitoring Documents**

- Data and Safety Monitoring Plan (if not included as part of the study protocol)
- Study reports generated for Independent Safety Monitor(s)
- Minutes from independent safety monitor(s) meeting(s)
- Recommendations and correspondence from the independent safety monitor(s)

**Other Documents**

- Unmasking procedures for blinded trials
- Certificate(s) of Confidentiality
- Other study documents

References: 21CFR312/812

[ICH Guidance: E6 GCP](#)

Contact [OCRmail@uthscsa.edu](mailto:OCRmail@uthscsa.edu) for an example electronic regulatory binder template.



Appendix A  
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Section	Document	Requirement/Purpose	File Location	Reference (GCP and Local)	Sponsor Investigator	IND/IDE	FDA Regulated	Non-FDA Regulated Non-Exempt Human Research	Exempt
ED-1	Protocol	To document investigator and sponsor agreement to the protocol, amendments and CRFs; and, to document revisions of trial-related documents that take effect during trial: <ul style="list-style-type: none"> <li>• Initial version that the site was registered</li> <li>• Amendments and Letters of Amendment</li> <li>• Subsequent versions</li> <li>• Investigator signature page</li> </ul> * NOTE: For IRB Exempt studies. IRB Exempt Application should be on file * NOTE: For Non-FDA Regulated Non-Human Research, Form BB, Form BC, Form CT, and/or Protocol should be present.	Regulatory binder	<ul style="list-style-type: none"> <li>• 21CFR312/812</li> <li>• ICH Guidance: E6 GCP, Sections 1.44, 1.45, 4.5, 5.23, 6, 8.2.2, 8.3.2</li> </ul>	Yes	Yes	Yes	No	No
ED-2	Protocol Training (Training Log)	Documentation that trial procedures were reviewed with the investigator and investigator's trial staff: <ul style="list-style-type: none"> <li>• Summary of start-up calls</li> <li>• Training meetings (Initiation, Implementation, Investigator Meeting, Teleconference, List of Training Attendees)</li> </ul>	Regulatory binder	<ul style="list-style-type: none"> <li>• 21CFR312/812</li> <li>• ICH Guidance: E6 GCP, Sections 4.5, 5.23, 8.2.20</li> </ul> AAHRPP Elements:III.1.C; III.2.A	Yes	Yes	Yes	No	No
ED-3	Delegation Log/ Signature Log (IRB Personnel List)	1. To document Principal Investigator delegation of significant trial related duties for FDA regulated studies. To outline the roles and responsibilities delegated by the PI to team members. IRB personnel list in combination with the research team roles and activities from the research application is acceptable to fulfill this requirement.	Regulatory binder	<ul style="list-style-type: none"> <li>• ICH Guidance: E6 GCP, Section 8.3.24</li> </ul> AAHRPP Elements: III.2.A; III.2.B;  VHA Handbook 1200.05	Yes	Yes	Yes	No	No

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ED-4	Curriculum Vitae (CV), Medical License, RN License, etc. (if applicable)	<p>1. The site must have on file CVs and/or other relevant documents (e.g. License, Scope of Practice, CITI training) evidencing qualifications and eligibility to conduct the trial and/or provide medical supervision of subjects. Includes the following key personnel:</p> <ul style="list-style-type: none"> <li>• Principal investigator (i.e., individual responsible for the grant/contract at the site).</li> <li>• Investigator responsible for day-today activities of the site.</li> <li>• For IND studies: Investigator of Record (IOR); All other investigators/sub-investigators and any other clinicians listed on a Form FDA 1572, Box # 6.</li> <li>• For non-IND studies: all other investigators/ sub-investigators and any other clinicians listed on an authorized prescribers list.</li> <li>• Study coordinator</li> <li>• Pharmacist of record</li> </ul> <p>2. Update to reflect significant changes:</p> <ul style="list-style-type: none"> <li>• Affiliation</li> <li>• Education</li> <li>• Responsibilities</li> </ul>	Regulatory binder	<ul style="list-style-type: none"> <li>• 21CFR312/812</li> <li>• ICH Guidance: E6 GCP, Sections 4.1, 4.3, 5.6, 8.2.10, 8.3.5</li> </ul> <p>AAHRPP Element: III.2.A</p>	Yes	Yes	Yes	Yes	No

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ED-5	Financial Disclosure	<ol style="list-style-type: none"> <li>1. To document financial aspects of the trial and the financial agreement between the investigator / institution and the sponsor for the trial.</li> <li>2. Certification or Disclosure <ul style="list-style-type: none"> <li>• Certify that there is no financial interest, or</li> <li>• Disclose specific financial interests.</li> <li>• Must complete FDA forms 3454 or 3455, or equivalent forms.</li> </ul> </li> <li>3. Applies to investigators and sub-investigators</li> <li>4. Applies to individuals who fit any of the following criteria: <ul style="list-style-type: none"> <li>• Sign the Form FDA 1572 (Investigator of Record)</li> <li>• Identified as an investigator in initial submissions or protocol amendments under an IND.</li> <li>• Identified as an investigator in the NDA (Non-Disclosure Agreement).</li> <li>• For studies not conducted under an IND, the individuals whom the sponsor considers to be investigators and sub-investigators.</li> <li>• Individuals who actually conduct and take responsibility for an investigation.</li> <li>• Individuals who have the ability and opportunity to significantly impact the data as determined by the site.</li> <li>• Spouses and dependent children of individuals indicated above.</li> </ul> </li> <li>5. The IRB may have additional requirements.</li> </ol>	Regulatory binder	<ul style="list-style-type: none"> <li>• 21CFR54</li> <li>• 42CFR50, Subpart F</li> <li>• 21CFR312 /812</li> <li>• ICH Guidance: E6 GCP, Section 8.2.4</li> <li>• FDA Guidance: Financial Disclosure by Clinical Investigators</li> <li>• NIH Notice OD-00-040</li> </ul>	Yes	Yes	Yes	No	No
ED-5a	Financial Disclosure	For local research, Form X for Conflict of Interest and iDisclose forms.	Regulatory Binder	HOP 10.1.6	Yes	Yes	Yes	Yes	Yes

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ED-6	IRB Approved Informed Consent Document	<p>1. Written informed consent form to document that consent is:</p> <ul style="list-style-type: none"> <li>• Obtained in accordance with regulations, GCP, and protocol.</li> <li>• Dated prior to participation of each subject in trial.</li> <li>• Provided for direct access to records.</li> </ul> <p>2. Non-English speaking subjects must be consented in a language they can understand.</p> <ul style="list-style-type: none"> <li>• Save all written translations.</li> </ul> <p>3. Consents obtained for screening purposes must be retained even if the subject was not enrolled in the protocol.</p> <p>4. To document revisions of these trial-related documents that take effect during trial, save all versions submitted and approved by site's IRB:</p> <ul style="list-style-type: none"> <li>• Informed consent form.</li> <li>• Any other written information provided to subjects.</li> </ul> <p>5. Continuing reviews are at the directive of the IRB.</p> <p>6. Changes in consent forms due to protocol amendments and important safety information must be submitted and approved by the IRB.</p> <p>NOTE: Waiver of consent documentation has been granted by FDA and/or IRB may apply to ANY category of study.</p>	Regulatory binder	<ul style="list-style-type: none"> <li>• 45CFR46</li> <li>• 21CFR50</li> <li>• 21CFR56</li> <li>• 21CFR312/812</li> <li>• ICH Guidance: E6 GCP, Sections 1.28, 4.8, 8.3.12, 8.2.3, 8.3.2</li> <li>• OHRP Informed Consent Guidance Information</li> </ul>	Yes	Yes	Yes	Yes	No
ED-7	Assent Form or study specific information sheet	<ul style="list-style-type: none"> <li>• Assent of children and permission of parents or legal guardians as determined by the IRB/IEC is required as per the provisions of 45CFR46.</li> <li>• State law where the research is taking place defines the age of a minor and requirements for emancipation.</li> <li>• The Assent Form or study specific information sheet is used for children ages 7-17 (IRB may require assent in ages 7-12 and assent is usually required in ages 13-17 unless waived by the IRB).</li> <li>• The requirement for assent of children and/or permission of their parents or legal guardians may be waived by the IRB as long as the criteria for waiving consent in the regulations (45CFR46) are met.</li> <li>• Keep on file all versions submitted and approved by the IRB.</li> </ul> <p>NOTE: Waiver of consent documentation has been granted by FDA and/or IRB may apply to ANY category of study.</p>	Regulatory binder	<ul style="list-style-type: none"> <li>• 45CFR46, Subpart D</li> <li>• 21CFR50</li> <li>• 21CFR56</li> <li>• FDA Information Sheets, Guidance for IRBs and Investigators</li> </ul>	Yes	Yes	Yes	Yes	No

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ED-8	IRB Approvals	<p>1. Copies of all materials submitted to the IRB, including any local committees as required by the IRB, for example but not limited to:</p> <ul style="list-style-type: none"> <li>• Mays Cancer Center's PRC</li> <li>• Radiation Use Committee</li> <li>• Other Hospital or UT Health SA affiliate's Committees per IRB requirements</li> </ul> <p>2. Dated proof of submission and IRB approval of the following for both initial submissions and revisions (if any). Revised documents must be labeled (e.g., date and/or version number) to differentiate them from previous versions.</p> <ul style="list-style-type: none"> <li>• Advertisements – to document that recruitment measures are appropriate and not coercive</li> <li>• Continuing/interim review of trial in accordance with federal regulations and IRB policy.</li> <li>• Stamped informed consent form</li> <li>• Protocol</li> <li>• Protocol Amendments and/or Letters of Amendment</li> <li>• Protocol-specific education materials</li> <li>• Subject compensation</li> <li>• Any other documents receiving IRB approval, including UPIRSO and Noncompliance Determinations</li> <li>• Any other written information to be provided to subjects, to document that subjects will be given appropriate written information (content and wording) to support their ability to give fully informed consent.</li> <li>• Any other pertinent communications with IRB or documentation required by the IRB.</li> <li>• Clarification memos as required by the IRB.</li> </ul> <p>3. Dated proof of IRB submission of the following for both initial submissions and revisions (if any). Revised documents must be labeled (e.g., date and/or version number) to differentiate them from previous versions.</p>	Regulatory binder	<ul style="list-style-type: none"> <li>• 45CFR46</li> <li>• 21CFR50</li> <li>• 21CFR56</li> <li>• 21CFR312/812</li> <li>• ICH Guidance: E6 GCP, Sections 3, 4.4, 4.5, 4.10, 5.11, 5.17.3, 8.2.3, 8.2.7, 8.3.2, 8.3.3, 8.3.19</li> <li>• OHRP IRB Guidebook</li> </ul>	Yes	Yes	Yes	Yes	Yes

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ED-9	IRB Approved Information Given to Study Subject	<ol style="list-style-type: none"> <li>1. To document that subjects will be given appropriate written information (content and wording) to support their ability to give fully informed consent.</li> <li>2. To document that recruitment measures are appropriate and not coercive.</li> <li>3. Includes the following: <ul style="list-style-type: none"> <li>• IRB-approved stamped informed consent form (long or short forms)</li> <li>• All applicable translations</li> <li>• Advertisement for subject recruitment (if used)</li> <li>• Education materials (protocol specific)</li> <li>• Any other written information, including screening and consent scripts</li> <li>• Protocol specific diaries and questionnaires</li> </ul> </li> </ol>	Regulatory binder	<ul style="list-style-type: none"> <li>• 45CFR46</li> <li>• 21CFR50</li> <li>• 21CFR56</li> <li>• ICH Guidance: E6 GCP, Sections 4.8, 8.2.3</li> </ul>	Yes	Yes	Yes	Yes	No
ED-10	Screening and Enrollment /Randomization Logs	<ol style="list-style-type: none"> <li>1. To document identification of subjects who entered pretrial screening.</li> <li>2. To document chronological enrollment of subjects by trial number.</li> <li>3. Screening and enrollment/randomization logs may be separate or combined.</li> <li>4. Include the following information: <ul style="list-style-type: none"> <li>• Initials of all patients screened for each study</li> <li>• Study ID if patient receives one</li> <li>• Date screened</li> <li>• Date randomized</li> <li>– If not randomized, indicate reason (screen failure - labs not within protocol specific range, meets exclusion criteria, etc.)</li> </ul> </li> <li>5. The log may also include current information regarding dates of subject visits and overall status in the study (completed, in progress, lost to follow up).</li> </ol>	Regulatory binder	<ul style="list-style-type: none"> <li>• 21CFR312/812</li> <li>• ICH Guidance: E6 GCP, Sections 8.3.20, 8.3.22</li> </ul>	Yes	Yes	Yes	Yes	Yes

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Section	Document	Requirement/Purpose	File Location	Reference (GCP and Local)	Sponsor Investigator	IND/IDE	FDA Regulated	Non-FDA Regulated Non-Exempt Human Research	Exempt
ED-11	Subject Identification Code List	<ol style="list-style-type: none"> <li>To document that the investigator keeps a confidential list of names of all subjects allocated to trial numbers upon enrolling in the trial.</li> <li>Allows investigator/institution to permit identification of all subjects enrolled in the trial in case follow-up is required.</li> <li>List needs to be kept in a confidential manner.</li> </ol>	Regulatory Binder(file at the end of study) Also file in study financial binder during the study.	<ul style="list-style-type: none"> <li>ICH Guidance: E6 GCP, Sections 1.58, 8.3.21, 8.4.3</li> </ul>	Yes	Yes	Yes	Yes	Yes
ED-12	Double Blinding	To protect the integrity of the research data. A copy of the Sponsor's SOP for unblinding must be on file at the site. Any premature unblinding must be documented.	Regulatory binder	<ul style="list-style-type: none"> <li>21CFR312</li> <li>ICH Guidance: E6 GCP, Sections 1.10, 4.7, 8.2.17, 8.4.6</li> <li>AAHRPP Element III.1.C.</li> </ul>	Yes	Yes	Yes	No	No
ED-13	Inv Product Accountability Log/Pharmacy Accountability Records	Accountability records must be kept for all study drugs/agents provided as part of the protocol (including temperature logs, excursions, product shipment or receipts, destruction records if done locally, expired products, product returned to sponsor). Drug/device should be stored in OCR-approved location.	Regulatory binder	<ul style="list-style-type: none"> <li>21CFR312/812</li> <li>ICH Guidance: E6 GCP, Sections 4.6, 5.13, 5.14, 8.2.15, 8.3.8, 8.3.23, 8.4.1</li> </ul>	Yes	Yes	Yes	No	No
ED-14	Record of Retained Body Fluids and/or Tissue Samples	If any blood specimens, other body fluids and/or tissue samples are retained for long-term storage at the site, document location and identification of the study related retained samples. (e.g., A laboratory data management or tracking system.)	Regulatory binder	<ul style="list-style-type: none"> <li>ICH Guidance: E6 GCP, Section 8.3.25</li> <li>OHRP Guidance: Issues to Consider in the Research Use of Stored Data or Tissues</li> </ul>	Yes	Yes	Yes	Yes	Yes

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ED-15	Serious Adverse Events (SAE) and Safety Reports	<p>1. Notification by originating investigator to sponsor of serious adverse events, related reports, and other safety information.</p> <p>2. Notification by sponsor to investigators of safety information.</p> <p>3. Where applicable, notification by sponsor or investigator to regulatory authorities and the IRB:</p> <ul style="list-style-type: none"> <li>• Unexpected, serious and related adverse drug reactions (within 5 days)</li> <li>• Other safety information (at yearly review)</li> <li>• IND Safety Reports, Safety Memos, and Safety Alerts (reported with yearly renewal, unless serious, unexpected and related to study, in which case, reported within 5 days of becoming aware of the event.)</li> <li>• Investigator's Brochures</li> <li>• UPIRSO Determinations</li> <li>• Local and non-local adverse events reviewed by PI</li> </ul>	Regulatory binder	<ul style="list-style-type: none"> <li>• 45CFR46</li> <li>• 21CFR50</li> <li>• 21CFR56</li> <li>• 21CFR312</li> <li>• ICH</li> </ul> <p>Guidance: E6 GCP, Sections 1.1, 1.2, 1.50, 1.60, 4.11, 5.16, 5.17, 8.3.16, 8.3.17, 8.3.18</p>	Yes	Yes	Yes	Yes	No
ED-16	Source Document Template	To include original source document template and current version if applicable provided by sponsor related to trial.	Regulatory binder	<ul style="list-style-type: none"> <li>• 21 CFR11</li> <li>• 21CFR312</li> <li>• ICH Guidance:</li> <li>• E6 GCP, Section 1.51, 1.52, 5.20, 8.3.13</li> </ul>	Yes	Yes	Yes	Yes	No
ED-17	Monitoring Log	Dated signature of monitor for each study visit with verification (initial) by site staff.	Regulatory binder	<ul style="list-style-type: none"> <li>• 21CFR312 /812</li> <li>• FDA</li> </ul> <p>Guidance: Monitoring</p> <ul style="list-style-type: none"> <li>• ICH</li> </ul> <p>Guidance: E6 GCP, Section 5.18</p>	Yes	Yes	Yes	No	No
ED-18	Monitoring Reports	<p>Copies of all site visit reports (hard copy or electronic) to document both the site visits and findings of the monitor. The local PI should document how the monitor findings were addressed.</p> <p>*Pre-study visit, Site Initiation visit, Interim Visits and Study Close out Visit.</p>	Regulatory binder	<ul style="list-style-type: none"> <li>• 21CFR312/812</li> <li>• ICH Guidance:</li> </ul> <p>E6 GCP, Sections 1.39, 5.18, 8.3.10</p>	Yes	Yes	Yes	No	No



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Section	Document	Requirement/Purpose	File Location	Reference (GCP and Local)	Sponsor Investigator	IND/IDE	FDA Regulated	Non-FDA Regulated Non-Exempt Human Research	Exempt
ED-19	Final / Close Out Monitoring Report	<ol style="list-style-type: none"> <li>1. A close-out report by the monitor to document that all activities required for site close-out are completed and essential documents are in the appropriate files. Includes the following: <ul style="list-style-type: none"> <li>• Disposition of subjects</li> <li>• Location of research records</li> <li>• Disposition of specimens</li> <li>• Disposition of study drug</li> <li>• IRB notification</li> </ul> </li> <li>2. Applies only to sites being closed (i.e., no longer enrolling new subjects or following any subjects on-study)</li> </ol>	Regulatory binder	<ul style="list-style-type: none"> <li>• 21CFR312/812</li> <li>• ICH Guidance: E6 GCP, Sections 4.13, 8.4.5</li> </ul>	Yes	Yes	Yes	No	No
ED-20	Final Study Report	<p>Final report by the investigator to the IRB, and where applicable, to the regulatory authorities to document completion of the trial. Include the following information:</p> <ul style="list-style-type: none"> <li>• Disposition of subjects</li> <li>• Location of research records</li> <li>• Disposition of specimens</li> <li>• Disposition of study drug</li> <li>• Other information as required by the IRB (e.g., number of patients screened, number enrolled, serious adverse experiences, etc.).</li> </ul>	Regulatory binder	<ul style="list-style-type: none"> <li>• 21CFR312/812</li> <li>• ICH Guidance: E6 GCP, Sections 4.13, 8.4.7</li> </ul>	Yes	Yes	Yes	Yes	No
ED-21	Communications/ Correspondence	<ol style="list-style-type: none"> <li>1. All important, significant communications, other than site visits, to document any agreements or significant discussions regarding trial administration, protocol violations, trial conduct, adverse event (AE) reporting, etc. For example: <ul style="list-style-type: none"> <li>• Letters</li> <li>• Meeting notes</li> <li>• Notes of telephone calls</li> <li>• Email messages</li> <li>• Faxes</li> <li>• Notes to File regarding study events/ clarifications / medical care</li> </ul> </li> <li>2. Includes significant communications to and from the Sponsor.</li> <li>3. Communications about a specific subject must be filed with source documents in the subject's research record.</li> <li>4. Save electronic media, originals, and/or certified copies.</li> </ol>	Regulatory binder	<ul style="list-style-type: none"> <li>• ICH Guidance: E6 GCP, Sections 4.4, 4.9, 8.3.11</li> <li>AAHRPP Element III.1.C.</li> </ul>	Yes	Yes	Yes	No	No

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ED-22	Form FDA 1572 (Statement of Investigator)	<ol style="list-style-type: none"> <li>1. Required for each initial protocol registration submission of a new protocol with an Investigational New Drug (IND) application (Form FDA 1571)</li> <li>2. The Investigator listed in Box 1 of the 1572 is the individual who must sign and date the form. This individual is referred to as the Investigator of Record (IOR).</li> <li>3. Only laboratories not specified in the protocol need to be listed in Section 4.</li> <li>4. Section 6 must list any individual: <ul style="list-style-type: none"> <li>• Responsible for the medical management of subjects.</li> <li>• Authorized to prescribe study medication.</li> <li>• This may include, but is not limited to, the following: <ul style="list-style-type: none"> <li>– MDs</li> <li>– Pharmacists</li> <li>– Nurse Practitioner</li> <li>– Physician's Assistant</li> <li>– Study Coordinator</li> </ul> </li> <li>• If there are no individuals that need to be listed, then record "NONE".</li> </ul> </li> <li>5. Update as study personnel and/or other data on the form change. Updated forms must be signed and dated by the IOR.</li> <li>6. The original version and any updated forms must be submitted to the sponsor (if applicable) and the FDA.</li> <li>7. A copy of the forms must be kept on file at the site.</li> </ol>	Regulatory binder	<ul style="list-style-type: none"> <li>• 21CFR312</li> <li>• ICH Guidance: E6 GCP, Sections 4.1, 4.3</li> </ul>	Yes	Yes	No	No	No

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Section	Document	Requirement/Purpose	File Location	Reference (GCP and Local)	Sponsor Investigator	IND/IDE	FDA Regulated	Non-FDA Regulated Non-Exempt Human Research	Exempt
ED-23	Investigator's Brochure (IB) /Device Brochure/ Package Insert or Equivalent	<ol style="list-style-type: none"> <li>1. To document that relevant and current scientific information about the investigational drug/agent has been provided to the investigator.</li> <li>2. Include updates to document that investigator is informed in a timely manner of relevant information as it becomes available.</li> <li>3. Keep on file a copy for EACH of the study drugs/agents used within the protocol.</li> <li>4. Include the following: <ul style="list-style-type: none"> <li>• Only the most recent version</li> <li>• Addendum to IBs (e.g., all IND safety reports related to the drug/agent).</li> </ul> </li> </ol>	Regulatory binder	<ul style="list-style-type: none"> <li>• 21CFR312</li> <li>• ICH</li> </ul> Guidance: E6 GCP, Sections 1.36, 5.12, 7, 8.2.1, 8.3.1	Yes	Yes	Yes	No	No
ED-24	Laboratory	<ol style="list-style-type: none"> <li>1. To document competence of local, central, or Group laboratories to perform protocol required tests and support reliability of results of medical/laboratory/standardized procedures/tests including normal ranges. One of the following must be on file: <ul style="list-style-type: none"> <li>• CLIA Certification of Compliance</li> <li>• CLIA Certification of Accreditation</li> </ul>           AND the agency certificate (e.g., CAP Certification of Accreditation)         </li> </ol>	Regulatory binder	<ul style="list-style-type: none"> <li>• 21CFR58</li> <li>• 21CFR312</li> <li>• 42CFR493.3</li> <li>• ICH</li> </ul> Guidance: E6 GCP, Sections 4.2, 8.2.11, 8.2.12 8.3.6, 8.3.7	Yes	Yes	Yes	Yes	No
ED-24	SOP/Manual of Operations	Protocol Specific	Regulatory Binder	AAHRPP Element I.1.D.	Yes	Yes	Yes	No	No

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Section Source Documents (SD)	Document	Requirement/Purpose	File Location	Reference (GCP and Local)	Sponsor Investigator	IND/IDE	FDA Regulated	Non-FDA Regulated Non-Exempt Human Research	Exempt
SD-1	Hospital, clinic, office records, Progress notes, medical history, Subject diaries, study questionnaires, Laboratory report/x-ray reports/ECG report	1. To document the existence of the subject and substantiate integrity of trial data collected. 2. To include original documents related to the trial, medical treatment, history of subject, and subject's condition while on-study or in follow-up. 3.PI should ensure out-of-range labs are reviewed with subject and assessed.  *NOTE: For Exempt studies, Questionnaires would be in this section.  Electronic media, original documents or certified copies	Source Document Binder	<ul style="list-style-type: none"> <li>• 21CFR11</li> <li>• 21CFR312/812</li> <li>• FDA Guidance:E6 GCP, Sections 1.51, 1.52, 5.20, 8.3.13</li> </ul>	Yes	Yes	Yes	Yes	Yes
SD-2	Inclusion/ Exclusion Checklist, Study visit Evaluation checklist	To document subject eligibility in the study during the screening process.  NOTE: regulatory exclusions (prisoners, employees, students, etc.)	Source document Binder		Yes	Yes	Yes	Yes	No

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SD-3	Signed informed consent including Assent, HIPAA, Subject Bill of Rights	<ol style="list-style-type: none"> <li>Written informed consent form to document that consent is: <ul style="list-style-type: none"> <li>Obtained in accordance with regulations, GCP, and protocol.</li> <li>Dated prior to participation of each subject in trial. Provided for direct access to records.</li> <li>Completed (signature/date/time/check box/initials) and signed by corresponding persons.</li> </ul> </li> <li>Consent process is documented and subject is given a copy of the signed document.</li> </ol>	Source Document Binder	OHRP Informed Consent Guidance Information AAHRPP Element III.1.F.	Yes	Yes	Yes	Yes	No
SD-4	Note to File (Memos), Correspondence (subject related)	<p>Study related NTF on subject participant</p> <p>Documentation of phone contact, email or mail</p>	Source Document Binder		Yes	Yes	Yes	Yes	No
SD-5	Concomitant medication list, adverse event, SAE, Procedure form	Document subject's concomitant medication before and during the trial, any adverse event, surgical/treatment procedures or serious adverse event. Documentation adverse events were reviewed by the PI.	Source Document Binder		Yes	Yes	Yes	No	No

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Section Data Collection (DC)	Document	Requirement/Purpose	File Location	Reference (GCP and Local)	Sponsor Investigator	IND/IDE	FDA Regulated	Non-FDA Regulated Non-Exempt Human Research	Exempt
DC-1	Case Report Forms/Data Collection Forms (both electronic and paper)	<ol style="list-style-type: none"> <li>1. Dated, completed case report forms (CRFs): <ul style="list-style-type: none"> <li>• To document that the investigator or authorized member of the investigator's staff confirms the observations recorded.</li> <li>• To document all changes/additions or corrections made to CRFs after initial data were recorded.</li> <li>• Signed if required by Group SOPs or if used as source documentation.</li> </ul> </li> <li>2. Originals retained by sponsor after study completion and/or site closure.</li> <li>3. Site retains copy</li> <li>4. If eCRFs are being used, ensure eCRFs meet all electronic security precautions for protection of PHI.</li> </ol>	File (CD for eCRF) in regulatory binder	<ul style="list-style-type: none"> <li>• 21CFR312/812</li> <li>• FDA Guidance: E6 Good Clinical Practice (GCP), Sections 1.11, 4.9, 5.5, 5.23, 8.3.14, 8.3.15</li> </ul>	Yes	Yes	Yes	No	No

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Section Financial (FN)	Document	Requirement/Purpose	File Location	Reference (GCP and Local)	Study Involves Clinical Services (Step 1 and 2)	Participant Payment (Step 1)
FN-1	Coverage Analysis	Coverage Analysis is a document that outlines what clinical procedures may be paid by Medicare/Insurance, and what procedures must be paid by the study. Consists of two parts: Qualifying Clinical Trial form and use of Velos eResearch if applicable	Study Specific Financial File	HOP 7.7.1 CTO SOP-005_Coverage Analysis	Yes	No
FN-2	Internal Budget	Internal Budgets for all Clinical Trials are based on the coverage analysis and on the contract(if applicable)	Study Specific Financial File	CTO SOP-005_Coverage Analysis	Yes	Yes
FN-3	Feasibility Assessment	Outlines the Scientific importance for the Study and balances it with probability of accrual and financial solvency	Study Specific Financial File	CTO SOP-004_ResearchBillingRisk	Yes	Yes
FN-4	Billing Statements	Monthly billing statements are provided to every coordinator	Study Specific Financial File		Yes	Yes
FN-5	Velos eResearch	Velos enables tracking of each patients' study events while on study.	Study Specific Financial File	HOP 7.7.1 CTO SOP-005_Coverage Analysis	Yes	Yes
FN-6	Signed Agreements	To document agreements between the involved parties, if any. These must be signed by an individual authorized by the Institution to sign on behalf of The Regents of the University of Texas. This includes: (CDA) - Confidential Disclosure Agreements (NDA) - Non-Disclosure Agreements (MTA) - MAterial Transfer Agreements (CTA) - Clinical Trial Agreements For Example: - Investigator/Institution and Sponsor (e.g., contracts, grants) - Investigator/Institution and Affiliated Sites (e.g., contracts) - Investigator/Institution and Authorities (where required)	Study Specific Financial File	HOP 7.7.1	Yes	Yes
FN-7	Subject Identification Code List	1. To document that the Investigator keeps a confidential list of names of all Subjects allocated to Trial numbers upon enrolling in the Trial. 2. Allows Investigator/Institution to permit Identification of all Subjects enrolled in the Trial in case follow-up is required. 3. List needs to be kept in a confidential manner. <b>NOTE: DO NOT KEEP FINANCIAL INFORMATION within the research subject record.</b> The Subject ID log (enrollment key) must be readily available to reconcile payments to subjects.	Study Specific Financial File	GCP E6, Sections: 1.58, 8.3.21, 8.4.3	Yes	Yes
FN-8	Participant Payment Form and Payment Plan	1. To document the payments issued to research participants equal the consent form language. 2. To ensure adequate internal business control of payment inventory 3. To maintain auditable financial records.	Study Specific Financial File	HOP 7.7.2 CTO Research Team Process Guide	Yes	Yes