

# ***ESSENTIAL DOCUMENTS***

***for***

---

**Study Title**

---

**Investigator**

---

**Study Site**

---

**Sponsor**

# ***ESSENTIAL DOCUMENTS DIRECTORY***

*“Essential Documents are those documents that individually and collectively permit evaluation of the conduct of a trial and the quality of the data produced”*

*FDA/ICH*

This binder serves as a repository and directory to all study documents and records in the ***Investigator File*** for this clinical trial. Should the need arise, contents of this binder can be expanded to other binders or folders (provided by the site) in any manner that maintains orderly organization of the file and assures ready access to all documents. Additional unlabeled divider pages have been included at the end of this document to aid in further refining this directory to accommodate local needs and preferences.

**THIS DIRECTORY IS TO BE UPDATED THROUGHOUT THE TRIAL AND MUST BE COMPLETE AND ACCURATE WHEN ARCHIVED AT THE CLOSE OF THE TRIAL.**

**Complete the following at end of study:**

*I have reviewed the Investigator Study File and found it to be complete and accurate.*

\_\_\_\_\_  
INVESTIGATOR SIGNATURE

\_\_\_\_\_  
DATE

# ESSENTIAL DOCUMENTS

Protocol & Amendments

Operations Manual

- Approved Case Report Forms

IRB Approved Consent Forms / Information Provided to Subjects

Subject Log / Clinic Lists in CPRS

IRB Submissions / Notifications / Approvals

Serious Adverse Events / Safety Reports

Notes-to-File

Investigator Agreements (with Sponsor, Institution, FDA, etc.)

Study Site Personnel (Signatures, Qualifications, Training)

Site-Sponsor Correspondence

- Conference call minutes (section tab provided)
- Newsletters (section tab provided)

Investigator Brochure (DIR) / VA Form 10-9012

Investigational Products (Accountability, Handling, Pharmacy)

Laboratory

Subject Files

Visitor Log

## *Forms and Tools:*

*Items used in binder may be obtained from the SMART Website  
<https://vaww.csp.research.med.va.gov/smart.cfm>*

## *References:*

*VHA Handbook 1200.5*

*VHA Handbook 1108.04*

*Good Clinical Practice: Consolidated Guidance, (ICH E6), Section 8.0*

# PROTOCOL & AMENDMENTS

---

- Study Protocol
- Protocol Amendments
- Sub-protocols

A list of all protocols, protocol amendments and sub-protocols received during the trial. Identify documents by date and/or version number or insert sponsor-generated lists of these documents.

PROTOCOL VERSION # / AMENDMENT #	DATE OF PROTOCOL

SUB-PROTOCOL VERSION #	DATE OF SUB-PROTOCOL

TO CONSERVE SPACE, PROTOCOLS MAY  
BE STORED IN SEPARATE BINDERS

## STANDARDS FOR MAINTAINING THIS SECTION

### **PROTOCOL & AMENDMENTS**

---

- All versions of the study protocol and amendments used in this trial must be available in the Investigator Study File at all times. In CSP trials, a cumulative listing of all revisions and amendments is provided to the Investigator with each update.
- Maintain a paper copy of the current version of the protocol to assure immediate access to current documents at all times.
- Maintain outdated protocols either as hardcopy or on CD
- At end of study, all versions and updates must be archived in the Investigator Study File, either in hardcopy or on CD.

# OPERATIONS MANUAL

---

- Operations Manual (procedure manual) and updates
- Operations Memos
- Other written instruction issued by Sponsor
- Sample case report forms (blank)

**Operations Manual** - a complete cumulative record of manuals and updates will be maintained by:

- Maintaining printed copies
- Retaining on CDs (provided by sponsor or prepared at site)
- Other \_\_\_\_\_

**CRFs** - A complete record of all CRFs used in this trial will be maintained by:

- Maintaining printed copies
- Retaining on CDs (provided by sponsor or prepared at site)
- Other \_\_\_\_\_

*check all that apply*

TO CONSERVE SPACE, OPERATIONS MANUAL MAY  
BE STORED IN SEPARATE BINDER

## STANDARDS FOR MAINTAINING THIS SECTION

### **OPERATIONS MANUAL**

---

- All versions of the Operations Manual used in this trial must be available in the Investigator Study File at all times. In CSP trials, a cumulative listing of all revisions is provided to the Investigator with each update.
- Maintain a paper copy of the current version of the manual to assure immediate access to current documents.
- Maintain outdated manuals in either as hardcopy or on CD.
- All versions of each CRF used in the trial must be kept in the Investigator Study File or be otherwise accessible at all times. Each CRF must be readily identifiable by version date or other identifying system that allows determination of period of use.
- At end of study, all versions and updates of the Operations Manual and CRFs must be archived in the Investigator Study File, either in hardcopy form or on CD.

# IRB-APPROVED SUBJECT CONSENT FORMS AND OTHER INFORMATION PROVIDED TO SUBJECTS

---

- ***Log of IRB-approved consent forms***
- Consent Forms - Unsigned copy of each version approved by the IRB
- HIPAA Forms - Unsigned copy of each version approved by the IRB
- Advertisements – all recruitment documents approved by the IRB
- Other written information provided to subjects as approved by the IRB

## STANDARDS FOR MAINTAINING THIS SECTION

### **CONSENT FORMS / INFORMATION PROVIDED TO SUBJECTS**

---

- This section is intended to provide an historical record all IRB-approved consent forms and other documents provided to subjects. NOTE: IRB review and approval is required for any printed information given to subjects and any recruiting materials used in the study.
- File in this section the IRB-approved consent and HIPAA authorization forms and any associated informational materials to be presented to subjects. IRB-approved recruitment materials should be filed in this section.
- File only the final approved document(s), one copy of each version approved during the trial. File the correspondence concerning these documents in the IRB Correspondence Section.
- Initiate a **Record of Approved Consent Form Versions**
  - Version (Document Control) – record the version number, date or other unique identifier that has been applied the form
  - Date received from IRB – record the date that the newly approved consent form is received back from the IRB. This date, rather than the date of IRB approval, is the date the Investigator will be expected to start using the form.
  - Necessary Action – record whether re-consent or other action is necessary for current active participants or if the revised form applies to future subjects only
- Initiate a **Record of Subject Consent–Re-Consent**, if necessary
  - Re-consenting current subjects – if the revised form contains information that may affect subjects' willingness to continue, the

STANDARDS FOR MAINTAINING THIS SECTION (CONT.)

**CONSENT FORMS / INFORMATION PROVIDED TO SUBJECTS**

---

information must be communicated to current active subjects. If re-consent is the method chosen to communicate the new information, this consenting must occur at the first opportunity, i.e., next scheduled visit, or sooner if necessary, e.g., special visits, mail, etc.

- Outdated consent and HIPAA authorization forms should be defaced with a note such as “**OBSOLETE – DO NOT USE**” to prevent inadvertent use of an expired form.



## **SUBJECT LOG / CLINIC LISTS IN CPRS**

---

- List of all subjects signing consent with date of enrollment or reason not enrolled

## STANDARDS FOR MAINTAINING THIS SECTION

### **SUBJECT LOG / CLINIC LISTS IN CPRS**

---

- Initiate a ***SUBJECT LOG***
  
- Any spreadsheet or log providing at least the minimal information listed on the previous page is acceptable. The log should be updated regularly during the trial and upon study closure.
  
- Subject lists in CPRS – review instructions for creating Clinic Lists in CPRS for Study Subjects. Grouping study subjects in this manner allows use of certain efficiency features available in CPRS:
  - CPRS can be programmed to send study staff instant notice of ER, urgent care and hospital admissions of study subjects
  - CPRS can be programmed to automatically forward progress notes by team members for Investigator acknowledgment (keeps Investigator informed, documents Investigator involvement)
  - This list also enables the institution to provide medical records access limited to patients signing consent and authorizing sponsor representatives to review medical records.



## IRB SUBMISSIONS / NOTIFICATIONS / APPROVALS

- ***IRB Submission Tracking Log***
- IRB membership lists for the duration of the study or documentation of Federal-wide Assurance (FWA), i.e., certification number and expiration date
- Documentation of IRB submissions and resulting approvals and acknowledgments including the following:
  - IRB approval of protocol, amendments to protocol, subject information sheets, consent form(s), recruitment tools, study personnel
  - IRB periodic approval to continue the trial
  - Periodic progress reports submitted to the IRB
  - Required notifications and reports, e.g., notification of study closure
  - Reports of unanticipated problems to the IRB
  - Reports of adverse events and safety information from the sponsor - see section labeled **SERIOUS ADVERSE EVENTS/ SAFETY REPORTS** following this section
  - Other submissions as required by the VA or sponsor

USE OF SEPARATE BINDER(S) FOR THIS SECTION MAY BE NECESSARY

## STANDARDS FOR MAINTAINING THIS SECTION

### **IRB SUBMISSIONS / NOTIFICATIONS / APPROVALS**

---

- Retain complete copies of all correspondence to and from the IRB.
- A cover letter or equivalent should accompany each submission to the IRB to clearly identify purpose of submission and all items included in the submission. If submissions are completed and submitted electronically, print paper copies to file in this section. Print and file IRB responses as soon as they are posted.
- Stamp the date of receipt on all correspondence received from IRB. Mark only the IRB cover letter, not the official document, e.g., do not stamp a consent form; stamp the approval letter.
- **IRB Submission Packets** – develop “packets” of materials related to each IRB submission. To form a packet, retain copies of all items submitted to the IRB and, when received, attach a copy of the IRB response(s) thus creating a complete record of each submission. Each submission packet can be recorded as a line item on the ***IRB Submission Tracking Log***.
- Adverse events must be reported to the IRB in the manner prescribed by the IRB. Know your IRB rules for reporting these events.
- Unanticipated problems involving risks to subjects or others may also require reports to the IRB. Know your IRB rules for reporting unanticipated problems.

IRB reporting requirements for Unanticipated Problems:  
(e.g., major and minor protocol deviations, confidentiality breaches)

(Obtain from IRB Manual)

*STANDARDS FOR MAINTAINING THIS SECTION (CONT.)*

**IRB SUBMISSIONS / NOTIFICATIONS / APPROVALS**

---

• **ALERT: KEEPING THE RESEARCH OFFICE INFORMED**

Assure that your Research Office is also notified of adverse events and other problems reported to the IRB as they must report the following to the VA Office of Research Oversight (ORO):

- Adverse events resulting in substantive action by IRB
- Unexpected deaths as determined by the IRB
- Unanticipated problems involving risks to subjects or others resulting in substantive action by IRB



# SERIOUS ADVERSE EVENTS / SAFETY REPORTS

---

- **Log of Serious Adverse Events (SAEs)**
- Documentation of Sponsor and IRB Notification of SAEs
- **Log of Safety Reports from Sponsor**
- Safety reports received from Sponsor
- Documentation of IRB notification of safety reports

## SAE REPORTING REQUIREMENTS FOR THIS TRIAL

IRB Requirements:

(Obtain from IRB Manual)

Sponsor Requirements:

(Obtain from Study Protocol)

- **ALERT: KEEPING THE RESEARCH OFFICE INFORMED**

Assure that your Research Office is also notified of any adverse event reported to the IRB as they may need to report the event to the VA Office of Research Oversight (ORO). See section labeled IRB SUBMISSIONS / NOTIFICATIONS / APPROVALS for details.

## STANDARDS FOR MAINTAINING THIS SECTION

### **SERIOUS ADVERSE EVENTS / SAFETY REPORTS**

---

- Adverse events may require reports to the IRB and/or sponsor. Know your IRB rules for reporting these events. See section labeled SERIOUS ADVERSE EVENTS / SAFETY REPORTS that follows this section.
- Initiate a ***Serious Adverse Events Log***.
- Initiate a ***Safety Reports Received from Sponsor Log***.

# SERIOUS ADVERSE EVENTS LOG

(SAEs occurring at this site)

Investigator: \_\_\_\_\_

Project: \_\_\_\_\_

Study Site: \_\_\_\_\_

Sponsor: \_\_\_\_\_

<b>Date SAE Occurred</b>	<b>Date Learned of Event</b>	<b>Subject Identifier</b>	<b>Event</b>	<b>Study SAE Form Completed (Y/N)</b>	<b>Date Reported to Sponsor*</b>	<b>Date Reported to IRB**</b>

*\*If required by the Sponsor (see protocol for Sponsor requirements)*

*\*\*If required by the IRB (see IRB requirements for adverse event reporting, i.e., definitions & timeframes)*

# **SAFETY REPORTS RECEIVED FROM SPONSOR**

Investigator: \_\_\_\_\_

Project: \_\_\_\_\_

Study Site: \_\_\_\_\_

Sponsor: \_\_\_\_\_

<b>Safety Report ID #</b>	<b>Event or Nature of Report</b>	<b>Date Received from Sponsor</b>	<b>Date Reported to IRB</b>	<b>IRB Acknowledged (Y/N)</b>

## NOTES-TO-FILE

---

- Documentation or explanation of unusual events, practices, problems or communications, e.g., inadvertent omissions in completing study procedures

NOTES-TO-FILE

## STANDARDS FOR MAINTAINING THIS SECTION

### NOTES-TO-FILE

---

- Format and Content - each Note-To-File must contain certain critical information, i.e., what happened, how it was remedied, and how recurrence will be prevented. Notes-to-File must be signed and dated.
- Where to File – The Note-to-File should be attached to the study document that is addressed or explained by the note. To aid in tracking, copies of all Notes-to-File should also be filed chronologically in this section or recorded on the **Note-To-File Log** that follows.
- Notes-to-File serve to explain unusual events or circumstances such as:
  - Consent problems and irregularities
  - Protocol deviations
  - Drug or device accountability issues
  - Discussions with sponsor for protocol interpretation or guidance
  - Discussions with IRB for interpretation or guidance on IRB rules
  - Patient management issues
  - Unusual site practices in study conduct, file maintenance, etc
  - “anything that needs explaining”
- Reports to IRB – Know your IRB rules for reporting unanticipated problems involving risks to subjects. Problems documented in Notes-to-File may require reporting to the IRB. See section labeled IRB SUBMISSIONS / NOTIFICATIONS / APPROVALS
- **ALERT: KEEPING THE RESEARCH OFFICE INFORMED**

Assure that your Research Office is also notified of any problem reported to the IRB as they may need to report the problem to the VA Office of Research Oversight (ORO).

**Note-To-File:**

Project: \_\_\_\_\_

Date: \_\_\_\_\_

Investigator: \_\_\_\_\_

Subject # (if applicable): \_\_\_\_\_

**EXPLANATION OF IRREGULARITY**

Check all that apply:

- Subject Consent issue
- Inclusion/Exclusion criteria not met
- Subject in simultaneous interventional trials
- Adverse event not reported to Sponsor as required
- Adverse event not reported to IRB as required (see local IRB guidelines)
- Drug or Device accountability issue
- Subject seen, or procedure performed, outside the allowed visit window
- Required study procedure not completed
- Other

(1) Description of irregularity:

---



---



---



---



---

(2) Remedy for this irregularity (if applicable):

---



---



---

(3) Steps to prevent recurrence (if applicable):

---



---



---

Record of notifying Sponsor (if applicable):

Date Sponsor representative notified: \_\_\_\_\_

Name of Sponsor representative contacted: \_\_\_\_\_

Study team member contacting Sponsor representative: \_\_\_\_\_

Other parties receiving this Note, e.g., IRB: \_\_\_\_\_

Study Coordinator: \_\_\_\_\_ Date: \_\_\_\_\_  
(Signature)

Investigator: \_\_\_\_\_ Date: \_\_\_\_\_  
(Signature)

*File this form with the study document or documents related to the event or issue that prompted this note.*



# INVESTIGATOR AGREEMENTS

---

- Agreements with Sponsor – Investigator Agreement
- Agreements with FDA
  - Form FDA 1572 (for drugs and biologics)
  - Investigator Signed Agreement (for devices)
- Investigator Disclosure Statements
  - Financial Conflicts of Interest
  - Professional Conflicts of Interest
- Other Investigator agreements

**INVESTIGATOR  
AGREEMENTS  
(FDA 1572, etc.)**

## STANDARDS FOR MAINTAINING THIS SECTION

### INVESTIGATOR AGREEMENTS

---

- Requirements for formal Investigator agreements, pledges, and disclosures vary among studies and may involve FDA, Sponsor, IRB and institution. In many trials, the Investigator signs the protocol to acknowledge agreement (with the Sponsor) to follow the protocol.
- Documents that may be filed in this section include:
  - Investigator Agreement – with sponsor to comply with protocol and other applicable requirements
  - Investigator Agreement – with IRB or Institution to comply with protocol and other applicable requirements
  - *FDA Form 1572 Statement of Investigator* (drugs & biologics) or *Investigator Signed Agreement* (devices), if applicable
  - Disclosure Statement (financial conflict of Interest)
  - Disclosure Statement (professional conflict of interest)
  - Investigator's Data Security Checklist
- Documents required for study team members should also be filed in this section

## STUDY SITE PERSONNEL

---

- ***Site Personnel Signatures/Delegation of Responsibility Log***
- Current CVs of all site personnel
- Other relevant documents evidencing qualifications (professional licensure, etc.)
- Records of personnel training on study procedures and other required training

## STANDARDS FOR MAINTAINING THIS SECTION

### STUDY SITE PERSONNEL

---

- This is a critically important section intended to document:
  - Study team members and the tasks delegated to each
  - Qualifications and training of each team member
- Forming a Study team – Each team member selected by the Investigator represents additional effort in training, supervising, registering with IRB and record keeping, so study teams should be limited in size and composition to that necessary to assure smooth study operations.
- Key Sub-Investigator – At least one sub-investigator must be selected who can function in place of the Investigator during absences.

### SIGNATURES & DELEGATED RESPONSIBILITIES LOG

- This log is signed by individuals meeting any of the following:
  - listed by name on the Consent Form
  - listed as a team member in the IRB approval document
  - listed on the FDA Form 1572 or equivalent
  - operating under a position description appearing in the Study Personnel Section of the protocol
- Designate as team members only individuals requiring formal study orientation / protocol training. Do not list individuals performing study related tasks in the normal course of their work at the facility unless study specific training is required or the Sponsor specifically directs they be listed. In CSP trials, for example, an EKG technician or phlebotomist typically would not be listed as a team member, but the Research Pharmacist would be.
- This log is also used to document the Investigator's delegation of study tasks. Tasks are to be delegated to qualified individuals in accordance with protocol requirements and applicable state and local scope of practice standards. Decisions requiring higher levels of clinical judgment such as eligibility, termination, adverse event relatedness and medical treatment are to be made by the Investigator or a clinically equivalent designee (Sub-investigator).

## STUDY SITE PERSONNEL

---

### TRAINING RECORDS

- Establish and maintain a *STUDY TEAM MEMBER TRAINING LOG* for each team member listed on *SIGNATURES & DELEGATED RESPONSIBILITIES LOG*
- Study specific training must be documented for all study team members on the members' training logs, e.g., Initial and Annual Study Meeting attendance, in-service by Investigator or other team members, periodic Investigator-team meetings, etc. Study team meetings can be recorded on the team meeting log that follows as further documentation of training and of Investigator supervision and oversight of the study.
- VA-mandated training in GCP, Human Subjects Protections and Cyber Security/Privacy/Research Data Security apply to only VA sites or sites treating veteran subjects.

### CURRICULUM VITAE AND PROFESSIONAL LICENSURE

- Current CVs must be maintained for each study team member. CVs should be updated and signed at least every two years.
- Documentation of current professional licensure, if applicable, shall also be maintained in this section.

### STUDY MANAGEMENT / INVESTIGATOR OVERSIGHT

- Periodic Meetings of the Investigator Study Team are highly recommended and should be documented. A team meeting log provided in this section can be used to record the date, attendees and discussion topics for both routine and specially scheduled meetings of team members, e.g., weekly Investigator meetings.
- Study team members' CPRS entries should be forwarded to the Investigator for acknowledgment to document Investigator awareness of study progress and oversight of study conduct.

## SITE PERSONNEL

# SIGNATURES & DELEGATED RESPONSIBILITIES

Investigator: \_\_\_\_\_

Project: \_\_\_\_\_

Study Site: \_\_\_\_\_

Sponsor: \_\_\_\_\_

List all study team members, i.e., individuals that require protocol training/orientation to perform tasks and procedures required for this trial. Initiate a *Study Team Member Training Log* for each member listed above (except pharmacist).

NAME (PRINT OR TYPE)	TITLE OR POSITION	Task* Codes		SIGNATURE	INITIALS	Dates (OF WORK ON STUDY)
		Codes	**PI's Initials			
	Investigator	ABCEF	NA			From: To:
	Coordinator					From: To:
	Sub-investigator					From: To:
						From: To:
						From: To:
						From: To:
						From: To:
						From: To:

<b>Delegated Responsibilities*</b>	<table style="width: 100%; border: none;"> <tr> <td style="width: 33%;">A = Make eligibility / termination decisions</td> <td style="width: 33%;">E = Evaluate adverse events (occurrence/severity)</td> <td style="width: 33%;">Other Study Tasks</td> </tr> <tr> <td>B = Obtain informed consent</td> <td>F = Evaluate adverse events (cause/relatedness)</td> <td>I = _____</td> </tr> <tr> <td>C = Direct medical care of subject (treatment decisions)</td> <td>G = Prescribe study drugs/devices</td> <td>J = _____</td> </tr> <tr> <td>D = Make data entries and corrections</td> <td>H = Maintain product accountability records</td> <td>K = _____</td> </tr> <tr> <td></td> <td></td> <td>L = _____</td> </tr> </table> <p style="text-align: center; font-size: small;">**Investigator's initials indicates approval of task delegation</p>	A = Make eligibility / termination decisions	E = Evaluate adverse events (occurrence/severity)	Other Study Tasks	B = Obtain informed consent	F = Evaluate adverse events (cause/relatedness)	I = _____	C = Direct medical care of subject (treatment decisions)	G = Prescribe study drugs/devices	J = _____	D = Make data entries and corrections	H = Maintain product accountability records	K = _____			L = _____
A = Make eligibility / termination decisions	E = Evaluate adverse events (occurrence/severity)	Other Study Tasks														
B = Obtain informed consent	F = Evaluate adverse events (cause/relatedness)	I = _____														
C = Direct medical care of subject (treatment decisions)	G = Prescribe study drugs/devices	J = _____														
D = Make data entries and corrections	H = Maintain product accountability records	K = _____														
		L = _____														

**TO BE SIGNED AT END OF STUDY:**

*I confirm that this list accurately reflects the delegation of responsibilities for the conduct of the study.*

Investigator Signature: \_\_\_\_\_ Date: \_\_\_\_\_



# STUDY TEAM MEMBER TRAINING LOG

Team Member Name: \_\_\_\_\_

Role/Title: \_\_\_\_\_

CSP #: \_\_\_\_\_

Investigator: \_\_\_\_\_

## VA Mandated Research Training (Annual)

Training Topic	Course/ Provider	Date	Course/ Provider	Date	Course/ Provider	Date	Course/ Provider	Date
<i>Human Subjects Protections</i>								
<i>Good Clinical Practice</i>								
<i>Cybersecurity Awareness</i>								
<i>VHA Privacy Policy</i>								
<i>Information Security 201 for R&amp;D Personnel</i>								
<i>Rules of Behavior</i>								

*Retain copies of training certificates as printed from the VA Learning website or other documentation as applicable  
Check with your Research Office for the definition of the "training year" at your facility*



## **SITE-SPONSOR CORRESPONDENCE**

---

- Correspondence between Investigator and Sponsor
- Correspondence between Investigator and Monitor
- Study newsletter(s)
- Conference call minutes

**USE OF SEPARATE BINDER(S) FOR THIS  
SECTION MAY BE NECESSARY**

## STANDARDS FOR MAINTAINING THIS SECTION

### **SITE-SPONSOR CORRESPONDENCE**

---

- All contacts with sponsor representatives **concerning study conduct** or **patient management** must be documented and retained in the Investigator Study File. This may include:
  - - Letters, memos, faxes
    - E-mails
    - Telephone calls or in-person discussions
    - Newsletters
    - Conference call minutes
- These items may be organized in any manner that facilitates immediate access. Correspondence related to certain topics may be more reasonably filed in other sections specific to those topics. Placing newsletters and conference call minutes in separate sections may be useful. Use of break-out binder(s) for this section may be necessary.
- Items related to study conduct or patient management received via email should be printed and retained in this section. If the electronic version is also to be retained, it should be saved to C Drive or network, not on personal email account.
- Maintaining a record of phone calls or in-person discussions concerning study conduct or patient management issues is also essential.
- In some trials, sponsors post correspondence on the study website. Any correspondence posted on website related to patient management or study conduct should be hard copied to the Investigator File to assure continued availability during and after the trial.

# TELEPHONE COMMUNICATIONS LOG

Investigator: \_\_\_\_\_ Project: \_\_\_\_\_

Study Site: \_\_\_\_\_ Sponsor: \_\_\_\_\_

***Record chronologically all contacts with sponsor related to study conduct or patient management***

Date	Person	Topic and Discussion

*All contacts with Sponsor representatives concerning patient management or study conduct should be documented using this log or similar method. A cumulative listing of such phone calls and other non-written communications between site and Sponsor provides a brief record of these contacts supplemented as necessary by additional details filed elsewhere in the Investigator File.*

# CONFERENCE CALLS

---

CONFERENCE  
CALLS

# NEWSLETTERS

---

NEWSLETTERS

# INVESTIGATOR BROCHURE

---

- Current Investigator Brochure from Sponsor (if applicable)
- Other information about the study intervention as provided by Sponsor

Location of Brochure\*  
or Drug Information Report \_\_\_\_\_

VAF 10-9012 on file \_\_\_\_\_

\* see definition next page

STORAGE OF INVESTIGATOR BROCHURE(S)  
OUTSIDE OF THIS BINDER MAY BE NECESSARY

## STANDARDS FOR MAINTAINING THIS SECTION

### INVESTIGATOR BROCHURE

---

- In CSP trials, the Drug Information Report (DIR) found in the Protocol and Operations Manual constitutes the INVESTIGATOR BROCHURE. The DIR consists of product information prepared specifically for the trial and/or a package insert, Investigator Brochure or other information provided by the manufacturer.
- In VA facilities, a Drug Information Form (VAF 10-9012) must also be completed to summarize information about the Investigational Product. This form must be placed in the subject's medical record by Pharmacy or the study team.
- Both the Investigator Brochure / DIR and the VA Form 10-9012 must be provided to Pharmacy Service and be filed or referenced in this section. In CSP trials, VAF 10-9012 is initiated by the Albuquerque Pharmacy Coordinating Center and provided to participating sites.

# INVESTIGATIONAL PRODUCT ACCOUNTABILITY

- Copies of shipping receipts
- Copies of dispensing records (pharmacy and/or clinic)
- Copies of disposition records (destruction or return to Sponsor)

NOTE: Complete the following at close of study:

*Investigational Product Accountability records are accurate and complete and will be archived:*

- in Pharmacy
- in Investigator File
- elsewhere \_\_\_\_\_

Final records were reviewed by \_\_\_\_\_  
STUDY TEAM MEMBER

*STANDARDS FOR MAINTAINING THIS SECTION*

**INVESTIGATIONAL PRODUCT ACCOUNTABILITY**

---

- The product accountability records are part of the Investigator Study File even though they may be maintained in Pharmacy.
- At end of study, these records may remain in pharmacy or be returned to study clinic to be archived by the Investigator.
- At end of study, these records must be reviewed by a member of the study team to assure they accurately and completely document
  - All receipts from sponsor
  - All dispensing to and returns by subjects
  - Final disposition of product

# LABORATORY

---

- Laboratory Accreditation Certificate(s)
- Normal values/ranges for laboratory tests in protocol
- Initiate ***Central Laboratory Specimen Tracking Log***, if applicable

## STANDARDS FOR MAINTAINING THIS SECTION

### **LABORATORY ACCREDITATION**

---

- These documents must be obtained and filed in this section for any laboratory providing test results directly to the Investigator for use in data collection or patient management. Such documents are not required if test results are provided directly to the sponsor.
- These documents are usually available to Investigators from the laboratory or Research Office.
- Maintain here a complete historical record of normal values for the entire period of study conduct. Update at least every two years.
- CAUTION – Normal values available from an institution's electronic medical records system, e.g., CPRS, reflect only current values. Previous normal values will be unavailable. Print and file current values at least every two years, sooner if indicated.



## SUBJECT FILE CONTENTS (Filed in Individual Subject Binders)

---

- Signed Consent Forms (see ***Subject Consent Master File*** for CSP trials)
- Copies of completed Case Report Forms (CRF)
- Copies of data queries and responses
- Source documentation for study data
- SAE information
- Correspondence related to the specific study subject
- Other subject specific items

SUBJECT FILE  
CONTENTS

SUBJECT FILES ARE MAINTAINED  
SEPARATELY - NOT FOUND IN THIS BINDER

## STANDARDS FOR MAINTAINING THIS SECTION

### SUBJECT FILES

---

- Subject Study Files are not kept in this binder. Locations of key portions of the Subject Study File are as follows:
  - Case Report Forms
    - if paper forms
      - in subject's CRF binder / folder
    - if electronic forms
      - maintain electronically during study
      - maintain on CD at end of study
  - Source Documents
    - in subject's CRF binder / folder and in subject's medical record
  - Consent Forms
    - copies may be kept in each subject's CRF binder / folder but all original signed consent forms should be filed together in the **Subject Consent Master File** provided by SMART.

# VISITOR LOG

---

- Sign-In Log for study visitors

STANDARDS FOR MAINTAINING THIS SECTION

**VISITOR LOG**

---

- Initiate *Visitor Log*
- Names of site monitors or other visitors must be recorded in this section each time the site is visited.



---

---

---