National Institute of Dental and Craniofacial Research

Tool Summary Sheet

Tool: Extramural Essential Documents Binder/File Tabs

Purpose: To provide an organizational framework and guidance for filing paper versions of essential study documents (or referencing location of an electronically stored file) and to provide a cover page with a description of the required contents for each binder section

Audience/User: Study coordinators or individuals responsible for establishing the Essential Documents Binder/File (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 GCP, 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
- Use the requirements note at the top of each binder tab to determine if that section is required for your study
- Multi-site studies – The lead site may choose to customize the binder tabs for the study and provide to all participating sites
- Electronic documents – The recommendation is to store paper copies of documents in the binder. However, if you elect to use only electronic copies of particular documents, the following guidelines should be observed.
    - Either a) place a paper placeholder in the relevant location of the binder that directs an individual to the electronic location, OR b) place a paper placeholder in one location in the binder that includes a list of all documents that are stored only in electronic format along with the specific electronic path for each item (relevant tool: *Essential Documents Storage Location Table*).
    - Electronic-only documents should be limited to documents that a) are easily accessible by site staff; b) an inspector, auditor, or clinical monitor can be provided with easy access to the relevant electronic materials during a site visit; and c) the electronic location is controlled, regularly backed up, and is not in danger of disappearing or changing in the foreseeable future.
    - For email correspondence, sites may want to include clarification in the binder that email will be archived to a permanent storage medium on a particular schedule (specify in documentation) and the media will be stored in the binder or an easily accessible location.

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

Tool Revision History:

Version		
Number	**Date**	**Summary of Revisions Made:**
4.0	09JUL2010	First published version
4.0	15MAY2011	Tool Summary Sheet title adjusted; remains v4.0 and footer version date remains the same
5.0	16SEP2011	Revisions incorporated and requirements notes added
6.0	11OCT2011	Medical license references revised and IRB Registration marked as optional
7.0	20JUL2012	Administrative edits and changes to reflect updates to Intramural Binder Tabs
8.0	12SEP2014	Removed IoR tab and revised Signed Consent Documents tab; updated hyperlinks; and completed administrative/clarifying edits

Extramural Binder/File Tabs

Introduction

The following tabs are recommended for use in the Essential Documents Binder/File for extramural studies. This document serves as a template and may be modified for study-specific requirements. Documents should be filed in reverse chronological order within each tab. It is the responsibility of the investigator to ensure compliance with GCP and applicable regulatory requirements.

To access the sample templates and tools included in the Extramural Binder/File Tabs, please visit the NIDCR Toolkit for Clinical Researchers website:

http://www.nidcr.nih.gov/research/toolkit/

Required for both observational and interventional clinical research studies

Protocol and Amendments

This section should include a copy of each:

- IRB-approved protocol
- Signed PI protocol signature page
- IRB-approved protocol amendment
- Signed PI protocol amendment signature page

If a protocol was not submitted or approved by the IRB, a memo to file needs to be generated to explain the surrounding circumstances and the PI needs to sign and date the document.

Link to NIDCR Protocol Template Tools:

http://www.nidcr.nih.gov/research/toolkit

Required for both observational and interventional clinical research studies

IRB-Approved Consent Documents

This section should include a copy of:

- All IRB-approved /stamped consent documents

A version number and date should be on each consent document.

An expiration date of the consent document on the actual document is preferable, but cross-reference to the IRB approval letter of the protocol may be required.

If applicable, the section should also include a copy of:

- All IRB-approved assent forms
- All IRB-approved short form consents for non-English languages*

*The short form consent for non-English languages should be used for a single subject who may be illiterate, blind, or otherwise unable to read the consent document. This should be used when the full consent document has to be read or translated for subject.

Required for both observational and interventional clinical research studies

IRB Documentation

This section should include:

- Federalwide Assurance (FWA) Number
- IRB Registration (optional)

Link to OHRP Database (FWA and IRB Registration):

http://ohrp.cit.nih.gov/search/IrbDtl.aspx

Required for both observational and interventional clinical research studies

IRB Approvals and Correspondence

This section should include a copy of:

- Approval letters (e.g., protocol, protocol amendment(s), consent documents, continuing review, etc.)
- Correspondence related to contingent approvals or stipulations
- Original IRB application/submission
- IRB correspondence
- Progress reports

If applicable, the section should also include a copy of:

- Approval letters for approved assent form
- Approval letters for short form consent for non-English languages*
- Submission/acknowledgement of Investigator's Brochure
- Approval letter/approved advertisement or recruitment materials
- Approval letter/approved written educational or other materials provided to study subjects

*The short form consent for non-English languages should be used for a single subject who may be illiterate, blind, or otherwise unable to read the consent document. This should be used when the full consent document has to be read or translated for subject.

Link to Informed Consent Checklist:

http://www.hhs.gov/ohrp/policy/consentckls.html

Required for both observational and interventional clinical research studies

Investigator Qualification Documentation

This section should include:

- Current Curriculum Vitae (CV) and/or other relevant dated documentation (e.g., biosketch) for all investigators
- A clinical (dental, medical, etc.) license for the Principal Investigator and each sub-investigator, if licensed

CVs may be updated if an investigator's qualifications increase or change during the course of the study.

Do not remove expired CVs as they demonstrate qualification for the entire duration of the study.

Licenses should be filed behind the corresponding investigator's CV. Do not remove expired licenses.

The investigators must be actively licensed in the state in which the study is conducted.

The name on the license must correspond to the name on the investigator's CV and the 1572, if applicable.

Required for interventional clinical studies using a drug, biologic, or device

Investigator's Brochure

(For any drug/product under investigation)

For studies that involve administration of investigational drugs/products, this section should include:

- Investigator's Brochure(s) (IB), or equivalent

Or

- Package Insert. Include labeling for approved medications.

The purpose of this document is to provide information on the mechanism of action, possible risks and adverse reactions, and the "expected" adverse reactions associated with the previous use of the drug/product.

If the package insert or the Investigator's Brochure is amended during the trial or is updated, it should be included here.

Required for clinical studies regulated by FDA under IND

FDA Form 1572 and 1571

FDA Form 1572 for IND studies when:

- A study involves an investigational drug

  OR

- The study sponsor requests it

FDA Form 1571 for investigator initiated INDs:

- Document required when an investigator is applying for an IND; part of the submission packet to the FDA

Instructions for Forms 1571 and 1572:

http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/InvestigationalNewDrugINDApplication/ucm071098.htm

Forms 1571 and 1572 can be downloaded from:

http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

STATEMENT OF INVESTIGATOR

(TITLE 21, CODE OF FEDERAL REGULATIONS (CFR) PART 312)

(See instructions on reverse side.)

Form Approved: OMB No. 0910-0014
Expiration Date: April 30, 2015
See OMB Statement on Reverse.

NOTE: No investigator may participate in an investigation until he/she provides the sponsor with a completed, signed Statement of Investigator, Form FDA 1572 (21 CFR 312.53(c)).

1. NAME AND ADDRESS OF INVESTIGATOR

Name of Principal Investigator			
Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

2. EDUCATION, TRAINING, AND EXPERIENCE THAT QUALIFY THE INVESTIGATOR AS AN EXPERT IN THE CLINICAL INVESTIGATION OF THE DRUG FOR THE USE UNDER INVESTIGATION. ONE OF THE FOLLOWING IS PROVIDED *(Select **one** of the following.)*

☐ Curriculum Vitae ☐ Other Statement of Qualifications

3. NAME AND ADDRESS OF ANY MEDICAL SCHOOL, HOSPITAL, OR OTHER RESEARCH FACILITY WHERE THE CLINICAL INVESTIGATION(S) WILL BE CONDUCTED — CONTINUATION PAGE for Item 3

Name of Medical School, Hospital, or Other Research Facility			
Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

4. NAME AND ADDRESS OF ANY CLINICAL LABORATORY FACILITIES TO BE USED IN THE STUDY — CONTINUATION PAGE for Item 4

Name of Clinical Laboratory Facility			
Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

5. NAME AND ADDRESS OF THE INSTITUTIONAL REVIEW BOARD (IRB) THAT IS RESPONSIBLE FOR REVIEW AND APPROVAL OF THE STUDY(IES) — CONTINUATION PAGE for Item 5

Name of IRB			
Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

6. NAMES OF SUBINVESTIGATORS *(If not applicable, enter "None")*

CONTINUATION PAGE – for Item 6

7. NAME AND CODE NUMBER, IF ANY, OF THE PROTOCOL(S) IN THE IND FOR THE STUDY(IES) TO BE CONDUCTED BY THE INVESTIGATOR

PSC Publishing Services (301) 443-6740 EF

8. PROVIDE THE FOLLOWING CLINICAL PROTOCOL INFORMATION. *(Select **one** of the following.)*

☐ For Phase 1 investigations, a general outline of the planned investigation including the estimated duration of the study and the maximum number of subjects that will be involved.

☐ For Phase 2 or 3 investigations, an outline of the study protocol including an approximation of the number of subjects to be treated with the drug and the number to be employed as controls, if any; the clinical uses to be investigated; characteristics of subjects by age, sex, and condition; the kind of clinical observations and laboratory tests to be conducted; the estimated duration of the study; and copies or a description of case report forms to be used.

9. COMMITMENTS

I agree to conduct the study(ies) in accordance with the relevant, current protocol(s) and will only make changes in a protocol after notifying the sponsor, except when necessary to protect the safety, rights, or welfare of subjects.

I agree to personally conduct or supervise the described investigation(s).

I agree to inform any patients, or any persons used as controls, that the drugs are being used for investigational purposes and I will ensure that the requirements relating to obtaining informed consent in 21 CFR Part 50 and institutional review board (IRB) review and approval in 21 CFR Part 56 are met.

I agree to report to the sponsor adverse experiences that occur in the course of the investigation(s) in accordance with 21 CFR 312.64. I have read and understand the information in the investigator's brochure, including the potential risks and side effects of the drug.

I agree to ensure that all associates, colleagues, and employees assisting in the conduct of the study(ies) are informed about their obligations in meeting the above commitments.

I agree to maintain adequate and accurate records in accordance with 21 CFR 312.62 and to make those records available for inspection in accordance with 21 CFR 312.68.

I will ensure that an IRB that complies with the requirements of 21 CFR Part 56 will be responsible for the initial and continuing review and approval of the clinical investigation. I also agree to promptly report to the IRB all changes in the research activity and all unanticipated problems involving risks to human subjects or others. Additionally, I will not make any changes in the research without IRB approval, except where necessary to eliminate apparent immediate hazards to human subjects.

I agree to comply with all other requirements regarding the obligations of clinical investigators and all other pertinent requirements in 21 CFR Part 312.

INSTRUCTIONS FOR COMPLETING FORM FDA 1572 STATEMENT OF INVESTIGATOR

1. Complete all sections. Provide a separate page if additional space is needed.
2. Provide curriculum vitae or other statement of qualifications as described in Section 2.
3. Provide protocol outline as described in Section 8.
4. Sign and date below.
5. FORWARD THE COMPLETED FORM AND OTHER DOCUMENTS BEING PROVIDED TO THE SPONSOR. The sponsor will incorporate this information along with other technical data into an Investigational New Drug Application (IND). INVESTIGATORS SHOULD NOT SEND THIS FORM DIRECTLY TO THE FOOD AND DRUG ADMINISTRATION.

10. DATE *(mm/dd/yyyy)*	11. SIGNATURE OF INVESTIGATOR **Sign**

(**WARNING**: A willfully false statement is a criminal offense. U.S.C. Title 18, Sec. 1001.)

The information below applies only to requirements of the Paperwork Reduction Act of 1995.

The burden time for this collection of information is estimated to average 100 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden to the address to the right:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

DO NOT SEND YOUR COMPLETED FORM TO THIS PRA STAFF EMAIL ADDRESS.

Next Page | Export Data | Import Data | Reset Form

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

INVESTIGATIONAL NEW DRUG APPLICATION (IND)

(Title 21, Code of Federal Regulations (CFR) Part 312)

Form Approved: OMB No. 0910-0014
Expiration Date: April 30, 2015
See PRA Statement on page 3.

NOTE: No drug/biologic may be shipped or clinical investigation begun until an IND for that investigation is in effect (21 CFR 312.40)

1. Name of Sponsor

2. Date of Submission *(mm/dd/yyyy)*

3. Sponsor Address

Address 1 *(Street address, P.O. box, company name c/o)*

Address 2 *(Apartment, suite, unit, building, floor, etc.)*

City | State/Province/Region

Country | ZIP or Postal Code

4. Telephone Number *(Include country code if applicable and area code)*

5. Name(s) of Drug *(Include all available names: Trade, Generic, Chemical, or Code)*

Continuation Page for #5

6. IND Number *(If previously assigned)*

7. (Proposed) Indication for Use

Is this indication for a rare disease (prevalence <200,000 in U.S.)? ☐ Yes ☐ No

Does this product have an FDA Orphan Designation for this indication? ☐ Yes ☐ No

If yes, provide the Orphan Designation number for this indication:

Continuation Page for #7

8. Phase(s) of Clinical Investigation to be conducted ☐ Phase 1 ☐ Phase 2 ☐ Phase 3 ☐ Other *(Specify)*: _____

9. List numbers of all Investigational New Drug Applications (21 CFR Part 312), New Drug Applications (21 CFR Part 314) , Drug Master Files (21 CFR Part 314.420) , and Biologics License Applications (21 CFR Part 601) referred to in this application.

10. IND submission should be consecutively numbered. The initial IND should be numbered "Serial number: 0000." The next submission (e.g., amendment, report, or correspondence) should be numbered "Serial Number: 0001." Subsequent submissions should be numbered consecutively in the order in which they are submitted..

Serial Number _____

11. This submission contains the following *(Select all that apply)*

☐ Initial Investigational New Drug Application (IND)
☐ Response to Clinical Hold
☐ Response To FDA Request For Information
☐ Request For Reactivation Or Reinstatement
☐ Annual Report
☐ General Correspondence
☐ Development Safety Update Report (DSUR)
☐ Other *(Specify)*: _____

Protocol Amendment(s)
☐ New Protocol
☐ Change in Protocol
☐ New Investigator
☐ PMR/PMC Protocol

Information Amendment(s)
☐ Chemistry/Microbiology
☐ Pharmacology/Toxicology
☐ Clinical ☐ Statistics
☐ Clinical Pharmacology

Request for
☐ Meeting
☐ Proprietary Name Review
☐ Special Protocol Assessment
☐ Formal Dispute Resolution

IND Safety Report(s)
☐ Initial Written Report
☐ Follow-up to a Written Report

12. Select the following only if applicable. *(Justification statement must be submitted with application for any items selected below. Refer to the cited CFR section for further information.)*

Expanded Access Use, 21 CFR 312.300

☐ Emergency Research Exception From Informed Consent Requirements, 21 CFR 312.23 (f)
☐ Charge Request, 21 CFR 312.8
☐ Individual Patient, Non-Emergency 21 CFR 312.310
☐ Individual Patient, Emergency 21 CFR 312.310(d)
☐ Intermediate Size Patient Population, 21 CFR 312.315
☐ Treatment IND or Protocol, 21 CFR 312.320

For FDA Use Only

CBER/DCC Receipt Stamp	DDR Receipt Stamp	Division Assignment
		IND Number Assigned

Previous Page | Next Page

13. Contents of Application – This application contains the following items *(Select all that apply)*

- ☐ 1. Form FDA 1571 *(21 CFR 312.23(a)(1))*
- ☐ 2. Table of Contents *(21 CFR 312.23(a)(2))*
- ☐ 3. Introductory statement *(21 CFR 312.23(a)(3))*
- ☐ 4. General Investigational plan *(21 CFR 312.23(a)(3))*
- ☐ 5. Investigator's brochure *(21 CFR 312.23(a)(5))*
- ☐ 6. Protocol(s) *(21 CFR 312.23(a)(6))*
  - ☐ a. Study protocol(s) *(21 CFR 312.23(a)(6))*
  - ☐ b. Investigator data *(21 CFR 312.23(a)(6)(iii)(b))* or completed Form(s) FDA 1572
  - ☐ c. Facilities data *(21 CFR 312.23(a)(6)(iii)(b))* or completed Form(s) FDA 1572
- 6. Protocol(s) *(Continued)*
  - ☐ d. Institutional Review Board data (21 CFR 312.23(a)(6)(iii)(b)) or completed Form(s) FDA 1572
- ☐ 7. Chemistry, manufacturing, and control data *(21 CFR 312.23(a)(7))*
  - ☐ Environmental assessment or claim for exclusion *(21 CFR 312.23(a)(7)(iv)(e))*
- ☐ 8. Pharmacology and toxicology data (21 CFR 312.23(a)(8))
- ☐ 9. Previous human experience *(21 CFR 312.23(a)(9))*
- ☐ 10. Additional information *(21 CFR 312.23(a)(10))*
- ☐ 11. Biosimilar User Fee Cover Sheet *(Form FDA 3792)*
- ☐ 12. Clinical Trials Certification of Compliance *(Form FDA 3674)*

14. Is any part of the clinical study to be conducted by a contract research organization? ☐ Yes ☐ No

If Yes, will any sponsor obligations be transferred to the contract research organization? ☐ Yes ☐ No

If Yes, provide a statement containing the name and address of the contract research organization, identification of the clinical study, and a listing of the obligations transferred *(use continuation page)*. **Continuation Page for #14**

15. Name and Title of the person responsible for monitoring the conduct and progress of the clinical investigations

16. Name(s) and Title(s) of the person(s) responsible for review and evaluation of information relevant to the safety of the drug

I agree not to begin clinical investigations until 30 days after FDA's receipt of the IND unless I receive earlier notification by FDA that the studies may begin. I also agree not to begin or continue clinical investigations covered by the IND if those studies are placed on clinical hold or financial hold. I agree that an Institutional Review Board (IRB) that complies with the requirements set forth in 21 CFR Part 56 will be responsible for initial and continuing review and approval of each of the studies in the proposed clinical investigation. I agree to conduct the investigation in accordance with all other applicable regulatory requirements.

17. Name of Sponsor or Sponsor's Authorized Representative

18. Telephone Number *(Include country code if applicable and area code)*

19. Facsimile (FAX) Number *(Include country code if applicable and area code)*

20. Address

Address 1 *(Street address, P.O. box, company name c/o)*

Address 2 *(Apartment, suite, unit, building, floor, etc.)*

City | State/Province/Region

Country | ZIP or Postal Code

21. Email Address

22. Date of Sponsor's Signature *(mm/dd/yyyy)*

23. Name of Countersigner

24. Address of Countersigner

Address 1 *(Street address, P.O. box, company name c/o)*

Address 2 *(Apartment, suite, unit, building, floor, etc.)*

City | State/Province/Region

Country: United States of America | ZIP or Postal Code

WARNING : A willfully false statement is a criminal offense (U.S.C. Title 18, Sec. 1001).

25. Signature of Sponsor or Sponsor's Authorized Representative — Sign

26. Signature of Countersigner — Sign

The information below applies only to requirements of the Paperwork Reduction Act of 1995.

The burden time for this collection of information is estimated to average 100 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden to the address to the right:

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

Please do NOT send your completed form to this PRA Staff email address.

Required for clinical studies regulated by FDA under IND or IDE

Financial Disclosure Forms

This section should include:

- Signed Financial Disclosure Forms (FDF) for the Principal Investigator and sub-investigator(s) listed on the 1572

The names of the Principal Investigator and sub-investigator(s) should match the names listed on the 1572. The protocol title and number should match the title and number listed on the 1572.

If any of the five financial interest questions are checked "Yes," a statement addressing the nature and amount of the interest, arrangement, or payment must be attached to the FDF. Appropriate identifiers, i.e., protocol number and investigator name, must be included on each document included in the submission.

This FDA form is required for any clinical study submitted in a marketing application that the applicant or FDA relies on to establish that the product is effective, and any study in which a single investigator makes a significant contribution to the demonstration of safety.

Link for additional information:

http://www.fda.gov/downloads/regulatoryinformation/guidances/ucm341008.pdf

Financial Disclosure

This information below is provided for the following clinical study. (*Please print or type, include attachments if necessary. Maintain a copy in the official study file.)*

Protocol Investigator/Subinvestigator	Site
Protocol Title	Protocol #
Investigational Product(s)	Pharmaceutical Co./Manufacturer(s)

If answer is YES to any of the below please attach a statement addressing the nature and amount of the interest, arrangement or payment.

Yes ☐	No ☐	Do you, your spouse or dependent children have a financial arrangement with the above named Pharmaceutical Company, whereby the value of compensation to you, your spouse or dependent children could be influenced by the outcome of the study? This includes compensation that could be greater for a favorable clinical result, compensation in the form of an equity interest in the above named Pharmaceutical Company, or compensation tied to sales of the product tested in the above study such as a royalty interest.
Yes ☐	No ☐	Do you, your spouse or dependent children have a proprietary interest in the above named Investigational Product, such as patent rights or rights under a patent, trademark, copyright or licensing agreement?
Yes ☐	No ☐	Do you, your spouse or dependent children, or any of you combined, have a significant equity in the above named Pharmaceutical Company, such as an ownership interest, stock options or any other financial interest whose value cannot be readily determined through reference to public prices, or any equity interest in the above named Pharmaceutical Company, (if it is a publicly traded organization) exceeding $50,000, or any combination of these?
Yes ☐	No ☐	Have you, your spouse or dependent children, or any of you combined, received payments from the above named Pharmaceutical Company in excess of $25,000, exclusive of the costs of conducting the clinical studies, such as honoraria, a grant or grants to fund ongoing research, compensation in the form of equipment, or retainers for ongoing consultation?
Yes ☐	No ☐	Have you, your spouse or dependent children had interests in a Pharmaceutical Company with a product that is in competition with the above named Investigational Product?

To the best of my knowledge, the information provided above is correct and complete. I understand that I am obligated to amend this statement during the conduct of the clinical studies listed above or during one year after the studies have been completed if there is any change in this information.

Signature of Investigator	Date

Disclosures should be retained in the Investigator Regulatory Binder.

Required for both observational and interventional clinical research studies

Study Communication

This section should include:

- A copy of all communication relative to the conduct of the protocol and agreements with other scientific collaborators, industry, and scientific directors, such as Material Transfer Agreement and Data Sharing Agreement. (Financial documents should not be included.)
- Important decisions regarding study conduct, such as Memos to File
- FDA Correspondence (see Regulatory Document History Log)

All printed communication (i.e., email) needs to be signed and dated by the individual printing and storing the document.

Communication about subject treatment/clinical care, protocol deviations, and study drug dosing should immediately be printed and stored in this tab.

- Email correspondence may be saved to a compact disc (CD) for electronic storage and noted in this section

Electronic media must be a permanent media, and must be appropriately secured and approved (i.e., password protected).

If saved to a CD or other electronic storage media, a memo to file needs to be generated describing the types of email on the electronic media, the start and stop dates of the email correspondence, and the signature and date of the individual creating the CD and writing the memo to file.

If a study team member receives a new computer or if a newer version of the email provider is used, it is highly recommended to create the CD and the memo to file at the time of the transfer to prevent any important study communication from being lost in the transition.

Regulatory Document History Log

Investigator Name:	Protocol:	IND Number:

List all documents submitted to the FDA.

Date of Correspondence	Type of Correspondence (i.e., submission, contact report, etc.)	Serial Number (If applicable)	Description

Required for both observational and interventional clinical research studies

Delegation of Responsibilities (DoR) Log

This section should include:

- An ongoing log that lists all study personnel and their specific responsibilities, signatures, initials, and obligation (start/stop) dates

Any changes in site study personnel require an update to the DoR.

Delegation of Responsibilities Log

Investigator Name:	Protocol:	Site Number:

List staff to whom the Principal Investigator (PI) has delegated significant study-related duties.

Name	Responsibilities*	Initials	Signature	Start Date	End Date	PI Initials/Date

By initialing above, I, the PI, declare that during the conduct of the above study, I have delegated the following study-related activities:

*Responsibilities Legend		
1. Administer Consent	6. Randomize Subjects	11. Complete Study Forms
2. Screen Subjects	7. Dispense Study Drug	12. Provide Discharge Instructions
3. Obtain Medical History	8. Drug Accountability	13. Make Follow-up Phone Calls
4. Perform Physical Exam	9. Assess Adverse Events	14. Query Management
5. Determine Eligibility	10. Complete Source Documents	

Signature of Principal Investigator: _____ Date: _____

Required for both observational and interventional clinical research studies

Clinical Research and Study Training

This section should include the following documents for all key personnel (investigators, coordinators):

- Educational completion certificates for Human Subjects Protection training
- Documentation of study related training

All key personnel working on NIH grants and contracts involving human research participants are required to complete training in Human Subject Protections. NIH has a free web-based training that satisfies this requirement.

http://phrp.nihtraining.com/users/login.php

Other free, optional web-based trainings that are recommended include:

Good Clinical Practices:

http://gcplearningcenter.niaid.nih.gov/

https://crt.nihtraining.com/login.php

If a certificate is not available at the end of a required training module, enter the appropriate documentation in the site Training Log.

Site-specific training: Consult your IRB or institution for training requirements.

Consider use of a central training binder to store non-study-specific training documentation for all study team members. If this strategy is used, file a signed and dated memo to file explaining where these training documents are stored.

Training Log

Investigator Name:	Protocol:	Site Number:

Printed Name	Signature	Title of Training	Date of Training

Required for both observational and interventional clinical research studies

Screening/Enrollment Log

This section should include:

- A log without identifying information that lists subjects who were screened (including screen failures) and enrolled in the study

Subjects may be tracked separately on logs, such as a coded list with a key.

Note: If screening and enrollment information is entered into an electronic data capture (EDC) system, please include a memo explaining this process.

Site Screening and Enrollment Log

Investigator Name:	Protocol:	Site Number:

Subject ID	Date of Consent	Version of Consent	Date Screened	Eligible for Enrollment?	Ineligibility Reason (if applicable)

Required for both observational and interventional clinical research studies

Signed Consent Documents

This section should include:

- All original signed consent documents

OR, if signed consent documents are kept in a separate binder or in the subject's medical or dental record:

- A signed and dated memo to file explaining where signed consent documents are stored and the reason for separate storage

The signed consent document must be retained even if a subject withdraws consent or fails the screening process.

Required for interventional clinical studies using a study product for research

Study Product Records

This section should include:

- Documentation of study product (drug, biologic, vaccine) disposition and accountability, or memo as to where records are located (e.g., Research Pharmacy) and who is maintaining accountability logs

For masked clinical studies, it is recommended that study product accountability records be filed in the research pharmacy to maintain the masking.

Investigational Product Accountability Log: Stock Record

Name of Institution:	**Product Name**:
Investigator Name:	**Manufacturer:**
Protocol No.:	**Dose Form and Strength**:
Protocol Title:	**Dispensing Area**:

Line No.	Date	Dispensed To / Received From	Dose	Quantity Dispensed and/or Received	Balance Forward / Balance	Lot No.	Recorder's Initials
Ex.	*15Feb2012*	*Manufacturer*	*10 mg*	*+ 100 tabs*	*500* / *600*	*98765*	*JAD*
1.							
2.							
3.							
4.							
5.							
6.							
7.							
8.							

Investigational Product Accountability Log: Subject Record

Name of Institution:	**Product Name**:
Investigator Name:	**Manufacturer:**
Protocol No.:	**Dose Form and Strength**:
Protocol Title:	**Dispensing Area**:

Line No.	Date	Subject ID Number	Subject's Initials	Dose	Quantity Dispensed and/or Received	Balance Forward / Balance	Lot No.	Recorder's Initials
Ex.	*15Feb2012*	*12345*	*ABC*	*10 mg*	*- 100 tabs*	*600* / *500*	*98765*	*JAD*
1.								
2.								
3.								
4.								
5.								
6.								
7.								
8.								

Required for both observational and interventional studies using clinical labs as a study procedure

Local Clinical Lab Certificates/Reference Ranges

For studies that utilize clinical laboratories for specimen testing, this section should include:

- Lab reference ranges if the reference range is not included on the lab form
- A copy of certifications or accreditations (CAP, CLIA, or State certificate) or a memo indicating that the laboratory maintains CLIA certification

Required for both observational and interventional clinical studies collecting clinical samples

Specimen Tracking Log

This section should include:

- A log of research samples, which can include the type of specimen, purpose of storage, location of storage (e.g., freezer #, shelf #, and location, box 3), and link to subject ID number.

If applicable, the log should be modified to track if consent for future use was obtained or withdrawn.

Specimen Tracking Log

Investigator Name:	Protocol:	Site Number:

Visit	Specimen Name/Type	Specimen ID (Accession #)	Date Collected	Date Shipped	Tracking #	Receiving Lab	Date Received	Comments

Required for both observational and interventional clinical research studies

Unanticipated Problems

This section should include a copy of each:

- Unanticipated problem report

Required for both observational and interventional clinical studies that are more than minimal risk

Serious Adverse Events (SAEs)

This section should include a copy of each:

- Serious Adverse Event form or memo
- “Dear Doctor” letter and IND safety report

Required for both observational and interventional clinical research studies

Protocol Deviations

This section should include:

- A copy of each Protocol Deviation form or memo, or a memo to file indicating if/where they are maintained electronically (e.g., in the clinical database)
- Protocol Deviation Tracking Log

Requirements for reporting protocol deviations are specific to each local IRB; review the requirements to make sure that they are followed appropriately.

Protocol Deviation Tracking Log

Protocol ID/Number:						**Site Name/Number:**					
Protocol Title (Abbreviated):											
Principal Investigator:						**Page number [1]:**					
Ref No.	**Subject ID**	**Date of Deviation**	**Date Identified**	**Deviation Identified By**	**Deviation Description**	**Dev. Type [2]** / **Resulted in AE (Yes/No)**	**Did Subject Continue in Study?**	**Meets IRB Reporting Req. (Yes/No)**	**IRB Reporting Date**	**Action Taken (if any)**	**Impact [3]** / **Initials [4]**
1											
2											
3											
4											
5											

Check if final page of log: ☐

Form Instructions:

[1] Each page should be separately numbered to allow cross-referencing (e.g., deviation #2 on p. 7)

[2] Deviation Type: (A-J) See codes below – Enter the appropriate deviation code from the list.

Protocol Deviation Codes:

- A – Consent Procedures
- B – Inclusion/Exclusion Criteria
- C – Concomitant Medication/Therapy
- D – Laboratory Assessments/Procedures
- E – Study Procedures
- F – Serious Adverse Event Reporting/Unanticipated Adverse Device Effect
- G – Randomization Procedures/Study Drug Dosing
- H – Visit Schedule/Interval
- I – Efficacy Ratings
- J – Other

[3] Impact: (A-D) See codes below – Enter the appropriate impact code from the list.

Impact Codes:

- A – Study Validity
- B – Safety
- C – No Impact
- D – Outcome Measures

[4] Insert the initials of the person completing the log entry.

Required for both observational and interventional clinical research studies

Clinical Site Monitoring Visits

This section should include:

- A site visit log signed by the clinical site monitor(s) at each visit
- A copy of each visit's correspondence, which can include the confirmation letter, agenda, follow-up letter, and all attachments

Monitoring Visit Log

Investigator Name:	Protocol:	Site Number:

Name	Signature	Purpose of Visit	Date of Visit

As needed for both observational and interventional clinical research studies

Other

This section should include:

- Other important study documents, such as Certificates of Confidentiality, literature or publications, Technology Transfer Agreement, submissions to Radiation Safety Committee, Radiation Safety Committee approvals, submissions to Office of Biotechnology Activities, etc.