**Tool Summary Sheet**

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| --- | --- |
| **Tool:** | Essential Documents Storage Location Table Template |
| **Purpose:** | To provide a template for organization of study-specific essential document storage locations. |
| **Audience/User:** | Principal Investigators and Site Staff |
| **Details:** | This template provides a table to organize storage locations for study-specific essential documents. Locations are listed to indicate if they are stored in the Essential Documents Binder/File (synonyms – Investigator Binder, Regulatory Binder, Investigational Site File [ISF] or Study Binder), filed in an alternate location, and/or stored electronically.  Once finalized, the PI should sign and date this table and file it at the front of the Essential Documents Binder. The table will serve as the Table of Contents for the Binder; reviewers can refer to this table to learn the storage location of all essential documents. If your study’s Essential Documents Binder expands into multiple physical binders, be sure to file a copy of the Table at the front of each binder. |
| **Best Practice Recommendations:** | * This table is a template that can be modified depending upon your study’s local and institutional requirements. Your study’s custom Essential Documents Storage Table should contain the specific essential documents and their storage locations for your study. * Add rows for any additional essential documents for your study, and delete any sections/documents listed that are not applicable to your study. For example, if your study does not use a study product for research, delete the ‘Study Product Records’ tab section/document rows. * For each document in the Table, either check the box to indicate that the documents are stored in the Binder OR enter the alternate storage location if the documents are stored electronically or filed in a location other than the Binder. Example alternate storage location entries could include: eIRB website URL; path to local drive/network location; Patient’s Medical Record File; Central Training Binder. * The ‘Notes’ field in this template includes notation when specific documents **MUST** be stored in the Binder/a specific location. For any documents that are not stored in the Binder, include study-specific notes to clarify how the documents are stored. Examples include:   + Protocols: Electronic folder for each year; folder name includes expiration date   + IRB-Approved/Stamped documents: Electronic folder for each protocol version; each folder includes IRB-approved protocol and scanned signed signature page   + Investigator Qualification Documentation: Electronic folder for each staff member * When documents are stored electronically or in a location separate from the Binder, consider filing a generic note in the appropriate binder tab location to refer the reviewer to this table for a list of all document storage locations. See the final page of this document for a sample note you can file in appropriate locations in the Binder. * Considerations for electronic storage:   + Must be secured, password protected, with access only available to dedicated study team members   + Can refer to eIRB website, shared drive on a local/site network, drop box folders, or Google drives   + Electronic folders should correspond to Binder Tab names   + Be descriptive and consistent in naming structure (both folder and document names) to facilitate retrieval of specific documents as needed (e.g., protocol\_v#\_approval date) * Remember that for all essential documents that are stored in a location other than the Binder (whether paper or electronic), the documents must be easily accessible by appropriate site staff, and site staff must be able to provide an inspector, auditor, or clinical monitor with easy access to the relevant materials during a site visit for purposes of verification as needed. * Text enclosed with <> is a placeholder for a specific detail (e.g., <protocol title>); replace as appropriate. * Ensure that all placeholder and example text is replaced with the study-specific information. * Please retain the Tool version identifier in the lower left hand section of the footer. You may choose to add “Based on” in front of “Tool Version”. * Delete this Tool Summary Sheet after development of your study-specific table. |

**Tool Revision History:**

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| --- | --- | --- |
| **Version Number** | **Version Date** | **Summary of Revisions Made:** |
| 1.0 | 24Sep2014 | First approved version. |

| **Documents** | **Storage Location** | | **Notes** |
| --- | --- | --- | --- |
| **Protocol and Amendments tab** | **Binder** | **Or Specify Storage Location** | **Notes** |
| Protocol Signature Pages  (and amendment signature pages) |  |  | Original protocol/amendment signature pages must be maintained in the Binder. |
| IRB-approved protocol  (and amendments) |  |  |  |
| **IRB-Approved Consent Documents tab** | **Binder** | **Or Specify Storage Location** | **Notes** |
| IRB-approved / stamped consent documents |  |  |  |
| IRB-approved assent forms |  |  |  |
| IRB-approved short form consents for non-English languages |  |  |  |
| **IRB Documentation tab** | **Binder** | **Or Specify Storage Location** | **Notes** |
| Federalwide Assurance (FWA) Number |  |  |  |
| IRB Registration |  |  |  |
| **IRB Approvals and Correspondence tab** | **Binder** | **Or Specify Storage Location** | **Notes** |
| Approval letters |  |  |  |
| Correspondence related to contingent approvals or stipulations |  |  |  |
| Original IRB application / submission |  |  |  |
| IRB correspondence |  |  |  |
| Progress reports |  |  |  |
| Submission / acknowledgement of Investigator’s Brochure |  |  |  |
| **Investigator Qualification Documentation tab** | **Binder** | **Or Specify Storage Location** | **Notes** |
| CVs for all investigators |  |  |  |
| Clinical license for PI and each sub-I |  |  |  |
| **Investigator’s Brochure tab** | **Binder** | **Or Specify Storage Location** | **Notes** |
| Investigator’s Brochure (IB) |  |  |  |
| Package Insert |  |  |  |
| **FDA Form 1572 and 1571 tab** | **Binder** | **Or Specify Storage Location** | **Notes** |
| FDA Form 1572 |  |  | Original. |
| FDA Form 1571 |  |  | Original. |
| **Financial Disclosure Forms tab** | **Binder** | **Or Specify Storage Location** | **Notes** |
| Signed Financial Disclosure Forms (FDFs) for PI and sub-Is on 1572 |  |  |  |
| **Study Communication tab** | **Binder** | **Or Specify Storage Location** | **Notes** |
| All communication related to the conduct of the protocol and agreements with scientific collaborators |  |  |  |
| Memos to File documenting important decisions regarding study conduct |  |  |  |
| FDA correspondence |  |  |  |
| Regulatory Document History Log |  |  |  |
| **Delegation of Responsibilities (DoR) Log tab** | **Binder** | **Or Specify Storage Location** | **Notes** |
| Delegation of Responsibilities Log |  |  | Original signatures must be stored in the Binder. An electronic version may be maintained in addition to the original DoR Log. |
| **Clinical Research and Study Training tab** | **Binder** | **Or Specify Storage Location** | **Notes** |
| Educational completion certificates for Human Subjects Protection training |  |  |  |
| Documentation of study-related training |  |  |  |
| Training Log |  |  | The Training Log must be maintained in the Binder and contain original signatures. |
| **Screening/Enrollment Log tab** | **Binder** | **Or Specify Storage Location** | **Notes** |
| Site Screening and Enrollment Log |  |  |  |
| **Signed Consent Documents tab** | **Binder** | **Or Specify Storage Location** | **Notes** |
| All original signed consent documents |  |  | Original consent documents must be maintained by the site; a copy is given to the subject. |
| **Study Product Records tab** | **Binder** | **Or Specify Storage Location** | **Notes** |
| Documentation of study product disposition |  |  |  |
| Investigational Product Accountability Log: Stock Record |  |  |  |
| Investigational Product Accountability Log: Subject Record |  |  |  |
| **Local Clinical Lab Certificates / Reference Ranges tab** | **Binder** | **Or Specify Storage Location** | **Notes** |
| Lab reference ranges |  |  |  |
| Copy of certifications and accreditations |  |  |  |
| **Specimen Tracking Log tab** | **Binder** | **Or Specify Storage Location** | **Notes** |
| Specimen Tracking Log |  |  |  |
| **Unanticipated Problems tab** | **Binder** | **Or Specify Storage Location** | **Notes** |
| Unanticipated Problem reports |  |  |  |
| **Serious Adverse Events (SAEs) tab** | **Binder** | **Or Specify Storage Location** | **Notes** |
| SAE Forms or memos |  |  |  |
| “Dear Doctor” letters |  |  |  |
| IND Safety Reports |  |  |  |
| **Protocol Deviations tab** | **Binder** | **Or Specify Storage Location** | **Notes** |
| Protocol Deviation Forms or memos |  |  |  |
| Protocol Deviation Tracking Log |  |  |  |
| **Clinical Site Monitoring Visits tab** | **Binder** | **Or Specify Storage Location** | **Notes** |
| Monitoring Visit Log |  |  | The Monitoring Visit Log must be stored in the Binder and contain original signatures. |
| Each visit’s correspondence |  |  |  |
| **Other tab** | **Binder** | **Or Specify Storage Location** | **Notes** |
| Certificates of Confidentiality |  |  |  |
| Literature/Publications |  |  |  |
| Technology Transfer Agreement |  |  |  |
| Radiation Safety Committee approvals |  |  |  |
| Office of Biotechnology Activities submissions |  |  |  |

Signature of Principal Investigator: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

PLEASE REFER TO THE

ESSENTIAL DOCUMENTS STORAGE LOCATION TABLE

AT THE FRONT OF THIS BINDER

FOR THE SPECIFIC STORAGE LOCATION

OF ALL ESSENTIAL DOCUMENTS

THAT ARE NOT FILED IN THIS BINDER