1. **INSTRUCTIONS**
	1. This log will identify required source data to be available at the sites for the study, as well as the format and location of the Source Documents (SDs) at the site. The log will be used to verify a site’s SD management process adheres to ICH GCP and regulations. The objective is to document the location of SDs at the time of site initiation, during, and after the study.
	2. The log consists of three sections as follows:
		1. *Source Data Identification at Site Initiation Visit* – document the location of SDs at the time of site activation.
		2. *Changes to the Source Data and/or Location after Site Initiation Visit* –

document any changes to the source data items (e.g., resulting from Protocol Amendment), or any changes to the type and/or location of SDs.

* + 1. *Site Close-out Visit* – document the agreement of Investigator to archive and retain SDs as per ICH GCP and note location where SDs will be archived.
	1. The **Clinical Lead (CL) or XXXXX** is responsible to customize the log with study-specific requirements.

**Site Initiation Visit**

* + 1. List each data point in a line noting the source and location.
		2. Add additional rows as required to reflect study-specific SD.
		3. Accurately number each page.

**During the Study**

* + 1. Make sure section 2 of the log is timely completed and signed by PI to reflect any changes to the source data items, resulting from Amendments, or changes in the organization and/or location of the SDs.
		2. Make sure to add page numbers as applicable.

**At Site Close-out Visit**

* + 1. Make sure section 3 of the log is completed with the location of the SDs after study completion, and PI signed and dated the agreement to keep the SDs as required by ICH GCP, University of Pittsburgh, and other applicable regulatory requirements.
		2. Make sure to complete the page numbering on all pages, including the total number of pages.

Only one source is expected for each item. If more than one source is available for an item, document why there are duplicated sources, and which is the original SD.

File the completed log in the Study Regulatory File.

| ***Source Data***  | ***Provide Original Source Document (SD) Details:***Provide details on the format/type of SD (e.g., medical chart, discharge summary, paper medical record, EMR) | ***Provide Original Source Document Location(s) at Site*:**Specify where the Source may be found (e.g., specify which file; in whose office, which ward; Medical Records Department, EMR system at Imaging department, Lab, etc.). If EMR / eSource system is used, specify the location of the source data within the system (e.g., which section or which tab). | ***Comments/******Additional Information***E.g., indicate when certified copies will be provided to Monitor or how Monitor will access SDs in case read-only access to EMR system is not granted (i.e., over the shoulder monitoring - reviewing EMR while Investigator team member navigates the system); any relevant information about the SDs at site, as applicable |
| --- | --- | --- | --- |
| *Ex: Subject ICF* | *eConsent**Paper Copy (participant)**Paper Copy (site)* | *Participant Binder* | *Participant provided with copy of signed consent. Consent completed electronically. Original in participant chart.*  |
| *Ex: Informed Consent Process* | *Paper Informed Consent Process Checklist* | *Participant Binder* |  |
| *Ex: inclusion / exclusion criteria*  | *EMR, paper medical records, lab reports (sponsor), paper screening documents, physical exam, progress note, Screening* | *Participant Binder; PI Office* |  |
| *Ex: Investigational Product Receipt* | *Pharmacy File* | *Central Pharmacy* |  |
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| *\*Copy/add rows as needed* |  |  |  |

My signature confirms the following:

* The source identification, format, and location information on this log is complete and accurate, and the information was communicated to all study staff members,
* I agree to maintain complete and accurate information on this log throughout the study, and
* I agree to grant Monitor direct access to all SD from all systems as indicated above, including any updates to the SDs.

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| --- | --- | --- |
| **Principal Investigator’s Name:** | **Principal Investigator’s Signature:** | **Date Signed:** |

**2. Changes to the Source Data and/or Location after Site Initiation Visit**

Capture here any changes occurred after the Site Initiation Visit (e.g., additional source data resulting from Amendments, changes to the SD location)

| ***Source Data*** | ***Provide Original Source Document Details:***Provide details on the format/type of SD (e.g., medical chart, discharge summary, paper medical record, EMR) | ***Provide Original Source Document Location(s) at Site*:**Specify where the Source may be found (e.g., specify which file; in whose office, which ward; Medical Records Department, EMR system at Imaging department, Lab, etc.). If EMR / eSource system is used, specify the location of the source data within the system (e.g., which section or which tab). | ***Comments/******Additional Information***E.g., indicate when certified copies will be provided to Monitor or how Monitor will access SDs in case read-only access to EMR system is not granted (i.e., over the shoulder monitoring - reviewing EMR while Investigator team member navigates the system); any relevant information about the SDs at site, as applicable | ***Investigator Signature & Date*** |
| --- | --- | --- | --- | --- |
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*Copy this page if needed.*

**3. Site Close-out Visit**

By signing below, I confirm the following:

* I agree to archive and retain all SDs, including certified copies of SDs used for monitoring purposes as required by ICH GCP, University of Pittsburgh, and other applicable regulatory requirements.
* SDs will be archived at the following location:

|  |  |  |
| --- | --- | --- |
| **Principal Investigator’s Name:** | **Principal Investigator’s Signature:** | **Date Signed:**  |