The below items are some of the requirements that are typically expected to be found in any research study’s files. Each document must be readily available and maintained in organized study files. Study and subject-related templates can be found on the OHR website under the “Investigator & Coordinator Documentation” tab in “Essential Study Documentation”: <https://www.jefferson.edu/university/human_research/resources/essential-study-documentation.html>. In some cases, the templates can be customized for a particular study. For any questions on the below, or if you have any new suggestions, please contact Johanna.Yates@Jefferson.edu or Patrick.Herbison@Jefferson.edu.

**Regulatory Approval**

This documentation is typically required for FDA regulated studies involving drugs, biologics, and devices. For these studies, a copy of the Investigational New Drug (IND) / Investigational Device Exemption (IDE) / study approval documentation (and all corresponding documents) is required.

**Protocols, Amendments, and Signature Pages**

Protocols and amendments, including the signature pages signed by the PI and, as applicable, the sponsor. This section is not for the IRB submission forms.

**Curriculum Vitae (CV) and Professional Licenses**

CVs and Licenses are important to maintain in order to show that all Investigators and key personnel are qualified to perform their respective study responsibilities. Each CV should be signed and dated, and updated and re-signed and dated every 2 years. Each signed and dated CV should be maintained for the entire length of time the research person is on the study. Licenses do not need to be signed and dated; however, they need to be valid and current every 2 years.

**FDA Form 1572**

For FDA regulated studies, the Statement of Investigator Form 1572 is a document that is required to be signed by the Principal Investigator when the study involves a new drug or biologic. This document is typically provided by the sponsor and requires full completion and sign–off by the PI before study startup. Significant updates, such as a PI or Protocol/IND change, requires a new FDA 1572 to be completed and signed off. Other minor updates, such as a change in Co-Investigators, does not require a new FDA 1572, but should still be documented in the study records and communicated to the sponsor.

**Delegation of Responsibility Log**

The PI should document in writing the study responsibilities delegated to all team members, including the PI. The best, and easiest, way to do this is with a delegation log. The delegation log is a list of personnel on the study showing their study responsibilities throughout the duration of the research study. Each study person on the delegation log should sign next to their printed name in order to show their acknowledgement of their role in the study. Dates for each study staff member should be present to show their individual start and end dates. The easiest way for the Principal Investigator to show oversight is by signing, or initialing, next to each staff’s study start date. In addition, the PI should sign, or initial, next to each staff’s study end date. A blank template is provided under “Essential Study Documentation” on the OHR website. This template should be modified to match the study protocol (i.e., if there are no subjects in the study, “Informed Consent Process” should be removed from the list of “Study Responsibilities”.) Study responsibilities should be delegated only to appropriate study personnel. For example, a Study Nurse Coordinator’s responsibility should not state “Physical Examination”, as a physical examination should only be completed by a physician, nurse practitioner, or a physician assistant. In addition, unless inapplicable, there should be no study responsibilities undelegated.

**Training Log**

Training should be documented in order to show that each study person has been trained on the protocol, and is now knowledgeable and capable, to perform the tasks documented in the delegation log. The best, and easiest, way to do this is with a training log. Those on the delegation log should usually be those on the training log. Each person on the training log should sign next to their printed name to show they have been adequately trained to perform the appropriate tasks, according to their responsibilities on the delegation log. The dates on the training log should be the date the study person was trained. Study personnel can be trained by the sponsor, Investigator, or by another appropriate designated study person (i.e., Principal Investigator). Ongoing training should be documented on the training log. A continuous training log may be used for ongoing training, or a separate log for each set of training may be used. In addition, appropriate study personnel should be trained after each protocol amendment. All training logs, as well as appropriate certificates, documenting all study-related training needs to be maintained.

**Screening and Enrollment Log**

An ongoing list of all subjects screened and enrolled in the study must be maintained throughout the duration of the study. Generally, this log also documents the status of each subject.

**Sample Case Report Forms (CRFs) and Signature Pages**

A sample of each Case Report Form (CRF) should be maintained. CRFs should include signature pages to be signed by the PI, the sponsor (as applicable), and the study person designated to complete CRFs. For CRFs that are considered subject-facing, (i.e., questionnaires), they should be IRB approved and have IRB approval stamps. For additional information, please see “IRB Approved Subject and Recruitment Materials” below.

**Sample Source Documents**

If possible, a collection of sample source data collection documents should be filed. It is important that this collection is blank and there are no identifiers found in any of the documents.

**Investigational Product Information - 1**

This documentation is typically required for a study involving  drugs, biologics, and devices. The most current version of the Package Insert / Investigator's Brochure / Device Manual and, if applicable, certificate(s) of analysis and sample investigational product labels should be maintained. All previous versions do not need to be physically stored in the study files; however, each version must be readily available.

**Investigational Product Information - 2**

This documentation is typically required for a study involving  drugs, biologics, and devices. If not already in the Protocol or Investigator’s Brochure/Device Manual, instructions for the storage and dispensing of investigational product and related materials must be maintained.

**Investigational Product Accountability**

This documentation is typically required for a study involving  drugs, biologics, and devices. At the site level, documentation of receipt, storage, shipping, return, and destruction of the investigational product (IP) and related materials (e.g., clinical supplies log) must be maintained. The easiest way to do this is with an ongoing log. On a subject level, documentation of IP that is dispensed and returned must be maintained on a subject-specific log. All of the above logs must show sign-off by the PI, or designated individual.

**Unblinding Procedure**

For blinded studies, the procedure for unblinding a subject, if not already stated in the protocol, must be maintained. The procedure should include the steps taken in the case of an emergency unblinding.

**Unanticipated Problems (UAP) Log**

Also known as the Deviation Log, the UAP Log is used to maintain, in one location, a record of all protocol deviations and violations that occurred in the study. All unanticipated occurrences should be documented on the log regardless of whether the occurrence is reportable to the IRB; the guidelines for what is considered reportable is up to the study’s IRB of record. The guidelines and timeframes for Jefferson IRB can be found in OHR Policy GA 120. Reportable occurrences get submitted to Jefferson IRB via the eazUP system on the OHR home page. As appropriate, UAPs must be submitted to the FDA and Sponsor/CRO as well. IRB and Sponsor approval/acknowledgement of the UAP should also be maintained. If there are no UAPs in the study, a blank template should still be readily available in the study files to show that deviations and violations are continually monitored and maintained.

**Adverse Events (AE) Log**

The AE Log is used to maintain, in one location, a record of all adverse events that occurred to subjects in the study. Commonly, a separate AE log can be used for each subject. All adverse events should be documented on the log regardless of whether the AE is reportable to the IRB; the guidelines for what is considered reportable is up to the study’s IRB of record. The guidelines and timeframes for Jefferson IRB can be found in OHR Policy GA 120. Reportable serious adverse events get submitted to Jefferson IRB via the eSAEy system on the OHR home page. As appropriate, AEs must be submitted to the FDA and Sponsor/CRO as well. If there are no AEs in the study, a blank template should still be readily available to show that adverse events are continually monitored and maintained.

**IND Safety Reports**

This documentation is typically required for a study involving a drug. Sponsors release IND Safety Reports that consist of pertinent safety information on a specific test article relevant to the protocol for all study sites. Sponsors commonly require PI sign off on each report. Each IND Safety Report and, when necessary, documentation that the information has been received by the IRB, should be maintained.

**Additional Safety Information**

This documentation is typically required for a study involving  drugs, biologics, and devices. Any additional risk information including changes to the risk profile of the investigational product, must be maintained.

**Financial Agreements**

A copy of the financial agreements with the sponsor, Medicare Coverage Analysis (MCA), and other financial agreements should be maintained or readily available

**Financial Disclosure Forms (FDFs)/Conflicts of Interest (COI)**

A copy of the disclosure by the Investigators of any financial interest or arrangement with the sponsor, or related to the investigational product(s), should be maintained. For sponsored studies, the sponsor typically provide the templates for Investigators to complete and sign. All Investigators and study personnel, regardless of study funding, must complete a COI disclosure via COI Smart system in order to remain compliant within Jefferson. Failure to complete an annual disclosure can lead to study start-up delay and even study termination.

**Insurance Statement**

Documentation of coverage for a research related injury to subjects should be readily available. In addition, this needs to be clearly stated in the consent form and approved by the budget/contracts team and the IRB.

**IRB Approval Letters and Submission Forms**

IRB approval letters and all IRB forms for each initial submission, amendment, continuing review, final report, etc. should be maintained. These should include the signed forms submitted to the IRB and, as applicable, the approved/signed forms returned by the IRB (e.g., OHR-12B, OHR-31). Keep all the documents for each submission together. These documents may be saved on the department shared drive; however, they must be kept in an organized and clear manner.

**IRB Approved Consent Forms**

IRB approved consent forms with the IRB approval stamps must be maintained. They should be filed in an organized manner in order to easily determine which document is the most current approved version(s).

**IRB Approved Subject and Recruitment Materials**

Subject-facing materials, such as questionnaires and surveys, with the IRB approval stamps must be maintained. In addition, advertisements and other subject recruitment materials showing IRB approval stamps should be maintained in the same section. All versions of each subject material should be available and organized to clearly indicate which is the most current IRB approved for use.

**IRB Rosters**

A copy of the IRB rosters that approved the initial study and subsequent submissions that received full review should be found with its approval.

**Normal Lab Ranges**

The normal ranges for the lab tests being performed for the study should be readily available. This should include any normal lab ranges that have been updated.

**Lab Certifications / Accreditations**

Copies of the certification / accreditation for any lab(s) being used for the study, where specimens are handled, must be readily available. Generally, a copy should be present in the lab as well. This section should also include the CLIA (Clinical Laboratory Improvement Amendments) and the CAP (College of American Pathologists) for any lab area(s) where specimens are processed.

**Biological Specimens**

Documentation of specimen collection and shipment should be easily accessible. Generally, this can be found in the protocol or a separate manual.

**DSMB Letters**

Copies of all Data Safety Monitoring Board (DSMB) information, plans, and reports should be readily available.

**Sponsor Monitoring Reports**

Sponsor monitoring reports and any responses or corrective action plans must be kept. These documents should be kept in an organized and reverse chronological order. In addition to the monitoring letters, the sponsor-provided monitoring log should be saved for ongoing use. This log details each date the monitor is on site to review all study and subject records.

**Study Results**

Interim and final study results (e.g., progress reports, clinical trial reports, final reports, publications, presentations) should be readily available. Once the study is closed and the final report has been received, all documents should be retained on site. University Policy 102.39 should be followed regarding record retention.