Regulatory Documentation for IND Studies:

Investigators are required to maintain the following documents when conducting an IND study.

DOCUMENT	Explanation
IRB Membership List/ Roster	This list documents the members of the IRB responsible for that particular study.
IRB Correspondence	All correspondences with the IRB must be kept on file. ♦ Submittal Package ♦ Initial Approval Letter ♦ Progress Reports ♦ Annual Renewals ♦ Protocol Amendments ♦ IND Safety Reports ♦ Final Reports ♦ Advertising
Investigator's Brochure	The sponsor provides the investigator with known information about the investigational agent in the Investigator's Brochure
Investigator CVs	The sponsor must be able to provide evidence of the investigator's qualifications to conduct the study. This is generally done by collecting the CV of the investigator and sub-investigators; medical licenses are often well.
Protocol	All versions of the study protocol must be retained in the regulatory study file.
Protocol Amendments	Any amendments to the protocol must be maintained n the regulatory study file.
FDA Form 1572 (21 CFR 312.53(c)) or Investigator Agreement for devices (21 CFR 812.43(c))	Any investigator conducting a study under an IND with a sponsor must complete and sign form FDA 1572, statement of investigator (312.53(c)). Section 9 reinforces the regulatory commitments that an investigator is making when involved in an IND study.
Informed Consent Form (Blank, approved version)	All versions of the informed consent form must be maintained in the regulatory study file.
Informed Consent Forms (signed by subjects)	All informed consent forms signed by the subject are part of the study file documentation. They may be kept in this file or in individual subject records. It is required that they be available for review by sponsor representatives and FDA inspectors.
Correspondences	Any correspondence related to the study, such as with the sponsor, clinical labs, pharmacy, must be kept in the study files.

Investigational Agent Records	It is a regulatory requirement that the investigator is able to account for every single unit of investigational agent shipped to the site.
♦ Shipping	The amount shipped to the site must be documented.
♦ Accountability	The amount dispensed to subjects and returned must be documented.
♦ Disposition	The amount used, destroyed, or returned to the sponsor must be documented.
Signature List	A list of all personnel authorized to make entries regarding the study are recorded on a signature log and kept with the study records.
Monitoring Log	To provide evidence that a sponsor monitored the progress of the clinical trial, the monitor should sign in on the Monitoring Log with each site visit.
Screening List	Some studies require that you keep a listing of all subjects screened for a trial.
Subject Enrollment Log	Some studies require that you keep a log of all subjects enrolled, and often times, will need to fax to the sponsor on a regular basis during the study enrollment period to monitor subject recruitment.
Subject Identification Code List	It is sometimes necessary to keep a list of contact information for subjects should it become necessary to contact them concerning new information about the test article.
CRFs (blank)	A copy of the Case Report Form, which collects pertinent data from the trial to enter into the Sponsor's database for analysis, should be kept in the file as a record of parameters collected.
CRFs(completed)	The sponsor collects the original completed CRFs but the site maintains a copy for each subject.
Source Documents	Source documents are the first place information about data is recorded. They serve to provide evidence of credible data. Generally these include subject's medical records, clinical laboratory results, diagnostic test results, clinic notes, etc. and are subject to record retention requirements according to the FDA regulations.
Lab Certification	Verification that the lab used to collect data is certified by a recognized accredited body thereby assuring credible laboratory results.
Lab Normal Value Ranges	The reference ranges for the clinical lab are maintained to evaluate the subject's results within the parameters of the lab's established ranges.