VIRGINIA COMMONWEALTH UNIVERSITY

VCU Make it real.

Essential Documents: Definitions, Purpose and Who Should Maintain.

Essential Documents are required to meet or demonstrate regulatory requirements of both sponsors and investigators

1. Assure IRB review and approval (312.66, 812.110, 812.150(a))
2. Maintain adequate and accurate case histories on each subject's participation in the trial (312.62(b), 812.140(a)(3))
3. Conduct study according to signed investigator statement, protocol, and applicable regulations (312.60, 812.100)
4. Personally conduct and supervise the investigation (312.60, 812.100)
   Ensure:
   - Appropriate delegation
   - Adequate training
   - Adequate supervision
5. Protect the rights, safety, and welfare of study subjects (312.60, 812.100)
6. The Investigator is responsible for providing Sponsor reports:
   - Progress reports
   - Safety reports
   - Deviations from investigational plan
   - Final Reports
   - Financial disclosure reports
   - The sponsor is responsible for the record of drug/device disposition:
7. Maintain adequate record of receipt and shipment of investigational drug/device
   - Assure return of all unused investigational drugs/devices from individual investigators participating in trial or authorize alternative disposition of unused product
   - Maintain written records of any disposition of the drug/device
8. The Investigator is required to maintain adequate records of the disposition of the drug/device (312.62, 812.140(a)(2))
9. The Investigator is responsible to ensure control of investigational drug/device (312.61, 812.110(c))
   - Drug/device will be administered only to those subjects enrolled in the clinical study and under investigator or designee's supervision
10. Sponsor and Investigator:
    - Retain records for 2 years after marketing or 2 years after investigational use is discontinued and FDA notified. See also VCU record retention policy.

NOTE: Sponsor/Investigators are responsible for both locations and Sponsors are responsible for assuring that Investigators maintain these documents as part of the monitoring program.

The following essential documents should be maintained in the Regulatory Binder or Study Binder:

Document	Purpose	Investigator	Sponsor
Form FDA 1571	The cover sheet for the initial IND/IDE submission as well as for all subsequent correspondence to the concerning the investigator-sponsored IND/IDE.		X
Form FDA 1572	Investigator's agreement to perform the study according to applicable federal regulations. (IND)	X	X
Form FDA 3674	All versions. Documents compliance with *Clinicaltrials.gov* registration requirements.		X
Investigator Agreement	Used for IDE studies. Similar to form FDA 1572. See VCU Template	X	X
IND or IDE Application	Copy of full application. Documentation of all information submitted to the FDA as part of the IND/IDE. Any changes, updates, amendments should also be maintained.		X
FDA Annual Reports	The Annual Report informs the FDA of the IND/IDE activities that have taken place over the past year is due within 60 days after the anniversary of the effective date of the IND/IDE.		X
FDA Final Report	Summarizes all activity and results of the IND/IDE (SR device)		X
Package insert	If there is no Investigator's brochure, include a package insert describing the medication used in the study. IDE trials often do not have an IB and provide only the insert for reference. (IDE)	X	X
Instructions for Use / Handling of the investigation product and trail related materials.	The document which specifies technical details of an investigational device and instructions for its use. Instructions are often provided with the Package Insert for training, reference and regulatory documentation. (IND/ IDE)	X	X

Document	Purpose	Investigator	Sponsor
Study Protocol / Research Plan, Amendments and Sample Case Report Forms/Data Collection Tools.	The signed protocol/research plan documents Investigator and Sponsor agreement to the protocol and Case Report Forms or Data Collection tools. Each version of the protocol should be dated for clarity and copies maintained in chronological order. The most current version of the IRB approved protocol should be clearly separated from outdated versions or amendments. Consider maintaining most current (approved) documents in plastic sheaths for easy identification. (IND/IDE)	X	X
Informed Consent Documents	The original informed consent approved by the IRB (stamped and dated) should be filed if there are modifications to the Informed Consent, the originals should be accurately dated and maintained in chronological order. Careful attention must be given to this process so that subjects are given the correct version of the Informed Consent document when they are enrolled into the study. Consider maintaining most current (approved) documents in plastic sheaths for easy identification. (IND/IDE)	X	X
Information Given to study subjects	All information provided to study subjects should be submitted to the IRB with the original protocol and filed in the regulatory binder. (IND/IDE)	X	X
Subject Recruitment tools, advertisements, brochures, reimbursement schedules, etc.	All information/wording used to recruit / inform study subjects should be submitted to the IRB with the original protocol and filed in the regulatory binder. (IND/IDE)	X	X
Study Contract	A copy of the contract between Sponsor and Clinical site (financial information may be maintained in the regulatory binder or elsewhere. If this document is maintained elsewhere note where. (IND/IDE)	X	X

Document	Purpose	Investigator	Sponsor
Conflict of Interest (COI) statements for the Principal Investigator and Investigators listed on form 1572, 1571 or equivalent.	The COI form is maintained in the regulatory binder. An updated COI form may be required at the close of a study. (IND/IDE). Investigators should complete the Certification of Financial Interest and as needed the Disclosure of Financial Interest. See VCU Templates.	X	X
Summary Conflict of Interest (COI) statements for the Principal Investigator and Investigators listed on form 1572, 1571 or equivalent.	The Sponsor should complete and hold on record for FDA form 3454 and 3455 as appropriate. Note these do not need to be submitted to FDA with the IND.		X
Copy of all Investigators Curriculum Vitae (CV) and a copy of the current medical, nursing or other practitioner	Documents the qualification and eligibility to conduct the trial and/or provide supervision of subjects and study staff. (IND/IDE)	X	X
Institutional Review Board Membership roster	Documents that the IRB is constituted in agreement with federal regulations and confirms that the Principal Investigator is not a voting member of the committee or was not involved with discussions/voting regarding this study. This roster should be available for each approval or IRB decision. (IND/IDE)	X	X
Medical / Laboratory / Technical Procedures and or tests required by the Protocol (Certification or Accreditation or Established Quality Control and or external Quality Assessment, other Validation, and Normal Ranges)	Documents competence of facility to perform required test and supports reliability of the tests. (IND/IDE)Documents competence of facility to perform required test and supports reliability of the tests. (IND/IDE)	X	X

Document	Purpose	Investigator	Sponsor
Sample of Label(s) attached to the Investigational Product			X
Shipping Records for Investigational Products and Trial Related Materials (Receipt and Return)	Documents shipment dates, batch number, method of shipment and allows tracking of investigational product and study related materials, batch numbers, review of shipping conditions and accountability. (IND/IDE)	X	X
Certificate(s) of Analysis of Investigation Product(s) received.	Documents the identity, purity, strength of investigational product(s) to be used. (IND)	X	X
Decoding / Instructions for breaking the Blind in Blinded Trials. And Master Randomization list if Sponsor	Instructions as to how, in the case of an emergency, the identity of the blinded investigational product can be revealed without breaking the blind for the remaining	X	X
Site Qualification Visit Report or equivalent	Documents that the site is deemed suitable for the research project by the sponsor	X	X
Site Initiation Visit Report	Documents what trial procedures were reviewed and who was trained at the clinical site.	X	X
Monitoring Visit confirmation and follow up letters	Documents all monitoring visits and findings from each visit.	X	X
IRB Correspondence	All correspondence with the IRB including, the IRB application, letters of initial approval, amendment (modifications) and status reports such as, annual renewal, study termination, final summary, etc. should be maintained.	X	X

Document	Purpose	Investigator	Sponsor
Data Safety Monitoring Board (DSMB) reports	Correspondence from/with the DSMB may be filed with Adverse Events / IRB Correspondence or individually.	X	X
Study Logs; • Drug/Device Accountability log • Monitoring Visit Log • Delegation of Responsibility Log • Site Signature Log • Study / Protocol Training Log • Screening Log • Enrollment Log • Adverse Event Log • Protocol Deviation Log • Subject Identification List	Study Logs should be available in the Regulatory Binder for reviews, auditing and monitoring. Logs should be maintained current with the ongoing research. Study sponsors may provide and require the use of certain logs. It is strongly advised that logs are used to summarize and organize a research project. Drug / Device Accountability, Delegation of Responsibility, Study / Protocol Training Log, Site Signature log and a subject ID list are required by IND / IDE studies.	X	X
Record of Retained Body Fluids / Tissue Samples	(If applicable) Documents the location and identification of retained samples if assays need to be repeated or samples saved for shipping at a later date.	X	X
Study Close Out Monitoring Visit Report or follow up letter	Final Monitoring report or follow up letter confirming clinical site completion of study requirements	X	X
Final Report to the IRB announcing study closure	The principal investigator's final report, which should be signed, dated and forwarded to the IRB and, if applicable, to the sponsor and/or the FDA	X	X
Clinical Study Report	Documents the results and interpretation of the research study	X	X

The following documents are also considered essential but may be maintained in individual subject binders:

Document	Purpose	Investigator	Sponsor
Signed Informed Consent Forms	Documenting IC is obtained in accordance with GCP, Protocol and dated prior to study participation.	X	
Completed, signed, dated Case Report Forms (CRF)	Documents that the Investigator or delegated research staff member confirms the observations recorded as study data	X	X
Source Documents	Documents the existence of the subject and substantiates the integrity of the collected trial data, includes original documents related to the trial, medical/surgical history, and medical surgical treatments documentation if indicated by the protocol	X	
Documentation of Data Corrections	Documents all changes / additions or corrections made to the CRF after the initial data was recorded	X	X
Notes to File	Any documentation used to explain or document additional information in an individual subject binder. (Can also be used with study binder. Either may use NTF it is maintained by whomever documented.)	X	X

Revision History:
Version1: June 9, 2014
Version2: August 3, 2015