

Essential Documents

UW Bioen 599

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Pre-study documents - 1

- Investigator documentation
 - CV, medical license
 - Sponsor-Investigator Agreement
 - Financial Disclosure
 - Confidentiality Agreement (not an FDA req't.)
- Site documentation
 - Pharmacy, Pathology labs, Clinical labs, Core labs
 - Lab normal values (as applicable)
 - Support personnel CV as appropriate

Pre-Study Documents - 2

- Correspondence
 - To/from sponsor/investigator (sponsor and site)
 - To/from IRB (site)
 - To/from FDA (sponsor site)
- Signed Protocol and CRFs
- IRB
 - IRB certification
 - Protocol approval form or letter
 - approved consent form
 - approved advertising materials

Pre-Study Medical Device Documentation

■ At Site

- Operator's Manual and/or Investigator's Brochure
- Components
- Principle of operation
- Training on use of product; training validation

■ At Sponsor's Site

- Software verification and validation
- Biocompatibility
- Electrical Safety, EMC, RFI
- Repair, replacement
- Training records

Ongoing Study Documents - 1

- Investigator
 - License renewal and updated CV
- Site
 - Updated certifications
- Any amendments to protocol, CRF changes
- IRB
 - Re-approval and ongoing review documents
 - Approval of amendments and consent forms for amendments
- Patient/Subject
 - Screening and enrollment logs
 - Signed consent forms (at site)
 - Affidavit of consent

Ongoing study documents - 2

- Patient/Subject – (Cont'd)
 - Case report forms
- Adverse Event reports
 - back-up documentation
 - Death reports
- Investigational Supplies
 - Shipping/receipt documents
 - Inventory/accountability list
 - Repair/replacement/return records
 - Updated Operators' Manual

Ongoing study documents - 3

- Monitoring records
 - Personnel signature sheet
 - Monitoring logs
 - Reports – sponsor facility
 - Summaries (action items) - site
- Data Safety Monitoring Committee reports (Sponsor site)
- Data queries and resolutions
- Reports
 - Investigator progress report(s)

End of Study Documents - 1

■ IRB

- Final report to IRB

■ Patient/Subject

- Completed, query-resolved CRFs

■ Adverse events

- Follow-up of event(s) completed

■ Investigational Supplies

- Accountability records completed
- Return and shipment records

End of study documents - 2

- Close-out Monitoring visit report
- Records
 - Records at site checklist
 - Sponsor records checklist
- Reports
 - Final investigator's report
 - Final statistical report
 - Final overall clinical report

End of Study Documents - 3

- Final Clinical Report for FDA Submission
- Complete copies of CRFs of any subject
 - who died during the course of the study
 - who discontinued from the study
 - who had an unexpected adverse event
 - who was inappropriately enrolled in the study
 - who did not give consent before study procedures were initiated

Close-Out Visit

- Documents, Investigator's copies of Case Report Forms, Device Inventory and accountability, adverse event reports, investigator's final report, etc. must be prepared for storage
- Retention labels should be placed on outer container to let PI know:
 - When contents of box may be destroyed
 - Where to look for specific items in case of FDA inspection
 - What to do with documents if PI moves to another facility

Clinical SOPs, 1

■ Clinical SOPs

- Must be written (not oral) and must be approved by management
- Must be reviewed yearly to see if updates are needed; if changes are made within the year, revised SOPs must be approved.
- It is the company's decision to make the SOPs detailed or general
- Should cover FDA and ICH guidelines

Clinical SOPs, 2

- SOPs should describe how sponsor will perform all regulated activities, e.g., documentation filing system, monitoring, records and reports
- SOPs should also describe management review
- SOPs must be maintained; in-house personnel are trained on SOPs and updates , as needed

Clinical SOPs, 3

- There should be SOPs for every activity the Sponsor is doing itself.
- If a Contract Research Organization (CRO) is used, the CRO must either have its own SOPs or follow those of the Sponsor.
- Whether or not a CRO is used, the Sponsor is ultimately responsible. Periodic oversight of the CRO should be done: visits, inspections, reviewing reports, etc.