Regulatory Binder

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Baystate Health | ADVANCING CARE. ENHANCING LIVES.

Record Keeping Requirements

- Investigators are required to maintain records of research activities
- Good recordkeeping verifies the integrity of study data and demonstrates compliance with regulations, policies and procedures
- Regulatory documents maintained on file depend on the nature the study and applicable regulations
- Regulatory files serve as a central location for maintaining study management documents
- Regulatory Binder should be maintained for each study

Record Retention

Baystate Health	7 years upon completion of the study
FDA	2 years after the marketing permit application is approved or terminated
	At the end of study when the FDA is notified that test articles were disposed or returned and a marketing permit is not sought

Regulatory Binder





AS OF MARCH 1, 2021, ALL FUNDED PROJECTS AND ALL INTERNALLY SUPPORTED PROJECTS REQUIRING AN EXPEDITED OR FULL BOARD IRB REVIEW REQUIRE USE OF FLORENCE.

Regulatory Binder Guidelines

Regulatory Binder should be established at the beginning of the study, prior to enrollment.

The individual(s) maintaining the binder should be on file with the IRB to ensure that all IRB correspondences and documents are received/filed in a timely manner.

Regulatory Binder Guidelines (cont)

The binder should be customized to meet the needs of your protocol. Depending on your study, some of the sections in the binder may not be required.

The binder should be stored in a safe and secure location, but accessible to study staff at all times. If sections of the binder are stored separately, a signed and dated note should be added to the file. If documents are stored in a central location, or electronically, write a note-to-file indicating location.

Regulatory Binder Sections

All Studies

- Protocol
- CVs, Licenses, & Trainings
- Logs
- IRB Documents
- Consent Forms
- Data Collection Forms

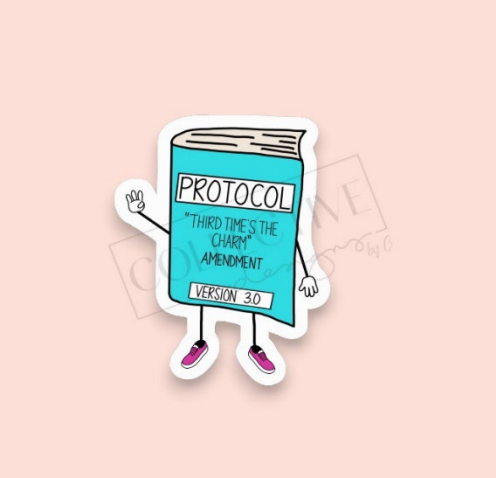
Study Specific

- Lab Documents
- Sponsor
- Drug/Device
- FDA
- Financial Disclosure
- DSMP

Protocol

Purpose

- Documents current study objectives and procedures approved by the IRB



- GCP Section: 8.2.2, 8.3.2

Contents

- Current IRB approved protocol
- All previous IRB approved protocols
- Signed Protocol Signature page
  (*not all studies will have)



CVs, Licenses, & Trainings

Purpose



Document qualifications and eligibility to conduct trial or conduct delegated tasks and/or provide medical supervision of subjects

Document qualifications and eligibility to conduct trial and/or provide medical supervision of subjects

Documentation of staff training which shows staff are trained and qualified to perform the tasks delegated to her/him

GCP: 8.2.10, 8.3.5, 4.1.1

CVs, Licenses, & Trainings (cont)

- Signed and dated CV, resume, or biosketch for all staff on delegation log
- Medical licenses/ professional certifications for IRB approved staff performing task (e.g., nurses, MDs, etc.)
- Staff training log
- CITI Training
  - GCP
  - Biomedical

Content



Logs

Purpose



Assist with the collection, organization and reporting of data for research and compliance purposes.



GCP: 8.2.10, 4.1.1, 8.3.20-8.3.25

Content

- Delegation of Responsibility log
- Enrollment log
- Tissue log
- Monitoring log
- Deviation Log
- Adverse Event Log

IRB Documents

Purpose



Demonstrates that appropriate regulatory authorities have reviewed and approved the study prior to initiation.



GCP: 8.2.7, 8.2.9, 8.3.2, 8.3.3, 8.3.4

Content

- Copies of all IRB correspondences (e.g. submissions, request for modifications, PI responses, approved documents,)

Consent Forms

Purpose

- Documents that the informed consent process and information given to subjects were reviewed and approved by the IRB.



- GCP: 8.2.7, 8.2.3, 8.3.2, 8.3.12

Content

- Current IRB approved consent form version with the IRB approval stamp
- Previously IRB approved consent form version with the IRB approval stamp
- Documentation of consent process



Data Collection Forms

Purpose



TEMPLATE FORMS USED TO COLLECT STUDY DATA.



GCP: 8.2.2

Content

- Blank set of case reports (CRF's), data collection sheets, or study questionnaires:
  - Inclusion/Exclusion Criteria
  - Labs
  - History and PE
  - AE / Con-meds
  - Questionnaires

Study Specific



Laboratory Documents

Purpose



VERIFIES THE COMPETENCY OF LAB FACILITIES AND THE RELIABILITY TO TEST RESULTS



GCP: 8.2.11, 8.2.12, 8.2.14, 8.3.6, 8.3.7

Content

- Current Lab Certification
  - CLIA
  - CAP
- Normal Reference Ranges
- CV for research lab director* (If you are using a research lab some sponsors may request the CV for the director of the lab)

Sponsor

Purpose



DOCUMENTS SIGNIFICANT DISCUSSIONS BETWEEN SPONSOR AND SITE REGARDING TRIAL.



GCP: 8.3.11

Content

Maintain copies of all significant correspondence to and from sponsor:

- Letters
- Emails
- Meeting notes
- Telephone call notes

Drug/Device

Purpose



Provide relevant & current scientific information about drug or device and its use in subject

GCP: 8.2.1, 8.3., 8.4.1, 8.4.2

Drug/Device

Content

Current Product Information

- Drug
  - Investigational New Drug (IND)
    - Current and previous versions of Investigator Brochure (IB)
  - FDA Approved Drug
    - Package Insert
- Device
  - Investigational Device Exemption (IDE)
    - Device Manual
  - Approved Devices
    - Information for Use

Shipment and Receipt Records

Manual of procedures (MOP)

Accountability Log

Massachusetts Controlled Substance Registry (MCSR)

If shipment, receipt and accountability are managed by research lab, a signed and dated note should be added to file.

FDA

Purpose

- Confirms compliance with regulations governing the use of investigational products.



FDA

Content

IND/ IDE Clinical Investigator (conducts study)	Statement of the Investigator/ Form1572 (drug)	FDA Financial Disclosures on file	Safety Reports submitted to Sponsor
IND/IDE Sponsor	IND/IDE application & 1571	Amendments to IND/IDE	Safety Reports to FDA
Annual Reports to FDA	Certification of Registration to Clinicaltrials.gov (Form 3674)	All documents and reports that clinical investigator submitted to Sponsor	Study Specific

IND exemption Letter

Financial Disclosure

Purpose

- FDA-Documents financial agreements between clinical investigators and the sponsor of the trial.
- Baystate-Documents any potential financial conflicts-of-interests on the part of investigators or coinvestigators.

- GCP: 8.2.4

Content



Signed and dated FDA Financial Disclosure for all investigators on the 1572 or IRB application



*The FDA form 3455 is generally used to document financial interests.

DSMP

Purpose

Documents the review and determinations of the DSMB

- GCP: 8.3.10, 5.18.3, 5.19

Content

Documentation of monitoring for subject safety, and data integrity:

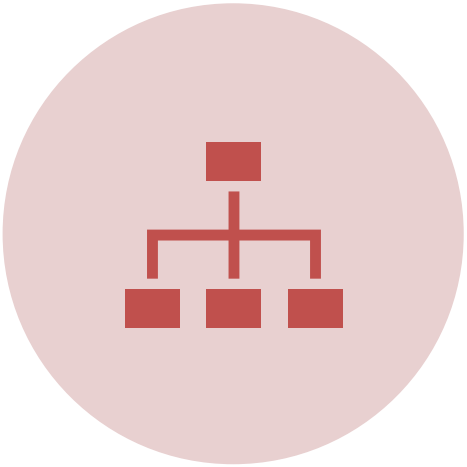
- Monitoring Log
- Emails, Letters, Agendas, Meeting minutes
- DSMB membership list
- Reports from DSMB meetings

Questions



Contact EQA Team – Service Now





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Join us in shaping the future of HRPP



Thank you!

See you September 18th, 2024

2:00 pm-3:00 pm