IRB

IRB

Requirements

- IRB Submissions (application, consent forms, supporting documents)
- IRB Approval Letters
- Continuing Review(s)
- Amendments
- Adverse Events
- Violations/Deviations
- Reporting Forms (DSMB reports, Investigator drug/device brochure updates)
- Close out Information
- Investigator response(s) to IRB notification (if applicable)

IRB Decisions

- Approval letters and/or notification of IRB decisions
- Approved recruitment materials
- Approved educational materials/additional study information distributed to subjects (e.g. subject diary)
- Info regarding Federalwide Assurance (FWA); IRB registration and IRB membership
- Letter to Sponsors
- Any additional correspondence relating to the study (e.g. e-mails)

Tips / Additional Information

- Copies of all signed and dated IRB submissions and correspondence between the study site and IRB should be kept on file.
- It is recommended to arrange documents in reverse chronological order to ensure that documentation provides an accurate history/timeline of study activity from approval to completion. Only one copy of each correspondence is needed.
- Request a copy of any missing documents from your protocol administrator or print them to include in the binder.
- If documents are filed electronically, write a signed and dated note to file indicating the location.
- If signed and dated correspondences cannot be maintained electronically (e.g. pdf version), keep a hard copy on file.
- Regulations/Guidelines-45 CFR 46
- 21 CFR 50
- 21 CFR 56

Applicable GCP sections:

- 8.2.7
- 8.2.9
- 8.3.2
- 8.3.3
- 8.3.4

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