CHANGE AFib Regulatory Binder: Essential documents *(items with * are needed for study activation)*

The Good Clinical Practice (GCP) Guidelines define Essential Documents as those documents which individually and collectively permit evaluation of the conduct of a trial and the quality of data produced. These documents serve to demonstrate compliance with standards of Good Clinical Practice and with all applicable regulatory requirements. Filing essential documents in a timely manner can greatly assist in the successful management of a clinical trial.

CHANGE AFib Required Documents: Templates for many of the items listed below are posted here: Resources for Participating Hospitals – Change AFib.

Once your site signs the CHANGE AFib agreement, access to the private resources section of the CHANGE AFib website will be provided. If you need copies of the template logs in advance of contract execution, please reach out to changeafib@heart.org.

1. Site Visit (Monitoring) Log

This provides documentation for the site that the study was monitored. The monitor and designated site staff both sign the log to verify the date the monitor was present. For consecutive days, each day is entered separately.

2. Delegation of Authority (Responsibilities) Log*

This log documents responsibilities assigned to research team members. It helps ensure the appropriate delegation of study related tasks

3. Study Personnel Education: Training Log*

- CITI/Human Subjects Training
- CHANGE AFib Training

This is a record of training, (e.g., protocol training or other study-specific training) of staff as well as any IRB required training.

4. CVs/Financial Disclosures/Investigator Statements*

This section should include Curricula Vitae, licenses, and certifications for study staff.

5. Screening/Enrollment Log

This section should include a log of subjects who were screened (and reason for screen failure) and enrolled. Some studies allow for re-screening of subjects.

6. Subject Visit Tracking Log

This log tracks all enrolled subjects' visits, reason for early termination and keeps visits scheduled as per protocol.

7.Subject Identification Code List

This is a confidential list of the names of all the subjects that provides a link between their identity and their study code to allow the Investigator to reveal the identity of any subject, if necessary. T*his list should remain confidential and should only be accessible by staff at your site.*

8. Consent Forms*

This section should include blank consent form document(s) (all IRB approved and stamped versions) stored in reverse chronological order with the current approved version first.

9. HIPPA Forms*

(Authorization, Waiver, and/or Research Preparation Purposes)

This section includes all IRB approved versions of any of the HIPAA forms (as applicable).

10. Protocol*

This section should include the protocol (and protocol signature page) and all amendments (and amendment signature page or pages), stored in reverse chronological order with the current approved version first.

11. IRB Letter*

This section should contain the most current IRB assurance letter.

12. IRB Approval(s) /Communication

This section should include copies of the original IRB application/submission, IRB approval letters (contingent and final approval), and all correspondence with the IRB (including emails) as applicable.

13. Protocol Deviations/Protocol Exceptions

This section should include correspondence relevant to the issue and copies of the documents stored in reverse chronological order with the most current documents first.

Please note that some Sponsor approved waivers may need to be approved by the IRB prior to implementation.

14. Adverse Events and Unanticipated Problems

This section should include correspondence/copies and acknowledgements of reports for internal AEs and unanticipated problems that were reported to Sanofi PV.

15. Educational Materials*

This section should include any IRB approved recruitment flyers, written educational, or other materials provided to study participants, stored in reverse chronological order with the most current documents first.

16. Blank Set of Case Report Forms