

The Christ Hospital IRB

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STANDARD OPERATING PROCEDURE

IRB Records

1. PURPOSE

1.1. This procedure establishes the preparation and maintenance of the documentation of IRB activities by the IRB Office.

2. PREVIOUS VERSION

2.1. 01/20

3. POLICY

3.1. It is The Christ Hospital's policy for the IRB to maintain accurate records of all activities involved in a research protocol at The Christ Hospital. These records shall be retained for at least 3 years after completion of the research or study closure, and the records shall be accessible for inspection and copying by authorized representatives of the any applicable federal department or agency at reasonable times and in a reasonable manner.

4. RESPONSIBILITY

4.1. IRB Office- The IRB Office shall maintain accurate records of the following:

4.1.1. IRB study files, comprised of, but not limited to the following (only as applicable to the research):

- 4.1.1.1. IRB Submission forms
- 4.1.1.2. Protocol
- 4.1.1.3. Scientific evaluations
- 4.1.1.4. Approved consent forms
- 4.1.1.5. Advertising Materials
- 4.1.1.6. Investigator Brochure
- 4.1.1.7. Progress Reports submitted by investigators
- 4.1.1.8. Reports of injuries to subjects
- 4.1.1.9. Records of continuing review activities
- 4.1.1.10. Copies of Correspondence between the IRB and the investigator(s)
- 4.1.1.11. Amendments
- 4.1.1.12. Data Safety Monitoring reports
- 4.1.1.13. Unanticipated Problems
- 4.1.1.14. Audit reports
- 4.1.1.15. Statements of significant new findings provided to subjects

4.1.2. IRB Meeting Minutes, as detailed in *SOP 1.04 Meeting Minutes and Conducting IRB Meetings*

4.1.3. IRB membership list, comprised of:

- 4.1.3.1. Member name
- 4.1.3.2. Earned degrees
- 4.1.3.3. Representative capacity

- 4.1.3.4. Indications of experience
- 4.1.3.5. Affiliation or other relationship between each member and The Christ Hospital
- 4.1.4. Maintain written procedures for the IRB, as detailed in *SOP 3.04 Policy Development*

5. PROCEDURE

5.1. IRB Office maintains records of all activities as follows-

- 5.1.1. Study Files
 - 5.1.1.1. Prior to electronic implementation beginning on September 21, 2020
 - 5.1.1.1.1. Assigns a study number and study folder for each new protocol
 - 5.1.1.1.2. All study correspondence from investigators date stamped
 - 5.1.1.1.3. Kept in paper form
 - 5.1.1.1.4. Stored in individual study folders or binders
 - 5.1.1.1.5. Maintained in a locked IRB file room
 - 5.1.1.2. At the commencement of electronic implementation on and after September 21, 2020
 - 5.1.1.2.1. Kept in electronic format
 - 5.1.1.2.2. Stored digitally in electronic database
 - 5.1.1.2.3. Maintained on a secure TCH drive
 - 5.1.1.3. Maintains files for at least 3 years after study completion or study closure
- 5.1.2. Meeting Minutes
 - 5.1.2.1.1. Prior to electronic implementation beginning on September 21, 2020
 - 5.1.2.1.1.1. Signed document kept in paper form
 - 5.1.2.1.1.2. Stored in Meeting Minutes Binder in IRB Office
 - 5.1.2.1.1.3. Stored for at least 3 years after all studies discussed at applicable meeting have been closed
 - 5.1.2.1.2. At the commencement of electronic implementation on and after September 21, 2020
 - 5.1.2.1.2.1. Signed document kept in electronic format
 - 5.1.2.1.2.2. Stored digitally in electronic database
 - 5.1.2.1.2.3. Stored for at least 3 years after all studies discussed at applicable meeting have been closed
- 5.1.3. Membership List
 - 5.1.3.1.1. Prior to electronic implementation beginning on September 21, 2020
 - 5.1.3.1.1.1. Kept in paper form
 - 5.1.3.1.1.2. Stored in IRB Binder in IRB Office
 - 5.1.3.1.2. At the commencement of electronic implementation on and after September 21, 2020
 - 5.1.3.1.2.1. Kept in electronic format
 - 5.1.3.1.2.2. Stored digitally on secure TCH drive
- 5.1.4. IRB Standard Operating Procedures
 - 5.1.4.1.1. Prior to electronic implementation beginning on September 21, 2020
 - 5.1.4.1.1.1. Signed document kept in paper form and electronic form
 - 5.1.4.1.1.1.1. Paper document stored in Standard Operating Procedures Binder in IRB Office
 - 5.1.4.1.1.1.2. Electronic document stored digitally on secure TCH drive

5.1.4.1.2. At the commencement of electronic implementation on and after
September 21, 2020

5.1.4.1.2.1. Kept in electronic format

5.1.4.1.2.2. Stored digitally on secure TCH drive

6. DOCUMENTS

6.1. None

7. DEFINITIONS

7.1. None

8. REFERENCES

8.1. SOP 1.04 Meeting Minutes and Conducting IRB Meeting and SOP 3.04 Policy
Development

8.2. 45 CFR 46.115(a)(b)

8.3. 21 CFR 56.108(a) and (b), 21 CFR 56.115(a)(b)

8.4. AAHRPP Standard II.5.A