
STANDARD OPERATING PROCEDURE

IRB Records

1.0 PURPOSE

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

2.0 POLICY

It is The Christ Hospital's policy that the IRB maintain accurate records of all activities involving research protocols at The Christ Hospital (TCH). IRB records shall be accessible for inspection and copying by authorized representatives of the institution and/or any applicable federal department or agency at reasonable times and in a reasonable manner. Records shall be retained for at least three years after completion of the research or study closure.

3.0 RESPONSIBILITY

Accurate records shall be maintained by the IRB office including IRB study files comprised of, but not limited to, the following (only as applicable to the research):

- 3.1 IRB Submission forms;
- 3.2 Research protocols;
- 3.3 Scientific evaluations;
- 3.4 Approved consent forms;
- 3.5 Advertising materials;
- 3.6 Investigator brochures;
- 3.7 Progress reports submitted by investigators;
- 3.8 Reports of injuries to subjects;
- 3.9 Records of continuing review activities;
- 3.10 Copies of correspondence between the IRB and the investigator(s);
- 3.11 Amendments;
- 3.12 Data Safety Monitoring reports;
- 3.13 Unanticipated Problems/Reportable Events;
- 3.14 Audit reports;
- 3.15 Statements of significant new findings provided to subjects;
- 3.16 IRB Meeting Minutes as detailed in [SOP 1.04](#) - Meeting Minutes / Conducting IRB Meetings;
- 3.17 IRB membership list, comprised of:
 - 3.17.1 Member name,
 - 3.17.2 Earned degrees,

- 3.17.3 Representative capacity,
- 3.17.4 Indications of experience,
- 3.17.5 Affiliation or other relationship between each member and The Christ Hospital;
- 3.18 Written procedures maintained for the IRB, as detailed in [SOP 3.04](#) - Policy Development and Communication for the Institutional Review Board and Human Research Protections Program.

4.0 PROCEDURE

The IRB office maintains records of all activities including, but not limited to:

4.1 Study Files

- 4.1.1 Paper Files - Prior to the September 21, 2020 implementation of electronic record keeping, study files were:
 - 4.1.1.1 Kept in paper form (hardcopy),
 - 4.1.1.2 Assigned a study number and study folder for each new protocol,
 - 4.1.1.3 Date stamped upon receipt of correspondence from investigators
 - 4.1.1.4 Stored in individual study folders, and
 - 4.1.1.5 Maintained in a locked IRB file room.
- 4.1.2 Electronic Files
 - 4.1.2.1 Electronic Record Keeping - On and after the September 21, 2020 implementation of electronic record keeping, study files are:
 - 4.1.2.1.1 Stored digitally in electronic format,
 - 4.1.2.1.2 Maintained on a secure TCH drive, and
 - 4.1.2.1.3 Maintained for at least three years after study completion or study closure.
 - 4.1.2.2 Mentor IRB - On and after June 1, 2022, at the commencement of the IRB's web-based IRB management system, Mentor IRB, study files are:
 - 4.1.2.2.1 Automatically assigned a study number and provided an individual protocol page in the secure Mentor IRB system for each new protocol,
 - 4.1.2.2.2 Stored digitally in the secure Mentor IRB system,
 - 4.1.2.2.3 Maintained in the secure Mentor IRB system, and
 - 4.1.2.2.4 Maintained indefinitely after study completion or study closure.

4.2 Meeting Minutes

- 4.2.1 Paper Files - Prior to the September 21, 2020 implementation of electronic record keeping, meeting minutes were:
 - 4.2.1.1 Signed and kept in paper form (hardcopy),
 - 4.2.1.2 Stored in Meeting Minutes binder in IRB office, and
 - 4.2.1.3 Stored for at least three years after all studies discussed at the applicable meeting(s) have been closed.
- 4.2.2 Electronic Files
 - 4.2.2.1 Electronic Record Keeping - On and after the September 21, 2020, implementation of electronic record keeping, meeting minutes are:

- 4.2.2.1.1 Signed and the document kept in electronic format,
 - 4.2.2.1.2 Stored digitally on a secure TCH drive, and
 - 4.2.2.1.3 Stored for at least three years after all studies discussed at applicable meeting(s) have been closed.
 - 4.2.2.2 Mentor IRB - On and after June 1, 2022, at the commencement of the IRB's web-based IRB management system, Mentor IRB, meeting minutes are:
 - 4.2.2.2.1 Stored digitally in the secure Mentor IRB system, and
 - 4.2.2.2.2 Stored indefinitely in the secure Mentor IRB system.
- 4.3 **Membership List**
 - 4.3.1 Paper Files - Prior to the September 21, 2020 implementation of electronic record keeping, membership lists were:
 - 4.3.1.1 Kept in paper form, and
 - 4.3.1.2 Stored in IRB binder in IRB office.
 - 4.3.2 Electronic Files
 - 4.3.2.1 Electronic Record Keeping - On and after the September 21, 2020 implementation of electronic record keeping, membership lists are:
 - 4.3.2.1.1 Kept in electronic format, and
 - 4.3.2.1.2 Stored digitally on secure TCH drive.
 - 4.3.2.2 Mentor IRB - On and after June 1, 2022, at the commencement of the IRB's web-based IRB management system, Mentor IRB, membership lists are stored digitally in Mentor IRB.
- 4.4 **IRB Standard Operating Procedures (SOPs)**
 - 4.4.1 Prior to the September 21, 2020 implementation of electronic record keeping:
 - 4.4.1.1 Signed documents were kept in paper form and electronic format,
 - 4.4.1.2 Paper documents were stored in the Standard Operating Procedures binder in the IRB office, and
 - 4.4.1.3 Electronic documents were stored digitally on the secure TCH drive.
 - 4.4.2 On and after the September 21, 2020 implementation of electronic record keeping, SOPs are:
 - 4.4.2.1 Kept in electronic format, and
 - 4.4.2.2 Stored digitally on the secure TCH drive.

5.0 REFERENCES

- 5.1 The Christ Hospital IRB Standard Operating Procedures
 - 5.1.1 [SOP 1.04](#) - Meeting Minutes / Conducting IRB Meeting
 - 5.1.2 [SOP 3.04](#) - Policy Development
- 5.2 Code of Federal Regulations
 - 5.2.1 [45 CFR 46.115\(a\)](#) and [\(b\)](#)
 - 5.2.2 [21 CFR 56.108\(a\)](#) and [\(b\)](#)
 - 5.2.3 [21 CFR 56.115\(a\)](#) and [\(b\)](#)
- 5.3 AAHRPP Domains and Elements: [II.5.A](#)