The Christ Hospital IRB | **Number:** 1.04
Submitted By: Erica Jones, CIP | **Effective Date:** 02/09
Approved By: Steve Roberts, MD | **Revision Date:** 10/25

STANDARD OPERATING PROCEDURE

Conducting IRB Meetings / IRB Meeting Minutes

1.0 PURPOSE

This procedure establishes the process of conducting IRB meetings and recording minutes of the meetings according to federal regulations and institutional policy.

2.0 POLICY

The Christ Hospital (TCH) Institutional Review Board (IRB) shall hold regular, convened meetings to review research study proposals including new submissions and continuing reviews of studies in progress, hear invited-speaker presentations (e.g., PIs, expert consultants), and to deliberate and vote on relevant issues. IRB meetings shall occur on the second Tuesday of each month beginning 7:30 a.m. Meeting minutes shall be taken to record all discussion, planned action items, and outcomes of member voting. Meeting minutes will be retained for no less than three years after the last study requiring convened IRB review on the agenda has been permanently closed.

3.0 RESPONSIBILITY

3.1 IRB Chair: Conducts convened IRB meeting according to procedure.

3.2 Convened IRB Members: Review and vote on agenda items requiring convened IRB Review.

3.3 Principal Investigator (or Representative): Presents on new, greater-than-minimal-risk research at the convened IRB meeting.

3.4 IRB Office: Records meeting minutes according to procedure.

4.0 PROCEDURE

4.1 IRB Chair:

- 4.1.1 Ensures that any member conflict of interest (COI) is disclosed prior to commencement of the meeting;
- 4.1.2 Calls meeting to order;
- 4.1.3 Ensures that a quorum is maintained throughout the meeting;
- 4.1.4 Follows the agenda unless unforeseen circumstances arise;

4.1.5 Excuses the PI or representative from the meeting after the PI or representative presentation is completed and prior to further IRB discussion and vote;
4.1.6 Leads the IRB to work toward resolution of any controverted issues (unresolved issues could be reason for disapproval); and
4.1.7 Calls for vote.

4.2 Convened IRB Members:
4.2.1 Review all agenda materials prior to the meeting utilizing checklists, as applicable;
4.2.2 Attendance is recorded by IRB staff and the chairman asks whether any member in attendance has any conflict of interest concerning any study on the agenda;
4.2.3 In the case of a COI, the member holding the COI must leave the room during discussion of and voting on the study associated with the COI;
4.2.4 Participates in discussion; and
4.2.5 Places vote.

4.3 Principal Investigator and/or Representative: Presents new protocol to the IRB and answers any IRB questions.

4.4 IRB Office:
4.4.1 Records the following information in the meeting minutes:
4.4.1.1 Date and place of the meeting;
4.4.1.2 Attendance of members present, members absent, and guests present;
4.4.1.3 Conflict of Interest regarding a particular study on the agenda, including:
4.4.1.3.1 Name of the member with a conflicting interest, and
4.4.1.3.2 Documentation of when the member leaves the meeting room due to the conflicting interest, and indicates that the member is absent because of said conflicting interest;
4.4.1.4 Quorum, including at least:
4.4.1.4.1 One more than half the number of roster members, and
4.4.1.4.2 One nonscientist member;
4.4.1.5 Call to order;
4.4.1.6 Approval of the previous meeting minutes along with any changes, if necessary;
4.4.1.7 Approval of Exempt/Expedited Report (Chairman's Report) consisting of the chair's expedited approvals/acknowledgments since the last convened meeting, such as:
4.4.1.7.1 Continuing Reviews,
4.4.1.7.2 Status Updates,
4.4.1.7.3 Amendments,
4.4.1.7.4 Study Closures;

4.4.1.8 All business requiring convened board review and approval (i.e., full-board new protocol submissions, full-board amendments, full-board continuing review reports, unanticipated problems involving risks to subjects or others, compliance issues, etc.) including the following, as applicable:

- 4.4.1.8.1 Written summary of discussion on controverted issues including resolution;
- 4.4.1.8.2 Required amendments;
- 4.4.1.8.3 Basis for requiring changes in research;
- 4.4.1.8.4 Basis for disapproving research;
- 4.4.1.8.5 Justification of any deletion or substantive modification of risks or alternative procedures contained in the DHHS-approved sample consent document;
- 4.4.1.8.6 Determinations required by regulations and protocol-specific findings justifying those determinations (unless already documented in the IRB records) for:
  - 4.4.1.8.6.1 Waiver or alteration of the consent process,
  - 4.4.1.8.6.2 Research involving pregnant women, fetuses, and neonates, and
  - 4.4.1.8.6.3 Rationale for significant risk/non-significant risk device determinations;
- 4.4.1.8.7 Vote and outcome documenting:
  - 4.4.1.8.7.1 Numbers for, against, or abstaining,
  - 4.4.1.8.7.2 Instances where an alternate member replaces a primary member, and
  - 4.4.1.8.7.3 Approval, Approval with Modification(s), Disapproval, or if tabled;

  Note: For research to be approved, it must receive approval of a majority (more than half) of IRB members present at the meeting. Proxy voting is not permitted.
- 4.4.1.8.8 Adjournment time.

5.0 REFERENCES

5.1 The Christ Hospital Standard Operating Procedures

- 5.1.1 SOP 1.03 – IRB Records
- 5.1.2 SOP 3.23 - Definitions

5.2 Code of Federal Regulations: 45 CFR 46.115(a)(2), 21 CFR 56.108(c)

5.3 AAHRPP Domains and Elements: II.1.D, II.2.D, II.5.B