The Christ Hospital IRB | **Number:** 1.04
Submitted By: Erica Jones, CIP | **Effective Date:** 02/09
Approved By: Steve Roberts, MD | **Revision Date:** 08/22

STANDARD OPERATING PROCEDURE

IRB Meeting Minutes / Conducting IRB Meeting

1.0 PURPOSE

This procedure establishes the process of conducting IRB meetings and recording minutes of the meetings according to regulation 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 at 7:30 a.m. Meeting minutes shall be taken to record all discussion, planned action items, and outcomes of member voting. Minutes of meetings 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 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 is disclosed prior to the meeting commences
- **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 should arise

4.1.5 Excuses the PI or representative from the meeting after their 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

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 In the instance of virtual meetings, attendance is electronically noted and each member is asked whether or not they have a conflict of interest concerning any study on the agenda

4.2.3 In the case of a COI, the member must leave the room during discussion of and voting on the particular study where the COI exists

4.2.4 Participates in discussion

4.2.5 Places vote

4.3 Principal Investigator and/or Representative:

4.3.1 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:

a. Name of the member with a conflicting interest
b. Documentation of when the member leaves due to the conflicting interest, indicating that the member is absent because of said conflicting interest

4.4.1.4 Call to Order

4.4.1.5 Quorum, including at least:

a. One more than half the number of roster members, and
b. One nonscientist member

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:

a. Continuing Reviews
b. Amendments
c. Study Closures
d. Status Updates

4.4.1.8 For 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.) includes the following, as applicable:

a. Written summary of discussion on controverted issues and their resolution
b. Required Amendments
c. Basis for requiring changes in research
d. Basis for disapproving research
e. Justification of any deletion or substantive modification of risks or alternative procedures contained in the DHHS-approved sample consent document
f. Determinations required by regulations and protocol-specific findings justifying those determinations (unless already documented in the IRB records) for:
    - Waiver or alteration of the consent process
    - Research involving pregnant women, fetuses, and neonates
    - The rationale for significant risk/non-significant risk device determinations
g. Vote and outcome documenting:
    - Numbers for, against, or abstaining
    - Instances where an alternate member replaces a primary member
    - Approval, Approval with Modification(s), Disapproval or if Tabled
        - For research to be approved, it must receive approval of a majority (more than half) of the members present at the meeting; proxy voting is not permitted
h. Adjournment time

5.0 DOCUMENTS

Mentor IRB: Minutes Reports template

6.0 DEFINITIONS

Not Applicable

7.0 REFERENCES

7.1 Standard Operating Procedures: SOP 1.03
7.2 Code of Federal Regulations: 45 CFR 46.115(a)(2); 21 CFR 115 (a)(2)
7.3 AAHRPP Standards: II.1.D; II.2.D; II.5.B

ADDENDUM
STANDARD OPERATING PROCEDURE 1.04
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1.0 PREVIOUS VERSIONS

Date Revised	Reason for Change	Revised By
09/09/22	Minor administrative changes	Becky Riddell
04/14/10	Addition of determining serious or continuing non-compliance	Becky Riddell
03/14/16	Addition of reporting IRB findings to the Institution	Becky Riddell
02/01/21	Template formatting change; meeting minutes retention change	Erica Jones
08/04/22	Adding Mentor IRB process updates and transitioning SOP to new SOP template format	Erica Jones

2.0 APPROVALS

IRB Chair, Steve Roberts, MD	Date of Approval