

The Christ Hospital IRB

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Number: 1.04

Effective Date: 02/09

Revision Date: 02/21

STANDARD OPERATING PROCEDURE

IRB Meeting Minutes / Conducting IRB Meeting

1 PURPOSE

- 1.1 This purpose of this procedure is to establish the process for conducting IRB meetings and for recording minutes of the meetings according to regulation and institutional policy.

2 PREVIOUS VERSION

- 2.1 10/19/09- Addition of criteria documented in minutes
- 2.2 04/14/10- Addition of determining serious or continuing non-compliance
- 2.3 03/14/16- Addition of reporting IRB findings to the Institution
- 2.4 02/01/21- Template formatting change; meeting minutes retention change

3 POLICY

- 3.1 This procedure establishes the process for conducting IRB meetings and for recording minutes of the meetings. Minutes of meetings may no less than three years after the last study requiring convened IRB review on the agenda has been permanently closed.

4 RESPONSIBILITY

- 4.1 **IRB Office** records meeting minutes according to procedure
- 4.2 **IRB Chair** conducts convened IRB meeting according to procedure
- 4.3 **Convened IRB members** review and vote on agenda items requiring convened IRB review
- 4.4 **Principal Investigator** or representative presents new greater than minimal risk research at the convened IRB meeting

5 PROCEDURE

- 5.1 **IRB Office** performs the following:
 - 5.1.1 Records the following information in the meeting minutes:
 - 5.1.1.1 Date and place of the meeting
 - 5.1.1.2 Attendance of members present, members absent and guests
 - 5.1.1.3 Conflict of Interest regarding a particular study on the agenda, including:
 - 5.1.1.3.1 Name of the member with a conflicting interest
 - 5.1.1.3.2 Documentation of when the member leaves due to the conflicting interest, indicating that the member is absent because of said conflicting interest
 - 5.1.1.4 Call to Order
 - 5.1.1.5 Quorum, which includes at least:
 - 5.1.1.5.1 One more than half the number of roster members, and
 - 5.1.1.5.2 One nonscientist member

- 5.1.1.6 Approval of the previous meeting minutes along with any changes, if necessary.
- 5.1.1.7 Acknowledgment of Chairman's Report
- 5.1.1.8 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:
 - 5.1.1.8.1 Written summary of discussion on controverted issues and their resolution
 - 5.1.1.8.2 Required Amendments
 - 5.1.1.8.3 Basis for requiring changes in research
 - 5.1.1.8.4 Basis for disapproving research
 - 5.1.1.8.5 Justification of any deletion or substantive modification of risks or alternative procedures contained in the DHHS-approved sample consent document
 - 5.1.1.8.6 Determinations required by regulations and protocol-specific findings justifying those determinations (unless already documented in the IRB records) for:
 - 5.1.1.8.6.1 Waiver or alteration of the consent process
 - 5.1.1.8.6.2 Research involving pregnant women, fetuses, and neonates
 - 5.1.1.8.6.3 The rationale for significant risk/non-significant risk device determinations
 - 5.1.1.8.7 Vote and outcome, which must document:
 - 5.1.1.8.7.1 Numbers for, against, or abstaining
 - 5.1.1.8.7.2 When an alternate member replaces a primary member
 - 5.1.1.8.7.3 Approval, Approval with Modification(s), Disapproval or Tabled
 - 5.1.1.8.7.3.1 In order for research to be approved, it must receive the approval of a majority (more than half) of the members present at the meeting. Proxy voting is not permitted.
- 5.1.1.9 Acknowledgment of Expedited Continuing Review
- 5.1.1.10 Acknowledgment of New Expedited Studies
- 5.1.1.11 Acknowledgment of Study Closures
- 5.1.1.12 Adjournment time

5.2 **IRB Chair** performs the following:

- 5.2.1 Ensures that any member conflict of interest is disclosed prior to the meeting commences
- 5.2.2 Calls meeting to order
- 5.2.3 Ensures that a quorum is maintained during the course of the meeting
- 5.2.4 Follows the agenda unless unforeseen circumstances should arise
- 5.2.5 Excuses the PI or representative from the meeting after their presentation prior to further IRB discussion and vote

- 5.2.6 Leads the IRB to work toward resolution of any issues of concern. Unresolved issues could be reason for disapproval.
- 5.2.7 Calls for vote
- 5.3 **Convened IRB members** performs the following:
 - 5.3.1 Reviews all agenda materials prior to the meeting utilizing checklists, as applicable
 - 5.3.2 Signs the meeting sign-in sheet and indicates any conflict of interest concerning any study on the agenda by checking the appropriate box on the sign in sheet
 - 5.3.2.1 If there is a conflict, they must leave the room during discussion and voting for that particular study
 - 5.3.2.2 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
 - 5.3.3 Participates in discussion
 - 5.3.4 Places vote
- 5.4 **Principal Investigator** or representative performs the following:
 - 5.4.1 Presents new protocol to the IRB and answers any IRB questions

6 DOCUMENTS

- 6.1 None.

7 DEFINITIONS

- 7.1 See SOP 3.23 Definitions for definitions of double underlined terms.

8 REFERENCES

- 8.1 45 CFR 46.115(a)(2);
- 8.2 21 CFR 115 (a)(2)
- 8.3 AAHRPP Accreditation Standard II.5.B