The Christ Hospital IRB
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STANDARD OPERATING PROCEDURE

IRB Meeting Material Distribution

1.0 PURPOSE

This procedure establishes the process to provide review materials to The Christ Hospital Institutional Review Board members prior to each monthly meeting.

2.0 POLICY

The Institutional Review Board meets on the second Tuesday of every month and meetings begin promptly at 7:30 a.m. It is essential that IRB members are given adequate time to review pertinent materials prior to the IRB meetings. IRB meeting materials are available for review in the web-based IRB management system, Mentor IRB, at least one week prior to the convened meeting. Hardcopies of the materials are provided upon request. The list of scheduled IRB convened meetings and materials submission deadlines is provided to each board member and may also be found on The Christ Hospital website and IRB SharePoint. The list may also be obtained by contacting the IRB Office.

3.0 RESPONSIBILITY & PROCEDURE

3.1 Investigator

3.1.1 New Protocols

The Principal Investigator or their designee is responsible for the preparation and submission of new protocols as outlined in IRB SOP 2.01 "Guidelines for New Protocol Submission" and IRB Reference Manual Section 7.0 "Research Protocol and Consent - Format and Requirements".

3.1.2 Active Protocols

The Principal Investigator or their designee is responsible for preparation and submission of study materials for the purpose of full board continuing review/renewal approximately three weeks prior to the convened IRB meeting date as outlined in IRB SOP 1.01 "Continuing Review" and IRB Reference Manual Section 3.0 "Continuing IRB Review of Existing Research Protocols".

3.2 **IRB Office**

3.2.1 Materials Due Date/Submission Deadline

The IRB office is responsible for setting the due date/submission deadline for materials requiring full board consideration. The deadline is set in Mentor IRB as approximately three weeks prior to the convened IRB meeting date.

3.2.2 Meeting Materials

The IRB office ensures that all meeting materials relevant to the current IRB meeting are available to board members, including but not limited to:

3.2.2.1 Meeting agenda;
3.2.2.2 Previous meeting minutes;
3.2.2.3 New study protocols that require full board review;
3.2.2.4 Major amendments/revisions that require full review;
3.2.2.5 Reportable Events/UAPs;
3.2.2.6 Exempt/Expedited Report (Chairman's Report) including documentation of all materials which the chairman has reviewed and approved/acknowledged since the prior convened meeting, such as:
  3.2.2.6.1 New minimal risk research projects,
  3.2.2.6.2 New exempt research projects,
  3.2.2.6.3 New Reliance Agreements,
  3.2.2.6.4 Not Human Subject Research determinations,
  3.2.2.6.5 Study closures,
  3.2.2.6.6 Minor amendments/revisions;
3.2.2.7 Education materials, as available; and
3.2.2.8 Additional correspondence as indicated by the chairman, study investigators, research coordinators, administration, etc.

All documents are stored in Mentor IRB. To allow sufficient time for review of meeting materials by IRB members, all materials are made available to members in Mentor IRB at least one week prior to the scheduled meeting date. Hardcopies of the meeting materials are printed and provided to members upon request.

3.2.3 IRB Packets (Hardcopies)

3.2.3.1 Printed copies of the meeting materials ("IRB Packets") are arranged in the same order as listed on the meeting agenda.
3.2.3.2 The IRB Packets are taken to The Christ Hospital mailroom (TCH MOB B-level) and sent to IRB members through:
  3.2.3.2.1 Inter-office mail to members who are working on-site, or
  3.2.3.2.2 The United States Postal Service (USPS) to members who are off site.

4.0 REFERENCES

4.1 IRB Standard Operating Procedures

4.1.1 SOP 2.01 - Guidelines for New Protocol Submission

4.1.2 SOP 1.01 - Continuing Review

4.2 IRB Reference Manuals

4.2.1 Reference Manual Section 7.0 - Research Protocol and Consent - Format and Requirements

4.2.2 Reference Manual Section 3.0 - Continuing IRB Review of Existing Research Protocols