

The Christ Hospital IRB
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STANDARD OPERATING PROCEDURE

Compliance with Human Subjects Regulations/IRB Requirements/Determinations

POLICY:

The Principal Investigator bears the ultimate responsibility for conduct of a research project. The Investigator must comply with the requirements of The Christ Hospital's Federalwide Assurance, the FDA, State laws and with the determinations of the IRB, as outlined in minutes, guidelines and other correspondence.

The Christ Hospital policy requires that any serious or continuing non-compliance with federal regulations affecting human subjects research or the requirements or policies of The Christ Hospital Institutional Review Board must be promptly reported to the IRB, the hospital, the sponsor, if any, and appropriate federal agencies, if required.

REFERENCE:

45 CFR 46.103(b)(5)(i); 21 CFR 56.108(b)(2); SOP 3.09: Protocol Violation, Deviation, and Non-Compliance Reporting; IRB Reference Manual Section 12: Allegations of Noncompliance

PROCEDURES:

IRB OFFICE STAFF:

1. When made aware of an allegation of noncompliance, the staff immediately notifies the IRB Chair, works with the Chair to compile any required background file information, and documents the allegation in writing.
2. Sends appropriate correspondence to the investigator and/or regulatory agencies as directed by the IRB (see #5 under **IRB MEMBERS** below).

IRB CHAIR:

1. The Christ Hospital IRB Chair makes a determination as to whether to pursue the matter with the Principal Investigator in writing, or in person, based upon the nature and seriousness of the alleged noncompliance. The Chair may also choose to send an IRB designee to meet with research team members and review study materials as appropriate. The purpose of such contact is fact-finding, i.e. to determine if indeed there is noncompliance. Utmost care is taken to maintain confidentiality when leaving messages for the Principal Investigator via voicemail or with administrative and support staff.
2. The Christ Hospital IRB Chair and/or designee documents the outcome of any and all communications and discussions in writing, with copies to the IRB files. Such

documentation should be factual, objective, and include timelines for resolution (e.g. meeting dates, response deadlines).

3. The Christ Hospital IRB Chair makes a decision based on the information gathered as to whether the allegation is credible.
4. If The Christ Hospital IRB Chair believes the allegation is credible, the Chair determines whether the noncompliance meets the definition of serious or continuing noncompliance or is included in a category for full board review. In making this determination the Chair may bring the issue to the full board meeting for discussion.
 - a. If the Chair determines that the noncompliance is not serious or continuing, and does not involve unanticipated risk to subjects or others, the Chair and PI work together to create an acceptable corrective action plan and require a full report to the convened IRB at the next scheduled meeting.
 - b. If the Chair determines that the noncompliance is serious, continuing, and involves unanticipated risk to subjects or others, the Chair reports the possible noncompliance for review by the convened IRB at the next scheduled meeting. If the Chair believes that the noncompliance is serious or continuing and that there is continuing risk of harm to current or future subjects, the Chair may suspend research activities, taking into consideration the welfare of currently enrolled subjects, until review by the full board. The Chair directs the IRB Office to contact the TCH Compliance Department for consultation prior to the meeting (compliance@tch.com, 513-585-2925, or compliance hotline 1-800-398-1496).
 - 1) The Chair or his designee will lead the discussion at the full board meeting and appropriate materials such as monitoring report(s) and communications with the Principal Investigator or other relevant individuals are included in the review. Approved IRB applications and other documentation from the IRB records may also be included as reference materials during the review.

IRB MEMBERS:

1. When a quorum of IRB members is present, and after discussion, the IRB shall vote on recommended actions. The board may select a Committee of Inquiry to include: Chair, Institutional Official, and three scientific members.
2. The IRB determines whether the noncompliance meets the definition of serious or continuing noncompliance.

Serious Noncompliance: Noncompliance that results in unexpected harm to subjects or others. This type of noncompliance may harm a person's physical, social, emotional, psychological wellbeing, social or legal welfare, or cause harm due to loss of the person's privacy or confidentiality. Examples of serious noncompliance may include the following:

- Human subjects research conducted without IRB approval
- Deviation from the IRB approved protocol or consent process

- Modification of protocol without prior IRB approval
- Failure to maintain regulatory documents
- Inadequate oversight of research

Continuing Noncompliance: Any noncompliance that occurs repeatedly to the point of suggesting a pattern or an underlying problem. Continuing noncompliance may occur due to a lack of knowledge (unintentional) or due to deliberate choice to ignore regulations or determinations of the IRB (intentional).

3. The IRB has the authority to suspend or terminate IRB approval of protocols that are found to be noncompliant with institutional policies and procedures, state laws, and/or federal regulations, taking into consideration the welfare of currently enrolled subjects. Other sanctions imposed by the IRB may include, but are not limited to, compliance audits, letters of reprimand, and restrictions on serving as an investigator on human subject protocols. The IRB may also put a hold on all other studies being conducted by the P.I. involved in the noncompliance. The IRB has the authority at any time to suspend or terminate approval of human research that is not being conducted in accordance with applicable laws and regulations, institutional policy or the IRB's requirements, or that has been associated with unexpected serious harm to subjects or others, or that for any reason is believed to impose unreasonable risks on subjects or others. Other sanctions may be imposed in response to findings of noncompliance, depending upon the severity and nature of the noncompliance including, but not limited to:
 - Notification to past and/or current subjects.
 - Mandatory education and mentoring requirements.
 - Protocol modification.
 - Increased monitoring or oversight.
 - Random or target audits.
 - More frequent continuing review.
4. The IRB determines which sanctions and/or requirements must be met for the study to proceed. If the investigator can meet these sanctions/requirements with simple concurrence, the IRB Chair determines when these are met and gives approval for the study to recommence. If sanctions or requirements require more than simple concurrence, the issue is returned to the full board for consideration of resumption of the research project.
5. The IRB Chairman directs the IRB Office to send written notification reports of serious or continuing non-compliance within 30 days of the initial determination and any subsequent follow-up reports to:
 - Institutional Official and Appropriate Hospital Department Head
 - Principal Investigator
 - [OHRP](#), when the research is covered by DHHS regulations
 - Other federal agencies when the research is overseen by those agencies, and they require reporting separate from that to OHRP.
 - FDA, when the research is FDA-regulated
 - i. Drug Products: CDER-OSI-GCPrefferrals@fda.hhs.gov
 - Biologic Products: CBERBIMONotification@fda.hhs.gov
 - Medical Devices: Email: bimo@cdrh.fda.gov

Any suspension or termination of approval shall include a statement of the reasons for the IRB's actions and shall be promptly reported to the investigator, Institutional Official and Department or Agency Head. [45 CRF 46.113]