The Christ Hospital IRB
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IRB REFERENCE MANUAL
SECTION 12
ALLEGATIONS OF NON-COMPLIANCE

12.0 ALLEGATIONS OF NON-COMPLIANCE

The Principal Investigator (PI) bears the ultimate responsibility for conduct of a research project. The PI must comply with the requirements of The Christ Hospital's Federalwide Assurance (FWA), the FDA, State laws and with the determinations of the IRB, as outlined in minutes, guidelines and other correspondence. [DHHS (45 CFR 46); FDA (21 CFR 50, 56, 312, 812)]

12.1 Conceptualizing Serious and Continuing Non-Compliance

12.1.1 Serious Noncompliance occurs when instances pose an actual or potential increased risk to the safety, rights and welfare of human research subjects because investigators fail to comply with federal regulations, state laws, TCH policies related to the protection of human subjects, and/or the requirements or determinations of the IRB; or because there is a systemic failure of the institution to follow or implement practices described in TCH policies and/or federal regulations or state laws related to the protection of human subjects in research.

12.1.2 *Continuing Noncompliance* is repeated occurrences of noncompliance by the same investigator or by the institution. Repetition may be of the same occurrence or different occurrences. This repetition may be in the same or in different protocols by a single investigator. Such repetition if unaddressed may affect the protection of human research subjects. For the institution, repetition may be of the same or different policies, procedures, regulations and/or laws.

12.2 Conceptualizing Protocol Deviations and Violations

Note: Serious or Continuing Noncompliance may take the form of a protocol violation or deviations. Some, but not all, protocol violations and deviations are considered serious or continuing noncompliance. Contact the IRB Office if there is uncertainty in reporting requirements.

12.2.1 Examples of Deviations include, but are not limited to the following:

• any emergent deviation from the IRB protocol made without prior IRB review to eliminate apparent immediate hazard to a research subject;
• implementation of unapproved recruitment procedures;
• use of an incorrect informed consent version;
• Missing original signed and dated consent form or missing pages from executed consent form;
• Inappropriate documentation of consent;
• Subject visit/procedure falls outside of the window of time indicated by the protocol, or is not done per protocol, and there is no increased potential for risk to the subject or any damage to the integrity or completeness of the data.

12.2.2 Examples of Violations include, but are not limited to the following:

• Intentional deviation from the protocol or regulations in a non-emergency setting
• any unintended or intended deviation from the IRB approved protocol that involves potential risks or has the potential to recur;
• enrollment of subjects not meeting the inclusion/exclusion criteria of an IRB approved protocol;

• failure to withdraw a subject meeting withdrawal criteria;
• inadvertent loss of samples or data;
• failure to obtain informed consent prior to initiation of study-related procedures;
• improper consent procedure;
• failure to follow federal and/or local regulations and policies;
• working under an expired professional license/certification, debarred or disqualified status;
• frequent minor deviations;
• any medication error involving dosing, administration and/or preparation of the study drugs;
• any lapse in study approval where there is a continuation of research activities (i.e. recruitment, enrollment, procedures, data analysis);
• failure to report unanticipated problems to the IRB and/or the sponsor; or
• any event that requires prompt reporting according to the protocol or the study sponsor.

12.3 Notifications of Noncompliance to the IRB

Information regarding noncompliance in human subject studies may come to the attention of the IRB through several pathways. These include information contained in application forms, IRB reporting forms, monitoring reports, or reports from collaborators, employees, subjects or others not directly involved in the research. (See SOP 3.06, "Compliance with Human Subjects Regulations or IRB Requirements or Determinations"). In cases that involve allegations of research *misconduct*, the Chair contacts the Institutional Official. This does not preclude the Chair or any member of the IRB from independently contacting the Institutional Official about any allegation of scientific misconduct. Inquiries or investigations into research misconduct do not preclude IRB review and actions. (See SOP 3.10, "Misconduct in Research")

12.3.1 Information outside of a full-board meeting:

When information comes to the attention of the IRB outside of a full-board meeting, the Chair of the IRB reviews the allegations of noncompliance. The Chair makes a determination as to whether the alleged practices appear to (1) cause injury or any other unanticipated problems involving risks to subjects or others, or (2) constitute serious or continuing noncompliance with IRB determinations or federal regulations. In such cases, the Chair may place a hold on the study procedures, taking into consideration the welfare of currently enrolled subjects, pending an investigation and review by the full IRB. If the Chair determines that the potential noncompliance did not involve any risk to subjects or others, and did not constitute serious or continuing noncompliance, the Chair may resolve the issue directly with the Principal Investigator and research team and render a report to the full IRB.

12.3.2 Identified during a full-board review:

When potential noncompliance is first identified during a full-board review, the full board makes a determination as to whether the alleged practices appear to (1) cause injury or any other unanticipated problems involving risks to subjects or others, or (2) constitute serious or continuing noncompliance with IRB determinations or federal regulations. In such cases, the full board may place a hold on the study procedures, taking into consideration the welfare of currently enrolled subjects, and determine how further investigation will be conducted according to the procedures indicated below.