The Christ Hospital IRB **Number:** 3.08
Submitted By: Erica Jones, CIP **Effective Date:** 06/05/09
Reviewed By: Michael Jennings, MD/Steve Roberts, MD
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Approved By: Steve Roberts, MD
(I.5.C, III.1.G, I.4.A)

STANDARD OPERATING PROCEDURE

Complaints and Inquiries for Research Participants, Investigators, Research Staff, and the Community

POLICY:

It is The Christ Hospital policy that the IRB and Office of the IRB maintain open communications with research participants, research investigators and staff, and members of the community as part of their mission to protect the rights, safety, and welfare of human research subjects. Communications include questions, complaints, inquiries for information, reports of concerns, or suggestions relating to specific research proposals or the Human Research Protection Program in general. Concerns, suggestions and/or complaints may come from any source including IRB Committee members, Investigators, participants and their families, Institutional personnel, other Institutional Committees, the hospital's Research Subject Advocate (Director of Social Services), the media, anonymous sources, or the public.

The Office of TCH IRB has implemented the Complaint or Concern Information Form in order to receive and respond to communications regarding complaints and inquiries in a confidential manner. The Office of the IRB shall catalog the nature and dates of all communications for periodic review for quality assurance and quality improvement purposes. Any allegations of conduct that potentially affect, in an adverse manner, the rights, safety, or welfare of human research subjects will be forwarded in a timely manner to the IRB Chair (or designee) and the Institutional Official, as appropriate, for a determination of further action to investigate and resolve the allegations.

REFERNCE:

45 CFR 46.116(a)(6-7); 21 CFR 50.25(a)(6-7)

PROCEDURE

INVESTIGATOR:

- Notifies the IRB of any participant or other individual's complaints regarding the research. The complaint may be reported at continuing review if it involves no risk to the participants or others or does not change the risk/benefit analysis (e.g., a participant complains that he/she does not like the Investigator's clinic hours and subsequently withdraws from the research).
- Reports complaints that involve potential risks to participants or others or result in a possible change in the risk/benefit analysis as an unanticipated problem (e.g., a member of the research team where the research is conducted complains that the research assistant has not maintained her research notes in a confidential manner which may have

potentially breached confidentiality) as soon as possible, but no later than 10 working days after the Investigator first learns of the complaint. (See SOP 2.05 Submission of Adverse Events, Safety Reports or Unanticipated Problems.)
- Cooperates with the IRB by making documents accessible, responding to written requests within the designated time frame, and being available for questions by the IRB.

IRB STAFF:
- Screens all inquiries by phone/mail/email/fax and directs to the appropriate personnel.
- Documents question or concern and answers as appropriate; takes to IRB Chair for further resolution if needed.
- Documents complaints, records as much information as possible (i.e., name, contact number, TCH department, etc., if the individual is willing to divulge that information) and refers to IRB Chair for immediate assessment and resolution.
- Reports all complaints to the IRB at the monthly meetings
- If complaint is taken to Committee meeting, documents actions as discussed in meeting minutes and sends correspondence as directed.
- Treats all reports received (e.g., mail, e-mail, fax or phone call) confidentially, and assures complainant that confidentially will be maintained.
- Maintains a file in the IRB office of all complaints, documenting dates, course of action, final outcomes, and any changes that were implemented.

IRB CHAIR:
- Reviews reports referred.
- For complaints, speaks to individual(s) involved to get clarification and/or further information, assuring complainant that confidentiality will be maintained.
- Discusses with Institutional Official those complaints that may be administratively resolved.
- Refers to the convened IRB complaints that cannot be administratively resolved for appropriate determination and referral, as necessary.

IRB COMMITTEE:
- If complaint is taken to the full board for consideration, the board reviews the complaint and may request a Committee of Inquiry be formed to further investigate.
- After review at committee meeting, or after receiving results of the inquiry, determines if any further actions are to be taken.
- Reviews all complaints at the monthly IRB meetings

REVISION HISTORY:

Date Revised	Reason For Change	Revised By