The Christ Hospital IRB **Number:** 2.08
Submitted By: Erica Jones, CIP **Effective Date:** 03/27/09
Reviewed By: Michael Jennings, MD/Steven Roberts, MD
Revised Date: 03/17
Approved By: Steve Roberts, MD
(I.1.D, III.1.A, III.2.A)

STANDARD OPERATING PROCEDURE

Investigator Compliance with Regulations

POLICY:

The individual investigator is the ultimate protector of the subject's rights and safety. Each investigator is obligated to be personally certain that each subject is adequately informed and freely consents to participate in the investigator's research. The investigator must personally assure that every reasonable precaution is taken to reduce the subject's risk to a minimum. The investigator also assumes responsibility for compliance with all federal, state and institutional rules and regulations related to research involving human subjects and human subject-derived information and materials. For example, the investigator may not initiate any research involving human subjects without TCH IRB review and approval.

REFERENCE:

45 CFR 46.102(d); 21 CFR 50.1; 21 CFR 45.120(c)

PROCEDURE:

Physicians wishing to conduct research at The Christ Hospital must sign a "Certification of Investigator Responsibilities", which is located at the end of the study application. These responsibilities include:

1. Review of all protocol submissions in their entirety and be fully cognizant of, and in agreement with, all submitted statements.

2. Familiarity with clinical research regulations and during the conduct of the study complying with these regulations.

3. Awareness of the Belmont Report and understanding the three ethical principles; respect for persons, beneficence, and justice, and adhering to these principles during the conduct of the study.

4. Assuring that adequate resources and facilities are available to carry out the proposed research projects.

5. Conducting research in strict accordance with all submitted statements except where a change may be necessary to eliminate an apparent immediate hazard to a given research subject.

- Notifying the IRB promptly of any change in the research procedures necessitated in the interest of the safety of a given research subject.
- Requesting and obtaining IRB approval of any proposed modifications to research protocol(s) or informed consent document(s) prior to implementing such modifications.

6. Ensuring that all co-investigators, and other personnel assisting in the conduct of research, have been provided a copy of the entire current version of the research protocol and are fully informed of the current (a) study procedures (including procedure modifications); (b) informed consent requirements and process; (c) potential risks associated with the study participation and the steps to be taken to prevent or minimize these potential risks; (d) adverse event reporting requirements; (e) data and record-keeping requirements; and (f) the current IRB approval status of the research study.

7. Ensuring no enrollment of any individual into a research study: (a) until such a time that the conduct of the study has been approved in writing by the IRB; (b) during any period wherein IRB renewal approval of a research study has lapsed; (c) during any period wherein IRB approval of a research study or research study enrollment has been suspended, or wherein the sponsor has suspended research study enrollment; or (d) following termination of IRB approval of a research study or following sponsor/principal investigator termination of research study enrollment.

8. In situations in which consent will be obtained from a Legally Authorized Representative (LAR) rather than the subject, understanding of the criterion per state or other law that these individuals must meet to consent on behalf of the subject to their participation in the procedures involved in the study.

9. Responding promptly to all requests for information or materials solicited by the IRB or IRB Office.

10. Submitting a research study in a timely manner for IRB approval (at least 21 days prior to the scheduled IRB meeting) and providing progress reports within the established timeframe to avoid study expiration.

11. Not enrolling any individual into a research study until such time his/her written informed consent is obtained, or, if applicable, the written informed consent of his/her authorized representative (i.e., unless the IRB has granted a waiver of the requirement to obtain written informed consent).

    - Employing and overseeing an informed consent process that ensures that potential research subjects understand fully the purpose of the research study, the nature of the research procedures they are being asked to undergo, the potential risks of the research procedures, and their rights as a research study volunteer.

12. Ensuring that research subjects are kept fully informed of any new information that may affect their willingness to continue to participate in the research study.

13. Maintaining adequate, current and accurate records of research data, outcomes and adverse events to permit an ongoing assessment of the risk/benefit ratio of research study participation.

14. Being cognizant of, and complying with, current federal regulations and IRB requirements governing human subject research including adverse event reporting, protocol deviations and violations, subject complaints and conflict of interest.

15. Making a reasonable effort to ensure that subjects who have suffered an adverse event associated with research participation receive adequate care to correct or alleviate the consequences of the adverse event to the extent possible.

16. Ensuring that the conduct of this research study adheres to Good Clinical Practice guidelines.

17. Ensuring that all listed investigators have the appropriate credentials to conduct the portion of the study in which they are involved.

18. Ensuring that the privacy of research subjects and the confidentiality of the study data will be appropriately maintained at the study site.

19. Understanding that payments in exchange for referrals of potential participants (i.e., finder's fees) are prohibited by The Christ Hospital.

20. In the event a hospitalized patient is to be asked to participate as a subject of my study, I will inform the patient's attending physician. Prior to approaching the patient, I will obtain the attending physician's approval of my requesting the patient's participation."

REVISION HISTORY:

Date Revised	Reason For Change	Revised By
06/04/15	Added where a physician can find the responsibilities	Becky