The Christ Hospital IRB
Submitted By: Erica Jones, CIP
Reviewed By: Steve Roberts, MD
Approved By: Steve Roberts, MD
(I.1.D, III.1.A, III.2.A)

Number: 2.08
Effective Date: 03/27/09
Revised/Reviewed Date: 09/22

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; 21 CFR 50

PROCEDURE:

Researchers wishing to conduct research at The Christ Hospital must sign an electronic signature affidavit in Mentor IRB which outlines the responsibilities of a principal investigator. The principal investigator must agree to:

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

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

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

4. Have adequate resources and facilities available to carry out the proposed research projects.
5. Identify and disclose financial interests according to organizational policies and regulatory requirements and, with the organization, manage, minimize, or eliminate financial conflicts of interest

6. Conduct 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 or others.

7. Notify the IRB promptly of any change in the research procedures necessitated in the interest of the safety of a given research subject.

8. Request and obtain IRB approval of any proposed modifications to research protocol(s) or informed consent document(s) prior to implementing such modifications.

9. Ensure that all sub-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.

10. Ensure 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.

11. In situations in which consent will be obtained from a Legally Authorized Representative (LAR) rather than the subject, understand 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.

12. Respond promptly to all requests for information or materials solicited by the IRB or IRB Office.

13. Submit continuing reviews (for applicable research) for IRB review and approval within the established timeframe listed on the study approval letter, thus avoiding study expiration.

14. Ensure that a final Continuing Review to close the study is submitted to the IRB upon completion of the research

15. Recruit participants in a fair and equitable manner

16. Not enroll 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 except in instances where the IRB has granted a waiver of the requirement to obtain written informed consent.

17. Employ 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. Ensure 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. Maintain 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. Be 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. Make 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. Ensure that the conduct of this research study adheres to Good Clinical Practice guidelines.

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

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

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

20. Inform and obtain approval of the attending physician prior to approaching and seeking enrollment of a hospitalized patient