9.0 INVESTIGATOR RESPONSIBILITIES

(I.1.D, III.1.A-G, III.2.A-D)

9.1 Principal Investigator Responsibilities

A Principal Investigator (PI) is the primary individual responsible for the preparation, conduct, and administration of research study in compliance with applicable laws and regulations and institutional policy governing the conduct of research. The PI undertakes the primary responsibility for protecting the rights and welfare of research participants and must be familiar with the ethical principles of human subject protection requirements of federal regulations, Federal Wide Assurance, and IRB policy and procedures.

9.2 Certification of Investigator Responsibilities

Individuals wishing to conduct research at The Christ Hospital must sign a PI Assurance and Responsibilities form, which is kept on file with the IRB Office. 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 comply with these regulations.

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

4. Have adequate resources and facilities are 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.

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 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.

10. Not enroll 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 to avoid study expiration.

14. Recruit participants in a fair and equitable manner.

15. Agree not to 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 that the IRB has granted a waiver of the requirement to obtain written informed consent.

16. Employ and oversee 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.

17. 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.

18. 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.

19. Be cognizant of, and comply 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.

20. 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.

21. Ensure that the conduct of this research study adheres to Good Clinical Practice guidelines.

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

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

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

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