**The Christ Hospital IRB**
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# STANDARD OPERATING PROCEDURE

## Investigator and Other Key Research Personnel Compliance with Regulations

## 1.0 POLICY

In human subjects research, the principal investigator (PI) bears the ultimate responsibility for the protection of research participants' rights and safety. The PI is obligated to ensure that each participant is adequately informed about and freely consents to participate in the research, and must assure that every reasonable precaution is taken to minimize any research-related risks to participants. The investigator also assumes responsibility for compliance with all federal, state, and institutional rules and regulations related to research involving human participants and human participant-derived information and materials, including not initiating any research involving human participants prior to review and approval by the Institutional Review Board (IRB).

The PI assumes accountability for the overall management of an approved research protocol. Such management encompasses the ethical, administrative, and fiscal aspects of the study, and the conduct of all study personnel in accordance with the IRB-approved study.

## 2.0 PROCEDURE

Researchers wishing to conduct research at The Christ Hospital (TCH) must sign an "Agreement to Comply with Human Research Regulations" which outlines the responsibilities of the principal investigator and other key research personnel.

### 2.1 Principal Investigator

The principal investigator must agree to:

2.1.1 Review protocol submissions in their entirety and be fully cognizant of and in agreement with all submitted statements;
2.1.2 Be familiar and comply with clinical research regulations during the conduct of the study;.
2.1.3 Read the Belmont Report and understand the three ethical principles underlying the conduct of research involving human subjects, and adhere to those principles during the conduct of the study;

2.1.4 Ensure that adequate resources and facilities are available to carry out the proposed research project(s);

2.1.5 Identify and disclose financial interests according to regulatory requirements and organizational policies, and, with the organization, manage, minimize, or eliminate financial conflicts of interest;

2.1.6 Conduct the 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 participant;

2.1.7 Notify the IRB promptly of any change in research procedures necessitated in the interest of the safety of a given research participant(s);

2.1.8 Request and obtain IRB approval of any proposed modifications to the research, including revisions to the approved research protocol or informed consent document(s), prior to implementing such modifications;

2.1.9 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:

- 2.1.9.1 Study procedures, including procedure modifications,
- 2.1.9.2 Informed consent requirements and process,
- 2.1.9.3 Potential risks associated with study participation and steps to be taken to prevent or minimize these potential risks,
- 2.1.9.4 Adverse event reporting requirements,
- 2.1.9.5 Data and record-keeping requirements, and
- 2.1.9.6 The current IRB approval status of the research study;

2.1.10 Not enroll any individual into a research study:

- 2.1.10.1 Until such a time that the conduct of the study has been approved in writing by the IRB,
- 2.1.10.2 During any period wherein IRB renewal approval of a research study has lapsed;
- 2.1.10.3 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, and
- 2.1.10.4 Following termination of IRB approval of a research study or following sponsor/principal investigator termination of research study enrollment;

2.1.11 Understand the criterion per state and/or other law regarding the use of a Legally Authorized Representative (LAR) in situations in which the IRB has approved informed consent to be obtained from a research participant's LAR rather than a research participant;

2.1.12 Respond promptly to all requests for information or materials solicited by the IRB or IRB Office;

2.1.13 Submit continuing reviews (as applicable) for IRB review and approval within the established timeframe listed on the study approval letter, thus avoiding study expiration;

2.1.14 Ensure that a study closure request is submitted to the IRB upon completion of the research to officially close the study;

2.1.15 Recruit participants in a fair and equitable manner;
2.1.16 Not enroll any individual into a research study until 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;
2.1.17 Employ and oversee an informed consent process that ensures that potential research participants fully understand:
2.1.17.1 The purpose of the research study,
2.1.17.2 The nature of the research procedures they are being asked to undergo,
2.1.17.3 The potential risks of the research procedures, and
2.1.17.4 Their rights as research study volunteer;
2.1.18 Ensure that research participants are kept fully informed of any new information that may affect their willingness to continue to participate in the research study.
2.1.19 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;
2.1.20 Be cognizant of, and comply with, current federal regulations and IRB requirements governing human participant research including adverse event reporting, protocol deviations and violations, participant complaints, and conflicts of interest;
2.1.21 Make a reasonable effort to ensure that participants 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;
2.1.22 Ensure that the conduct of the research study adheres to Good Clinical Practice guidelines;
2.1.23 Ensure that all listed investigators and other key research personnel have the appropriate credentials to conduct the portion of the study in which they are involved and are approved by the IRB prior to study conduct.
2.1.24 Ensure that the privacy of research participants and the confidentiality of the study data will be appropriately maintained at the study site;
2.1.25 Understand that payments in exchange for referrals of potential participants (i.e., finder's fees) are prohibited by The Christ Hospital; and
2.1.26 Inform and obtain approval of the attending physician prior to approaching and seeking enrollment of a hospitalized patient.

## 2.2 Key Research Personnel

All key research personnel must agree to:

2.2.1 Have sufficient training and experience to conduct the research in accord with the protocol including, but not limited to, any cultural sensitivities, cultural norms, and/or dialect spoken;
2.2.2 Fulfill training requirements in the CITI program's Human Subject Research (HSR) and Good Clinical Practice (GCP) courses, as applicable, and

understand the ethical standards and regulatory requirements governing research activities with human participants;

2.2.3 Ensure that the proposed research complies with the ethical principles outlined in the Belmont Report, human subject research regulations including Protection of Human Subjects 45 CFR Part 46, HIPAA (45 CFR 164), FDA 21 CFR 50 and 21 CFR 56), institutional policies, and applicable federal or state laws;

2.2.4 Report any real or potential conflicts of interest in compliance with the conflict-of-interest policies;

2.2.5 Ensure that they have been approved by the IRB as key research personnel prior to becoming involved in the conduct of the research study;

2.2.6 Ensure that all research activities have IRB approval and other ancillary approval required by the institution before human participants are involved and implement the research activity as it was approved by the IRB;

2.2.7 Ensure that the privacy of research participants is maintained;

2.2.8 Ensure the confidentiality and security of all information obtained from and about research participants is maintained; and

2.2.9 Ensure that any Monitoring Reports and Reportable Events are submitted to the IRB in a timely manner.

## 3.0 REFERENCES

3.1 Code of Federal Regulations

3.1.1 U.S. Department of Health and Human Services (HHS)

3.1.1.1 45 CFR 46

3.1.1.2 45 CFR 164

3.1.1.3 The Belmont Report

3.1.2 U.S. Food and Drug Administration (FDA)

3.1.2.1 21 CFR 50

3.1.2.2 21 CFR 56

3.1.2.3 Good Clinical Practice

3.2 AAHRPP Domains and Elements

3.2.1 I.1.D.

3.2.2 III.1.A.

3.2.3 III.2.A.