The Christ Hospital IRB
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STANDARD OPERATING PROCEDURE

Activities Subject to IRB Jurisdiction

POLICY:

It is the policy of The Christ Hospital that the Institutional Review Board has jurisdiction over all research involving human participants conducted within the institution as determined by its Assurance unless a reliance agreement has been established for the institution to rely on an external IRB for oversight.

I. Review and Approval of Human Participant Research.

A. All research involving human participants, and all other activities, which in part involve such research, regardless of sponsorship, must be reviewed and approved by TCH IRB unless a reliance agreement has been established.
   1. No intervention or interaction with human participants in research, including advertising, recruitment, and/or screening, may begin until the IRB has reviewed and approved the research.
   2. It is the responsibility of the IRB Chairperson or his/her designee or the full IRB Committee to determine what activities constitute "research" involving "human subjects" as defined by the Federal regulations and in accordance with the policy and procedure Determining Whether an Activity Represents Research Involving Human Subjects.
   3. Certification to the appropriate supporting Department or Agency will be made via the Principal Investigator (PI).

B. The Christ Hospital's Assurance with the federal government defines its jurisdiction over the review of research activities involving human participants. Regardless of sponsorship, the IRB must review all research involving human subjects research when any of the following apply:
   1. The research is sponsored by The Christ Hospital;
   2. The research is conducted by or under the direction of any investigator, employee, staff, or student of The Christ Hospital in connection with his/her institutional responsibilities;
   3. The research is conducted by or under the direction of any investigator, employee, staff, or student of this institution using any of its property or facilities;
   4. The research involves the use of non-public information maintained by The Christ Hospital to identify or contact human participants or prospective participants;

5. The Christ Hospital receives a direct Federal award to conduct human participant research, even where all activities involving human participants are carried out by a subcontractor or collaborator; and/or
6. The research is conducted in accordance with an Assurance filed with the Office of Human Research Protections (OHRP) in which The Christ Hospital IRB is designated as the IRB of record through an established Reliance Agreement.

PROCEDURE

The IRB Chair or staff will conduct an initial review of the proposed research to verify that The Christ Hospital IRB has jurisdiction.

A. If TCH IRB has jurisdiction, the IRB Chair will review the proposed research in accordance with applicable Human Research Protections Program and/or TCH IRB policies and procedures.
B. If TCH IRB has jurisdiction and a reliance agreement has been requested, a reliance agreement may be considered per SOP 1.21 Establishing Authorization Agreements and SOP 1.22 Reliance on External IRBs.
C. If TCH IRB does not have jurisdiction, a reliance agreement may be considered in certain circumstances per SOP 1.23 The Christ Hospital Institutional Review Board Serving as the IRB of Record.