The Christ Hospital IRB
Section: 09
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IRB REFERENCE MANUAL
SECTION 09
INVESTIGATOR RESPONSIBILITIES

9.0 INVESTIGATOR RESPONSIBILITIES

9.1 Principal Investigator Responsibilities

The Principal Investigator (PI) is the primary individual responsible for the preparation, conduct, and administration of the 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 per federal regulations (ref. 45 CFR 46), Federal Wide Assurance, and IRB policy and procedures.

9.1.1 Certification of Principal Investigator Responsibilities

Individuals 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:

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

b. Be familiar with clinical research regulations and comply with these regulations during the conduct of the study

c. Read the Belmont Report and understand the three ethical principles outlined therein: (1) respect for persons, (2) beneficence, and (3) justice; the PI must adhere to these principles during the conduct of the study

d. Have adequate resources and facilities available to carry out the proposed research projects

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

f. Conduct research in strict accordance with all statements submitted except where a change may be necessary to eliminate an apparent immediate hazard to a given research subject(s) or others

g. Notify the IRB promptly of any change in the research procedures necessitated in the interest of the safety of a given research subject(s)

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

i. 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:
    i. Study procedures including procedure modifications
    ii. Informed consent requirements and process
    iii. Potential risks associated with the study participation and the steps to be taken to prevent or minimize these potential risks
    iv. Adverse event reporting requirements
    v. Data and record-keeping requirements
    vi. IRB approval status of the research study

j. Not enroll any individual into a research study:
    i. Until such a time that the conduct of the study has been approved in writing by the IRB
    ii. During any period wherein IRB renewal approval of a research study has lapsed
    iii. 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
    iv. Following termination of IRB approval of a research study or following sponsor/principal investigator termination of research study enrollment

k. Understand the criterion per state or other law regarding situations in which consent will be obtained from a Legally Authorized Representative (LAR) rather than the subject, and that the LAR must meet on behalf of the subject to consent to the subject's participation in the procedures involved in the study

l. Respond promptly to all requests for information or materials solicited by the IRB or IRB office

m. 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

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

o. Recruit participants in a fair and equitable manner

p. 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

q. Employ and oversee an informed consent process which ensures that potential research subjects fully understand 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

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

s. Maintain adequate, current, and accurate records of research data, outcomes and adverse events, thus permitting an ongoing assessment of the risk/benefit ratio of research study participation

t. 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

u. 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

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

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

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

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

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

9.2 Key Research Personnel Responsibilities

The principal investigator is responsible for determining key research personnel; individuals who are directly involved in conducting research with study participants or who are directly involved in using study participants' identifiable private information during the course of the research. All key research personnel are responsible for protecting the rights and welfare of research participants and must be familiar with the ethical principles of human subject protection requirements per federal regulations outlined in 45 CFR 46, Federal Wide Assurance, and IRB policy and procedures.

9.2.1 Certification of Key Research Personnel Responsibilities

Individuals serving as key research personnel at The Christ Hospital must sign an electronic signature affidavit in Mentor IRB which outlines their responsibilities. Key research personnel must accept responsibility for protecting the rights and welfare of human research participants and agree to:

a. 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

b. Have fulfilled the human subject research training requirement (CITI) and understand the ethical standards and regulatory requirements governing research activities with human participants

c. Ensure the proposed research complies with the ethical principles outlined in the Belmont Report, human subject research regulations including 45 CFR 46, HIPAA (45 CFR 164), FDA (21 CFR 50 & 56), institutional policies, and other applicable federal or state laws

d. Report any real or potential conflicts of interests in compliance with the conflict-of-interest policies.

e. Ensure all research activities have IRB approval and other ancillary approval required by the institution before human subjects are involved and implement the research activity as it was approved by the IRB.

f. Ensure that the confidentiality and security of all information obtained from and about human subjects, and that the privacy of subjects is maintained.

g. Ensure that any Prompt Reports, Monitoring Reports and Adverse Events are submitted to the IRB in a timely manner.

Additional Information
See HHS publication Investigator Responsibilities FAQs