The Christ Hospital IRB
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STANDARD OPERATING PROCEDURE

Definitions

1 PURPOSE

1.1 This policy establishes the definitions followed by The Christ Hospital Institutional Review Board.

2 POLICY

2.1 Authorization Agreement: Also called a Reliance Agreement, is the agreement that documents respective authorities, roles, responsibilities, and communication between one institution/organization providing the ethical review and another institution or an investigator that is relying on the ethical review.

2.2 Collaborative Study: A study in which two or more institutions coordinate to complete portions of the research activities outlined in a specific protocol.

2.3 External IRB: An IRB from an external institution or organization that The Christ Hospital IRB may rely on for the ethical review of Human Research.

2.4 Human Research: Any activity that either:

2.4.1 Is Research as Defined by DHHS and involves Human Subjects as defined by DHHS, or

2.4.2 Is Research as Defined by FDA and involves Human Subjects as defined by FDA.

2.5 Human Subject as Defined by DHHS: A living individual about whom an investigator (whether professional or student) conducting research (1) obtains information or biospecimens through Intervention or Interaction with the individual, and uses, studies or analyzed the information or biospecimens; or (2) obtains, uses, studies, analyzes or generates Identifiable Private Information or Identifiable Biospecimens. For the purpose of this definition:

2.5.1 Intervention: Physical procedures by which information or biospecimens are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

2.5.2 Interaction: Communication or interpersonal contact between investigator and subject.

2.5.3 Private Information: Information about behavior that occurs in a context in which an individual can reasonable expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (for example, a medical record).

2.5.4 Identifiable Private Information: Private Information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.

2.5.5 Identifiable Biospecimen: A biospecimen for which the identity of the subject is or may be readily ascertained by the investigator or associated with the biospecimen.

2.6 Human Subject as Defined by FDA: An individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy human or a patient. A human subject includes an individual on whose specimen an investigational medical device is used. When medical device research involves in vitro diagnostics and unidentified tissue specimens, the FDA defines the unidentified tissue specimens as human subjects.

2.7 Institutional Official: The Institutional Official (IO) has the authority to take the following actions or delegate these authorities to a designee:

2.7.1 Ensure the HRPP has sufficient resources, including IRBs appropriate for the volume and types of Human Research to be reviewed, so that reviews are accomplished in a thorough and timely manner.

2.7.2 Determine what IRBs the Institution will rely upon.

2.7.3 Ensure that the research review process is independent and free of undue influence.

2.7.4 Create policies and procedures related to the IRB that are binding on the institution.

2.8 IRB of Record: The IRB that is responsible for the ethical review of Human Research on behalf of an institution/organization or individual investigator.

2.9 Multi-Site Study: A study which uses the same protocol to conduct non-exempt human subjects research at more than one site, with each site completing all research activities outlined in the protocol.

2.10 Participating Site: An Institution that participates in a Multi-Site Study or a Collaborative Study.

2.10 Reportable New Information: Information that becomes known during the course of a research study that will need to be reported to the IRB in a timely, meaningful way so that research participants can be protected from avoidable harms. This information may be Unanticipated Problems Involving Risk to Subjects or Others (UPIRSOs) and/or Non-compliance.

2.11 Unanticipated Problem Involving Risk to Subjects or Others: Any information, including any incident, experience, or outcome that meets ALL three of the following conditions: (1) is unexpected (in terms of nature, severity, or frequency) given the procedures described in the research protocol documents (e.g. the IRB-approved research protocol and informed consent document) and the characteristics of the human subject population being studied; (2) is related or possibly related to participation in the research (in this instruction, possibly related means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and (3) suggests that the research places human subjects or others at greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized, even if no harm has actually occurred.

3 RESPONSIBILITY

3.1 Individuals writing policies and procedures are to indicate terms defined in this policy with a double underline.

3.2 Individuals using policies and procedures are to consult this policy for the definitions of double underlined terms.

4 PROCEDURE

4.1 None.

5 DOCUMENTS

5.1

6 REFERENCES

6.1 21 CFR 50.3, 21 CFR 56.102, 21 CFR 312.3, 21 CFR 312.32, 21 CFR 812.2 (a), 21 CFR 812.3(p)

6.2 45 CFR 46.102

6.3 45 CFR 160.103