The Christ Hospital IRB
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STANDARD OPERATING PROCEDURE

Not Human Subjects Research Determinations

1.0 PURPOSE

This procedure establishes the process determining whether a project meets the regulatory definition of human subjects research, and therefore, subject to TCH IRB review.

2.0 POLICY

Investigators proposing a new project that does not constitute human subjects research should create and submit a new Not Human Subjects Research protocol in the web-based IRB submission system, Mentor IRB, for a final determination by the IRB Chairman or designee.

3.0 RESPONSIBILITY

It is the responsibility of the investigator for the initial determination whether an activity constitutes human subject research. The IRB Chairman or designee issues the final Not Human Subjects Research (NHSR) designation.

4.0 PROCEDURE

4.1 Investigator:

5.1.1 Submits an e-Application for Not Human Subjects Research through the web-based IRB submission system, Mentor IRB.

4.2 IRB Office:

4.2.1 Ensures that the submission is complete and is available in its entirety in Mentor IRB for IRB Chair or designee review.

4.2.2 Assigns the IRB Chair or designee as reviewer

4.2.3 Communicates all IRB determinations through Mentor IRB in a notification letter sent to the Principal Investigator and any research coordinator(s) as outlined in SOP 1.04, IRB Meeting Minutes / Conducting IRB Meeting.

4.3 IRB Chair or Designee

4.3.1 Reviews the e-application and determine if the study meets the criteria for human subjects research

4.3.1.1 If the research does not meet the criteria for human subjects research, the IRB Chair or designee makes a NHSR determination.

4.3.1.2 If the research meets the criteria for human subjects research, the IRB Chairman communicates which review type is necessary for the project.

5.0 DOCUMENTS

None.

6.0 DEFINITIONS

6.1 Human Subject (DHHS): A living individual about whom an investigator (whether professional or student) conducting research (i) obtains information or biospecimens through intervention or interaction with the individuals, and uses, studies or analyzes the information or biospecimens; or (ii) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.
(ref. 45 CFR 46.102(e)(1))

6.2 Human Subject (FDA): An individual who is or becomes a participant in research, either as a recipient of the test article or as a control and/or an individual on whose specimen a device is used. Under the FDA regulations and guidance, a human subject may include individuals whose de-identified tissue specimens are used in in vitro diagnostic medical device research. (ref. 21 CFR 56.102(e))

6.3 Intervention: A manipulation of the subject or subject's environment for the purpose of modifying one or more health-related biomedical or behavioral processes and/or endpoints. Examples include drugs/small molecules/compounds; biologics; devices; procedures (e.g., surgical techniques); delivery systems (e.g., telemedicine, face-to-face interviews); strategies to change health-related behavior (e.g., diet, cognitive/behavioral therapy, exercise, development of new habits); treatment strategies; prevention strategies; and diagnostic strategies. (ref. 45 CFR 46.102(e)(2))

6.4 Not Human Subjects Research: Activities that do not meet the definition of human subjects research.

6.5 Private Information: Includes information about data or behavior that occurs in a setting in which an individual can reasonably expect that no observation or recording is taking place. It includes information, which has been provided for specific purposes by an individual, and the individual can reasonably expect will not be made public (e.g., a

medical record). Private information must be individually identifiable in order to be considered information to constitute research involving no subjects. This may include identifiable private information obtained from a primary subject about a third party. (ref. 45 CFR 46.102(e)(4))

6.6 Research: A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. (ref. 45 CFR 46.102(l)) Under FDA regulations, research (clinical investigation) means any experiment in which a drug is administered or dispensed to, or used involving, one or more human subjects. (ref. 21 CFR 56.102(c))

7.0 REFERENCES

7.1 DHHS Regulation: 45 CFR 46.102(l); 45 CFR 46.102(e)(1); 45 CFR 46.102(e)(2); 45 CFR 46.102(e)(4)

7.2 FDA Regulation: 21 CFR 56.102(c); 21 CFR 56.102(e));