The Christ Hospital IRB
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STANDARD OPERATING PROCEDURE

Not Human Subjects Research Determinations

1.0 PURPOSE

This procedure establishes the process of determining whether a project meets the regulatory definition of human subjects research and therefore requires The Christ Hospital 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 to make the initial determination of 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

4.1.1 Creates a new protocol through the web-based IRB submission system, Mentor IRB by navigating to My Protocols and clicking Create New Protocol;
4.1.2 Inputs basic protocol details when prompted by selecting "Not Human Subjects Research (NHSR) Determination" under Review Type, generating an NHSR application;
4.1.3 Completes all required fields in the application; and
4.1.4 Electronically signs to document responsibility for the submission.

4.2 IRB Office

4.2.1 Ensures that the submission is complete and available in its entirety in Mentor IRB for IRB chair or designee review;
4.2.2 Assigns the IRB chair or designee the "CHAIR: NHSR Review" checklist in Mentor IRB; and
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 - Conducting IRB Meetings/IRB Meeting Minutes.

4.3 IRB Chair or Designee

Reviews the e-application and determines whether the study meets the criteria for human subjects research.

4.3.1 If the research meets the criteria for human subjects research, the IRB chair communicates which review type is necessary for the project. (i.e. Exempt, Expedited, or Full Board).

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

5.0 REFERENCES

Code of Federal Regulations:

5.1 US Department of Health and Human Services (DHHS): 45 CFR 46.102(e)

5.2 US Food and Drug Administration (FDA):

5.2.1 21 CFR 56.102(c)

5.2.2 21 CFR 56.102(e)