The Christ Hospital IRB
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STANDARD OPERATING PROCEDURE

Quality Improvement Projects

1.0 PURPOSE

The purpose of the standard operating procedure is to clarify when a Quality Improvement (QI) activity or project does not constitute human subjects research and is therefore not subject to IRB oversight, and provide a formal pathway for requesting a Not Human Subjects Research (NHSR) Determination from The Christ Hospital Institution Review Board (TCH IRB).

2.0 POLICY

It is the policy of The Christ Hospital IRB that all human subjects research requires IRB review and approval. Most quality improvement activities do not constitute human subjects research. However, quality improvement activities and projects that involve human participants and which also contribute to generalizable knowledge do constitute human subjects research, and therefore require IRB review and approval prior to beginning research activities. If a The Christ Hospital Health Network (TCHHN) associate would like the TCH IRB to formally evaluate whether a proposed project meets the criteria for Quality Improvement, the associate must make a submission in the IRB's electronic record management system, Mentor IRB, requesting a Not Human Subjects Research Determination. When a project qualifies, the TCH IRB will issue a letter confirming the NHSR determination.

3.0 DEFINITIONS

3.1 Quality Improvement: Systematic and continuous actions that lead to measurable improvement in health care services and the health status of targeted patient groups.

3.2 Human Subject: An individual about whom an investigator (whether professional or student) conducting research: (i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens. (Refer to 45 CFR 46.102(e).)

3.3 Research: A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

4.0 OVERVIEW

4.1 **QI Aims** - Quality Improvement seeks to standardize processes and structure to reduce variation, achieve predictable results, and improve outcomes for patients, healthcare systems, and organizations.

4.2 **QI Intent** - Quality Improvement activities and projects should be designed with a local focus on immediate improvement at the specific institution, organization, or clinic, rather than to prove a hypothesis for generalized, universal knowledge. The primary intent of QI activities and projects outcomes should be to simply report on what happened at the institution or program.

4.3 **QI and IRB Review** – Quality Improvement activities and projects that are standardized using systematic research methodologies with strong external validity in order to obtain reproducible results would be considered research. Such QI activities and projects require IRB approval. In addition, multi-site, collaborative projects typically provide generalizable results and therefore may require IRB review.

5.0 RESPONSIBILTITY

It is the responsibility of the TCH associate to make the initial determination of whether an activity constitutes human subjects research. To request a formal determination from TCH IRB, TCH associates should submit a Not Human Subjects Research (NHSR) application through Mentor IRB as outlined in SOP 1.06, "Not Human Subjects Research Determinations". The IRB chairman or designee issues the final Not Human Subjects Research (NHSR) determination which is communicated by the IRB office to the TCH associate through Mentor IRB.

6.0 REFERENCES

6.1 IRB Standard Operating Procedure: SOP 1.06 Not Human Subjects Research Determinations

6.2 United States Department of Health and Human Services: 45 CFR 46.102(e)