



Boston Children's Hospital

Institutional Review Board (IRB)

300 Longwood Avenue

Mailstop BCH 3164

Boston, MA 02115

Tel: (617) 355-7052

Fax: (617) 730-0226

www.bostonchildrens.org/research/irb

May 18, 2021

TO: Members of our Research Community, Collaborators, Sponsors, Funding Agencies, Coordinating Centers, Contract Research Organizations and Journal Editors

RE: Quality Improvement Projects

Boston Children's Hospital (BCH) recognizes that Quality Improvement (QI) is an integral part of its mission and a necessary component of ensuring excellence in the healthcare BCH delivers and the services BCH provides. The Institutional Review Board, or IRB, is charged with reviewing research that meets the criteria for involving human subjects conducted under the auspices of BCH. QI projects may not qualify as human subjects *research*, defined by Health and Human Services (HHS) as "a systematic investigation designed to develop or contribute to generalizable knowledge." While QI initiatives may yield results of interest to the healthcare community at large, the main intent of these projects is not to develop or contribute to generalizable knowledge but to improve a finite and usually specific and/or local program. If investigators decide to publish results of a QI project they are advised to disclose in the methods section that the data were obtained as part of a QI project.

Since QI projects are not the purview of the IRB it is the policy of our office that they do not receive review and the IRB does not issue formal written determinations regarding their status. However, the IRB administrative office often advises investigators on the concepts they should consider when trying to determine if QI projects require IRB review. Journals or sponsors who request clarifications on the guidance provided to investigators in making this determination may be directed to IRB Policy 1.4, "Identifying QI/Education/Competency Evaluations as Clinical Research," which is available at <https://www.childrenshospital.org/research/institutional-review-board/guidelines-and-policies>.

Sincerely,

A handwritten signature in cursive script that reads "Susan Kornetsky".

Susan Z. Kornetsky, MPH

Senior Director, Clinical Research Compliance

Boston Children's Hospital