



Institutional Review Board
300 Longwood Avenue
Boston, MA 02115

May 16, 2023

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

RE: Statement of Compliance

HHS Regulations

Boston Children's Hospital (BCH) holds a Federalwide Assurance (FWA00002071, Expiration Date: May 10, 2028), from the Office of Human Research Protections. Under this assurance, BCH complies with 45 CFR 46. BCH chooses to limit this assurance to federally funded research; however, the regulations under 45 CFR 46, including all of Subparts B, C, and D, provide the practical basis for the review and approval of all research at BCH regardless of funding.

Department of Defense – Navy

BCH also holds a Department of Defense – Navy Addendum (DoD N-A3266) to its FWA. Under this addendum, BCH abides by the Department of Defense's and the Department of the Navy's regulations for protection of human research participants when conducting, reviewing, approving, overseeing supporting or managing Navy-supported research with human subjects.

Department of Justice

Because BCH participates in research that falls under the jurisdiction of the Department of Justice, the Hospital also complies with the regulations found under 28 CFR 46.

FDA Regulations

Because BCH participates in clinical research that falls under the jurisdiction of the Food and Drug Administration (FDA), the Hospital also complies with the regulations found under 21 CFR 50 (including Subpart D), 21 CFR 56, 21 CFR 312, 21 CFR 361, 21 CFR 612, and 21 CFR 812.

Institutional Review Boards

BCH has two Institutional Review Boards (IRBs). Each IRB is composed in accordance with and operates in compliance with FDA, HHS, and applicable Defense regulations. IRB #1 is registered with HHS as IRB00000352. IRB #2 (Rapid Response) is registered with HHS as IRB00010042.

Belmont Report

BCH adheres to the ethical principles and guidelines for the protection of human research subjects set forth in the Belmont Report. These principles and guidelines include respect for persons, beneficence, and justice.

ICH/GCP Guidelines

BCH complies with ICH Guidelines on Good Clinical Practice where they are consistent with FDA and HHS regulations.

Accreditation

BCH has been fully accredited by the Association for the Accreditation of Human Research Protection Programs (AAHRPP) since June 2005.

Sincerely

A handwritten signature in black ink that reads "Susan Kornetsky".

Susan Z. Kornetsky, MPH
Senior Director, Clinical Research Compliance
Boston Children's Hospital