



INSTITUTIONAL AUTHORITY FOR THE IRB

Children's Hospital and Regional Medical Center's (hereinafter Children's) Institutional Review Board (hereinafter IRB) is a committee of the organized medical staff established pursuant to the authority granted by the Board of Trustees to the President and CEO of Children's Hospital to provide for the protection of the rights and welfare of human participants involved in any and all research and related activities at or under the auspices of Children's. Children's IRB will be governed by all applicable state and federal regulations, including but not limited to 45 CFR 46, 21 CFR 50 and 21 CFR 56.

Children's holds a Federal Wide Assurance (FWA #00002443) with the Office for Human Research Protections (OHRP). Children's assures that all activities related to human subjects research, regardless of funding, will be guided by the ethical principles in The Belmont Report and will comply with the Federal Policy for the Protections of Human Subjects, 45 CFR 46 and all its subparts, A, B, C, and D.

As directed by the President and CEO, the Vice President of Research shall function as the "Authorized Institutional Official" to ensure that Children's Hospital effectively fulfills its responsibility for protecting the rights and welfare of human subjects.

As directed by the President and CEO, the Chair and members of the IRB are appointed by the Medical Director with concurrence of the Medical Executive Committee and approval of the Board of Trustees.