



Statement of Compliance and Registration

December 13, 2019

The Children's Healthcare of Atlanta Institutional Review Board (Children's IRB) is duly constituted, has written procedures for initial and continuing review of human research, prepares written minutes of convened meetings, retains records pertaining to review and approval, and fulfills requirements for diversity of IRB membership.

The Children's IRB complies with all U.S. regulatory requirements related to the protection of human research participants. Specifically, the Children's IRB complies with 45 CFR 46, 21 CFR 50 and 56, 45 CFR 164.508-514 and applicable portions of 21 CFR 54, 21 CFR 312, 21 CFR 812, 21 CFR 814 and with other applicable federal and state laws and regulations governing IRBs and research with human research participants.

Although the Children's IRB has not officially adopted the ICH-GCP guidelines, the policies and procedures are generally in accordance with the ICH-GCP guidelines as published in the Federal Register, May 9, 1997, regarding IRB/IEC criteria 3.1 through 3.4 of E-6.

The Children's IRB has been fully accredited by the Association for the Accreditation of Human Research Protection Programs (AAHRPP) since 2009.

The Children's IRB is registered with OHRP/FDA; the institution organization number is IORG0001045 (effective through 09/09/2022); the federalwide assurance number is FWA00000644 (effective through 10/31/2024); and our IRB registration number is IRB00001436 (effective through 09/09/2022).