



COOK COUNTY HEALTH

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From: Betty Donoval, JD, MS
Director, Research Regulatory Affairs

To: Sponsors

Re: Compliance 2024

The Cook County Health Institutional Review Board (IORG0000119 expiration 03/15/2026) is included in the System's Federal Wide Assurance (FWA00001802 expiration 3/15/2028).

The IRB reviews human subject research protocols for all System affiliates:

John H. Stroger Hospital of Cook County
Provident Hospital
Oak Forest Health Center of Cook County
Ambulatory and Community Health Network
Ruth Rothstein CORE Center
Cermak Health Services
Cook County Department of Public Health

Authorized signatories include:

Michael Giovingo, MD, IRB Chair
Betty Donoval, JD, MS, Director Research Regulatory Affairs
Audrean LaGrone, BA, IRB Manager
Stacey Kincaid, MPH, Informed Consent Coordinator
Errick Christian MA, Scientific Officer
Whitnie DuChateau MS, Research Database Support Coordinator

The IRB follows 45 CFR 46, and IRB regulations contained in 21 CFR 50, 21 CFR 56, 45 CFR 160, and sub parts A and E of 45 CFR 164. The IRB also follows 21 CFR 11 for electronic records and signatures as part of IRBManager. The IRB is the privacy officer for human subject research and reviews for HIPAA compliance. The IRB is also largely ICH/GCP compliant within the limitations of the sponsor's compliance. The affiliation of every IRB member is noted on the roster.

Any questions should be directed to Betty Donoval, JD, MS at bdonoval@cookcountyhhs.org or (312) 864-4821.