



# COOK COUNTY HEALTH

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

To: Sponsors

Re: Compliance 2021

The Cook County Health Institutional Review Board (IORG0000119 expiration 9/4/2023) is included in the System's Federal Wide Assurance (FWA00001802 expiration 4/1/2024).

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:

Audrey French, MD, IRB Chair  
Betty Donoval, JD, MS, Interim Director Research Regulatory Affairs  
Audrean LaGrone, BA, IRB Manager  
Stacey Kincaid, MPH, Informed Consent 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](mailto:bdonoval@cookcountyhhs.org) or (312) 864-4821.