



Leadership

Toni Preckwinkle
President
Cook County Board of Commissioners

Debra D. Carey
Interim CEO
Cook County Health

Board of Directors

M. Hill Hammock
Chair of the Board

Mary B. Richardson-Lowry
Vice Chair of the Board

Hon. Dr. Dennis Deer, LCPC, CCFC
Mary Driscoll, RN, MPH
Ada Mary Gugenheim
Mike Koetting
David Ernesto Munar

Heather M. Prendergast, MD, MS, MPH
Robert G. Reiter, Jr.
Layla P. Suleiman Gonzalez, PhD, JD
Sidney A. Thomas, MSW

Cook County Health Single IRB Guidance

Researchers at Cook County Health frequently collaborate with external investigators and institutions in multi-site research studies. In an effort to reduce duplicate submissions and oversight by multiple IRBs for the same protocol, both OHRP and the FDA allow for the use of a single IRB (sIRB) through reliance agreement opportunities. Reliance agreements are arrangements between institutions allowing the IRB of one institution to rely on the IRB of another institution for review of human subjects research. These agreements delineate the roles and responsibilities of the involved parties.

Mandates. There are single IRB mandates that require certain types of federally funded studies that involve multiple institutions to use a single IRB to accomplish IRB review and approval for all of the institutions.

- **NIH Policy (effective Jan. 25, 2018).** This applies to domestic sites of NIH funded studies where each site will conduct the same protocol involving non-exempt human subjects research, whether supported by grants, cooperative agreements contracts or the NIH Intramural Research Program. It does not apply to Foreign Sites, career development (K), research training (T) or fellowship awards (F) and current awards. It does apply to all competing grant applications (new, renewal, revision, or resubmission). Please see <https://grants.nih.gov/policy/humansubjects/single-irb-policy-multi-site-research.htm>.
- **The 2018 Common Rule 45 CFR 46 (effective Jan. 19, 2020).** This applies to all sites in the United States participating in a federally funded cooperative research study (involves more than one site). This does not apply to cooperative research for which more than single IRB review is required by law (including tribal law passed by the official governing body of an American Indian or Alaska Native tribe) or research for which any Federal department of agency supporting or conducting the research determines and documents that the use of a single IRB is not appropriate. Please see <https://www.govinfo.gov/content/pkg/FR-2017-01-19/pdf/2017-01058.pdf>.

CCH as the Relying IRB. CCH relies on other IRBs when participating in multi-site research when required by the above mandates. CCH IRB will consider relying on other IRBs for industry sponsored and network studies on a case-by-case basis for multi-site, clinical research studies where the sponsor has selected a sIRB. Reliance on a commercial IRB will not be considered for CCH PI initiated unfunded research. Industry sponsored studies will be charged an administrative review fee of \$1,500.00.

Administrative Review. Studies where CCH relies on another IRB for review **must** still be submitted for administrative review to the CCH IRB via IRBManager. The CCH IRB conducts an administrative review to determine if the study is a reasonable fit for the CCH patient population and institutional capabilities. The CCH IRB also determines if personnel have completed their IRB training, assess any conflicts of interest, and serves as the HIPAA privacy board. The CCH IRB does not re-review the study for scientific or ethical concerns. The CCH IRB maintains the authority to

suggest protocol modifications, or opt-out of certain studies for administrative or human participant protection concerns on a case-by-case review basis, such as, but not limited to:

- 1) instances where participants may be randomized to an arm of the study which is inferior to CCH standard of care;
- 2) instances where the study requires interventions, staff effort, or facilities that CCH cannot provide; or,
- 3) the consent language does not meet the standard of clarity appropriate for CCH participants.

Steps for CCH to Rely on Reviewing IRB. In order to rely on an IRB, the investigator must first take the below steps. For studies already under a master reliance agreement (such National Cancer Institute's Central IRB), skip to step 3.

1. Email Research & Regulatory Affairs with your request to use a sIRB (bdonoval@cookcountyhhs.org). Fully fill out and attach the "Request to Use a sIRB" form available on our website. Remember to attach your protocol and any accompanying documents. Be sure to indicate if a reliance agreement is needed or if you plan on utilizing an existing master reliance agreement (ex. SMART IRB).
2. If your request for reliance is approved, Research & Regulatory affairs will work with the CCH investigator and the contact at the reviewing IRB to execute reliance.
3. Submit your application into IRBManager using the "Submission for CCH IRB Approval" form and select "Administrative Review for Central IRB Approved Studies." Make sure to include the IRB approval letter listing our site as approved. Also, make sure your informed consent and HIPAA authorization contains local context and language. See the requirements below.
4. Once the CCH IRB activates your study, you may begin. However, you must follow the reviewing IRBs policies and procedures as well as the CCH requirements below.

What is SMART IRB? SMART IRB is a platform designed to ease common challenges associated with initiating multisite research and to provide a roadmap for institutions. Freely available for institutions and investigators, SMART IRB is an integrated, comprehensive platform that allows flexibility in the size and scope of collaboration to enable IRB reliance for multisite studies across the nation. SMART IRB is the preferred method of establishing reliance with another IRB.

CCH has already signed onto the SMART IRB master reliance agreement. This eliminates the need to negotiate the terms of the reliance agreement with the other institution, which can often take weeks to months depending on if ancillary Legal and Compliance reviews are necessary. All that is needed is an executed authorization agreement that documents the reliance. This can be done utilizing the SMART IRB Online Reliance System (preferred) or a separate paper agreement. CCH investigators must follow the SMART IRB SOPs.

- SMART IRB (smartirb.org)
- Online Reliance System (smartirb.org/reliance/)
- Standard Operating Procedures (smartirb.org/assets/files/SMART_IRB_SOP-090816.pdf)
- Other Resources such as checklists and templates (smartirb.org/resources/)

Consent Form Requirements when Relying on an External IRB. The CCH IRB cannot issue final approval until the consent form includes all institutionally required elements. The requirements involve the following elements:

- Identification of CCH as a research site and the CCH PI;
- Inclusion of a CCH contact for emergencies;
- The HIPAA language must be CCH HIPAA language and include CCH researcher/staff and the CCH IRB as entities that will have access to PHI;

- The name and contact information for the CCH investigator needs to be provided for withdrawal of permission;
- Contact information for the CCH Research & Regulatory Affairs office must be included for participants' questions;
- If injury compensation language is included in the consent form, then it must match CCH institutional requirements.

Subsequent Submissions to CCH IRB.

- **Continuing Reviews.** Progress reports are not required; however, the PI **must** inform the IRB when the study has concluded via the “Progress Report/Final Report” form in IRBManager. The PI is responsible for ensuring that the study does not expire with the reviewing IRB.
- **Amendments.** Not all changes must be reported to the CCH IRB. If submission is required, please submit via the “Amendment/Modification” form in IRBManager.
 - Changes in procedures are **not required** to be submitted **unless** there is an indication of increased risk to participants and/or increased administrative burden on CCH resources. The PI must make the assessment and document it in protocol records. These records are auditable by the CCH IRB.
 - Changes in study personnel **must** be submitted.
 - Changes in funding **must** be submitted.
 - Changes in local recruitment procedures and advertisements **must** be submitted.
- **Reportable Local Problems.** The PI must report unanticipated problems that affect participant risk, and/or adverse events that occur per CCH IRB guidance. If/when, an adverse event occurs with a CCH patient participant, the PI must also report it through the eMERS system for compliance with CCH policy.

PI Assurances. The CCH Principal Investigator, as part of the request will need to lead the process and assure in writing to:

1. Take responsibility for the administrative and ethical implementation of all studies associated with this agreement according to all applicable CCH policies and procedures and applicable federal, state, and local laws.
2. Assure that all CCH investigators serving in any capacity with any study associated with the reliance agreement are appropriately on-boarded/badged and trained in human participant protections by the CCH IRB.
3. Assure that all conflict of interest (COI), including financial, (if any), of any CCH investigator associated with the reliance agreement will be reported to the CCH IRB via the “Financial Interest Statement” in IRBManager.
4. Assure that each study submitted to the CCH IRB for administrative review that is associated with the reliance agreement has obtained approval by the reviewing institution with documentation.
5. Assure that all studies associated with the reliance agreement and implemented within CCH will have consent documents that are linguistically and literacy level-appropriate; placed on CCH letterhead; have local contact information for the CCH PI and locally affiliated co-investigators, along with the Research & Regulatory Affairs office contact information and other local context information as appropriate.
6. Assure CCH HIPAA forms and data sharing agreements are used with approvals in place, in the event of data collection and sharing any PHI.
7. Upon execution of the reliance agreement, submit an administrative review application into IRBManager and receive an approved administrative review and approval by the CCH IRB before the research activity can begin.

8. Assure that any amendments or protocol revisions are assessed for any change in risk/benefit balance from the originally approved protocol, and submit in a timely fashion any such amendments to the CCH IRB via IRBManager.
9. Assure that adverse events (AEs) are reported to the CCH IRB via IRBManager in accordance with CCH incident reporting policy.
10. Assure that the documented terms of the reliance agreement language as finalized and executed by CCH and the other institution are followed.

CCH IRB as Reviewing IRB. In some cases, the CCH IRB may act as the reviewing IRB. However, the CCH IRB has limited staff and resources, so each study will be evaluated on a case-by-case basis whether we are suited to serve as the sIRB for the proposed multi-site or collaborative project. The main evaluation criteria are:

- The risk level of the proposed research
- The number of participating sites
- The location of the participating sites
- The number of years the study will require IRB review
- Other considerations such as (involvement of an IND or IDE, vulnerable populations, biosafety, number of unique consent forms, COI...etc.)

An invoice with the fees associated with your study based on the above criteria will be issued.

The CCH IRB maintains the right to opt-out of a given study proposed for administrative reasons or concerns about the protection of human participants even after the executing of a reliance agreement.



9/9/2020

Betty Anna Donoval, JD, MS
Interim Director Research & Regulatory Affairs

Date