Requests for the Cook County Health & Hospitals System (CCHHS) Institutional Review Board (IRB) to formally agree to rely upon IRB review and approval by another academic or non-profit IRB is determined on a case by case basis, involving CCHHS legal and compliance office review as needed. Process initiation must be led by a responsible CCHHS Principal Investigator (PI) and begins with the satisfactory completion of this form. Initial inquiries for such agreements that are not led by the CCHHS PI will not be considered.

| **Please Attach Proposed Reliance Agreement for Review** | |
| --- | --- |
| **Please indicate by [X] if the proposed agreement is to serve for one study, or multiple studies here: One \_\_\_\_ Multiple\_\_\_\_\_** | |
| Reviewing Institution Name: | |
| Reviewing Institution Principal Investigator Name: | |
| (Initial) Study Title: | |
| Study Abstract: (**Please attach full protocol proposal, accompanying documents, including consent language, if available**) | |
| Study Sponsor: | |
| CCHHS Principal Investigator Last Name: | CCHHS Principal Investigator First Name: |
| CCHHS Affiliate/Department/Division Name: | CCHHS Affiliate/Department/Division Head Name: |
| CCHHS PI Contact Information: Email address: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Office address: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Telephone number: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Pager/Cell number: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | |

**My signature below represents a committed pledge to:**

1. Take responsibility for administrative and ethical implementation of any and all studies associated with this agreement within CCHHS in terms of human subject/participant protection.
2. Assure that all CCHHS 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 CCHHS IRB.
3. Assure that all conflict of interest (COI), including financial, if any, of any CCHHS investigator associated with the reliance agreement will be reported to the CCHHS IRB.
4. Assure that all studies submitted to the CCHHS IRB for administrative review have obtained approval by the reviewing institution with documentation.
5. Assure that all studies associated with the reliance agreement and implemented within CCHHS will have consent documents that are linguistically and literacy level-appropriate; placed on CCHHS letterhead; have local contact information for the CCHHS PI and locally affiliated co-investigators, along with CCHHS IRB office contact information and other local context information as appropriate.
6. Assure CCHHS HIPAA forms and data sharing agreements are used with approvals in place, in the event of data collection and sharing any PHI identifiers.
7. Upon execution of the reliance agreement, submit an administrative review application to IRBManager and receive an approved administrative review and approval by the CCHHS IRB before the research activity can begin.
8. Assure that any amendments or protocol revisions are assessed for change in risk/benefit balance from the originally approved protocol, and submit any such amendments which change the risk/benefit balance to the CCHHS IRB via IRBManager in a timely manner.
9. Assure that adverse events (AEs) are reported to the CCHHS IRB via IRBManager in accordance with CCHHS incident reporting policy.
10. Assure that the documented terms of the reliance agreement language as finalized and executed by CCHHS and the other institution are followed.

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| --- | --- |
| **CCHHS PRINCIPAL INVESTIGATOR SIGNATURE** | **DATE** |
|  |  |

**Note:** The CCHHS IRB maintains the right to opt-out of a given study proposed for administrative reasons or concerns about human subject/participant protections. Examples include: when proposals indicate participants may be randomized to an arm that is inferior to CCHHS standard of care; interventions, staff effort or facilities proposed exceed what CCHHS can provide; or consent language does not meet clarity or simplicity standards appropriate for CCHHS patients.