

CMH IRB and NU IRB Reciprocal Agreement for Oversight of Research Protocols

CMH IRB Guidelines for Principal Investigators

Background

In an effort to facilitate the review of research and support those investigators who conduct research activities involving Children's Memorial Hospital and Northwestern University, the Institutional Review Boards for Children's Memorial Hospital (CMH IRB) and Northwestern University (NU IRB) have a reciprocal agreement in place that allows for facilitated review, approval and oversight of protocols that are conducted at both institutions. The agreement allows each of the institutions to rely on the other for review and continuing oversight of certain research protocols as described below.

- **CMH IRB Oversight:** For clinical research activities involving pediatric subjects, the NU IRB agrees to accept the review of the CMH IRB.
- **NU IRB Oversight:** For clinical research activities involving adult subjects, the CMH IRB agrees to accept the review of the NU IRB.

Note: Each institution reserves the right to have its own IRB review the research.

Guidelines for Submissions:

I have approval from the NU IRB and I need CMH approval too, what do I need to do?

If you have submitted your protocol, and supporting documents, and obtained approval from the NU IRB, the NU IRB is the IRB of record. Now you need the CMH IRB approval, and in order to do this you are required to submit the following documents to the CMH IRB:

1. NU IRB Approval Letter
2. NU IRB approved consent form(s) with the NU IRB approval stamp
3. Other approved documents – such as recruitment tools, surveys, that were approved by NU IRB, with the NU approval stamp.
4. The entire submission as it was submitted to the NU IRB: approved protocol, supporting documents, and IRB application.
5. Verification of Human Subjects Training.
6. The CMH OSP Form with appropriate signatures as required. This form is on the CMH IRB website at www.childrensmrc.org/researchadministration

I have approval from the CMH IRB and now I need NU approval as well, what should I do?

In this case, the IRB of record is CMH and in order to obtain NU IRB approval you will need to contact the NU IRB for their submissions requirements at IRB@northwestern.edu.

CMH IRB Review and Approval Process:

1. Once these documents are received at the CMH IRB, and after the CMH IRB staff has conducted a pre-review to ensure all required elements are in the submission packet, the submission is assigned a CMH protocol number for tracking purposes and the packet is forwarded to the IRB Chair for review.
2. The Chair will review the submission and within 3-5 business days will inform the PI of acceptance of the NU IRB review and oversight, or request additional information/require minor modifications as needed to make a determination regarding the acceptance of the NU approval and CMH IRB approval.
3. Once approved, the CMH IRB will issue the approval documents electronically to the PI.
4. Should the CMH IRB Chair, as permitted in this agreement, opt to send the submission to the full board, the duration of the process is that of a general full board submission.

CMH IRB Continuing Review Procedures:

1. For purposes of continuing review, the NU approval dates will be followed, as that is the IRB of record and charged with the study's oversight.
2. For the CMH IRB to accept the approval of the continuing review, the PI will need to follow the IRB policy for continuing review:
 - a. Per CMH procedure, a CMH IRB progress report for this study will be generated and sent to the CMH investigator.
 - b. The investigator should submit the report to the CMH IRB allowing for sufficient time to have the submission reviewed by CMH prior to the expiration date.
 - c. The NU IRB continuing review approval document(s) should be included with this progress report submission.
 - d. Protocols approved under the reciprocal agreement will be renewed with the new approval dates as assigned by NU.
3. Protocols not renewed by the NU IRB prior to the expiration date will be closed by the CMH IRB. A complete new initial review submission to both the NU and CMH IRBs will be required to reinstate the protocol.

CMH IRB Contact Information:

The CMH IRB is located at 2430 N. Halsted, 1st Floor, Research Administration Suite.
Mailing address: 2300 Children's Plaza, Box #205
Chicago, IL 60614

Email: IRB@childrensmemorial.org.

******Submission requirement: you must submit the documents electronically to the CMH IRB mailbox at irb@childrensmemorial.org, and one original hard copy******

CMH IRB Staff:

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