HRPP SOP #: 006	Date Issued: 12.1.22	Date Revised: N/A
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Title	Reliance on an External IRB
Scope	North Memorial Health, Maple Grove Hospital, Blaze Health
Responsibility	North Memorial Health Research Office

PURPOSE

This Standard Operating Procedure (SOP) establishes the requirements and processes for the Organization to rely on an external Institutional Review Board (IRB). This SOP applies to non-exempt research and exempt research requiring limited IRB review.

POLICY

1. The Organization shall rely upon external IRBs to review and approve all non-exempt human subjects research and make exempt determinations for research requiring limited IRB review. Reliance shall be documented in a reliance agreement that outlines the responsibilities of the reviewing IRB and the Organization (the relying institution).
2. The Organization's Institutional Official (IO) or their designee has the authority to determine whether to rely on a proposed external IRB. Criteria considered by the IO or designee shall include, but are not limited to, the following:
    a. The research is subject to a single IRB regulatory mandate established by the National Institutes of Health and/or the Department of Health and Human Services and the proposed reviewing IRB has been selected by the funding agency;
    b. The proposed reviewing IRB has an active registration with the Office of Human Research Protections (OHRP); and
    c. The proposed reviewing IRB is accredited by the Association for the Accreditation of Human Research Protection Programs (AAHRPP) or has established policies and procedures that have been reviewed by the North Memorial Health Research Office and determined to be consistent with the federal requirements for IRBs.
3. When the Organization cedes the ethical review of research to an external IRB, the Organization remains responsible for oversight of the research and for ensuring protection of human subjects. Organization responsibilities include but are not limited to:
    a. Protecting the rights, safety, and welfare of human subjects enrolled in research at the Organization;
    b. Ensuring that Organization researchers have the appropriate qualifications and training to conduct human subject research;
    c. Conducting monitoring/auditing in addition to or in cooperation with the reviewing IRB;
    d. Conducting conflict of interest reviews for Organization investigators and, when necessary, establishing management plans;

e. Conducting ancillary reviews (e.g. investigational pharmacy, radiation safety, etc.) to ensure the research is conducted in compliance with Organization policies and procedures;
f. Educating members of the Organization's research community to establish and maintain compliance with federal regulations and Organizational policies related to human subjects research; and
g. Ensuring compliance with determinations of the reviewing IRB.

4. Relied upon IRBs have the authority to:
    a. Approve, require modifications to secure approval, and disapprove human subjects research overseen and conducted by the Organization;
    b. Suspend or terminate approval of human subjects research not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to participants;
    c. Observe or have a third party observe, the consent process and the conduct of the human subjects research;
    d. Require researchers to disclose conflicts of interest according to the process agreed upon between the Organization and the reviewing IRB and require additional management controls beyond those required by the Organization, when necessary to ensure protection of participants;
    e. Serve as the HIPAA Privacy Board, as applicable, to fulfill the requirements of the HIPAA Privacy Rule for use and disclosure of protected health information for research purposes.

INVESTIGATOR RESPONSIBILITIES

1. Organization investigators requesting to rely on an external IRB are responsible for submitting a written request to cede review to the North Memorial Health Research Office. Requests to rely shall include:
    a. A copy of the Cede Request Cover Sheet;
    b. Copies of all study documents, including the protocol, informed consent, and all other subject-facing materials (e.g., recruitment materials, advertisements).
2. After the North Memorial Health Research Office conducts an administrative review and provides a signed copy of the Independent IRB Submission Cover Page back to the PI, the PI is responsible for:
    a. Submitting an application to the reviewing IRB to request approval of the Organization as a relying site;
    b. Submitting a copy of the reviewing IRB's approval letter to the North Memorial Health Research Office prior to initiating research;
    c. Initiating research activity, in accordance with the IRB-approved protocol and reviewing IRB policies and procedures.
3. Organization investigators conducting research under the oversight of an external IRB must follow the reviewing IRB's policies regarding conduct of the research. This includes but is not limited to:
    a. Timely submitting continuing reviews, as applicable;
    b. Promptly reporting any proposed changes to the research and not implementing such changes without prior IRB review and approval, except where necessary to eliminate apparent immediate hazards to subjects; and
    c. Promptly reporting non-compliance, unanticipated problems involving risks to subjects or others, unresolved participant complaints, protocol deviations and other events as specified in reviewing IRB policies.
4. Organization investigators must also comply with the following organizational

requirements:

a. Annually, on the anniversary date of receipt of the Organization's approval to initiate research, investigators must submit an administrative check-in to provide an update on research activities conducted during the previous year. This check-in must include a copy of the reviewing IRB's letter of approval for the continuation/renewal.
b. Local unanticipated problems, serious or continuing non-compliance, and unresolved subject complaints must be reported to the North Memorial Health Research Office;
c. Before a new study team member may be engaged in human subject research, a Personnel Modification must be submitted to the North Memorial Health Research Office for review and approval.
d. Protocol modifications that may require new or additional ancillary review (e.g., a change to the Investigator's Brochure that requires investigational pharmacy review) must be submitted to the North Memorial Health Research Office for review.
e. Maintaining research records in accordance with Organization policies.

NORTH MEMORIAL HEALTH RESEARCH OFFICE RESPONSIBILITIES

1. The North Memorial Health Research Office Director or designee is responsible for reviewing requests to cede review, determining whether a study is eligible to be ceded, and if so, whether all Organization requirements have been met.
    a. If the study is not eligible to be ceded (i.e., is not human subjects research, is human subjects research in which the Organization is not engaged, or is exempt research that does not require limited IRB review), the North Memorial Health Research Office will facilitate internal review and communication regarding any determinations to the PI, as appropriate.
2. If the study is eligible to be ceded, the North Memorial Health Research Office Director or designee will review the application packet to verify the following and contact the PI to request any missing materials:
    a. All Organization employees engaged in the research are in good standing with the Organization and have current human subjects protections training, Good Clinical Practice (GCP) training and Conflict of Interest (COI) training, as applicable;
    b. No Investigators have disclosed COIs related to the research that require management pursuant to Organization policies;
        i. If any Investigators have disclosed a COI, the North Memorial Health Research Office Director or designee will review the conflict and determine whether management is required pursuant to Organization policies.
    c. If the Organization's study team will obtain written informed consent, the site-specific consent includes the Organization's required language (i.e., subject injury language if the research involves more than minimal risk and HIPAA authorization language).
3. After all local requirements to cede review have been met, the North Memorial Health Research Office Director or designee shall:
    a. Complete the Independent IRB Submission Cover Page;
    b. Ensure reliance has been documented (e.g., via a fully executed institutional authorization agreement, or SMART Letter of Acknowledgement).
    c. Send the PI the following:

i. The signed Independent IRB Submission Cover Page indicating the Organization's approval to rely on the reviewing IRB; and
ii. A copy of the fully-executed reliance agreement.

d. Save a copy of the study packet.

REFERENCES

45 CFR 46

NIH Single IRB Policy

TABLE OF REVISIONS

Date	Description of Changes