HRPP SOP#: 005	Date Issued: 12.1.22	Date Revised: N/A
Version#: 01	**Issued by:** Institutional Official	**Authorized by:** Provider Services Legal

Title	Reporting to Regulatory Agencies & Sponsors Regarding Human Subjects Research
Scope	North Memorial Health, Maple Grove Hospital, Blaze Health
Responsibility	North Memorial Health Research Office

PURPOSE

The purpose of this policy is to establish guidelines to ensure that North Memorial Health meets its reporting obligations when reporting to federal agencies is required.

POLICY

The North Memorial Health Institutional Official (IO) will ensure that full, accurate, and timely reports are submitted to the appropriate regulatory agencies when required, in accordance with the reliance agreement between the Organization and the reviewing IRB.

PROCEDURES

1) The Director of the North Memorial Health Research Office is responsible for drafting reports to the relevant federal agencies for the following:
    a) Terminations of previously approved research;
    b) Suspensions of previously approved research, regardless of the reason for the suspension;
    c) Serious or continuing noncompliance as determined by the reviewing IRB;
    d) Unanticipated problems involving risks to participants and others.
2) Generally, all correspondence should include the following:
    a) Name of the institution conducting the research;
    b) Title of the research and grant proposal, as applicable;
    c) Name of the Principal Investigator (PI);
    d) The IRB study number;
    e) A detailed description of the issue;
    f) The IRB's findings;

g) Actions the IRB is taking or plans to take to address the issue; and

h) Any information regarding further recommendations, actions, or investigation to be taken, if applicable.

3) In the event that the reviewing IRB does not submit a report to the applicable regulatory agency, the IO is responsible for reviewing, signing, and sending the letter to the relevant federal agencies within fifteen (15) working days following the determination made by the reviewing IRB or the action taken by the Organization that led to the obligation to submit a report. Reports should be sent to:

   a) The Office of Human Research Protections (OHRP) for research regulated under the Common Rule. OHRP requires use of a web-based Incident Report Form.

   b) The Food and Drug Administration (FDA) for FDA-regulated research.

4) The North Memorial Health Research Office shall submit copies of reports to project sponsors (federal, state, foundation or private), as applicable.

5) A copy of the report should also be sent to:

   a) General Counsel, when appropriate

   b) The PI

REFERENCES

45 CFR 46
21 CFR 56
SOP – North Memorial Health Reliance on an External IRB

TABLE OF REVISIONS

Date	Description of Changes