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Title	Education and Training
Scope	North Memorial Health, Maple Grove Hospital, Blaze Health
Responsibility	North Memorial Health Research Office

PURPOSE

The purpose of this policy is to establish the Organization's requirements for investigators and research staff conducting human subjects research related to training and education on the protection of human subjects.

POLICY

The Organization has a legal and ethical responsibility to protect the rights, safety, and welfare of human subjects participating in research conducted by or within the Organization. Consistent with these responsibilities, the Organization requires every individual engaged in human subjects research conducted by the Organization to complete the web-based Collaborative Institutional Training Program (CITI) Basic Biomedical, or Good Clinical Practice (GCP) course prior to engaging in the research. Additionally, either the Biomedical refresher course or the GCP refresher course must be completed every three years.

Researchers and research team members who are not Organization employees but are conducting research within the Organization, using Organization Protected Health Information or interacting with Organization customers who are prospective research subjects, must provide documentation of current human subjects protections training.

Human subjects protections training may be completed for example via an industry sponsor's training portal or another organization's training portal but must be equivalent to the training offered through the CITI Basic Biomedical or GCP courses. The Director of the Research Office or their designee will be responsible for determining whether human subjects protections training taken by non-employees is adequate.

Sponsors, including federal agencies, may have additional training requirements. For example, the National Institutes of Health (NIH) requires investigators and clinical trial site staff who are responsible for the conduct, management, and oversight of NIH-funded clinical trials to complete Good Clinical Practice training every three years. The Organization commits to comply with any such additional training requirements.

Principal Investigators (PIs) are responsible for ensuring that study staff members engaged in research have completed human subjects protections training and take refresher training every three years. PIs are also responsible for maintaining human subjects protections training records in the study regulatory binder.

PROCEDURES

Prior to reviewing and making an exempt determination for proposed exempt human subjects research or agreeing to rely on an external IRB for research requiring limited IRB review or non-exempt research, the Research Office will confirm that all study staff listed on the application have current human subjects protection training, including, when applicable, additional sponsor training requirements (e.g., NIH-required GCP training).

The addition of new study team members will not be approved by the Research Office unless the individual(s) being added have current human subjects protections training. At the annual administrative check in, if study team members have lapsed human subjects protections training, the Organization may suspend all or part of the research activities until the individual(s) with lapsed training has completed the applicable refresher course. The Principal Investigator may opt to remove individuals who have not completed training from the study team to allow the research to continue.

REFERENCES

45 CFR 46
21 CFR 56

TABLE OF REVISIONS

Date	Description of Changes