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Title	Exempt Research
Scope	North Memorial Health, Maple Grove Hospital, Blaze Health
Responsibility	North Memorial Health Research Office

PURPOSE

The purpose of this policy is to outline the process and criteria for reviewing human subjects research eligible for an exempt determination.

POLICY

The North Memorial Health Research Office is responsible for determining whether proposed research qualifies for an exempt determination. Investigators do not have the authority to make exempt determinations.

Research determined to be exempt must still adhere to the ethical standards set forth in the Declaration of Helsinki, the Belmont Report, this policy, and Organizational requirements regarding human subjects protections training and disclosure of conflicts of interest.

For research to qualify as exempt, the research (as a whole) must satisfy one or more of the following regulatory categories:

1. **Category 1:** Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

    a. ***Commonly accepted educational settings*** traditionally implies schools. Educational settings may have a broader meaning, one that accounts for learning environments in which adults, clients, patients, professionals, or teachers commonly receive education.
    b. ***Research participation*** must not be a condition of the learning environment or any course curricula. Students and learners should retain the right to refuse to take part in research without sacrificing their standing in the educational setting.

2. **Category 2:** Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:

a. The information obtained is recorded by the investigator in such a manner that the identity of the human participants cannot be readily ascertained, directly or through identifiers linked to the participants; or

b. Any disclosure of the human participants' responses outside the research would not reasonably place the participants at risk of criminal or civil liability or be damaging to the participants' financial standing, employability, educational advancement, or reputation.

3. **Category 3:** Research involving benign behavioral interventions in conjunction with the collection of information from an adult participants through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:

    a. The information obtained is recorded by the investigator in such a manner that the identity of the human participants cannot be readily ascertained, directly or through identifiers linked to the participants; or

    b. Any disclosure of the human participants' responses outside the research would not reasonably place the participants at risk of criminal or civil liability or be damaging to the participants' financial standing, employability, educational advancement, or reputation.

        i. Benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the participants, and the investigator has no reason to think the participants will find the interventions offensive or embarrassing.

        ii. Examples of benign behavioral interventions that qualify for exemption include having participants play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

        iii. If the research involves deceiving the participants regarding the nature or purposes of the research, Category 3 is not applicable unless the participant authorizes the deception through a prospective agreement to participate in the research in circumstances in which the participant is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

4. **Category 4:** Secondary research for which consent is not required. Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:

    a. The identifiable private information or identifiable biospecimens are publicly available;

    b. Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human participants

cannot be readily ascertained directly or through identifiers linked to the participants, the investigator does not contact the participants, and the investigator will not re-identify participants;

c. The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR Parts 160 and 164, subparts A and E, for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b); or

d. The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for non-research activities, and conducted in compliance with 45 CFR 46.104(d)(4)(iv).

5. **Category 5:** Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine:

   a. Public benefit or service programs;

   b. Procedures for obtaining benefits or services under those programs;

   c. Possible changes in or alternatives to those programs or procedures; or

   d. Possible changes in methods or levels of payment for benefits or services under those programs.

6. **Category 6:** Taste and food quality evaluation and consumer acceptance studies,

   a. If wholesome foods without additives are consumed, or

   b. If a food is consumed that contains a food ingredient at or below the level and for a use to be found safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

7. **Categories 7 and 8** are not utilized by the Organization.

REGULATORY LIMITATIONS ON EXEMPT RESEARCH INVOLVING VULNERABLE POPULATIONS

1. **Children:** For research involving children, Category 2 only applies to studies involving educational tests and observations of public behavior when investigators **do not** participate in the activities being observed. If investigators engage with children, or if the research involves surveys or interviews, category 2 cannot be utilized. In addition, research with children involving benign behavioral interventions (Category 3) does not

qualify for exemption. All other exempt categories can be utilized for research involving children.

2. **Prisoners:** Research that proposes to enroll prisoners does not qualify for exemption unless the research is aimed at involving a broader subject population that only incidentally includes prisoners.

3. **Other defined vulnerable populations:** Organization research that proposes to enroll individuals who are cognitively impaired or economically or educationally disadvantaged will be reviewed by the North Memorial Health Research Office to determine whether exempt categories apply.

PROCEDURES

1. Investigators requesting an exempt determination must complete and submit an exempt application to the North Memorial Health Research Office for review.

2. The Director of the Research Office or their designee, is authorized to review applications for exempt research and make exempt determinations. Research that requires limited review (i.e., research that would be approvable as exempt under 45 CFR 46.104(d)(2)(iii) or (d)(3)(i)(c)) must be submitted to an external IRB for review so that expedited procedures can be used to conduct the limited review.

    a. The individual conducting the exempt review will determine whether the proposed research satisfies one or more of the exempt categories, and whether adequate provisions have been made to protect both the privacy of human participants and maintain the confidentiality of the data to be collected.

    b. The individual conducting the exempt review will document applicable exempt categories on the reviewer checklist and in the exempt determination letter. The reviewer will maintain a copy of the reviewer checklist and the exempt determination letter in Research Office records and send a copy of the exempt determination letter to the Principal Investigator.

3. The Principal Investigator may not initiate exempt research (which includes collecting data for research purposes) until after the Research Office has issued an exempt determination letter.

4. The Organization requires investigators conducting exempt research to complete and submit an administrative check in on an annual basis by completing the North Memorial Health Research Office Administrative Check In Form and submitting it to the Research Office for review.

    a. Administrative Check In applications must include:

        i. A report on the status of the research (e.g., active, open to enrollment, in data analysis only, closed);

        ii. A summary of any complaints received from participants enrolled by the Organization study team and their resolution; and

iii. A summary of any previously unreported serious or continuing non-compliance on the part of the Organization study team or local unanticipated problems (i.e., unanticipated problems that occurred locally or affected participants enrolled at the Organization).

5. Investigators conducting exempt research must submit any proposed changes to their research to the North Memorial Health Research Office for review prior to implementing such changes. The Research Office will review the proposed modification to ensure that the research still qualifies as exempt. If so, the Research Office will send a letter to the PI indicating that they may proceed with the proposed modification and, if applicable, indicating any new exempt categories under which the research is approved. If not, the Research Office will communicate with the PI to facilitate submission of an application to an external IRB.

REFERENCES

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

TABLE OF REVISIONS

Date	Description of Changes