NORTH
MEMORIAL HEALTH

RESEARCH REVIEW APPLICATION
INSTITUTIONAL REVIEW BOARD

Federal policies require that each project involving studies on humans be reviewed with respect to: 1. The rights and welfare of the individual(s); 2. The appropriateness of the methods used to secure informed consent and; 3. The risk and potential benefits of the investigation to the subject.

The following information is necessary for this review. If an item is not applicable, indicate by "NA". **Please type and use additional pages only as necessary.**

STUDY INFORMATION

Investigator/Project Director: _____ Phone: _____

Department: _____

Mailing Address: _____

_____

Co-Investigator(s):
Name: _____ Phone: _____
Name: _____ Phone: _____

Project Title: _____

Dates of Project: _____ to _____

FUNDING

Will this project be funded through outside sources or granting agencies? Yes _____ No _____
If yes, please list:

Investigational New Drug Permit (IND #) or Investigational Device Exemption (IDE #): _____

Humanitarian Use Device (HUD #) or Humanitarian Device Exemption (HDE #): _____

SUBJECT POPULATION

	ADULT		PEDIATRIC	
Number	Male: _____	Female: _____	Male: _____	Female: _____
Type	Normal: _____	Clinical: _____	Normal: _____	Clinical: _____
Age Range	_____ to _____		_____ to _____	

If the study includes the use of clinical patients, will approval be obtained from the attending physician? Yes _____ No _____ N/A _____ If so, how?

Aspects of this study involving the use of human subjects will be conducted in:
Hospital: Yes _____ No _____ Physician's Office: Yes _____ No _____ Other: _____

Indicate how subjects are initially chosen (e.g. records, classes, referral, etc) and/or contacted (telephone, ads, letter, etc) and any applicable or required characteristics. Be specific:

What are the inclusion and exclusion criteria for subject selection?

Will subjects receive inducements, reimbursements or rewards before, during or after the study?
Yes _____ No _____ If yes, explain:

Will the subjects or third-party payors be charged for any research-related procedure? Yes_____ No_____
If yes, explain including amount or estimate:

For evaluation of your project, please check which of the following are involved:

- ☐ Patients are experimental subjects
- ☐ Patients are control subjects
- ☐ Experimental drugs
- ☐ Approved drugs for "non-FDA approved" use
- ☐ Placebos
- ☐ Experimental devices
- ☐ Questionnaires
- ☐ Data banks, archives, medical records
- ☐ Ionizing Radiation
- ☐ Non-patient volunteers
- ☐ Pregnant subjects
- ☐ Minor subjects (less than 18 years old)
- ☐ Subjects whose major language is not English
- ☐ Fetal Tissue
- ☐ Surgical Pathology Tissue
- ☐ Placental Tissue
- ☐ Filming, video or voice recording of subjects
- ☐ Subjects who have Developmental Disabilities

ABSTRACT

Summarize study/project. Clearly state the hypothesis or research question of the study or program in which human subjects will be used. Specify what will be done to or for the subjects or participants.

Do not refer to "See Protocol" for abstract.

Include a full/complete copy of protocol/research plan with application.

RISK DETERMINATION

Does the research planned in this study involve:

- Possible invasion of privacy of subject or family, including use of personal information or records? Yes _____ No _____
- The use of drugs? Explain: Yes _____ No _____

- The administration of physical stimuli other than auditory and visual stimuli associated with normal classroom situations? Yes _____ No _____
- Deprivation of physiological requirements such as nutrition or sleep? Yes _____ No _____
- Deception as part of the experimental procedure? If the study involves the use of deception, the protocol must include a description of this fact and "debriefing procedure" which will be used upon completion of the study. Yes _____ No _____
- Any probing for information which an individual might consider to be personal or sensitive, including illegal activities? Yes _____ No _____
- The presentation to the subject of any materials which they might find offensive, threatening or degrading? Yes _____ No _____
- The requirement of physical exertion beyond activities of daily living? Yes _____ No _____
- The use of isotopes? If radioisotopes are used, this application must be accompanied by approval in writing from the Radiation Safety Committee. Yes _____ No _____

What other risks may subjects in this study be exposed to? Explain:

What precautions have been taken to minimize any risks indicated above?

What are the potential benefits to subjects for participating in this study?

CONFIDENTIALITY OF DATA

Will any data from this study be made a part of a permanent record (identifiable to the subject) that will be made available to a physician, employer, supervisor, student, FDA, etc?
Yes _____ No _____ If yes, explain:

What steps will be taken to ensure the confidentiality of data obtained in this study?

INFORMED CONSENT REQUIRED CRITERIA

Does the informed consent include: (If No, explain)

- A statement that the study involves research, and explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental? Yes _____ No _____
- A description of any reasonably foreseeable risks or discomforts to the subject? Yes _____ No _____
- A description of any benefits to the subject or to others which may reasonably be expected from the research? Yes _____ No _____
- A disclosure of appropriate procedures or courses of treatment, if any, that might be advantageous to the subject? Yes _____ No _____
- A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained? Yes _____ No _____
- For research involving more than minimal risk, an explanation as to whether any compensation, and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained? Yes _____ No _____
- An explanation of whom to contact for answers to pertinent questions about the research Yes _____ No _____
- An explanation of whom to contact for answers to questions about research subject's rights Yes _____ No _____
- An explanation of whom to contact in the event of research-related injury to the subject? Yes _____ No _____
- IRB Explanation at first mention: "...a group of individuals designated by the hospital under federal law to approve research studies. The North Memorial IRB monitors research related rights and safety of study subjects at North Memorial Medical Center." Yes _____ No _____
- A reference in the informed consent document to any requirements to provide or sign a HIPAA authorization when the HIPAA document is a separate item required for study participation. Yes _____ No _____
- A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled? Yes _____ No _____
- Anticipated circumstances under which the subject's participation may be terminated by the Investigator without regard to the subject's consent. Yes _____ No _____
- Federal required statement: 'A description of this clinical trial will be available on http://www.Clinical Trials.gov, as required by US Law. This web site will not include information that can identify you. At most, the web site will include a summary of the results. You can search this web site at any time.' Yes _____ No _____
- Signatures: · of those giving and obtaining consent · of any interpreters involved in the informed consent process · a relationship indication when the person consenting is not the study subject · the date and time of each signature being provided Yes _____ No _____

Include a sample copy of the Informed Consent Form with application.

INFORMED CONSENT ADDITIONAL ELEMENTS

When appropriate based on subject risk, one or more of the following elements of information shall also be provided to each subject.

- A statement that the particular treatment or procedure may involve risks to the subject (or the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable.
- Anticipated circumstances under which the subject's participation may be terminated by the Investigator without regard to the subject's consent.
- Any additional costs to the subject that may result from participation in the research.
- The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject.
- A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject.
- The appropriate number of subjects involved in the study.
- The informed consent requirements in these regulations are not intended to preempt any applicable Federal, State, or local laws which require additional information to be disclosed for informed consent to be legally effective.
- Nothing in these regulations is intended to limit the authority of a physician to provide emergency medical care to the extent the physician is permitted to do so under applicable Federal, State, or local law.

MINNESOTA STATUTES

In compliance with MN Statute 144.651 (Patient's Bill of Rights, Subdivision 10) I certify that I will obtain written, informed consent prior to a patient's participation in experimental research. I will respect the patient's right to refuse participation. I certify that, in compliance with this statute, I shall document both consent and refusal in the individual patient chart. This may be done either by placing a signed copy of the consent document into the chart or by placing a note in the chart which includes the:

- Title of Study,
- Date of Invitation to Participate,
- Name of Investigator Seeking Consent,
- Consent/Refusal of Patient,
- And, Signature.

VERIFICATION and APPROVAL of APPLICATION

I certify that the information furnished concerning the procedures to be taken for the protections of human subjects is correct. I will seek to obtain prior approval for any substantive modifications in the proposal and will report promptly any unexpected or otherwise significant adverse effects in the course of the study. I will conduct this study/project in conformance with Federal and IRB Oversight requirements.

_____ _____

Signature of Principal Investigator Date

_____ _____

Signature of Authorized Individual Granting Approval Date/Time

3300 Oakdale Avenue North • Robbinsdale, MN 55422-2900

Institutional Review Board
NEW STUDY Fee Statement

Invoice Date:

North Memorial Health
IRB Office
Robbinsdale Medical Building
3300 Oakdale Avenue North
Robbinsdale, MN 55422-2900

Phone: 763.581.0970

Fax: 763.581.0994

Project Title: _____

Principal Investigator: _____

Sponsor: _____

Make check payable to North Memorial Institutional Review Board.

Thank you.

☐ I am requesting fees be waived for this study.

Indicate reason for request: _____

Description:	Charges:	Credit:	Balance Due:
Initial Application	**$1000.00**		**$1000.00**

Office Use Only:

Please Remit With Application

Received Date: _____

Check Number: _____

Amount: $_____

Retain a Copy for Your Records

ATTACHMENT A: DEFINITIONS

Risks

The purpose of this section is to determine whether the human subjects involved in the proposed research project will be placed at risk. Definition follows:

Risk
Risk is the exposure of an individual to the possibility of injury as a direct or indirect consequence of participation in a scientific investigation. The examples which follow are intended to be representative but not exhaustive.

Physical
- Removal of organs or tissues for biopsy, transplantation or banking
- Administration of drugs or radiation
- Use of indwelling catheters or electrodes
- Requirement of, or potentiality for, strenuous physical exertion
- Ingestion or injection of a foreign substance into the body
- Undue stress or strong aversive stimulation on the body

Psychological
- Subjection to deceit or withholding of information
- Public exposure
- Humiliation
- Significant degree of discomfort
- Invasion of privacy
- Coercion
- Psychological damage

Social
- Loss of personal reputation or professional status
- Defamation of character
- Personal degradation in the eyes of others
- Placement in legal jeopardy
- Revelation of information related to sensitive social issues

Educational
- Over-use of subjects
- Participation in investigations which are not compatible with the educational goals of the institution or of the specific course from which subjects are drawn
- Collection of data which will serve to classify students

"Minimal risk" refers to investigative situations which may cause temporary and limited discomfort, irritation, or inconvenience. Examples are usually long contacts with the investigator; pursuit of potential embarrassing questions; prolonged boredom; venipuncture to obtain less than 40 ml of blood; collection of urine specimens.

"No risk" refers to investigations in which the subject is not, and cannot be, placed in jeopardy of any kind. Examples are discarded human materials obtained during surgery or in the course of diagnosis and treatment; non-intervening observation of anonymous public behavior when the behavior has not been filed, taped, photographed or permanently recorded; secondary use of data from anonymous individuals; and use of publicly available data whether or not individuals are identified.

ATTACHMENT B: CONSENT FORM RECOMMENDATIONS

The North Memorial IRB operates under Federal regulation and follows guidelines known as Good Clinical Practice established by the International Conference on Harmonization when reviewing research studies under its purview. We place great emphasis on the subjects' potential understanding of the consent form to be signed. To that end, we present a list of the minor grammatical and stylistic details which have frequently caused revision and delay in final approval of projects in the past. Also included is some of the reasoning behind our requirements. We strive to have the consent form be readable at an eighth-grade level.

- Avoid parenthesis. They interrupt the subject's reading flow of difficult material. Simply explain something the first time it is used.

- Avoid abbreviations except for common ones: e.g., ECG. Explain any such repeated abbreviation the first time it is used. Trying to save a few typed words in a long document only makes it harder for subjects to understand what is being presented.

- Be sure to modify the consent form with local names and phone numbers. When a consent form is presented with such statements as {Insert local names} or (Insert Name Here), it suggests a superficial and incomplete approach to the consent form, and—by extension—the rest of the project.

ATTACHMENT C: CHECKLIST

Please use the following checklist of items to ensure all the information is complete or has been addressed prior to submission to the Institutional Review Board.

The application states the research question (hypothesis) of the study	Yes _____	No _____
The application describes the subject population	Yes _____	No _____
Does the application summarize the tasks which the subject will be asked to complete?	Yes _____	No _____
Are the subjects placed at risk?		
Have you thoroughly described the risks in the application?	Yes _____	No _____
Have you made every possible provision for minimizing the risk?	Yes _____	No _____
Does the scientific merit of the study warrant placing subjects at risk?	Yes _____	No _____
Have you described the procedures employed to preserve confidentiality?	Yes _____	No _____
Have provisions been made to obtain consent from all individuals related to the study (e.g., subjects, physicians, parents, employers, etc.)?	Yes _____	No _____
Do the consent forms contain all the required elements of informed consent?	Yes _____	No _____
Have you described the procedures used to obtain informed consent?	Yes _____	No _____
Have all the questions in the application form been answered?	Yes _____	No _____
Have you attached copies of all the necessary instruments (questionnaires, tests, interview questions, solicitations, letters, research protocol, etc.)?	Yes _____	No _____
Has the application form been signed by the principal investigator:	Yes _____	No _____
Did you include the fee statement and payment or a request to have the fees waived? *** NOTE ** Application processing will not begin until after payment (or waiver request) is received.*	Yes _____	No _____
For studies involving a drug, have you contacted Pharmacy?	Yes _____	No _____
For device studies, have you contacted Surgery?	Yes _____	No _____
If your study requires an Order Set, have you contacted Quality at 763-581-4655?	Yes _____	No _____
For studies involving radiology, have you contacted Radiology?	Yes _____	No _____
If your study will require labs, have you contacted North Memorial Lab?	Yes _____	No _____

RETURN MATERIALS TO:

Institutional Review Board
3300 Oakdale North
Robbinsdale, MN 55422
763-581-0970

You may also e-mail your application, Informed Consent and Protocol to: IRB@northmemorial.com