Institutional Review Board
New Study Application

The Nebraska Methodist Hospital
8303 Dodge Street
Omaha, Nebraska 68114
(402) 354-4035

	MIRB ID#	IRB Meeting Date dd/mmm/yyyy	Attachment ID	Completed By (initial / date)
IRB Office Only				

This Application is to request initial review of a proposed clinical research Study involving human Subjects. This form is not for status reports of previously approved clinical research. This Application may be submitted by an investigator/researcher or their designee.

Submission to IRB Date:

TITLE of Clinical Research Study*

Principal Investigator's Name / Credentials*

Department / School*

Office Address*

Office Phone*

Email Address*

Employment Status*

- ☐ Employee or Contractor of Nebraska Methodist Health System or any affiliate
- ☐ Student of Nebraska Methodist College
- ☐ Student of
- ☐ Non-Employee / Non-Student

Sub-Investigator's Name / Credentials

Sponsor/Manufacturer's Name / Credentials*

Contact Information

Office Address*

Office Phone*

Email Address*

Study Conduct will take place:*

select all that apply

- ☐ Methodist Hospital Main Campus
- ☐ Methodist Women's Hospital
- ☐ Methodist Jennie Edmundson Hospital
- ☐ Methodist Fremont Health
- ☐ Methodist Physicians Clinic, specifically
- ☐ Other,

National Clinical Trial (NCT) Number or Clinical Trial Identifier (IDE)

Webpage / Link

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The proposed research involves the following vulnerable Subject populations:*

- ☐ Not Applicable
- ☐ Pregnant Women
- ☐ Infants / Children
- ☐ Disabled, define:
- ☐ Other

Please provide a summery statement addressing each of the following sections. If referencing a document, ensure all summary documents such as a protocol are part of the Application.

Nature and Purpose of the Study*

Describe the overall purpose of the Study.

Characteristics of Subject Population*

Describe the characteristics of the Subject populations, including but not limited to, the number of Subjects to be enrolled, age ranges, gender, ethnic background, health status, criteria for inclusion and exclusion, and justification for the utilization of any vulnerable populations.

Generalizability* **(only required if a non-industry sponsored study)**

Describe whether one intent of the study is to contribute to or develop generalizable knowledge, to generate conclusions or research findings can be applied to other groups or settings and yield the same or similar results

Method of Subject Selection*

Describe the methods to be employed in the identification and recruitment of potential Subjects.

Risks to the Subjects*

Describe the potential risks of taking part in the Study, including probability, severity, potential duration, and reversibility of risks.

Protection Against Risks*

Describe the procedures to be utilized to prevent or minimize any potential risks.

Benefits*

Describe any potential benefits to be gained by the Subject(s) as well as benefits to medical science or society in general.

Risk-Benefit Analysis*

Describe why the risk(s) to Subjects are reasonable in relation to the anticipated benefits to the Subject and/or in relation to the importance of the knowledge that may reasonably be expected to result.

Alternatives*

Describe any available alternatives for Subjects if subjects choose not to participate.

Informed Consent*

Describe the process by which you will obtain the informed consent from each Subject, addressing

I) who conducts the main consent discussion with the Subject.
II) when this discussion takes place.
III) who is present at this discussion and what materials are presented to the Subject.
IV) when the Subject is asked to sign the consent documents.
V) whether the Subject is provided with a copy of the consent document.
VI) whether you anticipate ever enrolling a Subject with a surrogate consent because the Subject is not competent to consent form himself/herself.
VII) any circumstances under which you might enroll a Subject without informed consent.

Privacy*

Describe how privacy and confidentiality of Subjects will be maintained, including how Study data will be protected.

Documentation*

List an documents being submitted with this application.

Financial Considerations*

Have Financial Disclosure Forms (FDF) been submitted on behalf of each applicable delegated staff member? *If no, provide a detailed explanation.*

☐ Yes ☐ N/A ☐ No

Do any delegated staff members have any financial or other significant interest in the sponsor/manufacturer? *If yes, provide a detailed explanation.*

☐ Yes ☐ N/A ☐ No

Will the subjects incur any additional costs or charges for participating in this study, beyond the standard of care? *If yes, provide a detailed explanation.*

☐ Yes ☐ N/A ☐ No

Will there be any compensation from the Study sponsor, Study group, or other interested party directly to any Study investigators or staff involved in the conduct of the Study, whether designated for the Study budget, fees, expenses, or otherwise? *If yes, provide detailed explanation.*

☐ Yes ☐ N/A ☐ No

Research / Investigator Status*

Has the proposed Study, or any substantially similar Study, previously been denied approval or had its approval suspended or revoked by this IRB or any other IRB. *If yes, provide detailed explanation.*

☐ Yes ☐ N/A ☐ No

Has Principal Investigator or any delegated staff ever been subject to any of the following, is currently under investigation for any of the following, or other formal action pending with could lead to such result as listed below. *If yes, provide detailed explanation.*

1. Revocation of approval to serve as an Investigator or delegated staff on a research Study.
   ☐ Yes ☐ N/A ☐ No
2. Debarment or disqualification from any government program, private grant, or research program.
   ☐ Yes ☐ N/A ☐ No
3. Criminal prosecution or civil lawsuit seeking criminal penalties, injunction, or damages related to clinical research.
   ☐ Yes ☐ N/A ☐ No

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Additional Information

Investigator's Certification

I certify the provided information on this form is complete and accurate to the best of my knowledge. I will advise The Nebraska Methodist Institutional Review Board of any changes to the above completed fields when I become aware. I also agree to all periodic reporting requirements, and with all applicable laws and regulations. I agree to The Nebraska Methodist Institutional Review Board's Schedule of Fees for processing required submitted documents within the required timeline.

Signature of Principal Investigator or designee*/**

Printed Name of Principal Investigator or delegated staff*

Title of Principal Investigator or delegated staff*

Date (If not provided above)

* required field

** An electronic signature or typed name constitutes a binding electronic signature for this study.