

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 Trial Participants. 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:\*

Methodist Hospital Main Campus

Methodist Women's Hospital

select all that apply Methodist Jennie Edmundson Hospital

Methodist Fremont Health

Methodist Physicians Clinic, specifically

Other,

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

Webpage / Link



The proposed research involves the following vulnerable Trial Participant populations:\*

	Not Applicable
	Pregnant Women
	Infants / Children
	Disabled, define:
	Other
	addressing each of the following sections. If referencing a document, cuments such as a protocol are part of the Application.
Nature and Purpose of the Study* Describe the overall purpose of the Study.	
	ation* oulations, including but not limited to, the number of Trial Participants to be enrolled, age range clusion and exclusion, and justification for the utilization of any vulnerable populations.
Generalizability* (only required if a non-industry  Describe whether one intent of the Study is to contribut be applied to other groups or settings and yield the same	te to or develop generalizable knowledge, to generate conclusions or research findings can
Method of Trial Participant Selection*  Describe the methods to be employed in the identificat	ion and recruitment of potential Trial Participants.
Risks to the Trial Participants*	

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 Trial Participant(s) as well as benefits to medical science or society in general.

### Risk-Benefit Analysis\*

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

#### Alternatives\*

Describe any available alternatives for Trial Participants if they choose not to participate.

#### **Informed Consent\***

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

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



### Privacy\*

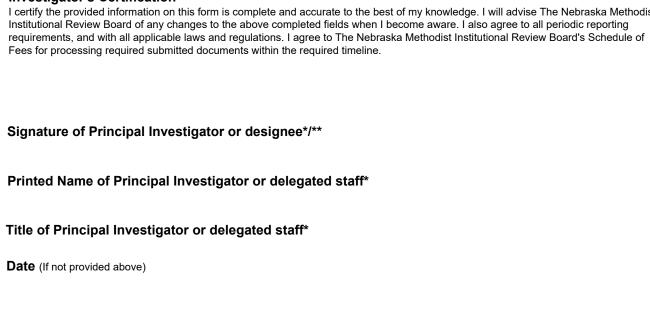
Describe how privacy and confidentiality of Trial Participants will be maintained, including how Study data will be protected.

Documentati	on*		
List an document	ts being submit	ted with this applic	cation.
Financial Co	nsideration	<u>ıs</u> *	
Have Financial D	isclosure Form	s (FDF) been sub	omitted on behalf of each applicable delegated staff member? If no, provide a detailed explanation.
Yes	N/A	No	
Do any delegate	d staff member	s have any financ	ial or other significant interest in the sponsor/manufacturer? If yes, provide a detailed explanation.
Yes	N/A	No	
Will the Subjects	s incur any add	itional costs or cha	arges for participating in this Study, beyond the standard of care? If yes, provide a detailed explanation.
Yes	N/A	No	
			ponsor, Study group, or other interested party directly to any Study investigators or staff involved in the Study budget, fees, expenses, or otherwise? <i>If yes, provide detailed explanation.</i>
Yes	N/A	No	
Research / I	nvestigator	Status*	
		/ substantially sim e detailed explana	ilar Study, previously been denied approval or had its approval suspended or revoked by this IRB tion.
Yes	N/A	No	
			ever been Trial Participant to any of the following, is currently under investigation for any of the Id lead to such result as listed below. <i>If yes, provide detailed explanation.</i>
1. Revocation	of approval to	serve as an Inves	tigator or delegated staff on a research Study.
Yes	N/A	No	
2. Debarment	or disqualificat	ion from any gove	ernment program, private grant, or research program.
Yes	N/A	No	
3. Criminal pro	osecution or civ	vil lawsuit seeking	criminal penalties, injunction, or damages related to clinical research.
Yes	N/A	No	



#### **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



<sup>\*</sup> required field

<sup>\*\*</sup> An electronic signature or typed name constitutes a binding electronic signature for this study.