METHODIST
The Nebraska Methodist Hospital
8303 Dodge Street
Omaha, Nebraska 68114
(402) 354-4000

Institutional Review Board
Request for Waiver of Consent and/or HIPAA Authorization Form

This form is to request the IRB waive either some or all components of informed consent and individual authorization for use or disclosure or Protected Health Information (PHI) under HIPAA regulations. Requirements for approval are in The Nebraska Methodist Hospital IRB Handbook. This form should be submission in addition to a Request for Review of Investigational Study.

TITLE of Clinical Research Study*

Principal Investigator's Name / Credentials*

Submission to IRB Date*

Summary of Report
Check all applicable fields

- ☐ Waiver of Informed Consent Form requirement
- ☐ Waiver of Authorization for Use and Disclosure of Information (HIPAA waiver)
- ☐ Alteration of some or all elements of informed consent (if alterations, specify)

Summary of Report*

Consent Waiver or Alteration

By requesting this waiver/alteration, you must certify each of the following elements will be met by providing an detailed explanation.

I certify this research involves no more than minimal risk to subjects. (Explain any/all risks and why they are no more than minimal.)

I certify the alteration/waiver will not adversely effect the rights and welfare of the subjects. (Explain.)

I certify this research could not practicably be carried out without the waiver or alteration. (Explain.)

METHODIST

The Nebraska Methodist Hospital
8303 Dodge Street
Omaha, Nebraska 68114
(402) 354-4000

Institutional Review Board
Request for Waiver of Consent and/or HIPAA Authorization Form

I certify, whenever appropriate, the subjects will be provided with additional pertinent information. (Confirm if appropriate, then explain method.)

HIPAA Waiver

By requesting this waiver of authorization for use and disclosure of information, you are certifying each of the following elements will be met, and for each element, must provide a detailed explanation.

I certify this study will involve no more than minimal risk to the privacy of individuals, including each of the following:

I have an adequate plan to protect individual identifiers from use and disclosure. (Describe.)

I have an adequate plan to de-identify individual personal health information (PHI) at the earliest opportunity consistent with the conduct of the research, except when there is a health or research justification for retaining the identifiers or retention is required by the law. (Describe the plan or the basis for any exemptions.)

I assure protected health information (PHI) will not be reused or disclosed to anyone else except as required by law, or for authorized research oversight, or for other research for which use/disclosure would be permitted under HIPAA. (Explain in detail.)

The Nebraska Methodist Hospital
8303 Dodge Street
Omaha, Nebraska 68114
(402) 354-4000

Institutional Review Board
Request for Waiver of Consent and/or HIPAA Authorization Form

I certify the research could not practicably be conducted without the waiver of individual authorization. (Explain.)

I certify the research could not practicably be conducted without access to and use of PHI. (Explain.)

I certify the PHI being accessed and used is minimally necessary PHI for research purposes. (Explain.)

Documentation*

List any documents submitted with this request

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.

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.