**** **FORM 6**

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**

**Use of Form:** This form is to be used by the Principal Investigator of a study, to request that the IRB waive (1) some or all of the requirements of informed consent, and (2) individual authorization for use or disclosure of Protected Health Information (PHI) under HIPAA privacy regulations. Waivers should be requested, and will be granted, **rarely**, and only if all of the criteria described in this form are clearly met. Before submitting this form, the Investigator should carefully study Tab V, Informed Consent and Privacy, in The Nebraska Methodist Hospital *Handbook for IRB Members and Investigators*.

This form should be submitted in addition to the separate form entitled Request for Review of Investigational Study.

**1. Title of Study**:

**2. Principal Investigator’s Name:**

**3. Date of this Request:**

**4. Specify nature of request (check all which apply):**

** Alteration of some or all elements of informed consent (if alterations, specify):**

** Waiver of informed consent requirement**

** Waiver of Authorization for Use and Disclosure of Information (HIPAA waiver)**

**5. Consent Waiver or Alteration. By requesting an alteration or waiver of informed consent, you are certifying that each of the following elements will be met, and for each element, must provide a detailed explanation:**

**a. I certify that the research involves no more than minimal risk to the subjects. (Explain all risks and why they are no more than minimal):**

**b. I certify that the waiver or alteration will not adversely affect the rights and welfare of the subjects. (Explanation):**

**c. I certify that the research could not practicably be carried out without the waiver or alteration. (Explanation):**

**d. I certify that whenever appropriate, the subjects will be provided with additional pertinent information after participation. (State whether or not this will be appropriate, and explain):**

**6. HIPAA Waiver. By requesting a waiver of authorization for use and disclosure of information (HIPAA waiver), you are certifying that each of the following elements will be met, and for each element, must provide a detailed explanation:**

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

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

**(ii) I have an adequate plan to destroy individual identifiers 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 law. (Describe the plan, or the basis for any exceptions):**

**(iii) I assure that 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):**

**b. I certify that the research could not practicably be conducted without the waiver of individual authorization. (Explanation):**

**c. I certify that the research could not practicably be conducted without access to and use of PHI. (Explanation):**

**d. I certify that the PHI being accessed and used is the minimally necessary PHI for the research purposes. (Explanation):**

**Investigator's Certification**: I certify that the foregoing is complete and accurate. I will advise the IRB Chairperson if there are any changes.

Signature of Principal Investigator:

Date Submitted: