



NKTIREC FORM 3.9: WAIVER OF CONSENT

Request for Waiver of Informed Consent

NKTIREC Code:
PRINCIPAL INVESTIGATOR:
PROTOCOL TITLE:

I am requesting a waiver of informed consent. I believe that this protocol is eligible for waiver or alteration of all required elements of informed consent because the protocol meets all of the following criteria:

1. The risk to the subject’s privacy is minimal.

The investigator of this study will use the minimum amount of protected health information necessary to conduct the research. This study will only need charts of eligible subjects. There will be no sensitive information (e.g., illegal drug use, sexual practices) to be collected. There is an assurance written below that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of protected health information would be permitted by the Privacy Rule.

2. This research cannot practicably be conducted without the use of the protected information.

3. This research cannot practicably be conducted without the waiver.

- a. The number of research subjects proposed.
- b. Difficulty of obtaining individual authorization and time since last contact with the research subjects.

RESEARCH ASSURANCES:

“As a principal investigator of the research described above, I make the following assurance to the NKTIREC Research Ethics Committee regarding the use and disclosure of protected health information.

*The investigators and research staff who used the disclosed protected health information in connection with this research will not reuse the protected health information or disclose to any other person or entity other than those authorized to receive it, except:

- 1. As required by law,
- 2. For authorized oversight of the research study, or
- 3. For other research which the use or disclosure of protected health information would be permitted by the Data Privacy Act of 2012

Name and Signature of Principal Investigator

Date