Waiver of Informed Consent (Form B)

Federal regulations require that investigators obtain the informed consent of each research participant (or the participant's legally authorized representative) and document consent with a written consent form. This requirement must be met in all cases, except in very specific circumstances in which the North Texas Regional Institutional Review Board (IRB) is authorized to grant a "waiver."

The IRB can grant two types of waivers:

(1) Waiver of documentation of informed consent; or

(2) Waiver of informed consent.

If a researcher believes that either waiver is necessary to the conduct of their research, then he/she may request a waiver from the IRB. Please select the appropriate waiver form, and provide the information necessary to make your request. Submit "Form A" or "Form B" (not both) with your IRB application materials.

Form B-Waiver of Informed Consent:

There are four conditions which may substantiate a waiver of informed consent:

(1) The research presents no more than minimal risk to subjects

Federal regulations define **minimal risk** as *"the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests."*

(2) The waiver will not adversely affect the rights and welfare of the subjects

This is a difficult criterion to address as federal regulations do not define "rights and welfare". However, the waiver cannot place the subjects at risk or waive any inherent rights available to human subjects participating in research.

(3) The research could not practicably be carried out without the waiver; and

For example, this can involve a protocol where incomplete disclosure is necessary to accomplish the research objective and informed consent does not intentionally affect the objective; or it is clearly not practical to obtain consent such as in observational studies.

(4) Whenever appropriate, the subjects will be provided with additional pertinent information after they have participated in the study

The subjects should be "debriefed" after the completion of the study or research procedure(s). This is particularly pertinent to deception studies.

Example: A retrospective chart review or an observational study can fall under these conditions.

PLEASE DO NOT SUBMIT WITH APPLICATION

NORTH TEXAS REGIONAL INSTITUTIONAL REVIEW BOARD

UNIVERSITY *of* NORTH TEXAS HEALTH SCIENCE CENTER

Request for Waiver of Informed Consent

Form B

I R B #

Investigator's Name:

Institution (UNTHSC or JPS): **Department:**

Project Title:

Informed consent refers to a process whereby the researcher obtains the willingness of the participant to be included in research once all the necessary elements of consent (specified in federal regulations) have been disclosed. All elements must be fully disclosed so the subject can make an informed decision to participate in research. Thus, when the North Texas Regional Institutional Review Board (IRB) grants a waiver of informed consent, it is either waiving the requirement of a consent process **entirely** or the requirement to **fully** disclose all elements of consent.

Please initial the appropriate blank:

_____ *(initial)* I am requesting a waiver of the consent process.

Explanation:

OR

_____ *(initial)* I wish to refrain from fully disclosing certain elements of consent? If so, please attach a separate document specifying which element (s) and why?

In order for the IRB to grant this waiver, **all** of the following conditions must be met. **Please initial next to *each* condition stating that these conditions have been (or will be) met**.

_____ *(initial)* The research involves no more than minimal risk to the participants.

_____ *(initial)* The waiver will not adversely affect the rights and welfare of the participants.

_____ *(initial)* The research could not practicably be carried out without the waiver. "Practicably" means there is no practical way to either implement a consent procedure or disclose all the elements of consent without jeopardizing the validity of the study.

_____ *(initial)* Whenever appropriate, the participant will be provided with additional pertinent information after participation.

Provide a brief explanation as to how your study protocol has met or will meet the above criteria.

Investigator's Signature_____ **Date**_____

IRB Chair's Signature_____**Date**_____