**NORTH TEXAS REGIONAL INSTITUTIONAL REVIEW BOARD**

*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**](#FormB)**-Waiver of Informed Consent:**

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

1. ***The research involves 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.”*

1. ***The research could not practicably be carried out without the waiver;***

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.

1. ***If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format;***

The study team should provide an explanation or justification for why the project cannot be completed without the use of the identifiable information or identifiable biospecimens (as opposed to using de-identified information or biospecimens).

1. ***The waiver will not adversely affect the rights and welfare of the subjects; and***

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.

1. ***Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after they have participated in the study***

The subjects or legally authorized representatives 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 THIS GUIDANCE DOCUMENT**

**NORTH TEXAS REGIONAL INSTITUTIONAL REVIEW BOARD**

***Request for Waiver of Informed Consent***

**Form B**

**IRB #**

**Investigator’s Name:**

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

**Title of Project:**

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 submit a separate document specifying which element (s) and why?

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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 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)* If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format.

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

\_\_\_\_\_ *(initial)* Whenever appropriate, the participant or legally authorized representative 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.**