

*Waiver of Documentation of Informed Consent
(Form A)*

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 UNTHSC IRB is authorized to grant a "waiver."

The UNTHSC 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 UNTHSC 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 A-Waiver of Documentation of Consent:

There are 2 conditions which may substantiate a waiver of documentation of informed consent:

- (1) *The only record linking the participant and the research would be the consent document and the principal risk would be the potential harm resulting from the breach of confidentiality. This refers to instances where participants could be seriously harmed if it became known that they were participants in the research.*

Example: Conducting interviews with street gang members about illegal gang activities. The only record of the name or other identifying information of the subject would be the signed form and knowledge of an individual's participation or information provided could lead to potential legal, social, or physical harm.

- (2) *The research presents no more than minimal risk of harm to participants and involves no procedures for which written consent is normally required outside of the research context.*

Example(s): This refers to procedures such as mail surveys or brief interviews over the telephone or at public events/venues that elicit non-sensitive information.

PLEASE DO NOT SUBMIT WITH APPLICATION

UNIVERSITY of NORTH TEXAS HEALTH SCIENCE
CENTER
OFFICE for the PROTECTION of HUMAN SUBJECTS
INSTITUTIONAL REVIEW BOARD

*Request for Waiver of Documentation
of Informed Consent
Form A*

IRB #

Investigator's Name:

Title of Project:

Documentation of consent means that participants are required to sign a consent form, thereby documenting their consent. A waiver of documentation means that the UNTHSC IRB is waiving the requirement to obtain the participant's signature. Even if this waiver is granted, a consent process must still be in place. The consent process must contain all the required elements of consent and usually consists of a consent form/verbal script that is read aloud to them.

For the UNTHSC IRB to grant this waiver, your research project must meet one of the following conditions. *Please initial the line next to the appropriate condition and explain why your research meets the condition in the space provided.*

_____ (initial) **Condition 1-** The only record linking the participant and the research would be the consent document and the principal risk would be the potential harm resulting from the breach of confidentiality. This refers to instances where participants could be seriously harmed if it became known that they were participants in the research.

Explanation:

OR

_____ (initial) **Condition 2-** The research presents no more than minimal risk of harm to participants and involves no procedures for which written consent is normally required outside of the research context.

Explanation:

Investigator's Signature _____ Date _____

IRB Chair's Signature _____ Date _____