UNIVERSITY OF NORTH TEXAS®

Institutional Review Board
Request for Waiver or Alteration of Consent Process

In most cases, written or electronic informed consent must be sought from each subject before research procedures begin. However, per HHS regulations, the IRB may approve research where investigators leave out or alter elements of informed consent if the research meets all the applicable regulations in 45 CFR 46.116(f).

Justification: To approve the waiver request, the IRB must have sufficient justification for ALL of the following criteria per 45 CFR 46.116(f). **For each statement below, check "yes" or "no" to determine if your study fulfills the requirement**. If the study cannot provide sufficient justification that the regulatory criteria are met, a waiver or alteration of the required elements of consent is not possible.

1. The research in its entirety involves no greater than minimal risk*. ☐ Yes ☐ No
2. The waiver of consent will not adversely affect the rights and welfare of the subjects. ☐ Yes ☐ No
3. 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. ☐ Yes ☐ No ☐ N/A
4. It is not practical to conduct the research without the waiver/alteration. ☐ Yes ☐ No
5. Whenever appropriate, subjects or legally authorized representatives will be provided with additional pertinent information after their participation. ☐ Yes ☐ No

**Minimal risk means that 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.*

Request for a waiver of documentation of written consent (no physical or electronic signature)

- Will you require this waiver for all subjects in the study, or only for some subjects (describe groups)?

- Indicate your method of obtaining Informed Consent without a written or electronic signature, i.e. verbal or passive consent.

Justification: To approve the waiver request, the IRB must have sufficient justification for AT LEAST ONE of the following criteria per 45 CFR 46.117(c). **Describe how your study fulfills at least one of the requirements below.** If the study does not meet at least one of the criteria, a waiver of the written or electronic signature is not possible.

1. The only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject (or legally authorized representative) will be given the option to take a copy of the consent form, and the subject's wishes will govern.

OR

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

OR

3. If the subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk* of harm to subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained.

**Minimal risk means that 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.*