

**INSTITUTIONAL REVIEW BOARD**

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

**Date:**

**Principal Investigator:**

**Study Title:**

**Protocol #:**

A Waiver of Documentation of Informed Consent may be appropriate when an IRB requires the process of consent but waives the requirement for the investigator to obtain a signed consent form for some or all subjects. The Waiver may be applied to all or part of the research.

1. Why are you requesting a waiver of the requirement to obtain the subject’s signature to document informed consent?

1. For which group or research activity are you seeking the waiver?

1. How will you determine that the subject has provided verbal consent or has implied informed consent? **Make sure the script you will be using to describe the study is included with your IRB application.**

1. Choose only ONE option below. Below the selected checkbox, explain why the research activity meets the regulatory criterion.

The only record linking the subject and the research would be the informed consent form and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject (or legally authorized representative) will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern.

That 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;

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.

I attest that I have carefully reviewed this Request for Waiver of Documentation of Informed Consent.

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**Principal Investigator Name Faculty Advisor Name** *(if PI is a student)*