WAIVER OF DOCUMENTATION OF INFORMED CONSENT

This form is intended for projects that use an informed consent process but do not collect documentation of that informed consent. This form should be completed and submitted along with the appropriate IRB application form and other relevant documents. If a project does not use an appropriate informed consent process, please use the "Waiver of Informed Consent" form.

Section 1. Protocol Information

Principal Investigator:

Project Title:

Is this research regulated by the US Food and Drug Administration? ☐ Yes ☐ No

Section 2. Request for Waiver of Documentation

Please check the appropriate justification below. Only one box should be checked. The IRB may require the investigator to provide subjects with a written statement regarding the research, even though the documentation requirement may be waived.

☐ 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 will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern. (Note: A waiver of documentation of informed consent is not permissible under this category if the research is subject to FDA regulations.)

☐ 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 the consent.

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

Explain the justification in more detail below. Attach additional paper if necessary.