WAIVER OF WRITTEN (SIGNED) CONSENT FORM

Justification for a Waiver. The IRB may waive the requirement for written (signed) consent if either of the following is true:

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 (e.g., study topic is sensitive and public knowledge of participation and responses could be damaging). *Participants should be asked whether they want documentation linking them with the research, and the participants' wishes will govern whether they sign the form.* (This justification cannot be used in FDA-regulated research.)

2. The research presents no more than minimal risk of harm to subjects and involves no procedures for which written (signed) informed consent is normally required outside of the research context (e.g., phone survey or interview).

For the IRB to consider your request, **answer in full** each of the following, ensuring that each explanation is detailed and thorough, and provide supporting documents as needed.

1. Title of the study in capital letters and bold font

2. Will waiving the written (signed) informed consent adversely affect subjects, their rights, or their welfare? Explain.

3. Will pertinent information be provided to the subjects later, if appropriate? If so, state when and how. If not, explain why not.

4. Explain the plan to protect identifiers adequately from improper use and disclosure.

Principal Investigator _____ Date _____

Co-Investigator(s) _____ Date _____