HS #:
LR Last Name: Barsever

Appendix P
REQUEST FOR A WAIVER OF WRITTEN (SIGNED) CONSENT

Please read the HRP webpage for information about the waivers of documentation of the informed consent process.

The IRB may, in some instances, waive requirement to obtain written (signed) consent in accordance with specific criteria [45 CFR 46.117(c)(1-2)]. To request approval for a waiver of written (signed) consent, the research must meet one of the following three criteria.

Please click the appropriate option below and complete the corresponding question(s):

☒ **Option 1:** The research qualifies for Exempt review (i.e., there is virtually no risk to subjects and it falls into one of the six (6) federally-defined exempt categories. *Research that qualifies for Exempt review is "exempt" from federal regulations; however the UCI IRB is required to confirm Exempt status.*

☐ **Option 2:** 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 *[45 CFR 45.117(c)(1)] .**

Notes: Under this circumstance, the IRB usually requires that the researcher submit a **study information sheet** that addresses the basic elements of informed consent. Per federal regulations, subjects must be asked whether they want to sign a consent document. If so, the IRB recommends they sign the study information sheet.

If Protected Health Information (PHI) is to be used, created, or disclosed as part of the research study, information on what PHI will be collected, with whom it will be shared, how it will be kept confidential, and when it will be destroyed must be conveyed to the participant unless you also request a Waiver of HIPAA Authorization (Appendix T).

a. Is the research subject to FDA regulations *i.e., the research involves drugs, medical devices, or biologics)*?
Yes - the research is subject to FDA regulations.

Note: this option cannot be selected for research subject to FDA regulations. Option 3 is available if the criteria for the waiver can be met. If the criteria for the waiver cannot be met, written (signed) consent must be obtained from subjects.

[If written (signed) consent is required, return to the Procedures link in the blue bar and "uncheck" Waiver of Written (signed) Consent].

No - the research is not subject to FDA regulations (answer question #b).

b. Explain why the primary risk of the research is the harm from a possible breach of confidentiality and clarify whether the *only* document linking the subject and the research would be the signed consent form:

☐ **Option 3:** 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 *[45 CFR 45.117(c)(2)].**

Notes:

Under this circumstance, the IRB requires that the researcher submit a **script, study information sheet or an introduction letter** that addresses the basic elements of informed consent.

If Protected Health Information (PHI) is to be used, created, or disclosed as part of the research study, information on what PHI will be collected, with whom it will be shared, how it will be kept confidential, and when it will be destroyed must be conveyed to the participant unless you also request a Waiver of HIPAA Authorization (Appendix T)

a. Explain why the research qualifies as minimal risk:

b. Provide a rationale why the research procedures would not normally require a signed consent form outside the research environment: