WAIVER OF DOCUMENTATION OF INFORMED CONSENT (45CFR46.117(C))

ALL APPLICATIONS MUST BE TYPEWRITTEN, SIGNED, AND SUBMITTED AS SINGLESIDED HARD COPY. PLEASE, NO STAPLES!

Responsible Project Investigator (RPD):

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<tr>
<th>Last Name:</th>
<th>First Name:</th>
<th>Dept. or Unit:</th>
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<td>Phone:</td>
<td>Fax:</td>
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Project Title:

To request a waiver of documentation (signature) of informed consent, please provide a response to EITHER of the following questions. Please be specific in explaining why either statement is true for this research.

(I) That 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 regulation.

(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. **

** In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.

RPI Signature: ___________________________ Date: _________________

IRB Member Approval: ___________________________ Date: _________________