

## Waiver of Informed Consent

All forms must be typewritten and submitted as an attachment with the IRB application.

### Section 1. PROTOCOL INFORMATION

<b>1A. Principal Investigator:</b>
<b>1B. Project Title:</b>
<b>1C. Is this research regulated by the U.S. Food and Drug Administration?</b> <input type="checkbox"/> Yes <input type="checkbox"/> No

### Section 2. REQUEST FOR WAIVER OF INFORMED CONSENT

<p>A consent procedure that does not document obtained consent through a physical signature may be approved by the IRB under certain conditions. To request IRB approval of a consent procedure that does not document consent through a physical signature, provide a response to <b>only one</b> of the following. Note that the IRB will require the investigator to provide participants with a written statement regarding the research even though the signature requirement may be waived.</p>
<p><b>2A. The only record linking the participant and the research would be the consent document, and the principal risk would be potential harm resulting from a breach of confidentiality. Each participant will be asked whether he/she wants documentation linking him/her with the research, and the participant's wishes will govern. (Note: A waiver of informed consent is not permissible under this category if the research is subject to FDA regulations.)</b></p>
<p><b>2B. The research presents no more than minimal risk of harm to participants and involves no procedures for which written consent is normally required outside the consent.</b></p>
<p><b>2C. The participants 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 participants, and there is an appropriate alternative mechanism for documenting that informed consent was obtained.</b></p>