WAIVER OR ALTERATION OF INFORMED CONSENT * (45CFR46.116(D))

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

Responsible Project Investigator (RPI):

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<th>Dept. or Unit:</th>
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Project Title: ___________________________________________________________________________

* FDA regulated research is not eligible for a waiver or alteration of informed consent. Research supported by the Department of Defense¹ may not be eligible for this waiver.

A consent procedure which does not include, or which alters, some or all of the elements of informed consent may be approved by the IRB under certain conditions. To request IRB approval of a waiver of the requirement to obtain informed consent completely, or of a consent procedure which does not include, or which alters, some or all of the elements of informed consent, please provide a response to ALL of the following questions. Please be specific in explaining why each statement is true for this research.

1. The research involves no more than minimal risk to the subjects.

   __________________________________________________________________________

2. The waiver or alteration will not adversely affect the rights and welfare of the subjects.

   __________________________________________________________________________

3. The research could not practically be carried out without the waiver or alteration.

   __________________________________________________________________________

4. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

   __________________________________________________________________________

☐ This research is not FDA regulated.
☐ This research is not funded by the Department of Defense.¹

RPI Signature: ______________________________________________________________________ Date: ______________________________________________________________________

IRB Member Approval: __________________________________________________________________ Date: ______________________________________________________________________

¹ If the research subject meets the definition of “experimental subject,” a waiver of consent is prohibited unless a waiver is obtained from the Secretary of Defense. If the research subject does not meet the definition of “experimental subject,” the IRB may waive consent.