WAIVER OF INFORMED CONSENT

This form is intended for projects that do not include a fully informed consent process. This form should be completed and submitted along with the appropriate IRB application form and other relevant documents. If a project does use an appropriate informed consent process, but no tangible documentation of that informed consent exists, please use the "Waiver of Documentation of Informed Consent" form.

Section 1. Project Information

Principal Investigator:

Project Title:

Is this research regulated by the US Food and Drug Administration? ☐ Yes ☐ No

Is this research regulated by the US Department of Defense? ☐ Yes ☐ No

Section 2. Request for Waiver

To request IRB approval of a study which does not include an informed consent process, please provide a detailed and specific response to the following questions. Attach additional paper as necessary.

Which aspects of the informed consent process will not be followed in this project? (Select all that apply)

☐ 1. Consent form omits relevant details and/or deceives subjects about the nature of the research

☐ 2. Subjects will not have the opportunity to ask questions before giving consent

☐ 3. Research involves secondary analysis of existing data for which broad consent was obtained

☐ 4. Research involves secondary analysis of existing data and it is not possible to solicit informed consent from the original subjects

☐ 5. Consent forms are not being used at all

☐ 6. Other (explain)

Explain why and how the research involves no more than minimal risk to the subjects.

Explain why the waiver will not adversely affect the rights and welfare of the subjects.

Are identifiable private information and/or biospecimens being collected? ☐ Yes ☐ No

If yes, explain why the research could not practicably be carried out without using such information or biospecimens in an identifiable format.

Explain why the research could not be practicably be carried out without the waiver of informed consent.

If a waiver of informed consent is approved by the IRB, will subjects be provided with additional pertinent information after participation? ☐ Yes ☐ No

Either describe this additional pertinent information or explain why it will not be provided to the subjects.