

**INSTITUTIONAL REVIEW BOARD**

**Request for Waiver or Alteration of Informed Consent**

**Date:**

**Principal Investigator:**

**Study Title:**

**Protocol #:**

**Section I.**

According to the basic elements of informed consent, the following information should be provided to each subject. Please check the box next to the element(s) you are requesting to alter or waive and proceed to the questions below.

A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject’s participation, a description of the procedures to be followed, and identification of any procedures which are experimental.

A description of any reasonably foreseeable risks or discomforts to the subject.

A description of any benefits to the subject or to others that may reasonably be expected from the research.

A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.

A statement describing the extent, if any, to which confidentiality of records identifying the subjects will be maintained.

For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained.

An explanation of whom to contact for answers to pertinent questions about the research and research subjects’ rights, and whom to contact in the event of a research-related injury to the subject.

A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subjects is otherwise entitled.

One of the following statements about any research that involves the collection of

identifiable private information or identifiable biospecimens:

1. A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility; or
2. A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

**Section II.**

Please provide a response to the following questions as they apply to your research. The IRB may waive or alter the requirement of informed consent under 45 CFR 46.116, provided that the IRB finds and documents that all of the following conditions are met. Please be specific in explaining why each statement is applicable to your research.

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

1. Explain why the research could not practicably be carried out without the requested waiver or alteration.

1. If the research involves using identifiable private information and/or identifiable biospecimens, explain why the research could not practicably be carried out without using such information or biospecimens in an identifiable format.

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

1. Explain how, whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation.

I attest that I have carefully reviewed this Request for Waiver or Alteration of Informed Consent.

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**Principal Investigator Name Faculty Advisor Name** *(if PI is a student)*