***Important Note**: This Request for Waiver is not applicable to FDA regulated studies*

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Request for Waiver of the Requirement to Consent Subjects or Alteration of Consent Elements

(Attachment for Human Research Review Application Section VII(3))

Check Applicable Box:

☐ Waiver of Consent Requested

☐ Alteration of Consent Elements Requested. Describe alterations below.

1. Will the research in its entirety involve greater than minimal risk*?

   ☐ YES - No waiver or alteration can be approved by the IRB.

   ☐ NO - Explain below how your research fits the minimal risk definition.

2. Is it practical to conduct the research without the waiver or alteration?

   ☐ YES - No waiver or alteration can be approved by the IRB.

   ☐ NO - Explain below why waiver or alteration is necessary to this research.

3. Will waiving/altering informed consent affect subjects' rights and welfare?

   ☐ YES - No waiver or alteration can be approved by the IRB.

   ☐ NO – Explain below why you feel subjects will not be affected.

4. Will pertinent information be provided to subjects later?

   ☐ YES – Explain below what and when information will be provided to the subjects.

   ☐ NO – Explain below.

**Minimal risks means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.*