**The University of Notre Dame**

**Request for Waiver of Consent**

IRB Number:       PI Name:

Protocol title:

**Waiver of Informed Consent**

According to 45 CFR 46.116(d), an IRB may approve a waiver or alteration of the informed consent process provided specific criteria are met. Please validate that the following criteria are met, as applicable, by providing a justification in the space provided.

[ ]  The research presents no more than minimal risk to subjects.

**Protocol Specific Justification**:

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

**Protocol Specific Justification**:

[ ]  The research could not practicably be carried out without the waiver (cannot be for the sake of convenience).

**Protocol Specific Justification**:

[ ]  Whenever appropriate, the subjects will be provided with additional pertinent information after they have participated in the study.

**Protocol Specific Justification**:

[ ]  The study is not FDA regulated.