**The University of Notre Dame**

**Request for Waiver of Parental Permission**

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.

**or**

According to 45 CFR 46.408(c), an IRB may approve a waiver of the requirement to obtain parental permission provided specific criteria are met. Please validate that the following are met by providing a justification in the space provided.

**[ ]** The research is designed for conditions or for a participant population for which parental or guardian permission is not a reasonable requirement to protect participants.

**Protocol Specific Justification:**

**[ ]** An appropriate mechanism for protecting the children who will participate in the research is substituted for parental permission (The choice of an appropriate mechanism depends on the nature and purpose of the research activities, the risk and anticipated benefit and the age, maturity, status or condition of the children who will be participating).

**Provide and justify the mechanism:**

**[ ]** The waiver is not inconsistent with federal, state or local law.