**The University of Notre Dame**

**Request for Waiver of Documentation of Consent**

IRB Number:       PI Name:

Protocol title:

**Waiver or alteration of the requirement for Documentation of Informed Consent (45 CFR 46.117)**

According to 45 CFR 46.117, an IRB may approve a waiver for written documentation of informed consent provided specific criteria are met. Please validate that all of the following are met by providing a justification in the space provided.

The research presents no more than minimal risk.

**Protocol Specific Justification**:

The research involves procedures that do not require written consent when performed outside of a research setting.

**Protocol Specific Justification**:

**OR**

The principal risks are those associated with a breach of confidentiality concerning the subject’s participation in the research.

**Protocol Specific Justification**:

The consent document is the only record linking the subject to the research.

**Protocol Specific Justification**:

Each participant will be asked whether they want documentation linking them to the research and the the participant wishes with govern.

**Protocol Specific Justification**:

The study is not FDA regulated.