Appendix 1: Waiver of Consent Request

WAIVER OF CONSENT

If you are requesting that the IRB approve a waiver of consent (you will not obtain informed consent from subjects) complete this section (not applicable for FDA regulated studies). In order for the IRB to approve waiver of informed consent the IRB must determine that the criteria listed below are met. In the box below, support how the study meets each criterion:

1. The study is not greater than minimal risk:

2. Waiving the requirements for informed consent will not adversely affect the rights and welfare of study subjects:

3. The research cannot be practicably carried out without the waiver of informed consent or alteration of the consent process:

4. (If applicable) there would be a plan to disseminate pertinent information to study subjects after the study is completed:

Waiver of Documentation of Consent/Verbal Consent

Indicate in the text box below if you are requesting a waiver of documentation of informed consent/assent (also called "verbal assent") for this study. The IRB can only allow a waiver of documentation of consent if the study meets one of the two procedures listed below (also subject to applicable regulations). In the text box explain how the study design meets one of the following two criteria:

1. The only record linking the subject to the research would be the consent document and the principal risk of having a signed consent form would be potential harm resulting from a breach of confidentiality:

2. That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context: