IRB Reviewer Checklist for Informed Consent Procedure and Documentation

A. Waiver or alteration of some or all elements of the informed consent process:

1. Is study FDA-regulated? YES NO

**If YES, STOP. FDA does not provide for any of the following waivers or alterations in this section.**

2. Is a waiver of the informed consent process being requested? YES NO

3. Is a waiver or alteration of some or all elements of informed consent being requested? YES NO

*(i.e., all required elements of 45 CFR 46.116 will not be applied)*

**If NO to both questions, skip to part B**

4. If YES to either question, the following criteria must be met [46.116]:

\_\_\_ The research involves no more than minimal risk to the subjects

\_\_\_ The research could not practicably be carried out without the requested waiver or alteration

\_\_\_ If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format

\_\_\_ The waiver or alteration will not adversely affect the rights and welfare of the subjects

\_\_\_ When appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation

5. May consent procedure or elements of informed consent be waived / altered? YES NO

# B. Documentation of Informed Consent

How will this study document informed consent?

\_\_\_ 1. Written consent form - embodies elements of informed consent as required by FDA & HHS regulations.

\_\_\_ 2. Short form written consent - states that the elements of informed consent required by FDA & HHS regulations have been presented orally to the subject/representative. A witness must be present. There must be a written summary of what is said to the subject. The subject/representative signs and dates the short form consent statement (OHR-8S). The witness signs and dates both the short form and the summary. The person obtaining consent signs and dates the summary. Copies of the signed and dated short form and summary are given to the subject/representative.

\_\_\_ 3. Waiver of written consent if one of the following criteria is met:

\_\_\_ The only record linking the subject and the research would be the informed consent form and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject (or LAR) will be asked whether or not the subject wants documentation linking the subject with the research, and the subject’s wishes will govern [46.117(c)(1)(i)]; or

**[Note: This criterion cannot be applied to FDA-regulated research]**

\_\_\_ 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. [46.117(c)(1)(ii)]

\_\_\_ If the subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects, and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained [46.117(c)(1)(iii)].

\_\_\_ 4. Electronic consent form – All elements of informed consent as required by FDA & HHS regulations are included. Copies of the signed and dated electronic consent form and summary are given to the subject/representative.

\_\_\_ 5. Study is exempt from 45 CFR 46.