



INSTITUTIONAL REVIEW BOARD

REVIEWER GUIDE: WAIVER OF DOCUMENTATION OF CONSENT

If you are granting a waiver of the requirement to obtain a signed consent form for some or all subjects [45 CFR 46.117(c)], you must document responses to each of the following statements:

1. The entire consent (or elements thereof) was waived under 45 CFR 46.116 (d).

YES NO

2. The only record linking the subject and the research is the consent document, and the principle risk is potential harm resulting from a breach of confidentiality. Subjects are asked whether they want documentation linking them to the research and their wishes will govern.

YES NO

3. The research involves no more than minimal risk of harm **and** involves no procedure for which written consent is normally required outside of the research context.

YES NO

If you have checked the "YES" box to at least one of the questions above, in order to grant the waiver you must describe the reason(s) the waiver is necessary.

Principle Investigator: _____

Title of Project:

Date of Review: _____