IRB Appendix M2 - Waiver of Signed Consent

Rev. March 2015

This form should be used for waiver of signed consent for anonymous research

Complete this form to request a waiver of signed consent for the proposed research. DHHS regulations permit waivers of signed consent if the research meets certain conditions. DHHS and FDA regulations differ regarding when an IRB may waive the requirement to document the informed consent process.

Do not complete this form to request a waiver or alteration of the entire consent process, use Appendix M1.

Principal Investigator:

Protocol Short Title:

1. Is the research subject to FDA regulations (e.g., involves use of a food, drug, biologic, device)? ◯ Yes ◯ No

If Yes, only section (2) may be used to request waiver of signed consent.
If No, either section (2) or (3) may be used to request waiver of signed consent.

Signed consent cannot be waived under the conditions of the last section below if the research involves a product regulated by FDA or the results of the research may be submitted to FDA as part of a marketing application.

2. Both answers below (2a and 2b) must be **No** for a waiver of signed consent:

a. Does the research present greater than minimal risk? ◯ Yes ◯ No

b. Does the research involve procedures for which written consent is normally required outside the research context? ◯ Yes ◯ No

If **No** --> explain how the research meets both (2a and 2b) of the conditions above.

3. Both answers below (3a and 3b) must be **Yes** for a waiver of signed consent:

a. Would the only record linking the participant and the research be the consent document? ◯ Yes ◯ No

b. Would the principal risk to the participant be potential harm resulting from a breach in confidentiality? ◯ Yes ◯ No

NOTE: *The participant should be asked whether he/she wants documentation linking the participant with the research; the participant's wishes will govern.*

If **Yes** --> explain how the research meets both (3a and 3b) of the conditions above.