FORM: Request for Waiver of Written Documentation of Informed Consent

Directions: Address the criteria listed below and attach this form to your application. Also, state in your application that you are requesting a waiver of written documentation of informed consent and describe what you will do to obtain consent in the procedure section of your application. The IRB often requires investigators to provide participants with a written information statement about the research when written documentation is waived; you may wish to include one in your initial application. 

NOTE that the UA IRB does not allow passive consent. You are welcome to call Research Compliance staff at 205-348-8461 to discuss your need for a waiver in advance of application submission.

(1) The only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality; subjects must be asked whether they want documentation linking themselves to the project or not (and the participants’ wishes will prevail); OR

(2) 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.

NOTE: The first criterion is not included in FDA. The second is in both FDA and HHS regulations, 21 CFR 56.109 (c). In cases where documentation is waived, the IRB may require PIs to provide subjects with a written statement about the research.