## Informed Consent – Waiver of Documentation of Informed Consent

**Waiver of Documentation of Informed Consent:** Below is the form used to request a waiver of documentation of informed consent (generally used for anonymous survey-based studies).

Under the 2018 Common Rule, a request for waiver of documentation is **permissible** when:

* The signature on the informed consent document would be the only record linking the subject to the research and the principal risk of harm to the subject would be a breach of confidentiality.  For example, for research on sensitive topics, such as domestic violence or illegal activities; **OR**
* The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside the research context.  For example, minimal risk research that involves surveys/interviews conducted via telephone or online.

Please complete this form with the requested information and be sure to upload a completed version as a separate document in the IRBNet submission.

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| **Request for Waiver of Documentation of Informed Consent** |
| **All forms must be typewritten and submitted to the Lakeland Regional Health IRB at www.irbnet.org.** |

**Section 1. PROTOCOL INFORMATION**

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| **1.1. Primary Investigator:** |
| **1.2. IRBNet Number:** |
| **1.3. Project Title:** |
| **1.4. Is this research regulated by the US Food and Drug Administration?**  Yes  No |

**Section 2. REQUEST FOR WAIVER OF DOCUMENTATION**

**A consent procedure which does not document obtained consent through a physical signature may be approved by the IRB under certain conditions. To request IRB approval of a consent procedure which does not document consent through a physical signature, provide a response to only one of the following. Note that the IRB may require the investigator to provide subjects with a written statement regarding the research, even though the documentation requirement may be waived.**

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| **2.1. 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. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject’s wishes will govern. (Note: A waiver of documentation of informed consent is not permissible under this category if the research is subject to FDA regulations.)** |
| **2.2. The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside the consent.** |
| **2.3. The subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, the research presents no more than minimal risk of harm to subjects, and there is an appropriate alternative mechanism for documenting that informed consent was obtained.** |