Institutional Review Board
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Waiver of Consent Documentation

To qualify for a waiver of consent documentation investigators must address in Part 2 Section 7 how the project meets **ANY** of the following criteria:

(1) That 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;

(2) That 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 legally authorized representative) will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or

(3) 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.

In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects or legally authorized representatives with a written statement regarding the research.

You may request a waiver of consent documentation by including response(s), in your IRB application, to **ANY** of the above listed waiver criteria.

Full Waiver/Alteration of Consent

To qualify for a full waiver/alteration of consent, investigators must address in Part 2 Section 7 how the project meets **EACH** of the following waiver criteria:

(1) The research involves no more than minimal risk to the subjects;

(2) The research could not practicably be carried out without the requested waiver or alteration;

(3) 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;

(4) The waiver or alteration will not adversely affect the rights and welfare of the subjects; and

(5) Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation.

You may request a waiver/alteration of informed consent by including responses, in your IRB application, to **EACH** of the above listed waiver criteria.