**Federal Information about Waiver or Alteration of Informed Consent Process and about Waiving Documentation of Informed Consent**

A. Federal Information about Waiver or Alteration of Informed Consent Process

An IRB may waive the requirement to obtain informed consent for research, or may approve a consent procedure that omits some, or alters some of all of the elements of informed consent, provided the IRB satisfies all of the below requirements:

1. The research involves no more than minimal risk to the participants. (Minimal risk is when the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.)

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 participants.

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

If the informed consent process is altered rather than waived entirely, IRBs may not legally omit or alter any of the following elements of the informed consent process:

* Language understandable by the participant or their legally authorized representative
* Information that a reasonable person would want to have in order to make an informed decision about whether to participate in the research
* An opportunity to discuss the information with the researcher
* A concise and focused presentation of key information about the research that is most likely to assist a prospective participant or their legally authorized representative in understanding the reasons why one might or might not want to participate in the research, organized and presented in a way that facilitates comprehension
* Information presented in sufficient detail relating to the research, organized and presented in a way that does not merely provide lists of isolated facts, but rather than facilitates understanding of the reasons why one might or might not want to participate
* A prohibition against including any language through which the participant or their legally authorized representative is made to waive or appear to waive any of the participant’s legal rights
* A prohibition against including any language that releases, or appears to release the investigator, the sponsor (if applicable), the institution, or its agents from liability for negligence.

B. Federal Information about Waiving Documentation of Informed Consent

An IRB may waive the requirement for the investigator to obtain a signed informed consent form for some or all participants if it finds any of the following:

1. The only record linking the participant and the research would be the informed consent form and the principal risk would be potential harm resulting from a breach of confidentiality. Investigators using this rationale must ask each participant or their legally authorized representative individually whether they want documentation linking the subject with the research, and the participant’s wishes will govern. Therefore, this rationale requires preparing consent forms with signature lines and leaving them blank in individual cases where the rationale applies and the participant wishes not to sign an informed consent form.

2. The research represents no more than minimal risk of harm to participants and involves no procedures for which written consent is normally required outside of the research context.

3. The participants or their legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm AND the research presents no more than minimal risk of harm to participants AND 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 participants or their legally authorized representatives with a written statement regarding the research; this will generally involve a consent form-type document but not requiring a signature.