GUIDELINE # 14: WAIVER OR ALTERATION OF THE INFORMED CONSENT, OR WAIVER OF DOCUMENTATION THE INFORMED CONSENT

I. PURPOSE

This guideline is to ensure that human subjects' research conducted complies with federal, state, and local laws, regulations, directives, and instructions. This guideline provides guidance that is used to obtain an approval of the waiver or alteration of the informed consent or waiver of documentation of the informed consent.

II. STATEMENT

All human subjects research, irrespective of the source of funding, conducted by A&M- SA faculty, staff, and students must be submitted and reviewed in accordance with the Federal research regulations, Texas A&M System Guidelines, A&M-San Antonio (A&M-SA) Institutional Review Board (IRB) policies and local consideration.

Informed consent is a process, not merely a form. Informed consent is a fundamental mechanism to ensure respect for persons through provision of thorough information about the research in which the individual is being invited to participate so that they can make an informed decision to participate voluntarily. In this sense, under certain circumstances Federal Regulations allow IRBs to approve the waiver or alteration of the informed consent [45 CFR 46.116] or waiver of documentation of the informed consent [45 CFR 46.117].

The A&M-SA IRB recognizes that under certain circumstances the informed consent or the documentation of the informed consent may be waived.

III. SCOPE

This guideline applies to all research conducted where the A&M-SA IRB serves as the Reviewing IRB.

IV. PROCEDURES

In this procedure "investigator" means a principal investigator or an individual authorized by the principal investigator and approved by the IRB to obtain consent for the specific protocol, such as a co-investigator, research assistant, or coordinator.

In accordance with Federal Regulations [45 CFR 46.116(f)(3)], in order for the IRB to consider applications, whether exempt, expedited, or full Review, seeking the approval of the waiver or alteration of the informed consent, the following circumstances must be present:

- The research is not FDA regulated.

- The research does not involve non-viable neonates.
- The research involves no more than Minimal Risk to the subjects.
- The research could not practicably be carried out without the waiver.
- 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 (subject to the Common Rule 2018).
- The waiver will not adversely affect the rights and welfare of the subjects.
- Whenever appropriate, the subjects will be provided with additional pertinent information after participation.
- If the waiver or alteration of the informed consent involves public benefit and service programs conducted by or subject to the approval of state or local officials, the study must document also the public benefit, or service programs and the procedures for obtaining benefits or services under those programs, including the possible changes in or alternatives to those programs or procedures [45 CFR 46.116(e)(3];

In accordance with Federal Regulations [45 CFR 46.117], in order for the IRB to consider applications, whether exempt, expedited, or full Review, seeking the approval of the waiver of documentation the informed consent, any of the following circumstances must be present:

- 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 (for example domestic abuse or illegal activities). 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;
- 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 (for example, online conducted recorded interviews);
- or; 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 (subject to Common Rule 2018).

The investigators have the responsibility to include all the information and justification in the application that will help the IRB to make a determination for the approval of the waiver or alteration of the informed consent, or the waiver of the documentation of the informed consent Under no circumstance human subject research data can be collected without the approval of the IRB.

V. REVISIONS

October 2024

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Title: Waiver or Alteration of the Informed Consent, or Waiver of Documentation the Informed Consent	
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