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1. PURPOSE

1.1. Under certain circumstances, the requirement to obtain or document informed consent from subjects may be waived by the IRB. Alternatively, the IRB may alter the requirement to obtain informed consent. This policy establishes the process and requirements to waive the documentation of.

2. REVISIONS FROM PREVIOUS VERSION

2.1. None

3. POLICY

3.1. Waiver to Obtain Informed Consent and Alterations of Informed Consent: The IRB may waive or alter the requirement to obtain informed consent, if the IRB finds (and documents with specificity) that **one** of the two sets of criteria below (either all of part A or all of part B criteria) are met.

(A1) The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs; and

(A2) The research could not practicably be carried out without the waiver or alteration. (45 C.F.R. § 46.116(c)).


or

(B1) The research involves no more than minimal risk to the subjects;

(B2) The waiver or alteration will not adversely affect the rights and welfare of the subjects;

(B3) The research could not practicably be carried out without the waiver or alteration; and

(B4) Whenever appropriate, the subjects will be provided with additional pertinent information after participation. (45 C.F.R. § 46.116(d)).

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3.2. Waiver of Documentation of Informed Consent: An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects, if the IRB finds (and documents with specificity) that **one** of the two sets of criteria below (either all of part A or all of part B criteria) are met.

(A1) 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.

(A2) Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern. (45 C.F.R. § 46.117(c)(1)).

or

(B1) 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. (45 C.F.R. § 46.117(c)(2)).

or

(B1) The subjects or legally authorized representative 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.

3.2.1. In cases in which the signed consent requirement is waived, the IRB may still require the PI to provide subjects with a written statement regarding the research.