

Informed Consent Waivers, Alterations, Exceptions, and Substitutions

In some cases, an IRB may approve a consent procedure that does not include, or that alters, some or all of the required elements of informed consent, or may waive the requirement to obtain informed consent. The following standards apply to all federally and non-federally supported human research that does not involve vulnerable populations. (Different rules for FDA-regulated studies apply).

Waiver or Alteration of Informed Consent

An IRB may waive or alter the requirements for informed consent only if it finds and documents that:

- (a) The research involves no more than minimal risk to the subjects;
- (b) The research could not practicably be carried out without the requested waiver or alternation;
- (c) 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;
- (d) The waiver or alteration will not adversely affect the rights and welfare of the subjects; and
- (e) Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation.

Alternatively, the IRB may approve a waiver or alteration of consent if it finds and documents that:

- (a) The research or demonstration project is to be conducted by or subject to the approval of state or local government officials; and
- (b) The project 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
- (c) The project could not practicably be carried out without the waiver or alteration.

Waiver of Requirement for Parental Permission

For research involving children as subjects, an IRB may waive the requirement to obtain parental permission if it finds and documents that:

- (a) The research involves no more than minimal risk to the subjects;
- (b) The waiver or alteration does not adversely affect the rights and welfare of the subjects;
- (c) The research cannot practicably be carried out without the waiver or alteration;
- (d) When appropriate, the subjects will be provided with additional pertinent information after participation; and
- (e) The research is not FDA-regulated.

Alternatively, the IRB may waive the requirement to obtain parental permission if it finds and documents that:

- (a) The research is designated for conditions or for a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects;
- (b) An appropriate mechanism for protecting the children who will participate as subjects in the research is substituted; and
- (c) The research is not FDA-regulated.

Waiver of Documentation of Informed Consent

The IRB may waive the requirement for documentation of informed consent if it finds and documents either of the following:

- (a) That 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 (in which case each subject must be offered the opportunity to receive the documentation); or
- (b) 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.

Even if the IRB approves a waiver of documentation of consent, the IRB may require the investigator to provide subjects with a written statement regarding the research.