ILLINOIS
Office for the Protection of Research Subjects

Research Guidance Document

WAIVER OR ALTERATION OF CONSENT

Description

The University of Illinois Urbana-Champaign IRB may approve a consent procedure that does not include, or which alters, some or all of the elements of informed consent or waive the requirement to obtain informed consent. The IRB needs to make and document specific findings to do so. This guidance outlines the specific determinations the IRB must make to approve a waiver or alteration of informed consent.

Investigators may request that the IRB waive or alter some or all of the elements of informed consent by completing the appropriate request(s) in the IRB application. The investigator must provide sufficient and specific information when requesting the waiver. The IRB uses a checklist to determine and document whether a waiver or alteration may be granted. Alternatively, determinations may be documented in IRB meeting minutes.

This guidance does not describe the waiver of informed consent for planned emergency research or exceptions from informed consent (EFIC). Please contact the OPRS office for more information on this topic.

General Waiver or Alteration of Consent

The most common use of the waiver or alteration is when it is granted under the following conditions (as outlined in 45 CFR 46.116):

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.

Waiver or Alteration of Consent for FDA-regulated Minimal Risk Clinical Investigations

In July 2017, the FDA announced that it does not intend to object to a minimal risk clinical investigation for which an IRB waives or alters the informed consent requirements as described below:

1. The clinical investigation involves no more than minimal risk (as defined in 21 CFR 50.3(k) or 56.102(i)) to the subjects;
2. The waiver or alteration will not adversely affect the rights and welfare of the subjects;
3. The clinical investigation could not practicably be carried out without the waiver or alteration; and
4. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

The FDA intends to withdraw this guidance after regulations are promulgated to permit a waiver or alteration of informed consent under appropriate human subject protection safeguards.

Waiver of Consent: Public Benefit or Service Programs

The waiver or alteration of consent for public benefit or service programs is generally not used at the University of Illinois Urbana-Champaign. However, the IRB may waive or alter the requirement to obtain informed consent if it meets the following conditions:

1. The IRB must find and document that 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:
    a. Public benefit or service programs;
    b. Procedures for obtaining benefits or services under those programs;
    c. Possible changes in methods or levels of payment for benefits or services under those programs; AND
    d. The research could not practicably be carried out without the waiver or alteration.

Additional Considerations

Assent

Generally, the IRB requires assent from children 7 or older but this may vary. The assent process may be entirely waived, consistent with the provisions for waiver of consent contained in 45 CFR 46.116. Depending on other factors (age, maturity, and psychological state of the children), the IRB may determine that assent is a requirement of all children, some of the children or none of the children. Please see the RGD: Assent for more information.

Broad Consent

Effective January 21, 2019, research may use broad consent for the storage, maintenance, or secondary research use of the identifiable private information or identifiable biospecimens. If an individual was asked to provide broad consent but refused, the IRB cannot waive consent for the storage, maintenance, or secondary research use of the identifiable private information or identifiable biospecimens. **The University of Illinois Urbana-Champaign IRB does not utilize the option for broad consent (54 CFR 46.116(d)).**

Points to Address

New Study Application:	1. **Study Information page:** Select "Waiver or Alteration of Informed Consent" when asked how consent will be obtained.

References & Links

FDA Guidance: IRB Waiver or Alteration of Informed Consent for Clinical Investigations Involving No More Than Minimal Risk to Human Subjects	*https://www.fda.gov/regulatory-information/search-fda-guidance-documents/irb-waiver-or-alteration-informed-consent-clinical-investigations-involving-no-more-minimal-risk*
Research Guidance Document: Assent	To be updated