

WAIVER OR ALTERATION OF CONSENT

Description

The University of Utah 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 (within the ERICA system). 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 see the IRB website 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\(f\)](#):

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 December 2023, the FDA published statutory changes to allow for a waiver or alteration of informed consent when a clinical investigation poses no more than minimal risk to the human subject and includes appropriate safeguards to protect the rights, safety, and welfare of human subjects. This rule permits an IRB to waive or alter certain informed consent elements or to waive the requirement to obtain informed consent, under limited conditions, for certain minimal risk investigations.

The rule is published in [21 CFR 50.22](#) and is consistent with the regulatory text of the revised Common Rule (45 CFR 26.116(f)) outlined above in this policy.

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 Utah. However, the IRB may waive or alter the requirement to obtain informed consent if it meets the following conditions:

Please contact the IRB Office at (801) 581-3655 or irb@hsc.utah.edu for additional guidance.



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.

Waiver of Parental Permission

In addition to the general waiver or alteration of consent in 45 CFR 46.116(f) which may be used to waive parental permission, [45 CFR 46.408\(c\)](#) allows the IRB to waive parental permission when it is not a reasonable requirement to protect subjects. As part of this waiver, an appropriate mechanism must be provided to protect the children who will participate in the research.

The University of Utah IRB does not routinely receive requests to waive parental permission under 46.408(c) and therefore, does not have a specific page in the ERICA application to request a waiver of parental permission under 46.408(c). Investigators who wish to request a waiver of parental permission under 46.408(c) must provide justification for the waiver.

- **Example:** Adolescents, ages 14-18, will be asked to participate in a survey about sexually transmitted infections (STIs) and collect health information. Minors at the participating institution are able to consent for testing and medical treatment related to STIs without parental permission under state law. The IRB determined that the waiver of parental permission was appropriate. An assent was provided to all participants which served as another mechanism to protect the participants.

FDA regulations do not have a comparable waiver of parental permission to match 46.408(c). The IRB will not allow such a waiver of parental permission for FDA-regulated research.

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 [IGS: 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 Utah IRB does not utilize the option for broad consent (54 CFR 46.116(d)).**

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Points to Address

- New Study Application:**
1. **Study Information page:** Select “Waiver or Alteration of Informed Consent” when asked how consent will be obtained.
 2. **Request for Waiver or Alteration of Consent:** Please select “Add” to request a waiver or alteration of consent. Complete all questions completely.

References & Links

*Exception from Informed
Consent (EFIC) & Planned
Emergency Research*

<https://irb.utah.edu/guidelines/efic/index.php>

*Investigator Guidance
Series: Assent*

<https://irb.utah.edu/guidelines/investigator.php>

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