



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 would need to make and document specific findings in order to do so. This guidance includes the specific determinations the IRB needs make in order 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:

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.

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



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 Utah. 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

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. **It should be noted that the University of Utah 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.
 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/fda-requirements/planned-emergency-research.php>

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