Issuing Department: Human Subjects Protection Program
Policy Number: 2011-008.2
Policy Title: Informed Consent – Waivers and Alterations

Purpose

The purpose of this policy is to set forth the requirements that must be met to allow the Institutional Review Board (IRB) to grant a waiver or alteration of the requirement(s) for obtaining informed consent or for granting a waiver of the requirement to document consent. This policy is not inclusive of the provisions set forth for emergency use of a test article or for planned emergency research for which separate policies exist. For purposes of this policy the term research and clinical investigation are considered synonymous.

Definitions

See policy 2011-007.0 for definition of:

Informed Consent Form	Informed Consent Process
Legally Authorized Representative	

Policy

UConn Health does not utilize the provision of broad consent. Therefore, the regulatory requirements related to waivers or alterations of elements of broad consent are not applicable to this policy. When the research is not federally funded/supported nor subject to FDA regulations the IRB will utilize the criteria for waiver/alterations set forth in 45 CFR 46 as guiding criteria but may exercise judgement in determining whether to grant the waiver/alteration. The IRB may also impose criteria in addition to that defined in regulation in determining whether to grant a waiver/alteration. In this policy the term subject is inclusive of the subject or the subjects legally authorized representative.

Waiver of Consent: The IRB may approve a waiver of the requirement to obtain consent if it finds and documents that the criteria noted in Option 1 or Option 2 below have been met. Option 1 is not applicable to research subject to FDA regulations.

Alteration of Consent: Except as described in the section titled Limitation of Alterations, the IRB may approve a consent form that alters some or all of the elements of consent that are allowed to be altered, or that omits some of the elements of consent that may be omitted if it finds and documents that the criteria noted in Option 1 or Option 2 below have been met. Option 1 is not applicable to research subject to FDA regulations.

- Option1: Waiver or alteration of consent in research involving public benefit and service programs conducted or subject to the approval of state or local officials.
    - the research or demonstration project is conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine one or more of the following items:
        - public benefit of service programs; or
        - procedures for obtaining benefits or services under those programs; or
        - possible changes in or alternatives to those programs or procedures; or
        - possible changes in methods or levels of payment for benefits or services under those programs; and
    - the research could not practicably be carried out without the alteration or waiver;

- Option 2: General waiver or alteration of consent
    - the research involves no more than minimal risk to subjects;
    - the research could not practicably be carried out without the alteration or waiver;
    - if the research involves using identifiable private information (IPI) or identifiable biospecimens (IB), the research could not practicably be carried out without using such IPI or IB^{+};
    - the waiver or alteration will not adversely affect the rights and welfare of the subjects; and
    - whenever appropriate subjects or legally authorized representatives will be provided with additional pertinent information after participation, for example when the research required the use of deception.

Limitation of Alterations: For federally-funded or supported research, unless consent is completely waived, the following elements of consent may not be omitted or altered:

- Before involving a human subject in research an investigator shall obtain the legally effective informed consent of the subject.
- Informed consent will be sought only under circumstances that provide the prospective subject sufficient opportunity to discuss and consider participation and that minimize the possibility of coercion or undue influence.
- The information that is given to the subject shall be in a language understandable to the subject.
- Exculpatory language which releases or appears to release the institution, sponsor or investigator from liability, or which makes or appears to make a subject waive any legal rights cannot be included in the ICF.
- The prospective subject must be provided with the information that a reasonable person would want to have in order to make an informed decision about whether to participate, and an opportunity to discuss that information.
- Informed consent as a whole must present information in sufficient detail relating to the research, and must be organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates the prospective subject's understanding of the reasons why one might or might not want to participate.
- The informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject in understanding the reasons why one might or might not want to participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension.

The assigned reviewer will make the final determination as to whether or not to approve the request for an expedited study and the Board will make the determination for full board studies.

Waiver of Documentation of Consent: In the situations outlined below, the IRB may still require that the consent process occur but waive the requirement to obtain documentation of consent. In order to do so the IRB must find that the criteria noted in Option 1, Option 2 or Option 3 have been met. Option 2 is also applicable to research subject to FDA regulations.

- Option 1:
  - the only record linking the subject and the research would be the informed consent form and the principal risk would be potential harm resulting from a breach of confidentiality (each subject must be asked whether the subject wants documentation linking the subject with the research and the subject's wishes will govern), **or**
- Option 2:
  - 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, **or**
- Option 3:
  - if the subjects 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. The IRB will evaluate alternative mechanisms on a case-by-case basis based on information put forth by the PI.
    - Option 3 is currently applicable only to non-exempt research that is not subject to FDA oversight. If regulations are implemented that extend this provision to FDA regulated research, UConn Health will also extend this provision.

If the requirement of documentation is waived, the IRB may require that the investigator provide the subject with a written summary of the research and if so the IRB must review and approve that summary. The PI may request, and the IRB may approve, that a consent form also serve as the written summary.

To Waive Documentation of the Consent Process for Screening, Recruiting, and Determining Eligibility

- The investigator will obtain information through oral or written communication with the prospective subject or legally authorized representative, or
- The investigator will obtain identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens.
- The research is not regulated by the US FDA.

To Waive Documentation of the Consent Process – Confidentiality

- The oral or written information provided to subjects includes all required and appropriate additional elements of consent disclosure.
- The research is not regulated by the US FDA.

To Waive Documentation of the Consent Process: Consent normally not required outside the research context

- The research presents no more than minimal risk of harm to participants.
- The research involves no procedures for which written documentation of the consent process is normally required outside of the research context.
- The oral or written information provided to subjects includes all required and appropriate additional elements of consent disclosure.

To Waive of Documentation of the Consent Process: Distinct Cultural Groups

- The subjects or legally authorized representatives are members of a distinct cultural group or community in which signing consent documents is not the norm.
- There is an appropriate alternative mechanism for documenting that informed consent was obtained.
- The oral or written information provided to subjects includes all required and appropriate additional elements of consent disclosure.
- The research is not regulated by the US FDA.

+ the element is applicable to federally funded or supported research for which the waiver/alteration is still necessary and for which the review has transitioned to meet the requirements of the 2018 revised Common Rule regulation. This may require investigators to submit a request for modification to update the previously approved waiver form.

Procedure

Research Conducted by or Subject to State or Local Government Officials: To request this method of waiver or alteration the investigator must complete and submit the form titled "Request for Waiver or Alteration of Consent for Projects Conducted by or Subject to the Approval of State or Local Government Officials."

Request to Waive Consent: The investigator must complete and submit the form titled "Request for Full or Partial Waiver of Informed Consent."

Request to Alter Consent: The investigator must complete and submit the form titled "Request to Alter Elements of Consent."

Request to Waive Documentation: If not addressed within the IRB application, the investigator must complete and submit the form titled "Request for Waiver of the Requirement to Document the Consent of Subjects."

Each form noted above addresses the regulatory criteria for approval. For each type of request the reviewer will determine if the criteria for approval are met, granting approval only when all criteria have been satisfied.

Standard screening and review procedures apply as noted in the policies for expedited and convened board review. For expedited research, the assigned reviewer will make the final determination as to whether or not to approve the request for an expedited study and document approval on the reviewer form.

For studies requiring review by the convened board the IRB Regulatory Specialist will document justifications in the minutes. Determinations made by the convened board will supersede the opinion documented by the individual reviewer on the reviewer form.

Related Policies

2011-007.0 – Definitions Applied to Policies
2011-008.0 – Informed Consent – Forms
2011-009.3 – Institutional Review Board – Expedited Reviews
2011-009.5 – Institutional Review Board – Review by Convened Board

Basis

45 CFR 46
21 CFR 56
21 CFR 50
FDA- Institutional Review Board Waiver or Alteration of Informed Consent for Minimal Risk Clinical Investigations 12/21/2023

Document Attributes

Date Effective: 1/22/2024

Replaced Version: 11/20/23

Reviewed and Approved By:

Richard H. Simon 22 Jan 24

Richard Simon, MD **Date**
Director Human Subjects Protection Program