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

Policy

Waiver / Alteration of Consent: The IRB may waive the requirement to obtain consent or may alter some or all of the elements of informed consent set forth in regulations. In order to do so the IRB must find and document that the criteria noted in Option 1 or Option 2 have been met. Option 1 is not applicable to FDA regulated research.

- Option1: the research 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;
  - procedures for obtaining benefits or services under those programs;
  - 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
  - the research could not practicably be carried out without the alteration or waiver;
- Option 2: the IRB finds and documents the following:
  - the research involves no more than minimal risk to subjects;
  - the waiver or alteration will not adversely affect the rights and welfare of the subjects;
  - the research could not practicably be carried out without the alteration or waiver; and
  - when appropriate subjects will be provided with additional pertinent information regarding participation, for example when the research required the use of deception.

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 or Option 2 have been met. Option 2 is also applicable research subject to FDA regulations.

- Option 1:
    - the only record linking the subject to the study is the signed consent document and the principal risk would be harm resulting from a breach of confidentiality (subjects must still be given the option of signing a consent document and the subject's wishes will prevail), **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.

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.

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 of the Requirement to Consent Subjects or to Make Alteration to the Elements of Consent for Projects Conducted by or Subject to the Approval of State or Local Government Officials."

Request to Waive or Alter Consent: The investigator must complete and submit either the form titled "Request for Waiver of the Requirement to Consent Subjects" or "Request for Alteration of Required 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 to Document Consent."

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,
FDA Guidance "IRB Waiver or Alteration of Informed Consent for Clinical Investigations Involving No More Than Minimal Risk to Human Subjects" July 2017

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Reviewed and Approved By:

Richard H. Simon *28 July 17*

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