

Human Research Protection Program Policies & Procedures



Waiver or Alteration of Informed Consent and Waiver of Authorization

Version 1.0
Date Effective: 8/22/2009

Research Integrity Office
Mail code L106-RI
Portland, Oregon 97239-3098
Phone: 5 03-494-7887
Fax: 503-494-5081

Background:

Informed consent is one of the fundamental principles of ethical conduct in the use of human subjects and is mandated by Federal Regulations at 45 CFR 46.116 [add FDA]. Generally, a potential research participant (or his or her legally authorized representative) must be given a complete explanation of the IRB-approved protocol, including a description of its risks, benefits and alternatives, and be given the voluntary and uncoerced choice to participate in research. Additionally, an individual's agreement to participate usually must be documented on an IRB-approved consent form.

Occasionally, however, there are reasons to waive written consent or to alter the requirements of consent. There are special regulatory allowances which permit an IRB to approve, under limited circumstances, a waiver of consent, an alternative form of consent, or a waiver of the requirement to document consent. The HIPAA Privacy Rule has its own list of criteria that must be met in order to waive a subject's written authorization to use and disclose individually identifiable health information for research.

Scope:

This policy applies to all research activities conducted at OHSU where the PI would like to omit or alter elements of informed consent.

I. Policy

- A. For research not subject to FDA regulations, the OHSU IRB may waive the requirement for obtaining informed consent or approve a consent procedure that leaves out or alters some or all of the elements of informed consent, provided that the OHSU IRB finds and documents that all of the following four criteria are met:
 1. The research involves no more than minimal risk to the subjects;
 2. The waiver or alteration will not adversely affect the rights and welfare of the subjects;
 3. The research 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.

- B. The IRB may approve a process that does not incorporate standard documentation requirements which are otherwise applicable to human subjects research. The criteria for such “waivers of documentation” are described below:
 - 1. The only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research and the subject’s wishes will govern; or
 - 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 (e.g. drawing a blood sample, or asking shoppers in a mall about the ambient lighting).
- C. For research subject to FDA regulations, except as allowed by the emergency use of a test article provision, the requirement for a written, signed informed consent document may only be waived if:
 - 1. The research presents no more than minimal risk of harm to subjects; and
 - 2. Involves no procedures for which written consent is normally required outside the research context.
- D. The following three criteria must be satisfied for the IRB to approve a waiver of authorization under the Privacy Rule:
 - 1. The use or disclosure of protected health information involves no more than a minimal risk to the privacy of individuals, based on, at least, the presence of the following elements:
 - a. an adequate plan to protect the identifiers from improper use and disclosure;
 - b. an adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law; and
 - c. adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research project, or for other research for which the use or disclosure of protected health information would be permitted by this subpart;
 - 2. The research could not practicably be conducted without the waiver or alteration; and
 - 3. The research could not practicably be conducted without access to and use of the protected health information.
- E. In cases where the documentation requirement is waived, the OHSU IRB may require the investigator provide research participants with a written statement regarding the research.

II. Process

- F. Investigator Responsibilities
 - 1. When requesting a waiver or alteration of informed consent, justification must be provided as to why the study meets the requirements for either a waiver of written consent or a waiver/alteration of consent.

- a. The justification requirement applies even in cases where the Investigator uses deception in research.
 - b. The justification may be submitted to the eIRB in the form of a memo.
 - 2. When a waiver or alteration is in place allowing participant anonymity, for example no signature line, the PI must maintain strict practices to protect privacy. This includes avoiding markings and identifications on consent forms and information sheets.
 - 3. The research team must provide additional pertinent information to the participant as the IRB has determined, this could include informing participants that research has been conducted under a waiver, without consent.
 - 4. Accounting for Research Disclosures
 - a. In general, the Privacy Rule gives individuals the right to receive an accounting of certain disclosures of protected health information made by a covered entity.
 - b. When a waiver of authorization is in place, accounting for disclosures is required.
 - c. For more Information on accounting for disclosure, see HIPAA Research Guidelines.
LINK
- G. OHSU IRB Responsibilities**
- 1. Review the submitted study information to determine the applicability of FDA law.
 - 2. Review the waiver request taking into account:
 - a. The level of risk of the study;
 - b. The extent to which privacy will be invaded;
 - c. The sensitivity of the information to which the investigators will have access;
 - d. The necessity of the data;
 - e. Plans for further contact of the subjects;
 - f. If the study involves procedures which normally require consent and
 - g. The feasibility of obtaining consent from all subjects.
 - 3. Approve or disapprove a waiver or alteration per the regulatory requirements.
 - 4. For studies requesting to use deception:
 - a. First, decide whether the information to be withheld would influence the decision of prospective subjects about participating in the research. Research should not be permitted at all if the subjects are not being informed of things they would consider material to a decision to participate.
 - b. Second, decide if subjects should be debriefed, either after participating in research unwittingly or after knowingly participating in research that involved some form of deception.
 - c. In order to grant the waiver, document the following three things:
 - a. the study presents no more than minimal risk;
 - b. the waiver would not adversely affect the rights and welfare of subjects; and

- c. the waiver is essential to the ability to carry out the research.
5. IRB minutes shall record the board decision for approval of waivers or alterations of consent and authorization. All elements must be documented in the minutes.
6. Approvals of waivers of informed consent, documentation of informed consent, or requirements for debriefing will be documented in the review communication to the PI. Additionally, waivers of authorization will be detailed, including requirements to account for disclosures.
7. In certain circumstances, for example when the PI has an ongoing relationship with the participants, the IRB may require that the PI provide additional pertinent data to volunteers.

Definitions

Authority

45 CFR 46.116(d)

45 CFR 164.508

45 CFR 164.512(i)

21 CFR 56.109(c)

21 CFR 56.23

21 CFR 56.24

HIPAA Regs: Guidance on Modified Final Privacy Rule (December 4, 2002).

Appendix A

- A. Examples of Situations Where a Waiver of Consent may be Reasonable:**
1. A retrospective chart review extracting minimal risk data, where it is impracticable to contact all of the participants for consent.
 2. A telephonic consent procedure under which the subject's legally authorized representative (LAR) is sent a faxed version of the informed consent document. A consent interview is conducted by telephone while the LAR has the document in hand. The LAR signs and returns the signed document to the PI by return fax before the subject is enrolled in the study. In cases where this process is used, a witness not connected with the study should monitor the consent process.
 3. A PI is conducting interviews in China with citizens about their religious beliefs. The only record of the name or other identifying information of the subject would be the signed consent form. The PI would like the signed consent form waived to decrease the risk of subjects being arrested, interrogated or imprisoned if Chinese authorities found out any of the subjects had spoken with the PI. Since Certificates of Confidentiality do not apply to researchers who are doing work outside of the United States, there is a possibility that respondents could be harmed for expressing their views on their religious beliefs.
- B. Examples of Situations Where a Waiver of Consent Request Generally will not be Approved:**
1. PI does not have enough money in his/her research grant to print consent forms and distribute them and file them;
 2. The research participants are also patients of the PI so the participants trust the PI to not involve them in something that might harm them;
 3. The PI currently has access to the patient records;
 4. There is no risk, but it is possible to obtain consent;
 5. There isn't enough staff to handle the paperwork involved in obtaining informed consent; or
 6. If the PI consents the research subjects, they will not want to participate in the study.