Northeastern University
Human Subject Research Protection

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Guidance: Waiver or alteration of informed consent

Overview

Under the Federal Policy for the Protection of Human Subjects (a.k.a. the "Common Rule"), the IRB may approve an informed consent process that:

- Waives the requirement to obtain informed consent, or
- Alters some or all of the elements of informed consent, or
- Waives the requirement to document informed consent (i.e., to obtain a signature)

Waiver of Informed Consent (45 CFR 46.116)

Waiver or Alteration of Consent Waiver of consent completely waives the requirement to obtain informed consent. Alteration of consent allows the investigator to leave out or alter elements of the informed consent.

For research that is no more than minimal risk the IRB may approve a request to waive some or all of the required elements of informed consent under specific circumstances. Waivers of informed consent are primarily requested for projects involving the secondary analysis of existing data or in projects involving deception.
To waive in total or to alter informed consent elements, the IRB must determine that:

- The research involves no more than minimal risk to participants.
- The research could not be carried out practicably without the waiver or alteration.
- If the research involves identifiable private information or **identifiable biospecimens**, this research could not be carried out practicably without using the information/specimen in an identifiable form.
- The waiver or alteration will not adversely affect the rights and welfare of the participants.
- Where appropriate, the s participants will be provided with additional information about their participation.
    - Note: The intent of this waiver criterion is to require debriefing for participants in deception research

Waiver of Documentation of Informed Consent (45 CFR 46.117)

21 CFR 50.109(c)): 1. That the only record linking the participant and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality.

For some research projects, the IRB may approve a request to waive the *documentation* of informed consent. This means that the study team must provide a participant with the required consent information, but the research team is not required to obtain the participant's signature on the informed consent document.

Participants should be offered a copy of the consent information for their records even when a signed document is not required for the project.

A waiver of documentation is **permissible** when:

- The signature on the informed consent document would be the only record linking the participant to the research and the principal risk of harm to the participant would be a breach of confidentiality. For example, for research on sensitive topics, such as domestic violence or illegal activities.
- The research presents no more than minimal risk of harm to participants and involves no procedures for which written consent is normally required outside the research context. For example, minimal risk research that involves surveys/interviews conducted via telephone or online.
- If the participants or legally authorized representatives 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 participants and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained

Note for FDA regulated studies: The FDA does not allow a waiver or alteration of the consent except in special circumstances.

Passive or implied consent

Passive consent is not true consent because it does not assure that participation is truly voluntary. This term is sometimes used in research with children to describe situations in which the investigator can assume that a parent is permitting a child to participate. For example, researchers collecting survey and behavioral data from children at school provide parents with information regarding the study by mail and ask the parent(s) to return a form if they do not want their child to participate. Sometimes this practice is referred to as an "opt out" procedure and is not consistent with the regulatory requirement for seeking and obtaining parental permission.

Terms such as "passive" or "implied" consent are not referenced in the federal regulations. However, the federal government does reference altered or waived informed consent documents. If the IRB determines that the conditions for waiver of parental permission can be met, then the IRB could waive

the requirement for parental permission under 45 CFR 46.408(c) or 45 CFR 46.116(c) or (d). Even though not required by the regulations, an IRB may require that parents be given the opportunity to refuse permission even when the IRB has waived the regulatory requirement to obtain parental permission.

References & Resources

§ 46.408 Requirements for permission by parents or guardians and for assent by children.

§ 46.116 General requirements for informed consent

§ 46.117 Documentation of informed consent

FDA: CFR, Title 21

HHS: Informed Consent FAQs

Use of Electronic Informed Consent Questions and Answers: Guidance for Institutional Review Boards, Investigators, and Sponsors