Northeastern University
Human Research

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(f))

A waiver of consent completely waives the requirement to obtain informed consent from participants or their legally authorized representatives. An alteration of consent allows the investigator to leave out or alter elements of the informed consent.

The IRB may approve a waiver or alteration request 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 consent, 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 practicably (feasibly) carried out** without the waiver or alteration.
- If the research involves **identifiable private information** or **identifiable biospecimens**, this research could not be practicably carried out without using the information or specimens in an identifiable format.
- The waiver or alteration will not adversely affect the **rights** and **welfare** of the participants.
- Where appropriate, the participants will be provided with **additional information** after their participation (e.g. debriefing for participants in deception research).

Waiver of Documentation of Informed Consent (45 CFR 46.117(c))

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 one of the following is true:

1. 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, research on sensitive topics, such as domestic violence or illegal activities.)
2. 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 surveys/interviews.)
3. The participants (or their legally authorized representatives) are members of a **distinct cultural group** or community in which signing forms is not the norm, the research presents **no more than minimal risk** of harm to participants, and there is an **appropriate alternative mechanism** for documenting that informed consent was obtained

Note for FDA-regulated studies: FDA only allows a waiver of documentation of consent under option #2 above.

Passive or implied consent

Passive consent is not true consent because it does not ensure 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. It 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 regulations do reference altered or waived informed consent. 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(f). Although 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 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: 21 CFR
HHS: Informed Consent FAQs
Federal guidance: Use of Electronic Informed Consent Questions and Answers: Guidance for Institutional Review Boards, Investigators, and Sponsors