Waiver of Informed Consent

In some cases, informed consent processes can be waived. If a waiver was granted, the researcher would not need to obtain informed consent from participants before conducting the study.

Waiver or alteration of the requirements for obtaining informed consent from adult subjects can occur under any of the following three provisions, according to HHS:

1. Public benefit or service programs: an IRB may approve a consent procedure that alters some or all of the elements of informed consent, or waive the requirement to obtain informed consent under HHS regulations at 45 CFR 46.116(c), provided that the IRB finds and documents that both of the following conditions are met:
    a. the research could not practicably be carried out without the waiver or alteration; and
    b. the research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine:
        - public benefit or 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.
2. Research in general: an IRB may waive or alter the requirement of informed consent under 45 CFR 46.116(d), provided that the IRB finds and documents that all of the following four conditions are met:
    a. the research involves no more than minimal risk to the subjects;
    b. the waiver or alteration will not adversely affect the rights and welfare of the subjects;
    c. the research could not practicably be carried out without the waiver or alteration; and
    d. whenever appropriate, the subjects will be provided with additional pertinent information after participation.
3. Research in emergency settings: an IRB may also waive the requirement for obtaining informed consent if it finds and documents that the research meets the requirements of the HHS Secretarial waiver under 45 CFR 46.101(i) that permits a waiver of the general requirements for obtaining informed consent in a limited class of research in emergency settings (PDF) - PDF exit disclaimer icon (23KB).

For research involving children, an IRB may waive the requirements for obtaining parental or guardian permission under any of the following four provisions:

1. The IRB makes and documents the required findings under 45 CFR 46.116(c) as described above.
2. The IRB makes and documents the required findings under 45 CFR 46.116(d) as described above.
3. The IRB determines that a research protocol is designed to study conditions in children or a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects (for example, neglected or abused children), and the following 2 additional criteria are also met:
    a. an appropriate mechanism is in place to protect the children, and
    b. the waiver is not inconsistent with federal, state, or local law (45 CFR 46.408(c)). The choice of an appropriate substitute mechanism (for example, appointing a child advocate or an assent monitor) for protecting children participating in research would depend on the nature and purpose of the activities described in the protocol, the risk and anticipated benefit to the research subjects, and the child's age, maturity, status, and condition (45 CFR 46.408(c)). Note that an IRB may waive the requirement for obtaining parental or guardian permission under 45 CFR 46.408(c) even if the research involves more than minimal risk to the child subjects.
    c. The IRB finds and documents that the research meets the requirements of the HHS Secretarial waiver under 45 CFR 46.101(i) that permits a waiver of the general requirements for obtaining informed consent in a limited class of research in emergency settings (PDF) - PDF exit disclaimer icon (23KB).