Waiver of Consent / Waiver of Documentation of Consent

The IRB may approve an informed consent document that does not include or alters some or all of the required elements, or waive the requirement to obtain informed consent entirely, including parental permission in the case of child enrollment under 45 CFR 46.116(f)(3). Under 45 CFR 164.512, the IRB may waive, alter, or partially waive the requirements for prospective authorization for use of protected health information (PHI) in research. Before the IRB can waive these requirements, it must assure that all of the conditions in the regulations are met and that its decisions are documented.

Criteria for Waiver of Consent

Under 45CFR46.117(c), the IRB may approve a consent procedure that does not include, or that alters, some or all of the elements of informed consent or that waives the requirement to obtain informed consent provided the IRB finds and documents the following:

1. The research involves no more than minimal risk to the subjects; and

2. The waiver or alteration will not adversely affect the rights and welfare of the subjects; and

3. The research could not be practicably be carried out without the waiver or alteration; and

4. If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format.

5. Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation.

For FDA-regulated research

FDA guidance currently allows for waiver of consent if the reviewing IRB documents that the above criteria are met. FDA does not intend to object to a sponsor initiating, or an investigator conducting, a minimal risk clinical investigation for which an IRB waives or alters the informed consent requirements as described above.

Waiver of broad consent:

If an individual was asked to provide broad consent and refused, the IRB may not waive consent for use of identifiable private information or biospecimens.

Waiver of documentation of informed consent

Documentation of informed consent may be waived by the IRB in certain situations if the consent document is the only record linking the subject to the research and the primary risk of such research is the harm resulting from breach of confidentiality. In these instances, the subjects will be consented, but will not sign the consent form.

The IRB Chair or IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either:

1. That 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 if the subject wants documentation linking the subject with the research, and the subject's wishes will govern. (These criteria are not allowed for FDA-regulated research.) **OR**

2. That 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. (These criteria are allowed for FDA-regulated research).

In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with an oral or written statement regarding the research. The information provided to the participants should include all required and appropriate additional elements of consent disclosure.

At 45CFR46.117(c)(1)(iii), waiver of documentation of informed consent is allowed, provided the criteria for waiver are met, for subjects (or the legally-authorized representatives) who are members of a cultural group or community for whom signing documents is not the norm. Subjects should be provided with oral or written information that includes all required consent elements. The IRB will determine if the researcher should provide participants with a written statement about the research. The waiver is dependent on the criteria that the research presents no more than minimal risk and there is an alternative method for documenting that informed consent was obtained.

Waiver or alteration of the consent process for a public demonstration project

For public demonstration projects conducted or approved by state or local government officials, a waiver of consent may be requested. The following criteria apply:

- The research is conducted by or approved by state or local government officials
- The research or demonstration project is designed to study, evaluate, or otherwise examine:
    - Public benefit or service programs
    - Procedures for obtaining benefits or services under those programs
    - Possible change in or alternatives to those programs or procedures

    - Possible changes in methods or levels of payment for benefits or services under those programs
- The research cannot practicably be carried out without the waiver or alteration
- The research is not regulated by the FDA