

IRB PROCEDURE STATEMENT

Procedure: Waiver of Written Consent – Request and Review

Procedure ID: 03-11-001

Effective: November 5, 2003

Revised: January 17, 2019

A. Background

Federal regulations (45 CFR 46.116) require informed consent to be obtained from every individual who participates in a research project before s/he begins participation.

The regulations (45 CFR 46.117(a)) also require informed consent to be documented by the use of a written consent form approved by the IRB and signed by the subject or the subject's legally authorized representative. The regulations also require a copy to be given to the person signing the form.

The regulations (45 CFR 46.117(c)) do however allow the IRB to waive the requirement for the investigator to obtain a signed consent form for some or all subjects if the Board 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 (or legally authorized representative) will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern;
- 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;
- or
- 3) If the subjects 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 subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained.

In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.

Waiver of Written Consent

The investigator has the responsibility to request and justify a waiver of written consent if one is desired. The IRB has the responsibility to review and either approve or deny the waiver request.

Note: Keep in mind that, as noted above, informed consent is required of all research subjects. Being granted a waiver of written consent does not eliminate the researcher's obligation to obtain informed consent from research subjects before they begin their participation in the project.

B. Procedure

a. The researcher completes an IRB application. If a waiver of written consent is desired at the time of initial application, the researcher indicates on the IRB application that s/he does not plan to obtain written consent (checks the "No" box in response to item VII.g.2 on the application), selects one of the two justifications, and describes how consent will be documented in the box provided.

If a waiver of written consent is requested as part of a requested amendment to a previously approved project, the researcher explicitly includes, in the description of the requested change, language requesting the waiver and the associated rationale.

b. The researcher submits the completed application/amendment request and all relevant materials (e.g., survey, consent-related documents, debriefing forms) to the IRB via IRBNet.

c. If the application/amendment request is reviewed through the expedited process, two IRB members review the waiver request as part of the expedited review process and determine if the conditions for granting a waiver of written consent have been met.

1. If the two reviewers do not concur relative to approving the waiver (one reviewer determines the waiver should be granted and the other reviewer determines the waiver should not be granted), the ORC will request the two reviewers confer to decide if concurrence can be achieved. If concurrence cannot be reached, the application/amendment request will be referred to the full Board for review at its next monthly meeting.
2. The ORC will notify the P.I. and advisor (if applicable), via IRBNet, of this referral.

d. If the application/amendment request is to be reviewed by the full Board, the determination regarding waiving written consent is made by the full Board during the monthly meeting at which the application/modification request is reviewed.

Waiver of Written Consent

e. The ORC notifies the P.I., and the P.I.'s advisor (if applicable), via IRBNet, of the outcome of the review. The notification letter and other applicable document(s) can be located in the "Board Documents" section of the relevant project in IRBNet.