



HSRB POLICY AND PROCEDURE STATEMENT

Policy/Procedure: Waiver of Written Consent – Request and Review

Policy/Procedure ID: 03-11-001 **Effective:** November 5, 2003

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 HSRB 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 HSRB 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;
- 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.

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

The investigator has the responsibility to request and justify a waiver of written consent if one is desired. The HSRB 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.

Waiver of Written Consent

B. Procedure

a. The researcher completes an HSRB application. If a waiver of written consent is desired at the time of initial application, the researcher indicates on the HSRB 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) and provides the rationale for requesting the waiver in the box provided.

If a waiver of written consent is requested as part of a requested modification 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/modification request (signed, dated, with the advisor’s signature if the P.I. is a student) and all relevant materials (e.g., survey, consent-related documents, debriefing forms) to the Office of Research Compliance (ORC).

c. The ORC checks the submitted application/modification request and determines if a waiver of written consent has been requested.

d. If a waiver of written consent has been requested, the ORC attaches a Request for Waiver of Written Consent review sheet to the application/modification request and submits the application/modification request for HSRB review.

e. If the application/modification request is reviewed through the expedited process, two HSRB 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/modification 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), in writing, of this referral.

f. If the application/modification 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.

g. The ORC notifies the P.I. and the advisor (if applicable), in writing, of the outcome of the review.