

HAC Policies and Procedures

Waiver of Consent and Waiver of the Requirement of Written Documentation of Consent

HAC Policies and Procedures

What is the difference between waiver of consent and waiver of documentation of consent?

Waiver of Consent

Waiver of consent (which includes waiver of the informed consent process **and** waiver of the documentation of consent) is only granted in specific cases that meet the criteria found at 45 CFR 46.116(d) . In order for the HAC to review a request for a waiver of the informed consent process, the investigator must clearly document, in the Description of Research Proposal (DRP), that the research complies with the following elements:

- 1) The research involves no more than minimal risk to the subjects;
- (2) The waiver or alteration will not adversely affect the rights and welfare of the subjects;
- (3) The research could not practicably be carried out without the waiver or alteration; and
- (4) Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

Waiver of consent is usually granted by the HAC for retrospective chart reviews in which there is no greater than minimal risk and in which no Protected Health Information (PHI) will be collected for the research.

Waiver of the Requirement to Obtain Written Documentation of the Consent Process

Waiver of the requirement to obtain written documentation of the consent process is found at 45 CFR 46.117 (c) which states that

An 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 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.

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.

HAC Policies and Procedures

This regulation does not involve waiver of the informed consent process. Rather, it involves waiver of the documentation of the informed consent process.

45 CFR 46.117 allows the investigator to alter the requirements for written documentation of informed consent via a “short form” document which does not include all of the required elements. It also allows the investigator to ask the subject if they want documentation to link them with the research and if the subject does not want the documentation, then the requirement for documentation may be waived. When requesting waiver of written documentation of the consent process, the investigator must submit a written description of the information that would be provided to subjects.

Requests for waiver of consent and waiver of documentation of consent are reviewed on a case-by-case basis and are not to be viewed as an option for most research. These exceptions to the requirements are heavily scrutinized by the Committee to confirm that all requirements are met.

What About HIPAA And The Waiver Of Authorization?

The HIPAA Privacy Rule which became effective on April 14, 2003, changed this standard of practice. The Privacy Rule has its own list of criteria that must be met in order to waive a subject's written authorization to use and disclose individually identifiable health information for research.

What Are The HIPAA Criteria To Waive Written Authorization?

The following criteria found at 45 CFR § 164.512(i) (2) (ii) are similar, but not identical, to the criteria in the Common Rule.

1. The research involves no more than minimal risk to the privacy of the subjects. The protocol must include, at a minimum, the following elements:
 - a) An adequate plan to protect identifiers from improper use and disclosure.
 - b) An adequate plan to destroy the identifiers at the earliest opportunity. Identifiers can be maintained if there is a health or research justification or if retention is required by law. The investigator must document such justification.
 - c) Adequate written assurances that the identifiable information will not be reused or disclosed except:
 - As required by law
 - For authorized oversight of the research project

HAC Policies and Procedures

- For other research for which the use or disclosure would be permitted
2. The research could not practicably be carried out without the waiver or alteration.
 3. The research could not practicably be conducted without access to and use of this identifiable information.

If I Request Waiver of Written Informed Consent or Waiver of Authorization, does this Request Automatically Require Review by the Full HAC?

No. The HAC Chairman will evaluate each protocol requesting waiver of consent and will determine if full review is required.

What About the Use of Oral Consent And/Or Authorization?

The process of using oral consent and/or waiver of written authorization should be documented in the subject's research notes by the investigator. Researchers should ask subjects if they wish to receive a copy of the Privacy Notice and provide the Notice if requested. The minimum necessary standard and the requirement to track disclosures do not apply.

Where Do We Request This Type Of Consent And/Or Authorization?

The protocol submitted to the HAC must address all three of the requirements outlined earlier in this policy. Particularly important are items above relating to identifiers. Some studies that previously fit into the "exempt" category may now require "expedited" or full Committee review.

The researcher must assure, in writing, that the protected information will not be reused or wrongly disclosed by the researcher. Practically, this item may be satisfied by the investigator stating that the information will only be used as described in the approved protocol, or in an amendment approved in writing by the HAC.

The HAC file is required to contain a "brief description" of the information to which access is requested. Therefore, a proper and clearly written protocol should fulfill this requirement.