

Guidelines of Requests for Waiver of Consent

In certain cases, federal regulations allow the IRB to approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent, or to *waive the requirement to obtain any informed consent*. Most complete waivers of consent involve studies in which there are minimal risks to subjects, but complete waivers are also possible in emergency care and a few other circumstances.

NOTE: Studies regulated under the FDA regulations differ from HHS regulations and are generally more restrictive in the area of waiver of informed consent. The differences are noted below.

I. Waiver of Informed Consent

Federal regulations at [45 CFR 46.116\(d\)](#) establish four criteria for waiving consent or altering the elements of consent in minimal risk studies. *There are no corresponding provisions in FDA regulations, and these criteria may not be used to waive or alter the elements of consent in FDA-regulated studies:*

1. The research involves no more than [minimal risk](#);
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.

Minimal risk is defined in [45 CFR 46.102](#) as “the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.”

Example of requests for waiver of consent that may be approved by the IRB:

- *Review of medical records of all patients who have undergone abdominal surgery in the past two years and correlate the data with blood chemistry values kept by pathology. Researchers are collecting limited data that will be assigned a random code # and the link is known only to the researchers. Results of the research will not affect clinical care of the individuals, since they will already have left the hospital.*

- 1) **Minimal risk:** evaluating patient records fits definition of minimal risk.
- 2) **Would not adversely affect rights and welfare of subject:** Surgery and associated blood chemistry values are clinically indicated, therefore would be done regardless of the research. No study results would affect clinical decisions about the individual's care.
- 3) **Research could not be practicably carried out without the waiver:** Identifying and contacting thousands of potential subjects, while not impossible, would not be feasible for a medical record review where results would not change care the individuals already would have received. (**Note:** In smaller studies, it is harder to argue that obtaining consent is not feasible, especially if subjects have not yet been treated or are still being seen.)
- 4) **Whenever appropriate, subject provided with additional pertinent information after participation:** Not appropriate in this case, since results of research would have no effect on the subjects; there is no anticipated benefit to subject that would change what has already occurred*

II. Waiver of Documentation of Consent

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Federal regulations [[45 CFR 46.117\(c\)](#)] allow the IRB to waive the requirement for obtaining signed consent if it finds that either:

1. 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 (*These criteria cannot be used for FDA-regulated studies*),
or
2. 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. *This paragraph only also applies to FDA-regulated studies per [21 CFR 56.109\(c\)\(1\)](#).*

The IRB can also waive signed consent in studies that meet the requirements for waiving all consent. Often *verbal consent* used with use of an information sheet or implied consent will still be required for most studies where a waiver of documentation of consent is granted by the IRB. Investigators may wish to replace signed consent with *implied consent* (e.g., a prospective subject is informed about a study where participation consists only of filling out an anonymous questionnaire; the person completes the questionnaire and, by doing so, agrees to participate in the research). The IRB will consider approving such requests based on appropriate justification and information regarding the consent process.

Examples of approvable waiver of documentation of consent:

- When the identities of subjects will be completely anonymous and there is minimal risk involved in the study. The signed informed consent would be the only record linking the subject to the study therefore it would be the only identifier in the study.
- When obtaining signed consent is not appropriate or feasible according to the cultural standards of the population being studied, and there is minimal risk involved in the study.
- When there is a possible legal, social or economic risk to the subject entailed in signing the consent form, e.g., for immigrants who might be identified as being illegal aliens, or for HIV antibody-positive individuals who might be identified as such by signing the consent form.
- When the study involved only a telephone interview.

Investigators may wish to replace signed consent with verbal consent. The IRB will consider approving such requests in limited circumstances, and will usually require use of an information sheet. If this is not feasible (for example, the only contact is by phone), the IRB may ask to see a *script* of what would be said to prospective subjects to evaluate the consent process.

Use of Information Sheets

As the regulations state, "in cases where the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research." In such cases, the IRB will usually call for use of an *information sheet* that includes most or all of the elements of a consent form but not the subject's signature.

*Example used was provided by *Institutional Review Board: Management and Function*, R. Amdur and E. Bankert, Chap. 6-6, "Research without Consent or Documentation Thereof," M. M. Elliott.)