

Waivers of Informed Consent Guidelines

Under certain circumstances, the IRB may

- waive the need to document informed consent, or
- waive the need to obtain informed consent, or
- approve an alteration to some or all of the elements of informed consent.

Waivers of informed consent are primarily relevant for projects involving the secondary analysis of existing data or in projects involving deception.

Requesting a Waiver of Documentation of Consent

For some research projects, the IRB may approve a request to waive the *documentation* of informed consent. This means that the study team must provide the participant with the required consent information, but the study team is not required to obtain the subject's signature on the informed consent document.

A waiver of documentation is permissible when:

- That the only record linking the subject and the [research](#) would be the informed consent form 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;
- 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
- 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.

Participants should be offered a copy of the consent information for their records even when a signed document is not required for the project

Requesting a Waiver or Alteration of Informed Consent Requirements

The IRB must ensure that the following four criteria are met prior to approving a waiver or alteration of consent. Investigators must provide the IRB with a justification of how their project meets EACH of the criteria:

1. The research poses no more than minimal risk to subjects.
Describe specifically how the proposed research poses no more than minimal risk to participants. Simply restating that it involves no more than minimal risk is not sufficient. Some considerations for assessing risk and formulating justification:

- Minimal risk means 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.

If you are conducting a record review or using data from medical records:

- Is the information sensitive in nature?
- Is the data being collected derived from clinically indicated procedures?
- What precautions are being taken to ensure there is no breach of confidentiality?

2. The research could not practicably be carried out without the waiver or alteration.

Describe why it would not be feasible to conduct the study without a waiver or alteration of informed consent. Consider the following:

- Is it likely that the data being reviewed contains out of date contact information for participants?
- Does the number of charts being reviewed make it impractical to contact each participant for consent?
- Would identifying and contacting each participant to obtain consent be prohibitive?

3. The waiver or alteration will not adversely affect the rights and welfare of the subjects who are involved in the research.

Describe why the waiver will not adversely affect participants. Consider the following:

- Are tests or procedures being done solely for this research or is data being collected on past procedures that are completed?
- Could the results of the research potentially affect participants' regular care?
- Would the use of their information affect participants' regular care or deprive them of care?
- Could participation in the study negatively affect participants' well-being?

4. Whenever appropriate, the subject will be provided with pertinent information after participation.

Describe whether information resulting from the study will be disclosed to subjects. Consider the following:

- Will the results from the study have any effect on subjects or their regular care?
- Are there any anticipated benefits that would change care subjects have already received?

NOTE: Waivers or alterations of consent cannot be granted for studies that are regulated by the Food and Drug Administration (FDA).

An example of a request for a waiver of informed consent

The researcher plans to determine whether some specific blood chemistry values change in individuals undergoing clinically indicated abdominal surgery and if there is a correlation of changes with the increased incidence of complications after surgery.

The proposed research plan is to:

Review the medical records of all individuals who have undergone abdominal surgery in the past 2 years. Data to be collected:

- Diagnosis before surgery
- Type of abdominal surgery
- Specific pre-surgery blood chemistry values
- Specific post-surgery blood chemistry values
- Description of the problems after surgery
- Age range of the individuals.

From a preliminary estimate, there are about 5,000 abdominal surgeries per year at the hospital. The researcher will double code the data so that only the researcher knows the link in the unlikely event the data must be verified for accuracy. The results of the research will not affect the clinical care of the individuals because the information will not be examined until after subjects leave the hospital.

Is there sufficient justification for IRB to approve a waiver of informed consent?

In this example, the IRB may determine that the criteria from 45 CFR 46 1[Sec.116(f)(3)] have been met based on the following rationale provided by the researcher:

1. The research involves minimal risk, as the review of subjects' medical records is for limited information. The information is not sensitive in nature, and the data are derived from clinically indicated procedures. There is an extremely low probability of harm to subjects' status, employment, or insurability. The precaution is taken to limit the record review to specified data and double coding of the data further minimizes the major risk, which is a breach of confidentiality. Contacting subjects to obtain their consent could be considered an invasion of privacy and cause subjects' undue anxiety.

2. The rights and welfare of the individual would not be adversely affected because the clinically indicated surgical procedure and the associated blood chemistry values were already completed, or would be completed, regardless of the research. None of the results of the research would affect the clinical decisions about the individual's care because the results are analyzed after the fact. Subjects are not deprived of clinical care to which they would normally be entitled.

3. The research could not be practicably carried out without a waiver. Identifying and contacting the thousands of potential subjects, although not impossible, would not be feasible for a review of their medical records for information that would not change the care they would already have received.

4. It would not be appropriate to provide these subjects with information about the results of the research as the results would have no effect on the subjects. The surgical procedure and post-surgical care have both been completed for these subjects. There is no anticipated benefit to subjects that would change what has already occurred.