

REQUESTING A WAIVER OR ALTERATION OF INFORMED CONSENT REQUIREMENTS

What is a waiver or alteration of informed consent requirements?

It is a consent procedure in which informed consent is not obtained from subjects; or that eliminates or alters some (or all) of the elements of informed consent as set forth in Federal regulations (45 CFR 46.116 (f))

Waiver of Consent: Informed consent is not obtained from subjects

Alteration of Consent: One or more of the [elements of consent](#) are altered or eliminated (e.g., in research involving deception)

The IRB must ensure that the following 5 criteria are met prior to approving a waiver or alteration of consent. Investigators must provide the IRB with justification of how their project meets EACH of the criteria:

1. The research or clinical investigation poses no more than minimal risk to subjects

Describe specifically how the proposed research poses no more than minimal risk to subjects. 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 or clinical investigation 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- Is it likely that the data being reviewed contains out of date contact information for subjects?
- Does the number of charts being reviewed make it impractical to contact each subject for consent?
- Would identifying and contacting each subject to obtain consent be prohibitive?



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3. If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format (Not required for FDA-regulated studies);

4. The waiver or alternation will not adversely affect the rights and welfare of the subjects who are involved in the research, and

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

- Are tests / 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 the subject's regular care?
- Would use of their information affect subjects' regular care or deprive them of care?
- Could participation in the study negatively affect the subjects' wellbeing

5. Whenever appropriate, the subjects or LARs will be provided with additional 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?

EXAMPLE OF A REQUEST FOR 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(d)]} 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 taken to limit the record review to specified data and double coding of the data further minimize the major risk, which is breach of confidentiality. Contacting subjects to obtain their consent could be considered an invasion of privacy and cause subjects undue anxiety.
- 2. 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 have already received.
- 3. The research does not involve using identifiable private information or identifiable biospecimens;**
- 4. 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**



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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.

One way to think about this criterion is: Would the subjects have a problem if they knew? Would they take issue with the fact that they weren't asked for consent to conduct the activity?

- 5. The criterion regarding providing subjects or LAR's additional pertinent information is not applicable or appropriate to this study.**