ALTERATIONS TO INFORMED CONSENT REQUIREMENTS

Waiver for Informed Consent and Waiver of Documentation of Informed Consent

What is Waiver of Consent

Waiving the requirement for obtaining informed consent means that the DSRB has determined that investigators need not obtain the subjects' informed consent to participate in research.

DSRB may waive the requirement for obtaining informed consent in research that meets all the following criteria:

a) The research involves no more than minimal risk to the subjects;

b) The waiver or alteration will not adversely affect the rights and welfare of the subjects;

c) Whenever appropriate, the subjects will be provided with additional pertinent information after participation;

d) The research could not practicably be carried out without the waiver or alteration; and

e) The research is not subject to FDA regulations.

Example of Waiver of Consent

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 number and the link is known only to the researchers. Results of the research will not affect clinical care of the individuals, since they have left the hospital.

What is Waiver of Documentation

The DSRB may waive the requirement for the Investigator to obtain a signed consent form for some or all subjects if the DSRB finds either

a) All the following are true:

i. The only record linking the subject and the research would be the consent document;

ii. The principal risk would be potential harm resulting from a breach of confidentiality;

iii. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern;

iv. The research is not subject to FDA regulations.

b) All of the following are true:

i. The research presents no more than minimal risk of harm to subjects; and

ii. The research involves no procedures for which written consent is normally required outside of the research context.

Example of Waiver of Documentation

A researcher plans to evaluate the effectiveness of a smoking cessation programme with women who are receiving prenatal care at the local health clinic. During a prenatal visit, any women who are already participating in the smoking cessation programme will be asked to complete a written questionnaire about the program. The one-time written questionnaire includes questions about how well the women are complying with the program and how they feel about their progress. There is no identifying information about the subjects on the questionnaire and whether the subjects complete the questionnaire has no effect on the care they may receive at the clinic.

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Applying for Waiver of Consent

In the DSRB Application Form, the Investigator is expected to provide specific examples from the proposed research study to demonstrate that the specific criteria are met.

1. Does the study pose no more than minimal risk to the Subjects?

Yes, the study poses no more than minimal risks because...

Examples:

•The study is a retrospective review of medical records, where the data evaluated is not sensitive in nature, hence fits the definition of minimal risk

2. Does the waiver of informed consent adversely affect the rights and welfare of the Research Participants?

No, the waiver will not adversely affect the rights and welfare of the research participants because....

Examples:

•The tests/data have been collected as part of the patient's normal clinical management. The analysed results from the research study will not affect the medical care and decision about the treatment of the patient.

•Previous consent has been obtained for the use of leftover or archived tissue for other research

3. Can the study be practically conducted without the waiver of informed consent?

No, the study may not be practically conducted without the waiver.

Examples:

•Patients are no longer contactable or lost to follow-up

•Medical records review involving thousands of records

Note: In smaller studies, it is harder to justify that obtaining consent is not feasible, especially if subjects have not been treated, or are still being seen.

4. Whenever appropriate, will the research participants be provided with additional pertinent information after participation?

Yes / No

(Note: The type of research results generated will determine whether it is appropriate to provide results to subjects)

Example:

•Using the example in page 5, it is appropriate not to provide further information. The research results do not affect the health status or provision of medical care to the subject.

•Conversely, if the results of a case notes review, indicate a strong correlation of a use a particular intervention to the development of serious health problems in several years, it is then appropriate to inform the subjects.

Where Can I Get More Information?

Investigator Manual Chapter 08 Guidance Documents (Informed Consent)

DSRB SOP 201-C08 Informed Consent Requirements

DSRB SOP 201-C09 Alteration to Informed Consent Requirements

OHRP Informed Consent FAQs
http://www.hhs.gov/ohrp/informconsfaq.html#q26