Waiver of Informed Consent

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1. Regulations and Overview

Informed consent is mandated by Federal policy (45 CFR 46 Section 116). Informed consent is also one of the fundamental principles of ethical conduct in the use of human subjects. Occasionally there are reasons to waive written consent or to alter the requirements of consent. Only the IRB can make the determination to waive some or all consent requirements.
Under some circumstances, described in the Federal Regulations, an investigator may feel that his/her study justifies a request to waive consent. The essential conditions of a waiver are:
1) that the research pose no more than minimal risk to subjects; 2) no adverse effects as a result of the waiver or alteration; 3) without the waiver or alteration the research in question could not be carried out; and 4)information will be provided after participation is completed, if appropriate.
If these conditions seem to apply, investigators may wish to consult the federal regulations: Federal Policy for the Protection of Human Subjects **§46.116 General requirements for informed consent; §46.117 Documentation of informed consent.**
http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.116

2. When would the IRB generally NOT approve a Waiver of Informed Consent?

1. I don't have enough money in my research grant to print consent forms and distribute them and file them.
2. These are my patients so I see them anyway and they trust that I will not involve them in something that might harm them.
3. I already have access to the patient records.
4. There isn't any risk even though it would be possible to get consent.
5. I don't have a staff member who can handle all the paperwork involved in obtaining informed consent.
6. If I consent people, they will not want to participate in the study.
7. The consent form will scare people. It seems so legalistic. (Note that in limited circumstances where local cultural norms or contexts exist making research impracticable due to taboos or stigma against signing documents, rationale for a waiver of signed consent may exist.)

3. How do I apply for a Waiver or Alteration of elements of Consent?

There is no "Waiver Form," per se. In the Consent Process section of your protocol, you must describe how all of the regulatory criteria are met to qualify for a waiver of informed consent. A request to waive written and verbal informed consent, or any of the required elements of informed consent must be accompanied by a complete explanation in response to the four statements below. Note that the decision to waive Informed Consent generally hinges on Item 3. The rationale for this item in particular must be well-developed and explained in the protocol.
1. The proposed research presents no more than minimal risk of harm to subjects.
2. The waiver or alteration of consent 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.

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

4. What are some examples of when the IRB might approve a Waiver of Informed Consent?

A. Example*: In conducting interviews with students they will be asked about their social network, including the names and some demographic information of their friends to determine how various student groups interact.* [Secondary subjects in research.]
Sample rationale*:*
1) No information that may be harmful or risky will be obtained about the student's network friends, so there is minimal risk.
2) The information obtained is commonly discussed by students, so novel information about the secondary subject will not be revealed and their rights and welfare will not be impacted.
3) It would be impossible to know ahead of time who will be discussed by the original student, making the study impracticable without the Waiver.
4) We will contact all students in the social networks to request their information be used in the study.

B. Example: *A chart review of approximately 2000 existing patient records to determine the recurrence rates of cancer after radiation treatment.*
Sample rationale*:*
1) *The current study will be reviewing pre-existing patient charts for information on treatment with radiation and cancer recurrence rates so there is very minimal risk to the subject.*
2) *The information taken from patient charts will not include any identifiable information so this study will not violate the subject's rights.*
3) *The study involves a chart review of all subjects diagnosed with breast cancer who went through radiation treatment at NMH in the last 10 years. It would be impossible to contact over 2000 subjects, some of whom will no longer be alive and others whom will have no current address information available.*
4) *This is not appropriate to our current study because there is no common medium to notify subjects of our findings.*

C. Example: *Subjects will be told that a placebo they are given actually contains an active ingredient in order to study what impact the placebo effect has on their perception of a stimulus.* [Studies involving deception or incomplete disclosure generally represent a deviation from the requirement that Informed Consent include an explanation of the research purposes and identification of any experimental procedures. For this reason they will always require a Waiver of some elements of Informed Consent]
Sample rationale:
1) The stimulus being studied does not present any risk of harm to the subjects, and only minimal psychological discomfort is expected once it has been revealed a placebo was used.
2) Subjects will be allowed to have their data removed from the study once the deception is revealed, maintaining their rights and welfare.
3) Because the study is specifically about the effect of the placebo, the study could not be accomplished without the deception and Waiver of Consent.
4) Subjects will be fully debriefed following participation about the use of the placebo and the full purposes of the study.

5. What is required for a Waiver of Written Informed Consent/Verbal Consent Process?

Waiver of written informed consent may be requested but this does not mean that verbal consent will not be utilized. A Waiver of Written Consent refers specifically to obtaining a signed form from the subject. A script for verbal consent should be submitted to the IRB for review. **A verbal consent script must**

provide all of the elements of consent, though it can do so in a more informal style. In addition, each subject should be provided with an information sheet that describes the study and gives contact names and numbers.

Normally, investigators will be asked to keep a log of those who were approached about the study, and offered verbal consent. A simple chart can indicate the subjects as subject 1, subject 2, and subject 3. A column can indicate that verbal consent was given and a date. Since a specific number of study subjects have been requested in the IRB application, it is important that investigators keep some record to indicate that they are not enrolling more subjects than they originally requested.

For more information about verbal consent, see the Verbal Consent Guidance document on our website, here: Waiver of Written Documentation of Informed Consent and Verbal Consent.

6. How do I obtain a Waiver of consent in Emergency Care Research?

Obtaining a waiver of consent in emergency research is an involved and generally lengthy process. The federal regulations 21CFR50.24 describe the situations where this can occur. The information provided here does not cover situations for requests to waive consent in emergency research. Investigators should contact OHRP for assistance in planning emergency research. This should also not be confused with Emergency Use Requests. Emergency use requests are for one time only, do not involve gathering data, and are not considered "research" in the standard definition, though such uses are approved by the IRB.