

Guidance Document:**Waiver of Informed Consent****Background**

Informed consent is one of the fundamental principles of ethical conduct in the use of human subjects, and is mandated by Federal policy (45 CFR 46 Section 116). Occasionally there are reasons to waive 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, a request to waive consent may be permitted. The essential conditions of a waiver are:

- 1) The research involves no more than minimal risk to subjects;
- 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.

If these conditions apply, an investigator may request the IRB waive some or all of the requirements for Informed Consent within their submitted Protocol Document.

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

In order to waive Informed Consent, all of the above requirements must be met. However, because informed consent is a core ethical principal in the conduct of research involving human subjects, such a waiver should be considered an exception to standard practice, and rare. Some reasons for not obtaining consent will not be accepted, such as:

- I don't have enough money in my research grant to print consent forms and distribute them and file them.
- These are my patients so I see them anyway and they trust that I will not involve them in something that might harm them.
- I already have access to the patient records.
- There isn't any risk even though it would be possible to get consent.
- I don't have a staff member who can handle all the paperwork involved in obtaining informed consent.
- If I consent people, they will not want to participate in the study.
- The consent form will scare people. It seems so legalistic.

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 the consent process is to be altered (is this a request for full waiver of consent, or only a partial waiver of some elements?), and how all of the regulatory criteria are met to qualify for a waiver of informed consent. A request to waive informed consent, or any of the required elements of informed consent must include 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.

- The proposed research presents no more than minimal risk of harm to subjects.
- The waiver or alteration of consent will not adversely affect the rights and welfare of the subjects.
- The research could not practicably be carried out without the waiver or alteration.
- Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

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:

- No information that may be harmful or risky will be obtained about the student's network friends, so there is minimal risk.
- 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.
- It would be impossible to know ahead of time who will be discussed by the original student, making the study impracticable without the Waiver.
- 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:

- The current study will be reviewing pre-existing patient charts for information on treatment with radiation and cancer recurrence rates. No new diagnoses will occur, and there are strict data

management procedures in place to protect subject confidentiality so there is minimal risk to the subjects.

- The information taken from patient charts will not include any identifiable information so this study will not violate the subject's rights.
- 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 that 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. For more information on the use of Deception and Incomplete Disclosure, please see the IRB's Guidance document on that topic, here: [Deception and Incomplete Disclosure.](#)]

Sample rationale:

- 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.
- Subjects will be allowed to have their data removed from the study once the deception is revealed, maintaining their rights and welfare.
- Because the study is specifically about the effect of the placebo, the study could not be accomplished without the deception and Waiver of Consent.
- Subjects will be fully debriefed following participation about the use of the placebo and the full purposes of the study.

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.