

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). However, 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. The general requirements that must be met for a Waiver of Informed Consent to be approved are:

- 1) The research involves no more than minimal risk to the subjects;
- 2) The research could not practicably be carried out without the requested waiver or alteration;
- 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;
- 4) The waiver or alteration will not adversely affect the rights and welfare of the subjects; and
- 5) Whenever appropriate, the subjects or legally authorized representatives 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?

To request a Waiver of Informed Consent you must describe how the consent process is to be altered in the Informed Consent section of your Protocol Document, as well as how all of the regulatory criteria are met to qualify for a waiver of informed consent. There is no "Waiver Form" to be completed. A request to waive informed consent, or any of the required elements of informed consent must include a complete explanation in response to the above criteria.

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

Identifiable data is being obtained from a large data repository. The data to be analyzed includes of archival video data, student demographics, test scores, etc. There are strict data access restrictions in that users can only access data using existing servers and cannot download any of the data. The data repository will only provide access to the data, but will not conduct any de-identification themselves.

Sample rationale:

- The data was originally collected as a part of minimal risk research studies. The data includes no information that would be stigmatizing, or lead to other risks to the participants.
- There is no way to re-contact all of the participants about whom data will be collected to obtain their consent for this research analysis – current contact information is not maintained.
- In order to link all of the data sets from the study participants held by the repository, the identifiable linking document must be used. There are no provisions available to obtain a complete set of non-identifiable, linked data.
- Participants provided consent originally for the storage and future, undefined use of the study data.
- This is not applicable as study participants are unable to be re-contacted.

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 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.