

Information about Waivers or Alterations of Consent¹

Background

Unless a study is “exempt,” federal regulations require that subjects give informed consent *prior to participation* in research; indeed, this is the cornerstone of ethical research with human subjects.

For most studies, the consent process involves conveying relevant information about the study to subjects, in a manner that is understandable and free from coercion or undue influence. A common component of the consent process is providing subjects with a written document containing all relevant [information](#) that they will read and sign, either physically or via electronic signature, if they agree to participate. The signature serves to document the informed consent process. Normally, obtaining signed consent from subjects prior to their participation is required.

Obtaining signed consent is problematic for some studies, such as those conducted online or in situations where subjects may be uncomfortable signing documents. In some cases, it is scientifically necessary to intentionally withhold certain information from subjects to avoid biased responses. In others, obtaining informed consent may not be possible (e.g., obtaining a large number of historical student records).

Federal regulations recognize these issues and allow the IRB to waive:

- Documentation of consent (i.e., subjects do not sign consent forms);
- Disclosure of some [elements of consent](#) (e.g., some of the required elements are excluded or incomplete); or
- The consent process in general (i.e., no informed consent process is needed).

In order for the IRB to waive consent requirements, certain conditions must be met, which are described in this document. Investigators seeking a waiver must provide justification in the IRB application. **Note:** Some research is subject to additional regulations, which may prohibit the IRB from waiving consent or documentation of consent, such as research with students or at schools that must abide by FERPA and PPRA regulations.

Waiving Documentation of Consent

A waiver of documentation of consent means that subjects are provided with all information necessary to give informed consent, but they do not need to sign a consent document. The IRB may waive the requirement to obtain signed informed consent if any of the following are true:

1. that the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a break of confidentiality (Note: Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject’s wishes will govern.);

¹ This document describes general conditions under which waivers may be granted. There are more stringent regulations that apply when research involves certain populations, such as children, prisoners, pregnant women, or adults with decisional impairment. For research involving these populations, contact the Office of Research Ethics for additional details if a waiver of consent or documentation of consent is desired.

2. that the research presents no more than minimal risk of harm² to subjects and involves no procedures for which written consent is normally required outside of the research context. (Note: This criteria also applies to FDA regulated studies under 21 CFR 56.109 (c))³; **or**
3. if the subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained.⁴

Even if documentation requirement of consent is waived, the IRB may require the investigator to provide subjects or legally authorized representatives with a written statement regarding the research.

Note: Studies regulated by the FDA also allow waivers of signed consent in certain cases that do not meet the minimal risk criteria but involve emergency research.

Common scenarios where a waiver of documentation of consent is appropriate

- Instances where the researcher will not meet with subjects in person, such as online or mail surveys, telephone interviews, etc.;
- Low-risk Procedures in preparation for an initial lab visit (e.g., fasting, completing questionnaires); documentation of consent may be waived for the preparatory procedures (signed consent is obtained during the first lab visit);
- Research with a population for whom signing a document is culturally inappropriate or otherwise makes them uncomfortable;
- Research with a population that cannot read or has limited literacy;
- Research where ensuring complete anonymity of subjects is important to reduce risk (e.g., with undocumented persons, collection information about illegal behavior, etc.)

Waiving Informed Consent or Some Elements of Consent

An IRB may approve a consent procedure which does not include, or which alters, some or all of the [elements of informed consent](#) if it finds and documents that

1. the research involves no more than minimal risk to the subjects; **and**
2. the waiver or alteration will not adversely affect the rights and welfare of the subjects; **and**
3. the research could not practically be carried out without the waiver or alteration; **and**

² “Minimal risk” is defined as “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 performance of a routine physical or psychological examination” (per 45 CFR 46.102 (h)).

³ Studies regulated by the FDA mostly involve testing medical devices, food additives, dietary supplements, or drugs.

⁴ Criterion 3 applies only to research subject to the 2018 Common Rule (i.e., approved after January 21, 2019 or formally transitioned to the 2018 Common Rule).

4. if the research involves using identifiable private information or identifiable biospecimens, the research could not be practicably carried out without using such information or biospecimens in an identifiable format⁵; **and**
5. whenever appropriate, the subjects will be provided with additional pertinent information after participation. Note: The intent of this criterion is to require debriefing for participants in deception research.

Studies regulated by the FDA allow waivers of consent only in certain cases involving emergency research if they meet the provisions stated in 21 CFR 50.23 and 21 CFR 50.24. Please contact the Office of Research Ethics for more details.

In order for the IRB to approve either of these waivers, there must be sufficient justification for doing so.

Common scenarios where waiving some elements of consent is appropriate (with sufficient justification)

- Research that requires subjects to be deceived or not fully informed about some aspects of the study in order to obtain valid results;

Common scenarios where informed consent can be waived (with sufficient justification)

- Secondary research using records⁶ when contacting persons is not practicable.
- Research involving manipulation of the environment in a public setting (e.g., posting flyers in a classroom about energy reduction benefits to see if persons are more likely to turn off lights), where it is not feasible to obtain consent from all persons who may enter a space.

Exception to Informed Consent for Screening, Recruiting, or Determining Eligibility

Effective January 21, 2018, the IRB may approve a research proposal in which an investigator will obtain information or biospecimens for the purpose of screening, recruiting, or determine the eligibility of prospective subjects without their formal informed consent if procedures are limited to:

1. obtaining information through oral or written communication from subjects (e.g., screening interviews or surveys), or
2. obtaining data from records or stored biospecimens.

When screening or recruiting procedures involve contact with subjects, they should be informed why the information is requested, how it will be used, key confidentiality provisions, and that providing the information is voluntary.

⁵ Criterion 4 applies only to research subject to the 2018 Common Rule (i.e., approved after January 21, 2019 or formally transitioned to the 2018 Common Rule).

⁶ Special permission is typically required from the office or institution that holds records and should be obtained prior to IRB approval of the research and of any waivers of informed consent. Further, other policies related to records (e.g., HIPPA for medical records or FERPA for student records) must be followed. These policies may prohibit the IRB from waiving consent or documentation of consent.

Document History

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