Information about Waivers of Consent

Unless a study is “exempt,” federal regulations require that subjects give consent prior to participation in research; indeed, this is the cornerstone of ethical research with human subjects. Such consent can be given only when subjects are adequately informed about the research in which they are asked to participate, including the purpose of the study, the procedures to be followed, the possible risks and benefits to subjects and society, the voluntary nature of their participation, how the data they provide will be handled and confidentiality maintained, any compensation subjects may receive, and whom they may contact for more information about the study and about the rights of research subjects.

For most studies, the consent process includes, among other things, providing subjects with a document containing all relevant information which they will read and sign if they agree to participate. Normally, obtaining signed consent from subjects prior to their participation is required by federal regulations. In some cases, obtaining signed consent is problematic due to the nature of the study. For example, a study that examines records of past ISU students may not be feasible if it is deemed necessary to obtain signed consent from students who no longer are on campus. Subjects in studies that examine highly sensitive subjects, such as sexual behaviors or illegal activity, may be uncomfortable signing documents that could link their identity to the results.

Federal regulations recognize these issues and allow the IRB to waive either documentation of consent (i.e., having subjects sign forms) or the consent process in general (i.e., no informed consent document is needed). In order for the IRB to waive consent requirements, certain conditions must be met. (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 which must abide by FERPA and PPRA regulations.)

Waiving Documentation of Consent

According to 45 CFR 46.117(c), an IRB may waive the requirement for the investigator to obtain a signed consent form from some or all subjects if it finds either

- 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.); or

- that the research presents no more than minimal risk of harm 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)).

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.

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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 for Responsible Research for additional details if a waiver of consent or documentation of consent is desired.

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.
Waiving Some or All of the Elements of Consent

45 CFR 46.116(d) states that 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

- the research involves no more than minimal risk to the subjects; and
- the waiver or alteration will not adversely affect the rights and welfare of the subjects; and
- the research could not practically be carried out without the waiver or alteration; and
- whenever appropriate, the subjects will be provided with additional pertinent information after participation.

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 for Responsible Research for more details.

In order for the IRB to approve either of these waivers, there must be sufficient justification for doing so. Investigators seeking a waiver must provide this justification as requested in the IRB application.

Examples:

Waiving Documentation of Consent

For a study using a mail survey of a non-sensitive topic, one could request a waiver of documentation of consent based on the fact that the non-sensitive nature of the survey presents minimal risk to subjects and that completing a survey does not normally require written consent outside of the research process. For research that examines highly sensitive topics, such as criminal behavior, a waiver of documentation of consent could be justifiable because subjects are placed at greater risk by signing a document that could identify them as participants in the study. In both of these examples, waiving informed consent altogether would be harder to justify because a consent document could easily be provided to subjects prior to their participation, and doing so does not limit the ability of the investigator to carry out the research.

In some cases, a waiver of documentation means that a written document is given to subjects prior to their participation, but no signature is required. This is common in mail surveys whereby subjects are provided a cover letter containing the elements of consent but are not asked for a signature.

In other cases, a waiver of documentation means that no written information will be provided to subjects at all. For example, in telephone surveys using random-digit dialing, the subjects are not identified before participation, rendering the use of cover letters difficult. A consent process could involve reading a script containing the elements of consent to subjects before beginning the survey. The script should be included with the IRB application packet and must have IRB approval.

In all cases, however, a waiver of documentation only means that subjects will not need to sign a document prior to participation in the study—subjects should still take part in a consent process, and, in some cases, receive a written document.

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4 See the document entitled “Elements of Consent” for a list and explanation of the elements that must be included in an informed consent document unless a waiver is requested and approved by the IRB.
Waiving Some Elements of Consent

It’s also possible to waive certain elements of consent if justification using the criteria listed above can be made. For example, normally, a required element of consent is to inform subjects of the purpose of the study and the procedures that will be followed. However, some research requires subjects to be deceived about the true purpose of the study or of the exact procedures used in order to obtain valid results. In these cases, the investigator must provide justification for a waiver of the elements they wish to exclude from the consent document. Normally, subjects will read and sign a consent document prior to participation unless a waiver of documentation has been approved.

Waiving All of the Elements of Consent

In very limited cases, waiving the consent process altogether is possible. Typically, studies that can be approved without obtaining subjects’ consent involve reviews of records, such as test scores or medical records. For example, a study that proposes to examine the association between ACT scores and college-level GPA for all ISU students over the past 10 years likely could not be carried out if it were necessary to obtain consent from all students whose records will be accessed to obtain the data. Most will have graduated and left ISU, locating them may be difficult or impossible, and requiring their consent would dramatically reduce the number of records that could be accessed. Provided the research involves no more than minimal risk to subjects and does not adversely affect their rights and welfare, a waiver of consent could be granted because the research could not be practicably carried out without it.

In sum, obtaining informed consent is a critical component of ethical research with human subjects. Normally, investigators are required to provide sufficient information about the study such that subjects can decide for themselves whether or not they wish to participate. A subject’s decision to participate should be documented through a signed consent form. However, there are instances where obtaining signed consent is not feasible or even not in the best interests of the subject. Further, there are limited times when obtaining consent can be waived altogether. The IRB will determine whether or not a waiver can be granted based on the regulations noted above in cases where the investigator has provided sufficient and specific reasons for doing so in the IRB application.

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5 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.