



[Home](#) › [Completed Gradebook Quiz View](#)

**i** There are pending regulatory changes that have a general compliance date of 21 January 2019. This module will be updated in January 2019 to reflect these changes. We invite you to review the [CITI Program's Final Rule Resources](#) for information on the changes to the Common Rule.

## INFORMED CONSENT - SBE

### Content Author

- **Lorna Hicks, MS, CIP**  
Duke University

## INTRODUCTION

There is general consensus on the importance of informed consent in research. Most people have the expectation that they will be treated with respect and as autonomous individuals. They also expect that they have the right to make decisions about what will and will not be done to them and about what personal information they will share with others.

However, researchers also are aware that there are circumstances in which obtaining and documenting consent in social and behavioral research may be a complex, and often challenging, process. For instance, potential subjects may be fluent in a language but not literate. Researchers may need to deceive research subjects in order to obtain scientifically valid data. Asking subjects to sign consent forms linking them to a study about illegal activities could put them at risk of harm.

The federal regulations provide sufficient flexibility to address some of these concerns, particularly for research posing no more than minimal risk of harm. For example, the regulations allow waivers of and alterations in the requirements for the consent and documentation processes.

## **Learning Objectives**

By the end of this module, you should be able to:

- Distinguish between consent as a process and the documentation of consent.
- Recognize the elements of consent.
- Determine when waivers are appropriate.
- Identify methods for ensuring comprehension of consent.



## **OVERVIEW OF INFORMED CONSENT**

Federal regulations require researchers to obtain legally effective informed consent from the subject or the subject's legally authorized representative (LAR). There are two parts to informed consent. The first is the process of providing information to prospective subjects. The second is documentation that the process took place and is a record of the subjects' agreement to take part in the study. In practice, informed

consent forms often are used as a means to provide information about a study, and, when signed, serve as documentation of consent. However, in some cases, an oral consent process without documentation may be approved by an Institutional Review Board (IRB).

## THE PROCESS



Informed consent is a process that begins with the recruitment and screening of a subject and continues throughout the subject's involvement in the research. It includes:

- Providing specific information about the study to subjects in a way that is understandable to them.
- Answering questions to ensure that subjects understand the research and their role in it.
- Giving subjects sufficient time to consider their decisions.
- Obtaining the voluntary agreement of subjects to take part in the study. The agreement is only to enter the study, as subjects may withdraw at any time, decline to answer specific questions, or complete specific tasks at any time during the research.

## DOCUMENTATION

Documentation of consent provides a record that the consent process took place. It generally consists of a consent form signed by the subject or the subject's LAR. In practice, this document often is used as a tool for engaging in the consent process. Informed consent may be documented by other means, such as audio or video recording, as approved by an IRB.

## INFORMATION THAT MUST BE PROVIDED TO SUBJECTS

Federal regulations at 45 CFR 46 (Protection of Human Subjects 2009) about informed consent list specific elements of information that must be provided to subjects. The elements are divided into two categories. The first includes basic elements to be provided to subjects. The second lists elements that must be included if appropriate. The two lists are provided below with comments.

## BASIC ELEMENTS

- A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental.
- A description of any reasonably foreseeable risks or discomforts to the subject.
- A description of any benefits to the subject or to others, which may reasonably be expected from the research.
  - If there are no direct benefits, the researchers may tell subjects what they hope to learn, how that knowledge will contribute to the field of study or how the knowledge might benefit others if such a case can be made.
- A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.
  - This requirement is primarily relevant for biomedical research. However, it might be applicable to social and behavioral research if behavioral interventions, such as novel teaching or therapeutic methods, are proposed.
- A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained.
  - The description must include a full disclosure of any state-mandated reporting requirements, such as suspicion of child abuse and/or neglect or harm to others, when warranted by the topic under investigation. State requirements vary, so IRBs and researchers must be aware of state-specific information.
- For research involving more than minimal risk, an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, what compensation will be provided, and where further information may be obtained.
- An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a

research-related injury to the subject.

- In some field research, there may not be any way for subjects to call or email anyone about their questions and concerns. Alternative means of communication must be established, such as a local contact on the research team.
- A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.
  - Most researchers in the social and behavioral sciences are not in a position to impose penalties. However, specific study-related assurances that there will be no negative consequences associated with choosing not to take part might be appropriate. For example, parents may need to be assured that if they choose not to participate in a school-based, school-approved study their children's grades or placement will not be affected.



## ADDITIONAL ELEMENTS



Depending upon the nature of the research and the risks involved, there may be additional required elements, including:

- A statement that the particular treatment or procedure may involve risks to the subject (or the embryo or fetus, if the subject is or may become pregnant), which are currently unforeseeable.
- Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent.
- Any additional costs to the subject that may result from participation in the research.
- The consequences of a subject's decision to withdraw from the research and

procedures for orderly termination of participation by the subject.

- Subjects need to know, for example, how their compensation will be affected if they choose not to complete an interview. Discussion of what happens to data already collected if they withdraw midway through the study also may be addressed in this section.
- A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject.
  - This requirement applies primarily to biomedical research involving new treatments and procedures, but also may apply to research on experimental behavioral interventions.
- The approximate number of subjects involved in the study.

## **INCENTIVES**

Incentives are payments or gifts offered to subjects as reimbursement for their participation. These must be described during the consent process as well as the conditions under which subjects will receive partial or no payment.

## **RECRUITMENT**

Recruitment is part of the consent process because it begins the process of providing information about the study. All recruitment strategies such as fliers, email messages, newspaper advertisements, phone scripts, and so on must be reviewed and approved by an IRB before they are used.

## **EXCULPATORY LANGUAGE**

Subjects may not be asked to waive or even appear to waive any of their legal rights. They may not be asked to release a researcher, sponsor, or institution from liability for negligence. Institutions may provide information about how liabilities will be covered.

## **ENSURING COMPREHENSION OF CONSENT INFORMATION**

Researchers are required to provide information in a manner understandable to the subjects. This requires preparing material in the subjects' language at the appropriate reading level. When a study is complex and/or the reading or educational level of the prospective study population is low, the role of dialog and explanation becomes an even more crucial part of the consent process.

## **ENSURING FREE CHOICE**

The principle of respect for persons requires that participation in research be truly voluntary, free from coercion or undue influence. Even when a study is innocuous, subjects must be informed that they do not have to take part, and they may choose to stop participating at any time.

## **SETTING AND TIME**



Researchers should consider ways in which the setting of the consent process might include elements of undue influence. Potential subjects might not feel entirely free to choose whether to take part in a research study if they are:

- Adolescents whose parents are in the room
- Adolescents in a group of other adolescents being recruited for the same study
- Parents who receive a letter from the school principal asking them for permission to enroll their children in a study
- Athletes recruited by their coach
- Employees asked to take part by their employer

Subjects must be given adequate time to consider whether they wish to take part in a study. This is particularly true if the study procedures involve more than minimal risk or will require subjects to disclose sensitive information.

Compensation or incentives to participate may not be so high that they override other considerations for potential subjects. Determining whether incentives are unduly influential depends on the research context and the financial and emotional resources of the subjects.

## **SAFEGUARDS FOR VULNERABLE SUBJECTS DURING CONSENT**

Federal regulations state that IRBs must ensure that appropriate safeguards are in place to protect the rights and welfare of subjects likely to be vulnerable to coercion or undue influence. Potentially vulnerable subjects include children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons. Additional safeguards for three of these groups are provided in subparts of the federal regulations for protecting research subjects: Subpart B for research on pregnant women, human fetuses, and neonates; Subpart C for prisoners; and Subpart D for children. Discussions of the additional protections for prisoners and children can be found in CITI Program modules "Research with Prisoners – SBE" and "Research with Children - SBE."

Safeguards employed for vulnerable subjects include, among many other strategies, assessing the decision-making capacity of potential subjects, requiring parental permission from both parents rather than just one parent for some studies with children, and ensuring that incentives are not coercive.

## **INFORMED CONSENT IN EXEMPT RESEARCH**

If an institution determines that a study meets the criteria for exempt research, the detailed regulatory requirements for informed consent in 45 CFR 46.116 do not apply. However, research that is exempt from federal regulations is still research with human subjects and the ethical principles as outlined in the *Belmont Report* still apply. Each institution or IRB decides how to handle informed consent in research that is eligible for exemption from the regulations.

## WAIVERS OF THE ELEMENTS OF CONSENT

Federal regulations allow IRBs to authorize researchers to modify the consent process by omitting one or more elements of information or to provide no information at all. The waiver or alteration of any or all of the elements of consent can be authorized only if these four criteria are met:

1. The research involves no more than minimal risk to the subjects.
  - "Minimal risk" means "the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in the daily life or during the performance of routine physical or psychological examinations or tests" (Protection of Human Subjects 2009).
2. The waiver or alteration will not adversely affect the rights and welfare of the subjects.
  - In the absence of specific legal rights, this criterion is often difficult to apply because the federal regulations do not define "rights and welfare." Also, the parties involved in the research process (researchers, IRBs, and the community of subjects) may not always agree on how to define subjects' rights and welfare. When a waiver is required because the research involves

deception, this requirement usually is interpreted to mean that subjects are not "tricked" into participating in a study that they would find objectionable.

3. The research could not practicably be carried out without the waiver or alteration.

- Impracticable does not mean time consuming, expensive, or inconvenient. It means that securing consent is not feasible, regardless of cost and time.
  - Impracticable may mean that without a waiver it would not be possible to answer the research question. Disclosing the purpose of the research may influence how subjects respond.

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

- This process often is referred to as debriefing. The debriefing process is an opportunity to provide subjects with information not disclosed during the initial consent process. It also provides an opportunity for subjects to withdraw and not have their identifiable data included in the research.

Note: Debriefing is not required in situations in which debriefing would cause more harm than good, for example, if subject selection was based on an undesirable or unflattering characteristic.

## USES OF WAIVERS

**Deception:** Outright deception can sometimes be justified as essential for investigating a particular phenomenon. For example, subjects may be told that a study is about perception of visual phenomenon, when in fact it is about susceptibility to peer pressure from the researcher's confederates.

**Complete Non-Disclosure:** If people know that they are being observed, they may

alter their behavior in such a way that obtaining meaningful results is not possible. Covert observation requires a waiver of all of the elements of consent if the research takes place in a setting in which subjects could reasonably expect that their behavior was not being observed and recorded.

## **WAIVERS OF PARENTAL PERMISSION AND CHILD ASSENT**

An IRB may waive the requirement to secure parental permission for children to take part in research, in accordance with the same criteria for waiving consent.

The regulations do not include a list of elements that must be included in a child assent process. It is up to an IRB to determine whether child assent is required, what elements must be included in the assent process, and whether the assent must be documented.

## **DOCUMENTATION OF INFORMED CONSENT**

When documentation of informed consent is required, there are two methods available:

1. The subject or the subject's legally authorized representative signs a form containing all the required elements of consent and any additional information necessary to provide complete disclosure. The person who signed the consent form is given a copy as a reference and reminder of the information conveyed.
2. The consent is done orally in language understandable to the subject and is documented by an impartial witness. This process uses two documents: (1) a short- form written consent document stating that the required elements of

consent have been presented orally to the subject or the subject's legally authorized representative, and (2) a written, IRB-approved summary of what will be said to the subject or the subject's representative. The subject signs the short form. The witness signs both forms. The person actually obtaining consent signs the summary. Copies of the short form and the summary are given to the subject.

Note: Illiterate English-speaking subjects can "make their mark" on the informed consent document, as long as it is consistent with applicable state or local laws.

## WAIVERS OF DOCUMENTATION

Documentation of the consent process is not always required. Note, however, that waivers of documentation are not waivers of the consent process itself. For waivers of consent, see the criteria noted above.

Documentation may be waived under two circumstances:

1. The principal risks are those associated with a breach of confidentiality concerning the subject's participation in the research, and the consent document is the only record linking the subject with the research. For example:
  - Research about women who have left abusive partners.
  - Research on the black market capitalist economy in Cuba in which illicit vendors will be interviewed in a safe space.
  - When the requirement for documentation is waived, the IRB may require the researcher to offer the subjects information about the study in writing.
2. Study participation presents minimal risk of harm to the subject and the research involves no procedures requiring consent outside the context of participation in a research study, for example, a telephone survey.

# SUMMARY

Informed consent includes both the process of sharing information and documenting that the process took place. To ensure that potential subjects can truly make informed decisions about whether to take part in research, issues of comprehension, language, and culture need to be considered in addition to the elements of information provided in the regulations. The regulations provide criteria for waiving any or all of the elements of information and the documentation of consent.

# REFERENCE

- Protection of Human Subjects, 45 CFR § 46 (2009).

**Original Release:** January 2004

**Last Updated:** November 2014

---

[Take the quiz for Informed Consent - SBE](#)

[View Post-Course Completion Options](#)

---

[Accessibility](#)

[Copyright](#)

[Privacy Policy](#)

[Terms of Service](#)

[Contact Us](#)