
Informed Consent

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There are 8 parts to this module that will require approximately 15 - 20 minutes to complete. Take the short quiz at the end of the module before going to the next module.

Introduction

There is general consensus on the importance of informed consent. Most people have the reasonable expectation that they be treated with respect as autonomous individuals. They also expect that they have the right to make decisions about what will and will not be done to their persons and about what personal information they will share with others. As a reflection of this general consensus, substantial portions of the federal regulations are devoted to the consent process.

However, researchers are keenly aware that there are circumstances in which obtaining and documenting consent may be a complex, and often challenging, process. For instance, potential subjects may be illiterate. Or researchers may not be able to achieve scientifically valid results if they have to disclose the purpose of a study. Or 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 with no more than minimal risk. For example, the regulations allow waivers and alterations of the consent and documentation processes.

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1.0 Overview of Informed Consent

The regulations require that legally effective informed consent be obtained from the subject or the subject's legally authorized representative. They also make an important distinction between the process itself and the documentation of the process.

1.1 The Process

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

- ▶ Providing specific information about the study to subjects in a manner comprehensible to them.
- ▶ Answering questions to better ensure subjects understand the research and their role in it.
- ▶ Giving subjects adequate time to consider their decisions.
- ▶ Obtaining the voluntary agreement of subjects to participate in the study. The agreement is only to enter the study, as subjects may withdraw at any time, or decline to answer specific questions or complete specific tasks.



1.2 Documentation

Documentation of consent provides a record that the initial process took place. It generally consists of a consent form signed by the subject or the subject's legal representative. In practice, this document is often used as a tool for engaging in the consent process, which consists of providing information about the research to potential subjects. Sometimes, informed consent can be documented by other means, as approved by an Institutional Review Board (IRB), for example, audio or video recording.

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2.0 Information That Must Be Provided to Subjects

The federal regulations about informed consent list specific elements of information that must be provided to subjects. The elements are divided into two categories. One category includes basic elements to be provided to subjects. The second category lists elements that are included if appropriate. The two lists are provided below with comments.

2.1 Basic Elements

- ▶ A statement that the study involves research, an explanation of the purposes of the research, the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures that are experimental.
- ▶ A description of any foreseeable risks or discomforts to the subject.
- ▶ A description of the benefits to the subject or to others.
 - ▶ **Note:** *If there are no direct benefits, the investigator may tell subjects what he or she hopes to learn, how that knowledge will contribute to the field of study or may benefit others if, indeed, such a case can be made.*
- ▶ A disclosure of any alternative procedures or treatments that may be advantageous to the subject.
 - ▶ **Note:** *This requirement is primarily relevant for biomedical research. However, it might be applicable to social and behavioral research if behavioral interventions are proposed.*
- ▶ An explanation of how the institution/investigator will maintain confidentiality of records.
 - ▶ **Note:** *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 investigators need to be aware of state-specific information. See the CITI module, Privacy and Confidentiality, for a more in-depth discussion.*
- ▶ For research involving more than minimal risk, an explanation regarding



whether medical treatment is available if injury occurs.

- ▶ **Note:** *This element applies primarily to biomedical research; however, there may be circumstances in which it applies to social and behavioral research. For example, if it is anticipated that subjects may experience emotional stress in a study about post-traumatic stress disorder, a discussion about options for support and referral might be required by an IRB.*
- ▶ Contacts for further information about the research study and about the rights of research subjects. If research-related injury is possible, subjects must be told whom to contact should injury occur.
 - ▶ **Note:** *In field research, particularly in developing countries, there may not be any way for subjects to call or e-mail anyone. Alternative means of communication must be established, such as a local contact on the research team.*
- ▶ A statement that participation is voluntary, that refusal to participate involves no penalty or loss of benefits, and that the subject may discontinue at any time.

- ▶ **Note:** *The use of the word "penalty" is usually not advisable. Most researchers are not in a position to impose penalties. Furthermore, to say "there will be no penalty if you choose not to be in this study" may be inappropriate, and perhaps disturbing, for example, when approaching community members for interviews about their perceptions of evolving race relations. On the other hand, if there is a power differential between investigators and subjects, such as teachers and students, or between subject groups, such as employers and employees, explicit statements must be included in the consent form indicating that there will be no negative consequences.*



All consent forms must state explicitly that subjects may withdraw at any time and may choose not to answer questions or complete specific tasks. In keeping with this requirement, Web-based surveys must be designed so that subjects are not forced to respond to a question before moving to the next one. (See the module, *Internet Research*, for more information.)

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2.2 Additional Elements

Depending upon the nature of the research and the risks involved, IRBs may invoke additional regulatory requirements, such as:

- A description of costs a subject might incur.
For example, transportation to the research site or childcare costs.
- A statement that any significant new findings that might affect a subject's willingness to participate will be provided to the subject.
- Consequences of a subject's decision to withdraw from a study, including how compensation will be affected.
Subjects need to know, for example, how their compensation will be affected if they choose not to complete an interview. If an institution uses a subject pool of students, the subjects will need to know how many credits they will receive for their participation and under what circumstances they will receive partial credit. Discussion of what happens to data collected to date may also be addressed in this section.
- A statement that there may be unforeseeable risks.
This requirement applies primarily to biomedical research involving new treatments and procedures.



2.3 Recruitment

Recruitment is part of the consent process, because it begins the disclosure process. Thus all recruitment strategies—such as fliers, e-mail messages, newspaper ads, phone calls, and so on—must be reviewed by an IRB before they are implemented.

2.4 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 an investigator, sponsor, or institution from liability for negligence. Institutions may provide information about how liabilities are covered.

3.0 Waivers of the Elements of Consent

Federal regulations allow for the waiver or alteration of any or all of the elements of consent provided if, and only if, four criteria are met. These waivers allow researchers to modify the consent process by omitting one or more elements of information or to provide no information at all. When the regulations were written, it was deemed important to include a waiver provision for research on behavior that could not be accomplished if subjects were fully informed about why the research was being conducted.

3.1 Criteria for Waiver

The four criteria for a waiver of any or all of the required elements of informed consent are:

1. **The research involves no more than minimal risk to the subjects.**
 - "Minimal risk" means that "the probability and magnitude of harm or discomfort 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."
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 "rights and welfare" are not defined in the regulations. 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 is usually interpreted to mean that subjects are not "tricked" into participation 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. Researchers will have to provide acceptable evidence to their IRBs that securing consent is not feasible, regardless of cost and time.

4. **Whenever appropriate, the subjects will be provided with additional pertinent information after participation. This process is often 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 data included in the research.

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3.2 Common Uses of Waivers in Social and Behavioral Sciences

Waivers are often needed when research involves incomplete disclosure, deception, or covert observation.

Incomplete Disclosure: In social and behavioral sciences research, the requirement to describe the purpose of the research may be waived in order to counter the "demand effect." When subjects know what a researcher is looking for, they may be inclined to provide it, or alternatively, not to provide it.



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).

Observation: 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 unless the research has been determined to be exempt from the regulations because 1) the observation concerns public behavior of individuals who cannot be identified in the data, or 2) that if they could be identified, there is no risk involved in such identification.

4.0 Ensuring Comprehension of Consent Information

Researchers are required to provide information in a manner understandable to the subjects. Some considerations regarding comprehension are discussed below.

4.1 Reading Level

Consider the following phrases that were included in actual consent forms:

"We are interested in the negotiation and articulation of gender roles within your community."

"We are studying the efficacy of dyadic modalities in problem solving exercises."

"Goals are postulated to exist within hierarchies."

Although experts may understand these statements, most potential subjects would be baffled. Consent forms should avoid jargon and be written at a reading level that is appropriate for the study population. It is estimated that the average reading level of Americans is the eighth grade; however, many read at a much lower 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. Investigators are obligated to ensure understanding to the best of their ability. Techniques for gauging comprehension include both eliciting questions from subjects and asking questions, for example, "Could you describe in your own words what the study is about and what you will be asked to do?"



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4.2 Language Issues

The consent process should be conducted in the subject population's primary language and the consent forms should be translated into that language. An IRB may require independent confirmation of the accuracy of the translation.

4.3 Cultural Issues

Comprehension may be affected by cultural differences other than language, such as comfort in asking questions of the researcher. For example, a doctoral student who had lived in Haiti for years prior to becoming a researcher enlisted a community member to assist in the consent process. He knew that his potential subjects would be more comfortable asking questions of a compatriot than of him, even though he was fluent in Creole. After the initial consent process, he left the room for a period of time sufficient to allow questions to be asked.

4.4 Layered Consent

Sometimes subjects may need to choose among several options. For example, they may agree to be interviewed but not agree to be videotaped. In the same study they may need to decide whether they wish their real names to be used. These options must be easy to select when the subject is signing the form. Separate signature lines for each option are often used, as are boxes to check or initial.

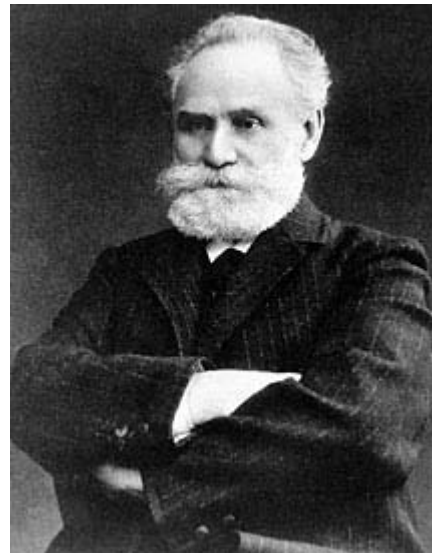
4.5 Use of Second Person

Consent forms should be written in the second person, as if the researcher were conversing with the potential subjects. For example, "If you agree to be in the research, you will be asked to complete four surveys that are designed to..." However, it is typical to use "I" to refer to the subject in the signature portion of the form. For example, "I have read the description of the research, and I have been given the opportunity to ask questions..."

4.6 Format

If the material is complex and/or the IRB anticipates that subjects may have difficulty understanding the material, the IRB may suggest that researchers format their consent forms so they are easier to read and understand. Techniques such as the following can help to achieve that goal:

- ▶ Bold-faced headings within the document.
- ▶ Headings that describe the basic structure of the study, for example, "You will be asked to complete three questionnaires" as a heading followed by more information about when, where, and how long.
- ▶ Liberal use of white space.
- ▶ Legible font size.
- ▶ Bulleted lists.



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5.0 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 participate, they may choose not to answer particular questions or complete specific tasks, and they may choose to stop participating at any time.

5.1 Setting and Time

Investigators should consider ways in which the setting of the consent process might include elements of coercion. Potential subjects might not feel entirely free to choose whether to participate 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.
- ▶ Undocumented immigrants facing an official-looking person at their door.
- ▶ Employees asked to participate by their employer.

Subjects must be given adequate time to consider whether or not they wish to participate in a study. This is particularly true if a study has more than minimal risk or will require subjects to disclose sensitive information.

5.2 Incentives

Incentives are payments or gifts offered to subjects as reimbursement for their participation. Payment may become coercive if it is so high that it overrides other considerations for potential subjects. Determining whether incentives are coercive depends on the research context and the financial and emotional resources of the subjects. Another potential problem is that if incentives are too attractive, subjects might misrepresent themselves in order to participate in the study.



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5.3 Safeguards for Vulnerable Subjects

The 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 children and prisoners can be found in this course. Research on pregnant women, fetuses, and neonates is discussed in CITI's biomedical course.

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

6. 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 standards as outlined in the Belmont Report still apply. Each institution or IRB decides how it will handle informed consent in research that is eligible for exemption.

7. Documentation of Informed Consent

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

1. The subject or the subject's legal representative signs a form containing all the required elements of consent and any other elements 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 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. Although the subjects may not be able to read, they may have a family member or friend able to do so. (If the subject population has no written language, researchers should consult their IRBs about audio- or video-recorded documentation of consent.)

Note: Illiterate English-speaking subjects can "make their mark" on the

informed consent document, as long as it is consistent with applicable state laws.

8.0 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. (The options for waivers available in the federal regulations apply either the consent process itself or to the documentation of the process.)

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, which assesses factors that affected their ability to leave.
 - 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 investigator to offer 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 by environmental educators hypothesizing that knowledge about the exploration of oil reserves in Utah's Red Rock National Park is positively related to proximity to the site and income level.



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