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Informed Consent - SBE

Southern Methodist University - Social & Behavioral Research

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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 (at 45 CFR 46, Subpart A) 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.

Key Terms

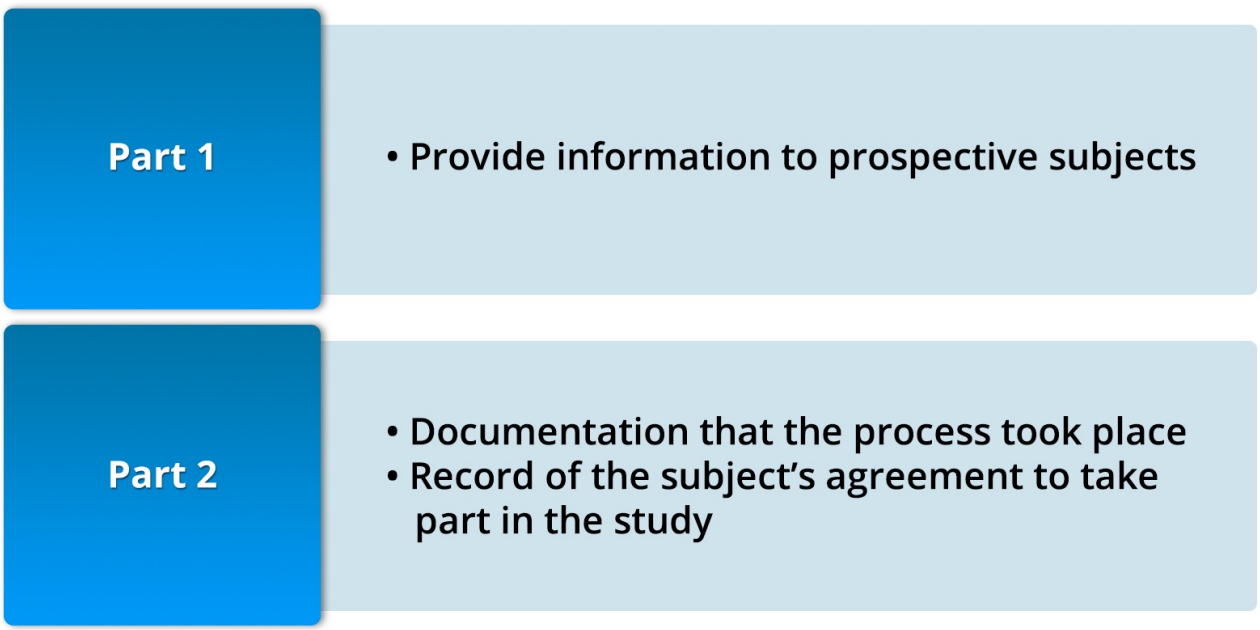
- **Broad Consent** is prospective consent for unspecified future research using identifiable private information or identifiable biospecimens.
- **Key Information** is the concise and focused information presented at the beginning of a consent discussion that is most likely to assist an individual in understanding the reasons why or why not to participate in the study.
- **Legally Authorized Representative (LAR)** means an individual or judicial or

other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research. If there is no applicable law addressing this issue, LAR means an individual recognized by institutional policy as acceptable for providing consent in the non-research context on behalf of the prospective subject to the subject's participation in the procedure(s) involved in the research (Protection of Human Subjects 2018).

- **Vulnerable** means subjects in research studies vulnerable to the possibility of coercion or undue influence.

Overview of Informed Consent

Federal regulations require researchers to obtain legally effective informed consent from the subject or the subject's LAR (Protection of Human Subjects 2018). There are two parts to informed consent.



Consent should begin with a concise and focused presentation of the key information that is most likely to assist a subject in understanding the research, what is expected of them, and the potential risks of harm and benefits.

Regulations require that this information be understandable to the subject and presented in a way that facilitates comprehension (Protection of Human Subjects 2018). The emphasis is on presenting information that a "reasonable person" would want to have in order to make an informed decision to participate, providing an opportunity to discuss, and ensuring subject (or LAR) comprehension.

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 regulation does allow the exchange of consent information to take place face-to-face or by mail, telephone, internet (online), fax, or video. An electronic format for the consent and signatures is also allowed.

Proper Use of Key Information

The key information provided at the beginning of the informed consent may not contain all the information a potential subject needs to make a decision to participate.

In the following video, we explore proper use of key information.

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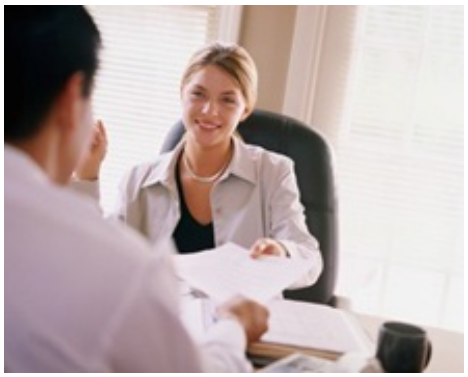
Click on the arrow to play the video.

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 at any time withdraw,

decline to answer specific questions, or complete specific tasks 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 2018) list specific elements of information that must be provided to subjects about informed consent. 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

The basic elements of informed consent list nine items that must be included, as noted in the regulations at 46.116(b). When appropriate, an analysis or commentary regarding the regulatory element is included in italics.

46.116(b)(1)

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 that are experimental.

46.116(b)(2)

A description of any reasonably foreseeable risks or discomforts to the subject.

46.116(b)(3)

A description of any benefits to the subject or to others that 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.

46.116(b)(4)

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.

46.116(b)(5)

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. State requirements vary, so IRBs and researchers must be aware of state-specific information.

46.116(b)(6)

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.

46.116(b)(7)

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.

46.116(b)(8)

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.

46.116(b)(9)

One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:

i. A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility; or
ii. A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

The requirement does not apply to all research; only research that involves the

collection of identifiable information or biospecimens. Research not involving the collection of information or biospecimens would not require this statement.

Limits on Confidentiality

Although the research may contain additional safeguards and protections to limit the potential breach of confidentiality, researchers should still inform subjects that this risk of harm will still exist. Especially in SBE research when researchers may collect sensitive or personal information, they should disclose this potential risk to subjects during the consent discussion.

The following video illustrates a researcher discussing the limits on confidentiality with a potential subject.

Click on the arrow to play the video.

Additional Elements (46.116[c])

Depending upon the nature of the research and the risks involved, there may be additional required elements, as noted in the regulations at 46.116(c). These additional elements are only required when applicable, so not all consent forms or discussions would include them. When appropriate, an analysis or commentary regarding the regulatory element is included in italics.

46.116(c)(1)

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) that are currently unforeseeable.

46.116(c)(2)

Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's or the legally authorized representative’s consent.

46.116(c)(3)

Any additional costs to the subject that may result from participation in the research.

46.116(c)(4)

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.

46.116(c)(5)

A statement that significant new findings developed during the course of the research that 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.

46.116(c)(6)

The approximate number of subjects involved in the study.

46.116(c)(7)

A statement that the subject’s biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit.

46.116(c)(8)

A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions.

46.116(c)(9)

For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).

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.

In the following video, researchers discuss considerations for developing recruitment materials and potential pitfalls.

04:10

Click on the arrow to play the video.

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.

Non-exculpatory language

Your participation in this research is voluntary. If you choose not to participate, or change your mind later, your decision will not affect your relationship with the researcher or your right to other services that you may be eligible for.

Exculpatory language

You waive any right to sue or for compensation for injuries that your may receive as a result of participating in this study.

Broad Consent (46.116[d])

Broad consent, as noted in the regulations at 46.116(d), is an optional alternative process of obtaining consent for the storage, maintenance, and secondary research use of identifiable private information and identifiable biospecimens (Protection of Human Subjects 2018). Researchers should consult with their institution and IRB policies as broad consent may not be implemented at all places.

Read more about broad consent...

Ensuring Comprehension of Consent Information

Researchers are required to provide information in a manner understandable to the subjects. The regulations emphasize that consent must begin with a “concise and focused presentation” to the subject and provide information that would help the subject determine whether to participate (Protection of Human Subjects 2018).

Effective informed consent includes providing sufficient detail about the research and presenting information in a way that is not just a list of facts. This requires preparing material in the subject's 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 and 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

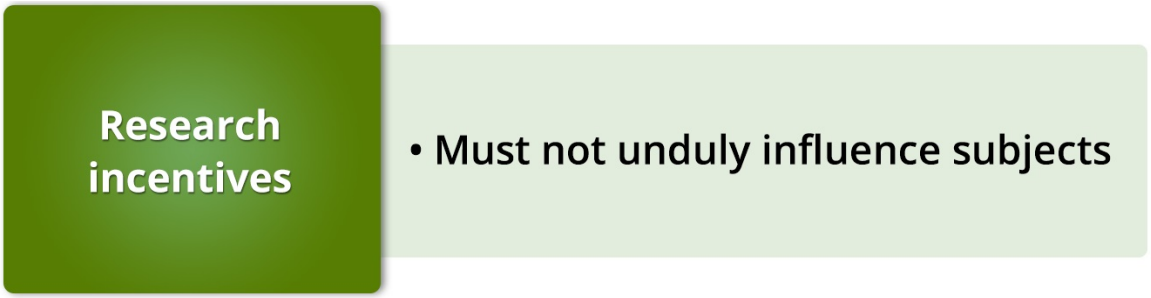
Researchers should consider ways in which the setting of the consent process might include elements of undue influence. Potential subjects might not feel entirely free to choose whether to take part in a research study if they are:

- 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, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons. Additional safeguards for three groups are

provided in the regulations:

- Subpart B for pregnant women, human fetuses, and neonates involved in research
- Subpart C for research involving prisoners as subjects
- Subpart D for children involved as subjects in research

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.

Under the 2018 Requirements version of the Common Rule, some exempt research requires a limited IRB review (administrative review). In two of the exempt categories, limited IRB review is required to ensure there are adequate confidentiality and privacy safeguards. In the other two categories, limited IRB review is required for broad consent in studies involving identifiable private information or identifiable biospecimens.

Remember, if an individual was asked to provide broad consent and refused, an IRB cannot waive consent for the storage, maintenance, or secondary research use of the identifiable private information or identifiable biospecimens.

Waivers of the Elements of Consent

The federal regulations at 46.116(f) 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 five criteria are met**.**

Regulatory Criteria	**Explanation**
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 2018).
The research could not practicably be carried out without the requested 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.
If the research involves using identifiable private	Identifiable private information is private information for which the identity of the

information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format.	subject is or may readily be ascertained by the investigator or associated with the information. An identifiable biospecimen is a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.
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.
Whenever appropriate, the subjects or legally authorized representatives 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.

Note: As noted in the regulations, broad consent has additional requirements and limitations.

Waiver for Screening, Recruiting, or Determining Eligibility

Under 46.116(g), the IRB may also approve a research study when the investigator will obtain information or biospecimens for purposes of screening, recruiting, or determining eligibility for the study without the informed consent of the prospective subject or the subject's legally authorized representative, if either of the following conditions are met:

1. The investigator will obtain information through oral or written communication with the prospective subject or legally authorized representative.
2. The investigator will obtain identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens.

Examples of When Partial and Complete Waivers Would Be Used in Deception and Complete Non-Disclosure

In social and behavioral research, deception and complete non-disclosure of information to subjects may be necessary to avoid subject response bias in the research. The IRB must review the research plan for deception or complete non-disclosure of information to ensure there is adequate justification for the technique as well as an adequate debriefing plan for after the research.

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 (by

hand or electronically) 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: English-speaking subjects who have low literacy (nonreaders) 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 earlier.

Under the federal regulations at 46.117(c)(1), an IRB may waive documentation under three circumstances (Protection of Human Subjects 2018):

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 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.
3. Subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, 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.

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 (2018).

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This module has a quiz.

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