

Elements of Informed Consent

Obtaining consent from subjects prior to their participation in a study is the foundation of ethical research. To give *informed* consent, however, subjects must be given:

- the information that a reasonable person would want to make an informed decision about whether to participate, and
- an opportunity to consider and discuss that information.

Federal regulations specify certain information that must be shared with subjects to ensure they are appropriately informed (“elements of consent”). Some is required for all research; other information needs to be included only when applicable for the study.

In most cases, information about the study is provided in writing via a consent form. Verbal consent may be appropriate if a study is low-risk and procedures are easy to understand when shared verbally (via a script). In many cases, subjects sign the form to signify their voluntary agreement to participate, although online methods are increasingly used (where subjects read the document online and click a radio button to signify agreement). Whether written or verbal consent is planned, the IRB must review the information that will be shared with research participants.

Information provided during the consent process (whether in a consent form or verbally) must be:

- conveyed in language understandable to the subjects, with attention to issues such as literacy of the subjects, the need for translation for non-English speakers, or any visual limitations that would require larger font size;
- sufficiently detailed (including all required elements and any additional information that may be meaningful to subjects);
- well organized; and
- presented in a manner that facilitates comprehension of the reasons one may or may not want to participate.

Consent information must NOT

- include any exculpatory language where the subject (or their legally authorized representative) waives or appears to waive their legal rights, or that releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence, or
- merely provide lists of isolated facts.

Informed consent must be obtained in a manner that minimizes undue influence or coercion. Investigators should design a consent process with this in mind. Implementing steps to minimize undue influence or coercion is especially critical when power imbalances exist between investigators and potential participants (e.g., when an investigator wishes to include their students or their subordinates/employees, in their research).

Templates to develop informed consent forms are available on the [IRB website](#). However, these templates are only a guide. **Templates can and should be adapted to fit the study plans and needs of the potential study participants.** Regardless of format, informed consent forms or scripts must contain all required elements, which are listed in this document.

Key Information Section

For federally-funded studies: If a consent form is lengthy (more than four pages), informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a subject in understanding the reasons why they might or might not want to participate. **This information shared must be organized and presented in a way that facilitates comprehension—not merely list isolated facts or points.** It should be tailored to the context of the study and target population. In general, the following factors are expected as part of this summary:

- That consent is being sought for *research* participation, that participation is voluntary, and subjects may discontinue at anytime with no penalty or negative consequences.
- The purpose of the research, expected duration/time commitment, and major research procedures.
- Reasonably foreseeable risks and discomforts.
- Reasonably expected benefits.
- Appropriate alternatives to study participation, when applicable.
- Costs participants may incur from participation.
- Compensation and medical treatment for research-related injuries

Required Elements of Consent for all Research

1. Information about the research, including:

- a. **A statement that the study involves research.**
- b. **An explanation of the purposes of the research.**
- c. **The expected duration of the subject's participation.**
- d. **A description of all procedures to be followed.**
- e. **Identification of any products which are experimental.**

The procedures subjects will encounter should be clearly outlined. Be sure to indicate plans for audio or video recording, the nature/topics of survey or interview questions, and any other pertinent information.

For complex projects, a table showing study visits and associated procedures or a graphical diagram or timeline may be helpful. Consider including photos or illustrations of devices participants will be asked to wear or use.

Consent forms for studies of investigational articles (e.g., drugs, biologics, or devices) should include a statement that a purpose of the study includes an evaluation of the test article. Statements that indicate test articles are safe, or statements that the safety has been established in other studies, are not appropriate when the purpose of the study includes the determination of safety. Studies that examine efficacy should also include assessment of the effectiveness of the test article as a study purpose but should not make claims of effectiveness.

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

The risks or discomforts associated with procedures relating to subjects' participation in the research should be explained in the consent form. Risks and discomforts are not limited to physical harm and include possible psychological, social, legal, and/or economic harm.

3. A description of any benefits to the subject or to others which may reasonably be expected from the research.

The description of benefits to the subject should be clear and not overstated. If no direct benefit is anticipated, that should be stated.

Potential societal benefits should also be included. Also, when benefits may accrue to the investigator, the sponsor, or others, these benefits may be materially relevant to the subject's decision to participate, and they should be disclosed in the informed consent form.

4. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.

To enable an informed choice to participate in the research study, subjects should be made aware of the full range of options available to them. Consent forms should briefly explain any pertinent alternatives to entering the study. This is particularly relevant to studies that use ISU students as subjects and provide course-related credit for their participation. Students should be given an alternative method of earning course-related credit that does not involve participating in research. As with other required elements, the consent form should contain sufficient information about alternatives to ensure an informed decision.

5. A statement that describes the extent, if any, to which confidentiality of records identifying the subject will be maintained and that notes the possibility that external regulatory agencies, such as the funding agency, the Food and Drug Administration, and the Institutional Review Board (IRB), may inspect the records.

Subjects should be informed of the extent to which the investigator intends to maintain confidentiality of records identifying the subjects, including the measures used for this purpose (e.g., locked cabinets, encrypted and password-protected computers, etc.). In addition, subjects should be informed that internal and external regulatory agencies, such as the IRB or FDA (if applicable), may inspect study records (which may include individual medical records).¹ If any other entity, such as the sponsor or funding agency for the study, may gain access to the study records, the subjects should be so informed.

Subjects should also be informed of any limitations to their confidentiality. For example, in research where deductive disclosure, or indirect identification, cannot be prevented, subjects should be informed that confidentiality cannot be guaranteed. In some cases, subjects' identities may be shared in reports of results—this information should be clearly disclosed in informed consent forms.

If the study collects reportable information (e.g., ongoing child abuse, imminent threat of harm to self or others), subjects should be informed that such information will be reported to authorities.

Example wording to describe regulatory access and other issues related to confidentiality protections can be found in the [Informed Consent Templates](#).

¹ For studies regulated by the FDA, a statement that the FDA may review research records is a required element of consent.
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6. For research involving **more than minimal risk**, an explanation as to whether any compensation and/or medical treatments are available if injury occurs and, if so, what they consist of or where further information may be obtained.

Example wording can be found in the [Informed Consent Templates](#).

7. **Compensation plans, if any.**

If subjects will be compensated for their participation, the consent form should include this information. Methods of providing compensation should be described.

It is considered undue influence to require full completion of the study to receive compensation. However, compensation can be prorated for partial participation. For example, in a study that involves three visits to a lab, total compensation can be split with partial amounts provided for each visit. The amounts do not have to be equal for each visit—higher or lower amounts can be provided at any given visit if desired by the investigator. Any plans to prorate compensation must be described in the consent form.

The ISU Controller's Office requires that subjects complete the ISU Research Participant Receipt Form. If payment amounts exceed \$100, subjects should be informed that they will need to provide their social security number on this form in order to be compensated (See [Research Participant Payments](#) for more information.)

8. **An explanation of whom to contact for answers to questions about the study itself and the rights of research subjects and whom to contact in the event of a research-related injury to the subject.**

The consent form(s) should provide the name(s) and contact information of the specific persons or offices subjects may contact for questions about

- a. the research study itself—the principal investigator and, for student projects, the supervising investigator.
- b. the research subjects' rights—the ISU Office of Research Ethics. (Example wording is available in the [Informed Consent Templates](#)).

9. **A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.**

For surveys or interviews, consent forms should also state that subjects can skip any questions they are not comfortable answering.

For studies conducted in a school, program, medical clinic or similar settings, subjects should be informed that their choice of whether or not to participate will have no adverse effect on their ability to receive services or medical care, will not affect their grades or standing as a student, etc.

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

- a. A statement that identifiers might be removed from the information or biospecimens, and after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research without additional informed consent; OR
- b. A statement that the subjects' information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

Example wording may be found in the [Informed Consent Templates](#).

Documenting Participants' Informed Consent

Unless documentation is [waived by the IRB](#), consent forms should include a mechanism to document the participants' informed consent. When signed consent is obtained, space should be included for the participant or their legally-authorized representative to sign and date the form, either by handwritten or electronic signature. When consent is obtained online or electronically, "checkboxes" or radio buttons may be included.

In some cases, it may be appropriate to document varying levels of consent. For example, subjects may be asked for agreement to allow researchers to contact them in the future, for their explicit permission to be video recorded, for use of recordings in reported results, etc. In these instances, consent forms should include methods of documenting each type of permission (e.g., checkboxes, separate lines for signature or initials, etc.).

To promote verification of the subject's consent, including space for the printed name of the participant (and, when applicable, their legally-authorized representative) is recommended. Signatures are commonly illegible, and the printed name allows researchers to easily verify a person's documented consent.

Additional Elements of Informed Consent, required when appropriate

When appropriate, the following information must also be provided to each subject:

1. **A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus if the subject is or may become pregnant) which are currently unforeseeable.**

This statement should accompany information about known or foreseeable risks to the embryo or fetus.

If measures should be taken to prevent pregnancy (e.g., use of contraception) during the study, that should be explained as well.

2. **Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent.**

When applicable, subjects should be informed of circumstances under which the investigator may terminate their participation without their consent. An unexplained statement that the investigator and/or sponsor may withdraw subjects at any time does not adequately inform subjects of anticipated circumstances for such withdrawal.

A general statement that the investigator may withdraw subjects if they do not "follow study procedures" is usually not appropriate. Subjects are not in a position to know all the study procedures. Subjects may be informed, however, that they may be withdrawn if they do not follow the instructions given to them by the investigator.

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

If the subject may incur an expense due to their involvement in the research, the costs must be explained in sufficient detail as to prepare the subject for such a possibility.

4. **The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject.**

When withdrawal from a research study may have deleterious effects on the subject's health or welfare, the informed consent should explain any withdrawal procedures that are necessary for the subject's safety and specifically state why they are important to the subject's welfare. An unexplained statement that the subject will be asked to submit to tests prior to withdrawal does not adequately inform the subject as to why the tests are necessary for the subject's welfare.

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.**
6. **The approximate number of subjects involved in the study.**

If the number of subjects in a study is material to the subject's decision to participate, the subject should be told not only the approximate number of subjects involved in the study but also why the number of participants is important (e.g., a small number may compromise confidentiality).

7. **A statement that subjects' 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.**
8. **A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to the subject.**

If so, the conditions under which results will be disclosed should be described.

9. **For research involving biospecimens, subjects must be informed of 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).**

For Clinical Trials

If the study is a clinical trial that will be [registered on ClinicalTrials.gov](https://www.clinicaltrials.gov), research participants *must* be informed of the availability of clinical trial information on ClinicalTrials.gov. Federal regulations require the following language to be included verbatim in informed consent forms for applicable clinical trials initiated on or after March 7, 2012 and/or for all NIH-funded clinical trials subject to registration:

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

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