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 enough relevant information to help them make a decision. Federal regulations specify certain information that subjects must be provided. Some is required for all research; other information may be included only when applicable for the study.

In most cases, information about the study is provided in writing (i.e., a consent form). Verbal consent may be appropriate if a study is low-risk and procedures are easy to understand when shared verbally. 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.

To facilitate understanding, the consent form must be written 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.

Informed consent forms may 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.

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

For federally-funded studies: If a consent form is lengthy (i.e., more than four pages), informed consent should include 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 lists of isolated facts or points.

On the IRB website are templates that researchers may use to develop an informed consent form. 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, must contain all required elements, which are listed below:

Required Elements 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 whether or not audio or video recording will be included, the nature of questions that will be asked in a survey or interview, and any other pertinent information.

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 safety 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.

   Compensation to subjects is not considered to be a study benefit, but if subjects are to 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 Payment Process for more information.)

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

Study 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). 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.

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. 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 for Responsible Research. (Example
   wording is available in the Informed Consent Templates).

8. 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.

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

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1 For studies regulated by the FDA, a statement that the FDA may review research records is a required element of
consent.
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

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. When consent is obtained online or electronically, “checkboxes” or radio buttons may be included.

In some cases, it may be appropriate to document varying types of consent. For example, subjects may be asked for agreement to allow researchers to contact them in the future, or 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.).

Additional Elements of Informed Consent, required when appropriate

When appropriate, one or more of 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 their participation may be terminated by the investigator without the subjects’ consent. An unexplained statement that the investigator and/or sponsor may withdraw subjects at any time, does not adequately inform the 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 because he or she is participating in the research, the costs must be explained in sufficient detail as to prepare the potential 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 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 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, 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.*