Elements of Informed Consent

Obtaining consent from subjects prior to their participation in a study is the foundation of ethical research. To adequately give consent, however, subjects must be adequately informed about what they are being asked to participate in. Federal regulations specify certain information that subjects must be provided in order for them to give “informed consent” to become research subjects. The requirements include eight pieces of information or “elements;” additional elements that must be included when appropriate are also listed.

Each of these elements should be incorporated into a document that will normally be signed by subjects prior to participation.1 Provisions must be made to provide a copy of the document to participants. The document must be written in language appropriate for 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. On the Forms page of the IRB website is a template that researchers can use to develop this document. However, this template is only a guide. It can and should be adapted to fit the study for which it is used. Any adaptations, however, must contain all required elements, which are listed below:

Required Elements

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 in the consent document. Be sure to note whether or not audio or video taping will be included, the nature of questions that will be asked in a survey or interview, any exclusion criteria that apply to the research, and any other pertinent information.

   Consent documents 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 involve efficacy should also include 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 document. Risks and discomforts are not limited to physical harm and include possible psychological, social, and/or economic harm.

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1 For information about waiving some or all of these elements, see the document entitled “Information about Waivers of Consent.”
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 document.

Compensation to subjects is not considered to be a benefit, but if subjects are to be compensated for their participation, the consent document should include this information. Methods of providing compensation should be noted, particularly related to the need for subjects to complete the ISU Research Participant Receipt Form. This form is required by the ISU Controller’s Office. 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.)

Compensation cannot be provided based on completion of the study as this is considered undue influence. 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 included in the consent document.

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 documents 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 document 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, password-protected computers, etc.). In addition, subjects should be informed that internal and external regulatory agencies, such as the IRB or FDA, may inspect study records (which 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.

Here is an example of a statement that can be used regarding regulatory agency access:

Records identifying participants will be kept confidential to the extent permitted by applicable laws and regulations and will not be made publicly available. However, federal government regulatory agencies [List all other applicable groups: e.g., NIH, the

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

The following statement can be used when a risk of injury during the research is possible:

Emergency treatment of any injuries that may occur as a direct result of participation in this research is available at the Iowa State University Thomas B. Thielen Student Health Center, and/or referred to Mary Greeley Medical Center or another physician or medical facility at the location of the research activity. Compensation for any injuries will be paid if it is determined under the Iowa Tort Claims Act, Chapter 669 Iowa Code. Claims for compensation should be submitted on approved forms to the State Appeals Board and are available from the Iowa State University Office of Risk Management and Insurance.

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

This requirement contains two components, each of which should be specifically addressed. The consent document should provide the name of a specific office or person and the telephone number to contact for answers to questions about

   a. the research study itself—the principal investigator and, for student projects, the supervising faculty member; 
   b. the research subjects' rights—the ISU Office for Responsible Research. If you have any questions about the rights of research subjects or research-related injury, please contact the IRB Administrator, (515) 294-4566, IRB@iastate.edu, or Director, (515) 294-3115, Office for Responsible Research, Iowa State University, Ames, Iowa 50011.

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, be sure to also note that subjects can skip any questions they are not comfortable answering.

Note: Consent documents should include a signature line for the participant unless a waiver of documentation of consent has been approved. If the study involves minors, a signature line for a parent or guardian should also be included.

Additional Elements of Informed Consent

When appropriate, one or more of the following elements of information shall 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

A statement that there may be unforeseen risks to the embryo or fetus may not be sufficient if animal data are not available to help predict the risk to a human fetus. Investigators should ensure that subjects who agree to enter a study fully understand the potential risks that the study poses. If
measures to prevent pregnancy (e.g., use of contraception) should be taken while in the study, that should be explained.

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 statement that the investigator may withdraw subjects if they do not "follow study procedures" is 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**

   When it is anticipated that significant new findings that would be pertinent to subjects’ continued participation are likely, the IRB should determine that a system or a reasonable plan exists to make such notification to subjects.

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).