What must be included on a consent form?

Federal Requirements

As described in the federal regulations, consent forms must include these essential elements:

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 which are experimental;

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

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

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

5. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;

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;

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; and

8. A statement that participation is voluntary, refusal to participate will involve no penalty or decrease in 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.

Where appropriate, regulations further provide that the following additional information be provided:

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

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

3. Any additional costs to the subject that may result from participation in the research;
4. The consequences of a subject’s decision to withdraw from the research and procedures for orderly termination of participation by the subject;

5. A statement that significant new findings developed during the course of the research which may relate to the subject’s willingness to continue participation will be provided to the subject; and

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

**Institutional Requirements**

1. The first page of the consent form should be printed on departmental letterhead, and the Principal Investigator and contact information should be identified on the first page.

2. For student projects, the words “University of South Alabama” should be listed in the header on the first page of the consent form. In addition, advisers’ names and phone numbers may also be listed with the student’s name and contact information.

**IRB Pointers**

*Font/Typeface preferences*

The IRB recommends that all consent documents be printed in an appropriate typeface no smaller than 12 point type and one inch margins.

*Page Numbering*

Number each page of the consent form.

*Title Page of Consent*

The title of the study should appear on the first page of the consent form. The title should match as it is listed in the IRB application unless there is a reason to change the title in which the IRB will need to approve the change.

*Inform Consent Document*

The IRB date-stamped informed consent must be used when consenting potential subjects for study recruitment. The date stamp indicates the date approved and date of expiration. Forms that have been expired should not be used.

*Readability*

An eighth grade reading level is encouraged in consent forms and should be written in lay language.

*Student Projects*

The IRB Handbook for Student Researchers should be followed as a guide in preparation and submission of IRB applications and consent forms, if applicable.