

Consent Writing Guide

The consent must be "informed" as well as "voluntary". There must be a full disclosure of procedures, risks and benefits. Subjects must be willing volunteers and not coerced into participation nor penalized for non-participation. The consent form should include enough information that subjects can make an informed decision. Subjects must be given the opportunity to ask questions about their participation in research before signing the consent form. If the consent form is altered after IRB approval, it must be resubmitted to the IRB.

Be sure the language of the consent form is at the level of the least education participant that will be contacted. A six grade level is appropriate if a general adult population is used and the education level is not known. Obtaining consent is a process of providing meaningful information and not merely signing the consent form.

The consent form should be written in second person, except for the final consent statement that is written in first person.

The consent should use the headings that appear on the sample. These headings are for convenience in reading and to guide the subjects through the document. The consent form should be easy to read; use a 12-pt Times New Roman font or equivalent.

Elements of Informed Consent and Sample Basic Consent Form:

Title: The title of the consent form must include the words "research subject".

Introduction: What is being studied, why subjects were invited to participate, how treatment differs from normal treatment (if applicable), and the names of the investigator(s) including their title(s) and affiliation.

Procedures: Inform subjects what would steps will occur if they choose to participate. Subjects should know what is expected of them, where they need to go, and the amount of time they will be asked to give, as well as the duration of their participation (i.e., data collected all at once, data collected three times once a month, etc.).

Risks/Discomforts: This section should include potential legal, economic, psychological, emotional, and physical risks. Very few studies have no risks. Most have minimal risks. If there are minimal risks then this should be stated. All potential risks must be specifically stated. This section should also address specific ways the researcher will minimize risks.

Benefits: The benefits section should contain an unbiased statement that discusses personal and/or societal benefits. It should not read like an advertisement. If there are no benefits to the individual that should be stated and societal benefits listed. If there are no benefits to society, then the value of the research may be negligible and may not be approved.

Alternatives: (if applicable) This section should discuss the therapeutic or treatment options open in lieu of participation in this study. If there are none, then leave this section out.

Confidentiality: There needs to be a statement that information will remain confidential and will be reported as a group and not as data identifiable to specific person, unless the research subject has specifically agreed to be identified. Research subjects should be informed about what will become of the data when the study is complete and measures are in place to protect the confidentiality of data.

Compensation: (if applicable) If money is offered in exchange for research participation it should not be disproportionate nor reflect payment for acceptance of risk. Extra credit, drawings, vouchers, etc are also described in this section. Research subjects should be informed if compensation is pro-rated and in the instance of a drawing their chances of winning.

Participation: Include these statements verbatim. Participation in this research study is voluntary. You have the right to withdraw at any time or refuse to participate entirely without affecting your...(class status, grade, or standing with the university).

Questions about Research: Subjects have the right to be able to contact the investigator if any questions come up. Student researchers, the faculty advisor's name and contact information should be included. This must be visible on the consent form. Please include name, phone number, address and/or email. Include area codes and country codes where appropriate.

Questions about Your Rights as Research Participants: There needs to be a person not involved with the study who can answer questions about the rights of a research subject. This person is the IRB Administrator, Brigham Young University, A-285 ASB Campus Drive; Provo, UT 84602; (801) 422-1461; irb@byu.edu. If the project goes through a college subcommittee, this person may be the chair of the college committee. For international research, this can be a program or NGO director who can speak the local language and is easily accessible to participants. This must be visible on the consent form. Please include name, phone number, address, and email address.

Signatures: There should be a consent statement in first person indicating that the participant understands and has received a copy of the consent form and agrees to participate in the research. When using a signed consent form, all participants over the age of 18, unless cognitively impaired, must sign a consent form written in the language they can understand.