

Elements of Informed Consent

Researchers must obtain the signed *informed consent* of participants. For those less than 18 years of age, the researcher must obtain the signed informed consent of parents or legal guardian and all reasonable attempts must be made to obtain each participant's *assent*, which is defined as the participant's agreement to participate in the study.

The informed consent must include the following in sequential order and in language which the participants can understand:

1. Statement of purpose of the study.
2. Short description of methodology and duration of participant involvement.
3. Statement of risks/benefits to the participants.
4. Statement of data confidentiality.
5. Statement regarding the right of the participant to withdraw from the study at any time without negative consequences.
6. An offer to answer any questions the participant may have about the research.
7. Contact information of all Principal Investigators, and also contact information for Trident Technical College's Institutional Review Board
8. Line for signature of participants and/or parents or legal guardian except for questionnaire research in which return of questionnaire gives implied consent.
9. Statement that participant is 18 years of age or older unless parent or legal guardian has given consent.

In situations where participants will be **deceived**, items 1 and 2 are omitted and participants are told (on the signed form) that disclosure of the purpose and/or methodology could bias the outcome of the study. In this case, **after the study is complete**, each participant must be presented with a description of the purpose and methodology as carried out and this document must be signed by the participants "after the fact" in order to guarantee informed consent.

Sample Informed Consent

The following suggestions are offered as **guidelines**. The exact language is the decision of the researcher. Keep in mind, however, that the Institutional Review Board must determine if the participants will be giving **informed consent**. (Note: that in the case of children, it is **assent**).

Dear (student, parent, sir, madam, etc.):

We are conducting a study to determine _____ . In this study, you (your child/ward) will be asked to _____ . Your participation should take about _____ minutes.

There are no risks to you (your child/ward).

or

The only risks to you (your child/ward) include _____

All information will be handled in a strictly confidential manner, so that no one will be able to identify you (your child/ward) when the results are recorded/reported.

Your (your child's/ward's) participation in this study is totally voluntary and you may withdraw at any time without negative consequences. If you wish to withdraw at any time during the study, simply _____

Please feel free to contact _____ (names(s), title(s) of principal researchers) at _____ phone) if you have any questions about the study. Or, for other questions, contact the TTC Development Office Grants Specialist (843-574-6610).

If the participant is of age (18 years old or older), use:

I understand the study described above and have been given a copy of the description as outlined above. I am 18 years of age or older and I agree to participate.

Signature of Participant Date

If the participant is not of age, use:

I understand the study described above and have been given a copy of the description as outlined above. I agree to allow my child/ward to participate with his/her assent when possible.

Signature of Parent/Guardian Date

ASSENT format:

I understand what I must do in this study and I want to take part in the study.

Signature of Child/Ward Date

**Human Subjects Research Project
Consent Form Checklist**

N/A	YES	NO	
			1. Is the consent form written in “lay language”?
			2. Is it free of any language that requires the subjects to waive their legal rights, including any release of the investigator, sponsor or college or its agents from liability for negligence?
			3. If minors are included in the study, is provision made for obtaining parental consent?
			4. Does the consent form include each of the following basic elements of informed consent?
			a. A statement that the study involved research, an explanation of the purposes of the research and the expected duration of the subject’s participation.
			b. A description of the procedures to be followed.
			c. A description of any benefits to the subject or others.
			d. A description of any reasonably foreseeable risks or discomforts.
			e. A statement describing the extent to which confidentiality of records identifying the participant will be maintained.
			f. Information regarding whom to contact for answers to questions about the research study and the research subject’s rights.
			g. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits, and the participant may discontinue participation at any time without penalty or loss of benefits.
			h. Appropriate FERPA notice and waivers (if appropriate).

If there was a “NO” response to any of the above questions, the consent form must be revised accordingly unless the investigator can satisfactorily justify why it is appropriate as submitted.