Cape Cod Community College
Institutional Review Board

ELEMENTS OF INFORMED CONSENT

Unless otherwise authorized by the IRB, researchers are responsible to obtain the signed **informed consent** of participants. This is to ensure that only those human subjects who have consented to participate are involved in the research. For those less than 18 years of age, the researcher must obtain both the signed informed consent of parents (or legal guardians) and the assent of the minor to participate in the study.

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

1. Statement that the study involves research and the purpose of the research study.

2. Short description of procedures and methodology to be used as well as the duration and description of participant involvement.

3. Statement of any foreseeable risks/benefits to the participants.

4. Statement of data confidentiality and how that will be accomplished.

5. Statement that participation is voluntary and that the participant may withdraw from the study at any time without penalty or consequences.

6. An offer to answer any questions the participant may have.

7. Contact information of all Principal Investigators, and also contact information for the Cape Cod Community College Institutional Review Board at IRB@capecod.edu

8. Line for signature of participants and/or parents or legal guardian except for questionnaire research in which return of questionnaire identifies the participant.

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 debriefed and provided with a description of the purpose and methodology as carried out. The document (or a second document) should be signed by the participants 'after the fact' in order to provide documentation of debriefing and to provide participants with additional contact information should there be any adverse events after the debriefing is over and the research is completed.

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SAMPLE Consent Form

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 review and approve the informed consent process and all documentation associated with it. (Note: that in the case of minors, it is considered 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 more risks to you (your child/ward) than encountered in a daily life. **OR** The only risks to you (your child/ward) are minimal and include _____.

All information will be handled as confidentially as possible. There is always a slight risk of disclosure from participating in any research study. If identifying information is collected, it will be kept confidential by the Principal Investigator and measures will be taken to protect your identity, such as securing the information in a locked cabinet.

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

Please feel free to contact _____ [name(s), title(s) of principal researcher(s)] at _____ (phone) if you have any questions about the study. Or, for other questions, contact Cape Cod Community College's Institutional Review Board at IRB@capecod.edu

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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	Print Name of Participant

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	Print Name of Parent/Guardian

ASSENT format: (If participant is younger than 18 years of age)
I understand what I must do in this study and I want to take part in the study.

_____	_____	_____
Signature of Minor	Date	Print Name of Minor

_____	_____	_____
Signature of Principle Investigator	Date	Print Name/Principle Investigator

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The form below is designed to be an aid to the Researchers to help insure that the participants' involvement is voluntary and that the consent form includes all of the necessary elements of informed consent.

Human Subjects Research Projects
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.