NORTH·SHORE
COMMUNITY COLLEGE
Real Opportunities

Institutional Review Board
ELEMENTS OF INFORMED CONSENT

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 North Shore Community College Institutional Review Board.

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.

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 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 North Shore Community College's IRB Contact (978-762-4000 ext 5496).

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: (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

_____ _____
Principal Investigator Signature Date

_____ _____
Co-Investigator/Student Signature (if appropriate) Date