___/___/____ | Northern Essex Community College Institutional Review Board | _____

Date Submitted | | File Number

Northern Essex Community College
Institutional Review Board
FULL IRB REVIEW PROTOCOL SUMMARY FORM

Title of Research Project

Principal Investigator/Project Director	Department	Phone Extension	Email address
Co-investigator/Student Investigator	Department	Phone Extension	Email address
Co-investigator/Student Investigator	Department	Phone Extension	Email address

Anticipated Funding Source: _____

Projected Duration of Research: _____ **months** **Projected Starting Date:** _____

Other organizations and/or agencies, if any, involved in the study: _____

Please answer the questions below and return this form with:

- A memo that briefly describes the intent of the project
- A completed copy of the Consent Form Checklist
- A copy of the Consent Form that will be provided to the participants

I. Project Information:

A. Project Activity Status:

- ☐ **New Project**
- ☐ **Periodic Review of Continuing Project**
- ☐ **Revision to Previously Approved Project**

B. This project involves Northern Essex Community College students

☐ **Yes** ☐ **No**

C. Human Subjects from the following populations will be involved in this study

- ☐ **Minors**
- ☐ **Mentally Disabled**
- ☐ **Elderly**
- ☐ **High School Students**
- ☐ **Prisoners**
- ☐ **None of the above**

D. Total number of subjects to be studied:_____

II. Abstract Describing Project and Purpose (Include a description of all experimental methods to be used and design and program activities; what measures or observations will be taken in the study? If any questionnaires, tests or other instruments are to be used include a brief description and a copy of such instrument.)

III. Protocol (Who will be the research subjects? How will they be solicited or contacted? Include any recruitment letters or other recruitment materials with this document; How much time will be required of each subject? Describe procedures to which humans will be subjected – use additional pages if necessary)

V. Precautions (What steps will be taken to insure that each subject's participation is voluntary? What, if any, inducements will be offered to the subjects for their participation?)

VI. Confidentiality of data (Describe the methods to be used to ensure the confidentiality of data obtained, including plans for publication, disposition or destruction of data, etc)

VIII. Consent (Attach a copy of all consent forms to be signed by the subjects and/or any statements to be read to the subject)

I certify that the protocol and method of obtaining informed consent as approved by the Northern Essex Community College's Institutional Review Board will be followed during the period covered by this research project. Any future changes to the research project will be submitted to the IRB for review and approval prior to implementation.

_____ __/__/__ _____ __/__/__

Investigator/Project Director Signature Co-Investigator/Student Signature (if appropriate)

Signature of IRB Committee Chair:				**Date:**__/__/__
IRB Chair: Check 1 box:	☐ **Approved**	☐ **Approved with Restrictions**	☐ **Tabled**	☐ **Disapproved**

Northern Essex Community College
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 is it appropriate as submitted.

Northern Essex Community College
Institutional Review Board

ELEMENTS OF INFORMED CONSENT

Researchers must obtain the ***informed consent*** of participants. For those participants less than 18 years of age, the researcher must obtain the 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.

7. Contact information of all Principal Investigators, and also contact information for the College's Institutional Review Board (Director of Institutional Planning & Research, 978-__)

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.

Northern Essex Community College

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 Director of Institutional Planning and Research (978-_____).

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

Attach Consent Form that will be provided to the participants