INSTITUTIONAL REVIEW BOARD APPLICATION FOR IRB AUTHORIZATION

INSTRUCTIONS

Individuals seeking to conduct research studies that involve either the faculty, staff, students, or administration of the college or utilize the College's facilities ***must*** get both project approval and IRB authorization before the collection of data commences. Per definition by the U.S. Department of Health and Human Services (HHS), research is defined as "a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge" If an activity uses human subjects data that is regularly and routinely gathered at the institution, does not require new, additional, or significantly altered data gathering procedures, or if the activity is not sponsored by an external agency or does not test a hypothesis, it probably is **not** research (e.g. assessment of student learning). Specifically, the following activities conducted by the College's internal constituents at Suffolk County Community College are always exempt from IRB review even though they involve human subjects:

- Assessment of student learning at the classroom or program level
- Analysis of existing data sets
- Collection of data to fulfill county, state, federal, or system requirements
- Institutional analyses

Although the educational projects or research studies may meet the criteria for exemption, ***all*** external constituents ***must*** complete an application for IRB authorization form. In addition, all internal constituents engaged in activities that meet the definition for research (i.e. dissertation) must complete a form. Completion of this form is ***highly*** recommended if there is any question or doubt about whether a project or study involving human subjects or the analysis of potentially sensitive data requires IRB authorization. Should the IRB be made aware of a project that should have been authorized before initiation, a letter will be sent from the IRB noting that the project or study must be halted while a review is conducted. The types of reviews and timelines are presented in the IRB Policy and Standard Operating Procedures Manual.

ACTIVITIES EXEMPT FROM COMMITTEE REVIEW

Federally funded Education/Research activities involving human subjects in the following categories may be exempt from review by SCCC's Institutional Review Board. The principal investigator/project director is authorized to make the first determination of eligibility for exemption, however, the College makes the final determination on exemption prior to providing authorization.

*The following exemptions do **NOT** apply when (a) **deception** of subjects may be an element of the research; (b) subjects are **under the age of eighteen**; (c) the activity may **expose the subject to discomfort or harassment** beyond levels encountered in daily life; or (d) **fetuses, pregnant women, human in vitro fertilization, children, or individuals involuntarily confined or detained in penal institutions** are subjects of the activity.*

EXCEPT FOR THE ABOVE EXCLUSIONS, the federally-approved Categories of Exemption are:

1. Research conducted in established or commonly accepted educational settings involving normal educational practices, such as: (a) research on regular and special education instructional strategies; (b) research on the effectiveness of or the comparison among instructional techniques curricula, or classroom management methods.

2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (a) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; **and** (b) any disclosure of the human subjects' responses outside the research reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, or achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under Category 2 if: (a) the human subjects are elected or appointed public officials, or candidates for public office, **or** (b) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

4. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified directly or through identifiers linked to the subjects.

5. Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: (a) public benefit or service programs; (b) procedures for obtaining benefits or services under those programs; (c) possible changes in or alternatives to those programs or procedures; or (d) possible changes in methods or levels of payment for benefits or services under those programs.

6. Taste and food quality evaluation and consumer acceptance studies: (a) if wholesome foods without additives are consumed, or (b) if a food is consumed that contains a food ingredient or at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level

found to be safe by the U.S. Food and Drug Administration or approved by the U.S. Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

Exempting an activity from review does not absolve investigator(s) from ensuring that the welfare of human subjects in the activity is protected and methods used and information provided to gain subject consent are appropriate to the activity.

Project Title:
Principal Investigator's Name:
Phone Ext Email Address

Co-investigator:
Phone Ext Email Address

Co-investigator:
Phone Ext Email Address

Co-investigator:
Phone Ext Email Address

Projected Duration of Project: **Projected Starting Date:**

Form Submission Date:

Exempt? (see definitions on page one – check one) ☐1 ☐2 ☐3 ☐4 ☐5

I. Study Description

1.Summary:
*(*Maximum 250 words)

2.Will this study involve ANY interaction with human subjects (including obtaining consent)?

☐ YES →

☐ NO → select the type of research you will be conducting from the list below (you may select more than one).

☐ Analysis/Review of data that exists at time of application submission (e.g., Institutional information, academic records or databases etc.)

☐ Analysis/Review of data that does not already exist at time of application submission

3. Subject Data

a. Data collected for the study will be obtained:

☑ anonymously (no way to link sample with subject identity): No identifiers listed on the De-Identification form will be used.
☑ in a coded manner: (a link to the subject is retained; it is possible to find out the identity of the subject from whom the data were obtained, i.e., initials, social security #, medical record #, etc.)
☑ in a fully identified manner (e.g., name)

b. Are you planning on using data for future, as yet unspecified research?

☐ NO
☐ YES, **Must be disclosed on informed consent documents**

II.Subject Information

1. List all inclusion and exclusion criteria for subject selection.

2. Subject gender for this protocol: Females only Males only Both genders

3. Total number of subjects at all locations needed to complete this study and answer the research hypothesis:

4. Federal mandates require that you include minorities (including American Indians, Alaskan Native, Asian, Native Hawaiian, Pacific Islander, Black [not of Hispanic origin] and Hispanic)in your research unless you can justify their exclusion.
5. If non-English speaking participants are included then the IRB-approved English version of the consent form(s) will be translated into a foreign language and an affidavit of accurate translation will be submitted as soon as possible as an amendment

III.Subject Recruitment/Compensation

1. **Describe how, and where subjects will be recruited for participation in this study.** Discuss how this recruitment plan will ensure access to the number of subjects proposed for this study.

2. **Will any flyers, posters, letters, e-mails, pamphlets, brochures, print advertisements, on-air advertisements or phone calls be used to recruit subjects? ***

☐ No
▣ Yes→ Specify (if not already provided in #1above):

***All recruitment material, including scripts and/or videos for on-air ads or phone calls, must be approved.**

3. **If using written material for recruitment, will these materials be mailed/e-mailed to potential subjects?**

☐ No
▣ Yes

4. Will subject be offered compensation for participating in the research?
   ☐ No
   ☐ Yes → Answer:

a. Describe the nature of the compensation or incentive, providing amounts and schedule of payments:

b. Are the terms of payment specified in the 'Payment to You' section of the informed consent form?
   ☐ No
   ☐ Yes

IV.Risks

The purpose of this section is to determine if subjects will be placed "at risk" -- i.e., exposed to the possibility of physical, psychological, sociological, or other harm as a consequence of any activity proposed in the research project. Note that According to HHS Regulations, minimal risk means "The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests."

1. What is the overall risk (physical and nonphysical) to research subjects in this study?
   ☐ Minimal
   ☐ Greater than minimal
   ☐ Unknown

2. If the classification is minimal risk, please justify why that category is appropriate,
3. If the classification is greater than minimal risk, please explain:

V.Privacy & Confidentiality

1.Explain provisions to protect privacy interests of subjects. This refers to how investigators will approach or contact subjects and/or access private information from or about subjects during and after their involvement in the research (e.g. time, place, etc. of recruitment, consent discussions, research procedures).

2.Will the data collected in the course of the study be considered sensitive data, e.g. mental health, immigration status, SS#, etc.?
   ☐ No
   ☐ Yes →Answer the following:

If yes, what specifically will you be collecting that would be considered sensitive?

a. Why is this data is needed?

b. Could any of this data, if disclosed, have adverse consequences for subjects or damage their financial standing, employability, insurability, or reputation?
☐ No
☐ Yes →Will a Certificate of Confidentiality be obtained?
☐Yes
☐ No

c. What specific safeguards will be employed to protect confidentiality of data, e.g.,coding or removal of identifiers as soon as possible, limitation of access to data, use of locked file cabinets, protection of computer-based data systems, etc.?
d. Will data that can identify individual subjects be published or in any way be disclosed to third parties other than project personnel (e.g., sponsors)?
☐ No
☐ Yes → Please explain here and be sure to incorporate in consent form:

VI.Consent

1.Will you be obtaining documented, fully informed, consent from the subjects in this study?
☐ Yes→ Confirm that the consent form presented is actual form and not a draft.
☐ Confirmed → **Proceed to Question 2**
☐ No, Answer the following:

a. Are you requesting a waiver from the informed consent requirement, or, are you planning on withholding information from the subjects in the consent process (e.g., deception)?
☐ No → **Continue to next question (1.b).**
☐ Yes→ Please explain:

b. Will deception, including withholding of information, be used in this research?
☐ No
☐ Yes→ complete:
Describe the deception being used in this study:
Explain why deception is necessary in this research:

2.Describe **where** consent will be obtained (e.g. online or in person, etc.):

3.Describe **when** consent will be obtained (e.g., during the initial meeting, prior to initial meeting, in classroom setting, etc.). Be sure to include details concerning any waiting period between the consent process and obtaining documented consent.

VII. Research Involving the Internet

1.Will your research involve use of the internet?
☐ NO
☐ YES → **Answer questions a-e**

a. How is the internet being used in this research:
   ☐ Recruiting subjects over the internet
   ☐ Observation of internet activity
   ☐ Collecting data over the internet
   ☐ Other, specify:

b. Describe the use of the internet in this research:

c. Describe how informed consent is being documented:

d. Is online activity (e.g., chat rooms) being observed?
   ☐ No
   ☐ Yes →
      a. Describe the setting and nature of the online activity:
      b. Will the subjects be aware that their activity is being observed?
         ☐ Yes
         ☐ No → Justify:

e. How will you protect the confidentiality of subject information? Include technical information such as encryption, firewalls, etc.

Please submit this form to Dr. Helen Wittmann, IRB Co-Chair, at wittmah@sunysuffolk.edu. For any questions, please contact the Office of planning and Institutional Effectiveness 631-451-4828

Are the following required attachments included?

Home institution's IRB Approval (if applicable)	☐ yes	☐ N/A
Informed Consent form	☐ yes	☐ N/A

Is a letter of support from SCCC required?	☐ yes	☐ No