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, 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 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 that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

2. Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, if at least one of the following criteria is met: (i) information obtained is recorded in such a manner that hum an subjects cannot readily be identified, directly or through identifiers linked to the subjects; (ii) any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or (iii) information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by 45 CFR 46.111 (a)(7) that, when appropriate, there are adequate privacy and confidentiality protections in the study.

3. Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met: (i) information is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects; (ii) any disclose of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or (iii) the information is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by 45 CFR 46.111(a)(7) that, when appropriate, there are adequate privacy and confidentiality protections in the study.

4. Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met: (i) the identifiable private information or identifiable biospecimens are publicly available; (ii) the information, which may include information about biospecimens, is recorded by the investigator in such a manner that subjects cannot readily be identified, directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify the subjects; (iii) the research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under the Health Insurance Portability and Accountability Act (HIPAA), 45 CFR Parts 160 and 164, subparts A and E, for the purposes of "heath care operations" or "research," as those terms are defined at 45 CFR 164.501, or for "public health activities and purposes" as described under 45 CFR164.512(b); or (iv) the research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for non-research activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of1974, 5 U.S.C. 522a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq.

5. Research and demonstration projects which are conducted or supported by a Federal Department or Agency, or otherwise subject to the approval of Department or Agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and which are designed to study, evaluate, improve or otherwise examine: (i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs. Note: Federal entities conducting or sponsoring research covered by this exemption are required to publish a publicly available list of the projects covered by this exemption before the research begins.

6. Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient 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 Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

7. Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review and makes the determinations required by 45 CFR 46.111(a)(8). This exemption can only be used when there is broad consent from the subjects for the storage, maintenance, and secondary research use of their identifiable materials.

8. Secondary research use involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met: (i) Broad consent for the storage, maintenance, and secondary research use of the identifiable information or identifiable biospecimens was obtained in accordance with 45 CFR 46.116 (a)(1)–(4), (6), and (d); (ii) documentation of informed consent or waiver of documentation of consent was obtained in accordance with 45 CFR 46.117; and (iii) an IRB conducts a limited IRB review and makes the determination required by 45 CFR 46.111(a)(7) and makes the determination that the research to be conducted is within the scope of the broad consent referenced in 45 CFR 46.104(d)(8)(i); and (iv) the investigator does not include returning individual research results to subjects as part of the study plan.

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: E-mail Address:

Co-Investigator's Name:

Phone Ext: E-mail Address:

Co-Investigator's Name:

Phone Ext: E-mail Address:

Co-Investigator's Name:

Phone Ext: E-mail Address:

Projected Duration of Project: Projected Start Date:

Form Submission Date:

Exempt? (See definitions on page two – check one):

◯ 1 ◯ 2 ◯ 3 ◯ 4 ◯ 5 ◯ 6 ◯ 7 ◯ 8

Study Description:

I. Study Description

1. 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 the time of application submission.

2. 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. If any gender is being excluded please explain:

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

3. Federal mandates require that you include minorities (including American Indians, Alaskan Native, Native Hawaiian, Pacific Islander, Black [not of Hispanic origin] and Hispanic) in your research unless you can justify their exclusion.

4. 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 the study.

2. Will any flyers, posters, letters, e-mails, pamphlets, brochures, print advertisements, or on-air advertisements or phone calls be used to recruit subjects*
   - ◯ No
   - ◯ Yes – Specify (if not already provided in #1 above)

   Specify

*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?
   - ◯ Yes
   - ◯ No
4. Will subject be offered compensation for participating in the research?
   - ◯ No
   - ◯ Yes, please explain below.

   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?
      - ◯ Yes
      - ◯ No

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 and 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, Social Security #'s, etc.?
   - ◯ No
   - ◯ Yes – Please answer the following:

   a. What specifically will you be collecting that could be considered sensitive?

   b. Why is that data needed?

   c. Could any of this data, if disclosed, have adverse consequences for subjects or damage their financial standing, employability, insurability, or reputation?
      - ◯ No
      - ◯ Yes

      If yes, will a Certificate of Confidentiality be obtained?
      - ◯ Yes
      - ◯ No

d. 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.?

VI. Consent

1. Will you be obtaining documented, fully informed, consent from the subjects in this study?
   - ◯ Yes – please confirm that the consent form presented is the actual form and not a draft.
     - ☐ Confirmed – proceed to question 2
   - ◯ No
   a. If no, 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)?
      - ◯ Yes
      - ◯ No – Continue to question 1b

   b. Will deception, including withholding of information, be used in this research?
      - ◯ No
      - ◯ Yes – If yes, 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 the 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?
   - ◯ Yes, please answer a - e
   - ◯ No

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? If yes, please describe the setting and nature of the online activity: Will the subjects be aware that their activity is being observed? If no, please justify:

- ◯ No
- ◯ Yes, please describe the setting and nature of the online activity:

Will the subjects be aware that their activity is being observed?

- ◯ Yes
- ◯ No, please 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 attachments included?

- ☐ Home institution's IRB Approval (if applicable)
- ☐ Informed Consent form
- ☐ Is a letter of support from SCCC required?