Suffolk
COUNTY COMMUNITY COLLEGE

Policy on Institutional Review Board and Human Subjects' Protection

I. Introduction

Suffolk County Community College (the College) is committed to the protection of students, employees, and others who may conduct or participate in research or externally-funded educational projects involving human subjects, which are sponsored by, or associated with, the College. In accordance with the regulations of the United States Department of Health and Human Services, Office for Human Research Protections (OHRP), and requirements of federal grant agencies and the State of New York, the College's Institutional Review Board (IRB) is charged with ensuring this protection and rendering decisions regarding research and educational projects that impact the College community. The primary role of the IRB is to ensure that the College's students, faculty, staff, and administrators, as well as individuals involved in College-approved and sanctioned research or educational projects, are protected from unnecessary harm and risk.

II. Definitions

A. **Human Subjects.** Living individual(s) about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with an individual, or (2) identifiable private information (45 CFR 46.102[d]).

B. **Research.** A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. (45 CFR 46.102[d]) If the activity meets this standard, it is defined as research (e.g. dissertation research). 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 likely does **not** constitute research (e.g. assessment of student learning).

III. Policy and Duties of the IRB

A. All proposed research or educational projects involving human subjects will be reviewed by the IRB to ensure compliance with all applicable law, rules and regulations.

B. This policy applies to the following:

1. All College faculty, staff, and students using College facilities or the facilities of an off-campus site for the purpose of conducting research or for externally funded projects involving human subjects;

2. Persons who are not College employees or students who wish to use College facilities for such projects; and

3. Persons who wish to conduct projects with College employees or students as subjects, regardless of the project's location.

C. The IRB shall be empowered and responsible to:

1. Determine whether proposed research or educational projects constitute "research." In the case of any such research project, the IRB will meet to approve, request revision, or deny approval of the research activity's protection protocol for human subjects.

2. Determine if research activities are exempt from IRB oversight.

3. Provide oversight of human subject protection for ongoing research involving human subjects.

4. Ensure adherence to this policy and to the procedures and processes outlined in the *IRB Manual* (manual is located on the OPIE section of the SCCC website).

5. Ensure that research conducted at the College is conducted ethically, in accordance with the principles outlined in the *Belmont Report* (see the IRB procedures manual on the SCCC website).

IV. Membership of the Institutional Review Board

A. The membership of the institutional review board shall include the following:

1. IRB Chairperson (Representative from the Office of Planning and Institutional Effectiveness);

2. An instructional faculty member from each campus (selected by Campus Governance representatives);

3. A faculty or staff member selected by the President;

4. A faculty or staff member selected by the Office of Planning and Institutional Effectiveness; and

5. One external representative

B. In addition to this membership, a representative from the Offices of Grants Development, Legal Affairs, Academic Affairs, and Student Affairs will serve as ex-officio members.

C. To ensure an IRB membership with the education, experience, and expertise to evaluate research projects, the following criteria must be adhered to:

1. Instructional faculty representatives are to be selected from either a physical or social science and, where possible, should have human subjects research experience and a terminal degree;

2. The Chair and appointed members should have human subjects research experience, when possible; and

3. The external representative may not be related to any officer or employee of the College. Such representative should represent a community interest, and/or have a background in ethics or human rights advocacy.

V. Mandatory Training

All members of the IRB, as well as persons who conduct research directly or indirectly with human subjects, must undergo training on the protection of human subjects. Given the limited scope of research conducted at the College, this requirement is fulfilled through mandatory review of the *Belmont Report* by the membership of the IRB.

VI. Prohibited Research

In adherence to the College's mission, the College will not engage in, nor support, research projects involving students, faculty, administration, or staff that require clinical trials, drug trials or medical device research.

VII. Policy Violations

A. Should any alleged violations of this policy occur, the allegations will be brought before the IRB at a convened meeting. The body will review the reported violation and determine if additional information or further investigation is required. Affected supervising administrator(s) will be copied on all correspondence between the review board and the involved parties. If it is determined that a violation of this policy has occurred, the IRB will require that the activity in question be halted until corrective action is taken.

B. In situations where participant safety is compromised, and/or the violations are apparent, the Chair of the IRB, in consultation with other members and administrators, as appropriate, will require immediate suspension of the activity prior to review by the full membership. If the IRB determines that the violation involves possible scholarly or scientific misconduct, the Vice President for Academic and Student Affairs and the Vice President for Planning and Institutional Effectiveness will be notified. While the IRB can and will assist in the investigation, the review board will adhere to the decisions made by the Vice-Presidents which must consider all appropriate actions in light of established College assurances, policies, and procedures.

VIII. Policy Review

A. **Annual Review.** This policy shall be reviewed on an annual basis.

B. **Comprehensive Review.** This policy shall be reviewed five (5) years from the effective date or one year from a change in CFR 45, Part 46.

IX. Effective Date

This policy shall be effective as of August 21, 2014.

Board of Trustees
August 21, 2014