

# Essex County College College Regulation

## REG 6-14 INSTITUTIONAL REVIEW BOARD

### **Purpose:**

The Essex County College Institutional Review Board (ECC IRB) regulation is intended to serve three purposes. The primary purpose of this regulation is to ensure the privacy and protection of Essex County College students and employees as human subjects for any and all research conducted utilizing these populations. This includes research conducted by external researchers as well as internal researchers whose research falls outside of the direct roles and responsibilities outlined in their job description.

The secondary function of this regulation is to ensure that any research conducted by students or employees of Essex County College that is in any way affiliated with the College, and involves the study of human subjects, is done in a manner that protects human subject privacy and makes all reasonable attempts to protect the welfare of human subjects. This secondary purpose pertains to all human subjects regardless of whether they are affiliated with Essex County College, particularly populations considered particularly vulnerable as per federal regulation.

The tertiary purpose of this regulation is to give the College a mechanism to ensure that all research being conducted at Essex County College that falls outside the confines of official College operations is in accordance with the institution's mission, vision, and values.

### **Definition(s):**

**Principal investigator(s):** A Principal Investigator or PI is the individual responsible for the preparation, conduct, and administration of a research project being conducted under the oversight of the ECC IRB.

**Human Subjects Research:** According to 45 C.F.R 46, Protection of Human Subjects, a human subject is "a living individual about whom an investigator (whether professional or student) conducting research:

- Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
- Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens."

### **Application:**

- The ECC IRB will be composed of at least seven members, including designees from: The Office of General Counsel, the Office of Institutional Effectiveness, Planning, and Assessment, the Office of Compliance, The Office of Student Affairs, the Office of Academic Affairs; and two members of the faculty appointed by the President of Essex County College, to serve three-year terms to ensure that the review board is sufficiently qualified through diversity, maturity, experience and expertise of its members for advice and counsel to safeguard the rights and well-being of human subjects.
- Designees from the Office of the General Counsel responsible for Compliance and the Office of Student Affairs will serve as Co-Chairs of the ECC IRB.
- If the ECC IRB reviews research that involves a vulnerable category of participants, it will consider including one or more additional members who have expertise on the population in question. These invited

members do not vote. ECC IRB members must recuse themselves from involvement with any IRB decisions where a potential conflict of interest, such as a financial or political interest exist.

- The ECC IRB will be trained, guided by and operate in compliance with applicable sections of all relevant local, state and federal laws and regulations including, but not limited to: 45 C.F.R Part 46; 21 C.F.R Part 50; 21 C.F.R Part 56; 34 C.F.R Part 97, 34 C.F.R. Part 98; 34 C.F.R. Part 99; 34 C.F.R. Part 350; 34 C.F.R. Part 356.
- The ECC IRB shall meet once a month in formal session during the academic year if there are completed IRB proposals awaiting a determination.
- To be eligible for review, an applicant must submit a completed IRB application which can be found on the Institutional Effectiveness, Planning, and Assessment website.
- The following types of proposals are exempt from IRB review: data gathered for the purposes of internal decision-making and institutional improvement by employees with job descriptions expressly outlining these functions. Research conducted by employees for the purpose of fundraising, market research for the purposes of admissions recruiting, recruiting efforts for faculty or staff, and statistical data collected for the management of institutional affairs, including surveys of students, prospective students, and alumni, so long as these functions are expressly outlined in the job description of the employee. Please note that a proposal that does not clearly fall into one of these categories should be presented to the ECC IRB Co-Chairs for a decision of whether the research is exempt. Note: The principal investigator(s) themselves cannot make the determination as to whether a proposal is exempt from review by the ECC IRB.

<p>Responsible Official(s): Co-Chairs of the ECC IRB.</p>	<p><b>Reference:</b> N.J.S.A. 18A: 64A-12(o); 45 C.F.R Part 46; 21 C.F.R Part 50; 21 C.F.R Part 56; 34 C.F.R Part 97, 34 C.F.R. Part 98; 34 C.F.R. Part 99; 34 C.F.R. Part 350; 34 C.F.R. Part 356.</p> <p>BP-6-4</p>
<p>Regulation History: 3/22</p>	<p>Attachment(s):</p>