

Purpose

Sets forth an Administrative Policy/Procedure regarding the protection of human subjects in research conducted by Johnston Community College faculty, staff, students, or external researchers on populations because of their affiliation with the College.

General Policy

In an effort to support higher education's commitment to knowledge advancement and scholarship, Johnston Community College is dedicated to assisting researchers in collecting data for their research projects. At the same time, JCC must protect the rights and welfare of its employees and students. Additionally, JCC must ensure that employees and students are not overburdened with requests for information. The following process serves to outline the guidelines for Johnston Community College's participation in both internal and external research requests.

Applicable References:

Code of Federal Regulations Title 45 – Part 46 – Protection of Human Subjects

U. S. Department of Health & Human Services Office for Human Research Protections (OHRP)

The Belmont Report

Definitions

- A. **Research** – As defined by 45 CFR 46.102(d), research “means systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.
- B. **Human Subject** – As defined by 45 CFR 46.102(f), a human subject “means a living individual about whom an investigator (whether professional or student) conducting research obtains 1. data through interaction with the individual, or 2. identifiable private information.”
- C. **Federalwide Assurance** – According to the OHRP, “The Federalwide Assurance (FWA) is the only type of assurance of compliance accepted and approved by OHRP for institutions engaged accepted and approved by OHRP. FWAs also are approved by the OHRP for federalwide use, which means that other departments and agencies that have adopted the Federal Policy for the Protection of Human Subjects (also known as the Common Rule) may rely on the FWA for the research that they conduct or support.”
- D. **Institutional Review Board (IRB)** – an administrative body established to protect the rights and welfare of human subjects recruited to participate in research activities conducted under the auspices of the institution with which it is affiliated.
- E. **IRB Approval** – From 45 CFR 46.102(h), IRB approval means the determination of the IRB that the research has been reviewed and may be conducted at an institution within the constraints set forth by the IRB and by other institutional and federal requirements.
- F. **Institutional Official** – OHRP describes the institutional official as “the individual authorized to act for the institution and, on behalf of the institution, obligates the institution to the Terms of Assurance.” OHRP recommends that the institutional official not be the chair or member of any IRB designated under the FWA to avoid conflict of interest between the duties of the IO and the IRB review function.”

Policy Provisions**Structure of the JCC's Human Rights Protection Program (HRPP)**

1. The President shall serve as the College's institutional official. As described by the OHRP, the institutional official is responsible for
 - a. Designating one or more IRBs that will review research covered by the institution's Federalwide Assurance (FWA)
 - b. Providing sufficient resources, space, and staff to support the IRB's review and record keeping duties
 - c. Providing training and educational opportunities for the IRB and investigators
 - d. Setting the “tone” for an institutional culture of respect for human subjects
 - e. Encouraging that all staff engaged in conduct or oversight of human subject research participate in education activities
 - f. Serving as a point of contact for OHRP, or delegating this responsibility to another appropriate individual

2. The institutional official shall complete the CITI Institutional/Signatory Official: Human Subject Research course or other similar training.
3. The institutional official shall serve as the signatory authority for the FWA. FWA is effective for 5 years and must be renewed every 5 years. Any changes in the person serving as the institutional official will be updated on the College's FWA.
4. The institutional official shall delegate to the Executive Director of Planning, Research, Effectiveness, and Strategy the operational oversight of JCC's HRPP. Executive Director will serve as the Human Protections Administrator with duties to include:
 - a. Recruiting, appointing, suspending or terminating IRB members
 - b. Carrying out periodic evaluation of IRB members
 - c. Being the point of contact for correspondence addressing human subject research with the OHRP, FDA and other agencies, including required reports to federal agencies
 - d. Ensuring that IRB members and researchers are qualified to conduct research in accordance with ethical standards and applicable regulations
 - e. Reviewing and approving Standard Operating Procedures (SOPs) for the IRB and HRPP
 - f. Overseeing daily operations of the IRB and HRPP in accordance with the SOPs
5. The Executive Director of Planning, Research, Effectiveness, and Strategy shall also serve as the Chair of the JCC Institutional Review Board and ensure that JCC's IRB operates as outlined in *Johnston Community College Institutional Review Board Charter and Standard Operating Procedures* (See Attachment A)
6. The JCC Institutional Review Board shall be registered with the OHRP and renewed every three (3) years.
7. The institutional official cannot approve research that has been disapproved (or not yet approved) by the IRB.

Guidelines for Reviewing Research Projects on Populations Affiliated with the College

In making its decision to conduct an IRB review of submitted proposals, the College's first priority must be a focus on factors promoting JCC's mission. Any submitted proposal must meet the minimum standard of having the likelihood of providing knowledge that contributes to the long-term success of JCC's faculty, staff, and students.

In reaching the conclusion to review research with populations affiliated with the College, the Executive Director of Planning, Research, Effectiveness, and Strategy will take into consideration the following factors:

- a. Has the researcher made a strong and compelling case that the research will provide insight into learning and student success factors and is the research aligned with JCC's mission?
- b. Has the proposal clearly articulated how findings will be communicated to the JCC community?
- c. Have all costs which will be incurred by the JCC community been fully considered; do the benefits outweigh the costs, and has provision been made to reimburse JCC for any unusual data collection expenses?
- d. Has the research been determined to be in compliance with FERPA requirements?
- e. In the opinion of the Executive Director of Planning, Research, Effectiveness, and Strategy, is the research design sufficiently rigorous to lead to meaningful insights?
- f. Has the researcher identified a JCC full-time faculty or staff member who is willing to serve as the internal contact/sponsor for the research? Has the individual acknowledged acceptance of this role and has the individual identified the value of the research findings to his/her area of responsibility?
- g. In the opinion of the Executive Director of Planning, Research, Effectiveness, and Strategy, have the individuals comprising the research sample been overly burdened with requests to serve as research subjects?

Requests to Conduct Research on Populations Affiliated with the College

1. All employees must send request for participation in research projects to the Executive Director of Planning, Research, Effectiveness, and Strategy.
2. Once the request is received, the Executive Director will contact the researcher for completion of the Application for Review by JCC Institutional Review Board. (See Attachment B)
3. As outlined in the *Johnston Community College Institutional Review Board Charter and Standard Operating Procedures* (See Attachment A), the Executive Director, who also serves as IRB Chair, will review the Application for Review by JCC Institutional Review Board forms eligible for exempt or expedited review or, if significant risk is inherent in the study, refer the petition to the IRB for full board review. If a research protocol requires review by the full IRB board, the procedures of the IRB charter will be followed.

4. Research protocols from researchers who have already obtained IRB approval from an external IRB will be reviewed by the Executive Director of Planning, Research, Effectiveness, and Strategy. Researchers must submit copies of their approved (IRB) application. Additionally, researchers must also submit copies of any materials they plan to give to participants, such as introductory letters and informed consent forms.
5. After reviewing all of the researcher's materials, the Executive Director of Planning, Research, Effectiveness, and Strategy will consult with employees impacted by the research request. Additionally, the Executive Director will consult as needed with Student Services, Financial Aid, Human Resources and any other office to determine if the research request conflicts with any privacy laws.
6. The Executive Director of Planning, Research, Effectiveness, and Strategy will determine how the research request fits into the existing workflow of employees and students. The Executive Director will ensure that participants are not overburdened with multiple requests for information either from institutional sources (ex. course evaluations, graduate surveys, etc.) or research requests. The Executive Director will consult with the college president concerning requests that were addressed directly to the president.
7. As needed, the Executive Director of Planning, Research, Effectiveness, and Strategy will convene the JCC IRB. The Executive Director will send a letter to the researcher either approving, approving with restrictions, tabling, or disapproving the research request.
8. The Executive Director of Planning, Research, Effectiveness, and Strategy will archive all correspondence with researchers and minutes of the IRB.