



Rowan College of South Jersey

Administrative Procedure: 3016 **INSTITUTIONAL REVIEW BOARD**

The purpose of this administrative procedure is to ensure that data requests and research projects conducted by any College office, employee, student, or affiliate are sound and do not violate board policy, College operating procedures, ethical responsibilities, and federal and state regulations concerning protection of human participants or the appropriate use and interpretation of data.

Scope

Employees of the College or appropriate external researchers may conduct research projects, including those that involve the use of human subjects, under appropriate circumstances and with appropriate safeguards. Such persons are called the Principal Investigators (PI).

The research should deal with the teaching/learning environment or with the College's policies, procedures, or operations. Research activities that involve (1) intervention or interaction with human subjects, (2) the collection of identifiable private data on living individuals, and/or (3) data analysis of identifiable private information on living individuals requires Institutional Review Board ("IRB") review and approval prior to the initiation of the research.

Definitions

Non-affiliated personnel are defined as individuals not recognized as having a direct relationship to the College (e.g. not a faculty member, staff member, or student of the College). For non-affiliated personnel, only research that is tightly aligned with the College's goals will be considered for approval. If accepted, non-affiliated personnel must follow all the same procedures as affiliated personnel.

A human subject is defined as a living individual about whom an investigator (whether professional or student) conducting research obtains:

- a. data through intervention or interaction with the individual, or
- b. identifiable private information (45 CFR 46)

Research is defined by the U.S. Department Health and Human Services as “a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.” (45 CFR 46)

Exemptions

In general, research that utilizes data which will not be used beyond the classroom, is for internal institutional usage only, and/or is collected for the purpose of reporting to state or federal stakeholders does not require review by an IRB. Examples of research efforts not requiring IRB action include:

- Data collection which will not result in a formal presentation, poster session, abstract, or publication, master’s thesis or doctoral dissertation. If the possibility exists, but is not known, that the research may result in a formal presentation or publication, then prior to conducting the research, the protocol must be reviewed by an IRB.
- Simulations of human experimentation.
- Data collection for educational purposes in which no data will be reported outside of the classroom and all data are properly destroyed (reporting and discussion of data within the class is acceptable).
- Data collection for the purpose of reporting to state or national accrediting bodies or other agencies to which the College is required to generate and submit reports as part of its regular operations.

Process

All research and related data requests must be initiated through the Office of Institutional Research. Submission of the required documentation does not provide the necessary assurances for Human Subjects Protection. Approval, in the form of a letter, must be received prior to initiation of the research. The process to apply for approval to conduct research is as follows:

1. Submit a Request to Conduct Research

Individuals who plan to conduct research at the College must submit a Request to Conduct Research Request Form to the Office of Institutional Research (Appendix A). The request must include the following documentation:

- Completed IRB application and disposition from requestor’s affiliated college/university. In general, unsponsored research will not be approved.
- Certification that all principal investigators and key project personnel will successfully complete the “Protecting Human Research Participants” course from the National Institutes of Health. A similar training program is acceptable.

2. Review Process for Sponsored Research

Requests will be reviewed and a determination of whether to approve will be made as follows:

- The request is reviewed by an IRB committee (“Committee”) to include, at a minimum, the requestor’s immediate supervisor, the Dean of Institutional Research and the Vice President and Provost. Additional reviewers may be required depending on the scope of the project. Additional documentation/information about the proposed research may be requested at this time.
- The Committee's recommendation is submitted to the President or his/her designee for review. Final approval is determined by the President.
- The Office of Institutional Research will notify the requestor via email of the determination (approved/not approved). The notification will include a copy of the official approval or denial letter from the College President or designee.

3. Review Process for Non-Sponsored Research

In general, the College requires the Institutional Review Board of the principal investigator’s affiliated college or university to certify Human Subject protections are met. Research requests submitted by individuals without such affiliation are typically not approved. In rare instances, an ad hoc Committee will be formed to conduct Human Subjects review for unsponsored requested research. These requests must also submit the Human Subjects Questionnaire for Non-sponsored Research (Appendix B).

The ad hoc Committee will include four (4) committee members representative of the College community including: two faculty representatives, one dean's representative, and one Administration representative. The Dean of Institutional Research will serve as an ex officio member of this ad hoc Committee.

Institutional Data

All research projects requiring the assistance of the Office of Institutional Research will be contingent upon available resources. The Office of Institutional Research reserves the right to determine appropriate time frames if the data request for an approved research project is extensive.

Reporting Requirements

Approved projects must adhere to the following reporting requirements:

Amendments

If a significant change from a previously approved protocol is to be made, an amendment must be submitted for review. There is no set form for this procedure. Investigators should reference the original protocol form as a guide to the type of information required when submitting an amendment.

Adverse Events

Investigators are required to report adverse and/or unexpected events that are experienced by human subjects in research protocols. Federal policy [45 CFR 46] includes adverse event reporting as a component of mandatory continuing review of approved protocols, with the stipulation that serious adverse events be reported immediately, if they occur.

Final Research Reports

Once approved, a copy of the final research report is required to be submitted. Electronic copies are preferred and submitted to Dean of Institutional Research, Rowan College of South Jersey, 1400 Tanyard Road, Sewell, NJ 08080.

Area: Academic Services

Approved: 07/01/19

President's Authorization:



References:

Rowan College of South Jersey Board of Trustees Policy Manual, *3205 Institutional Review Board*

Title 45 Code of Federal Regulations, Part 46 (45 CFR 46)

Title 21 Protection of Human Subjects, Part 50, and Institutional Review Boards, part 56

The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research. Washington, D.C.: U.S. Government Printing Office, 1978. DHEW Publication No. (OS) 78-0012. Reprinted in Federal Register 44 (April 18, 1979): 23192.

Appendix (Volumes I and II) to The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research. Washington, D.C.: U.S. Government Printing Office, 1978. DHEW Publication No. (OS) 78-0013 and (OS) 78-0014.

Administrative Procedure: 3205 Institutional Review Board