

PIERPONT COMMUNITY & TECHNICAL COLLEGE
Board of Governors Policies and Procedures
PP-3048

SHORT TITLE: Research Involving Human Subjects

REFERENCES: West Virginia Code §§ 18B-1-6; Federal Regulations 45 C.F.R. § 46, 21 C.F.R. § 50 (Protection of Human Subjects), 21 C.F.R. § 56 (Institutional Review Boards), 38 C.F.R. § 16, and 45 C.F.R. §§ 160, 162, and 164; applicable West Virginia state statutes and regulations; and the principles of the Belmont Report

EFFECTIVE:

AMENDED: February 16, 2021

REPEALED:

REVIEWED: June 10, 2020; October 28, 2020

SECTION 1. PURPOSE

This policy establishes the policy and procedure for research or externally-funded educational projects involving human subjects, which are sponsored by or associated with Pierpont Community & Technical College (Pierpont).

SECTION 2. SCOPE AND APPLICABILITY

This policy applies to (1) all Pierpont 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 but 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.

SECTION 3. DEFINITIONS

3.1 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 (See 45 CFR 46.102[d]).

3.2 Institutional Review Board (IRB). The committee that is responsible for the ethical

conduct of research involving human subjects. The committee that reviews, monitors, and approves human subject research; protects the rights and welfare of human subjects; and assures that clinical research is conducted according to federal regulations, state law, and IRB policies.

- 3.3 IRB Research Handbook.** A handbook containing all procedures and policies of the IRB process at Pierpont. will be reviewed and maintained by the Faculty Senate Institutional Review Board and amended as necessary and when there are applicable changes in Federal, State or Institutional Policies.
- 3.4 Protocol.** The formal design or plan of a research activity; any protocol submitted to the IRB must include the elements specified according to the procedures outlined in the *IRB Research Handbook*.
- 3.5 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 and 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).

SECTION 4. POLICY

Pierpont Community & Technical College (Pierpont) 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. Pierpont maintains an Institutional Review Board (IRB) to ensure that its 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.

SECTION 5. BACKGROUND OR EXCLUSIONS

The Institutional Review Board is a Standing Committee of Pierpont's Faculty Senate, which governs the makeup and charge of the Institutional Review Board.

SECTION 6. GENERAL PROVISIONS

- 6.1 IRB Charge and Goals.** Pierpont's Institutional Review Board (IRB) is charged with protecting those involved in such research and educational projects and with rendering decisions consistent with the regulations of the United States

Department of Health and Human Services and the Office for Human Research Protections (OHRP) and the requirements of federal grant agencies and the State of West Virginia. The IRB shall be empowered and responsible to ensure that:

- 6.3.1 **Protection of Participants.** The IRB will ensure that the rights and welfare of research participants are protected.
 - 6.3.2 **Minimization of Risks.** The IRB will consider and minimize risks to research participants.
 - 6.3.3 **Maximization of Benefits.** The IRB will identify and maximize the potential for benefit.
 - 6.3.4 **Consent.** The IRB will ensure that all volunteer research subjects have been provided with enough information to give legally effective informed consent and have agreed to participate.
 - 6.3.5 **Ethical Compliance.** The IRB will ensure that research is conducted in an ethical manner in compliance with established standards.
 - 6.3.6 **Legal Compliance.** 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.
- 6.2 **Mandatory Training.** All members of the Institutional Review Board must complete the Responsible Conduct of Research (RCR) training by July 1 for the upcoming academic year or have a valid certification that covers the upcoming academic year.
- 6.3 **Response Time.** All research conducted pursuant to this this policy must be approved by Pierpont's IRB, and the IRB will respond to all research projects within two weeks of the proposal.
- 6.4 **Handbook.** The Institutional Review Board will determine procedures and exemptions and will publish an *IRB Research Handbook* that contains all procedures and policies of the IRB process at Pierpont. The IRB will review the handbook annually and amend it as necessary in response to applicable changes in Federal, State, or Institutional Policies.

SECTION 7. RESPONSIBILITIES

Pierpont's Institutional Review Board (IRB) is responsible for the interpretation and application of this policy.

SECTION 8. CANCELLATION

This policy does not cancel an existing policy.

SECTION 9. REVIEW STATEMENT

This policy shall be reviewed every five (5) years from the effective date or within one year from a change in CFR 45, Part 46. IX. Upon such review, the President or the President's designee may recommend that the policy be amended or repealed.

Attachments: None

Distribution: Members of the Board of Governors, President of the College, Vice President of Finance and Administration, and Assistant to the President

Revision Notes: June 10, 2020—This revision reorganizes policy sections pursuant to PP-1000.B, inserts applicable statutory and regulatory references, and eliminates provisions more appropriate for a handbook than a policy.