

Piedmont Virginia Community

Section II – General Administrative Services Policy

II – 70.7 Institutional Review Board Policy

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| Policy #: | II – 70.7 |
| Effective: | July 2024 |
| Revised: | New policy as of effective date |
| Responsible Dept: | Institutional Research and Effectiveness |

1. Purpose

The Institutional Review Board (IRB) is an administrative body established to protect the rights and welfare of human research subjects recruited to participate in research activities conducted under the auspices of the institution with which it is affiliated.

2. Policy Statement

This Institutional Review Board Policy outlines the general responsibilities of PVCC's IRB, its membership, and processed for research approval.

3. Responsibilities

PVCC's Institutional Review Board (IRB) protects the rights and welfare of human subjects involved in research. The responsibilities of the PVCC IRB shall include, but are not limited to, the following:

- Determining which research requests involving human subjects require review;
- Approving requests for research involving human subjects;
- Conducting initial and continuing reviews of human subjects' research;
- Reporting findings and actions to the investigator and the institution; and
- Ensuring reporting of changes and unanticipated problems involving risks or noncompliance.

The College's IRB will follow guidelines and make determinations consistent with mandates applied to Institutional Review Boards.

Membership

The membership of the IRB shall include the following:

- The Associate Vice President of Institutional Research and Effectiveness;
- A full-time college credit Instructor from Business, Mathematics, and Technology division;
- A full-time college credit Instructor from Humanities division;
- A full-time college credit Instructor from Health and Life Sciences division;
- A College dean; and
- A representative not affiliated with the College.

The Associate Vice President of Institutional Research will serve as IRB chair. The committee shall

convene as required. Minutes of each meeting shall be recorded, and notifications shall be made to the originators of research proposals.

The Office of Institutional Research and Effectiveness (IER) is responsible for the administration and oversight of research integrity at the College. IER has responsibility for overseeing the functioning of the IRB, dissemination and administration of this policy and communications with external researchers. Any PVCC employee who receives an inquiry or request regarding the conduct of research as specified in Section 1 should forward the inquiry to the IER Office.

4. Procedures for Implementation

Federal wide Assurance (FWA)

Any research that is conducted or supported by any U.S. federal department or agency must be done through a Federal wide Assurance to ensure compliance with federal regulations (see [this link](#)). For the purposes of the FWA, federally supported means the U.S. Government provides any funding or other support. This type of research will require additional training for both Principal Investigators (PIs) and IRB Members, as well as additional registration with the Office of Human Research Protections. Researchers should reach out to IRB@pvcc.edu if they believe that their research is connected to or supported by the U.S. Government.

Initial Review

Current PVCC faculty and staff should refer to this policy for detailed instructions on submitting research proposals *prior to recruiting participants or collecting data*. This process may require a full review by PVCC's Institutional Review Board. It is recommended that any requests submitted be done well in advance. Researchers not affiliated with PVCC, including PVCC students, interns, undergraduate or graduate students at other institutions, or other external researchers, must first obtain permission from the Associate Vice President of Institutional Research and Effectiveness (IRB@pvcc.edu) before submitting any proposals listed below. This process may require a full review by PVCC's Institutional Review Board. It is recommended that any requests submitted be done well in advance.

Research involving human subjects falls into three distinct categories, listed below. If a researcher is unsure which category applies to their proposed research, they are encouraged to contact IRB@pvcc.edu for clarification.

4.1 Exempt Research

Consistent with federal guidelines defined in Title 45 Code of Federal Regulations Part 46, the following research activities are **EXEMPT** from IRB review:

- Research conducted in established or commonly accepted educational settings involving normal educational practices, such as:
 - research on educational instructional strategies; and
 - research on the effectiveness of instructional techniques, curricula, or classroom management methods.

- Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:
 - information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and
 - any disclosure of the human subjects' responses outside the research reasonably places the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.
- Research involving the collection or study of existing, data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified directly or through identifiers linked to the subjects.
- Taste and food quality evaluation and consumer acceptance studies:
 - if wholesome foods without additives are consumed; or
 - if a food is consumed that contains a food ingredient at or below the level found to be safe by the U.S. Food and Drug Administration or approved by the U.S. Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

Exempt research does not require IRB review. However, an exempt research activity does not absolve the investigator(s) of the requirement for ensuring that the welfare of subjects is protected and that methods used to gain subject consent are appropriate.

4.2 Expedited Research

Certain types of research qualify for an 'expedited' review (see [this link](#)). These are activities that:

- Present no more than minimal risk to human subjects, and
- Involve only procedures specified in federal regulations (see above link). The activities listed should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on the list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.

An expedited review consists of a review of research involving human subjects by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB in accordance with the requirements set forth in Section 45 CFR 46 ([linked here](#)). Any researcher seeking an expedited review should fill out and submit the appropriate sections of the application form according to the form instructions. **Application forms must be submitted at least three (3) weeks prior to the proposal deadline to provide time for review and processing.**

4.3 Non-Exempt Research

The above exemptions do NOT apply—and research activities will require full IRB review—in

any case when:

- Deception of subjects may be an element of the research;
- Subjects are under the age of eighteen;
- Subjects are elected or appointed public officials or candidates for public office;
- Subjects are under federal statutes which require, without exception, that the confidentiality of personally identifiable information will be maintained throughout the research and after;
- The activity may expose the subjects to discomfort or harassment beyond levels encountered in daily life; or
- Fetuses, pregnant women, human in vitro fertilization, children, or individuals involuntarily confined or detained in penal institutions are subjects of the activity.

The IRB shall review non-exempt research protocols involving human subjects to ensure that:

- The rights and welfare of human subjects used in research studies are protected;
- Risks have been considered and minimized;
- Benefits have been identified and maximized;
- All human subjects volunteer to participate in research after being provided with legally effective informed consent; and
- Research is conducted in an ethical manner and in compliance with established standards.

Any researcher seeking approval for non-exempt research should fill out and submit the appropriate sections of the application according to the form instructions. **Application forms must be submitted at least three (3) weeks prior to the proposal deadline to provide time for review and processing.**

1. Research Approval

For expedited and non-exempt research, the IRB (or IRB official, if appropriate) may take one of the following four actions regarding the proposed research: *Approved*, *Approved Subject to Restrictions*, *Tabled*, or *Disapproved*. All approved research must follow requirements in the *PVCC Policy II-70.4 Research Policy*.

2. Continuing Review

The IRB may conduct continuing review of research at intervals appropriate to the degree of risk, but not less than once per year.