

Policy on Research Involving Humans - 071

Policy Statement

Pacific Coast University for Workplace Health Sciences is committed to compliance with the *Tri-Council Policy Statement 2* and requires that research projects involving humans participants undertaken by any person (including faculty, staff, students, visiting professors, adjunct professors, visiting professional associates, research associates, postdoctoral fellows) under the auspices of Pacific Coast University for Workplace Health Sciences or within our jurisdiction, or using any University resources, must be reviewed and approved by the Pacific Coast University for Workplace Health Sciences Research Ethics Committee (PCUREC). This includes research that is: conducted on or off campus; funded or unfunded; conducted b y formally affiliated organizations and institutes.

Pacific Coast University for Workplace Health Sciences only endorses undergraduate and graduate student principal investigators conducting research when such research is under the supervision a course advisor and within the jurisdiction of an academic program. PCUREC will only consider such applications and not those conducted outside the jurisdiction of an academic program.

The PCUREC Policies and Procedures and other documents and forms applicable to the research ethics review process are available on the University website. Related Policy Research Integrity Policy Research Ethics Review Conflict of Interest Research Investigation of Potential Misconduct Student Codes of Conduct

Definitions

The TCPS2 definitions:

- Research an undertaking intended to extend knowledge through a disciplined inquiry or systematic investigation.
- Participant an individual whose data or responses to interventions, stimuli, or questions by a researcher are relevant to answering a research question.

The TCPS2 outlines the minimum ethical standards for research involving human participants and Pacific Coast University for Workplace Health Sciences is at liberty to develop higher standards where appropriate. Where the University, external agency or discipline has a higher standard or additional requirements for the protection of human participants, the higher standard will take precedent.

Conflict of Interest: A conflict of interest may arise when activities or situations place an individual or institution in a real, potential or perceived conflict between the duties or responsibilities related to research, and personal, institutional or other interests (*Tri-Council MOU, Schedule 14*). These interests include, but are not limited to, business, commercial or financial interests pertaining to an institution and/or the individual, their family members, friends, or their former, current or prospective professional associates. See the University Policy on Research Conflict and the general Conflict of Interest Policy of the University.

A conflict of interest may involve the institution, researcher, or PCUREC member. Any real, potential or perceived conflict of interest must be disclosed. If the committee determines that there is in fact a conflict



of interest, the committee member is expected to recuse themselves or, failing that, they may be recused by the chair of the committee.

Procedures

PCU-WHS has a strong continuing commitment to maintaining the highest ethical standards in the conduct of research by faculty, staff, students and all others who conduct research in the University's name. We strive to ensure that every member of our University community understands that as we create new knowledge and teach our students it is important that our work reflect the highest standards of scientific and professional conduct. The purpose of this policy is to provide guidelines describing how we set and apply ethical standards in the ongoing research and teaching at the University. To this end PCU- WHS subscribes to the Tri-Council Policy Statement concerning on research ethics.

The second edition or the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS2) is a joint policy of Canada's three federal granting agencies (Tri-Council): Canadian Institutes of Health Research (CIHR); Natural Sciences and Engineering Council of Canada (NSERC); and Social Sciences and Humanities Research council of Canada (SSHRC). In order to receive and administer Tri- Council funding, Canadian institutions must comply with the policies set out in the Memorandum of Understanding on the Roles and Responsibilities in the Management of Federal Grants and Awards (Tri- Council MOU). The TCPS2 falls under Schedule 2 of the Tri-Council MOU.

The Pacific Coast University for Workplace Health Sciences Research Ethics Committee (PCUREC) is responsible for the administration and ethics review of human participatory research conducted under the auspices or jurisdiction of the University. The PCUREC review process is intended to provide assurance to research participants, researchers, and the University, that participants will be respected and protected, and will be involved in ethically sound research. PCUREC:

- a. will maintain, develop, and revise internal policies and procedures as appropriate;
- b. has the authority to approve an ethics application, approve an ethics application subject to modifications, or reject an ethics application; and
- c. is responsible for reviewing and approving all amendments to approved applications; monitoring on-going research; and terminating projects that do not conform to ethical standards.

Membership of the PCUREC:

The PCUREC composition shall be determined by PCUREC for approval by the Academic Council. All PCUREC members are to be appointed by the Academic Council Research Committee. The following requirements shall be satisfied among the members:

- at least one member is knowledgeable in ethics;
- at least two members having broad expertise in research methods;
- at least one member knowledgeable in legal principles, but who shall not be the University's legal counsel; and
- composed of both men and women.

A detailed outline of the PCUREC membership can be found in the Terms of Reference of the PCUREC

Research Requiring PCUREC Review:

The following research requires ethics review and approval by PCUREC prior to the start of research: a. research involving living human participants; and



b. research that involves human biological materials, as well as human embryos, fetuses, fetal tissue, reproductive materials and stem cells. This applies to materials derived from living and deceased individuals.

Given the breadth of possible research topics and methods to be reviewed, this policy cannot exhaustively cover all possible circumstances or ethical issues that may arise. It is the responsibility of the researcher to verify with PCUREC whether review and certification is required, prior to commencement of the research project.

A proportionate approach is required to research ethics review. Consequently, the PCUREC shall review research activities to determine the level of foreseeable risk to participants. Based on the judgment of the PCUREC, activities with a lower the level of risk shall be assigned a lower the level of scrutiny through delegated review. Activities with a higher the level of risk will be subjected to a higher of scrutiny through a full PCUREC review.

See TCPS2 article 6.12 for levels of foreseeable risk.

• In line with this principle, ethical review of course-based research activities which are intended solely for pedagogical purposes can be delegated by the PCUREC to PCU-WHS department, faculty or equivalent level to non-PCUREC members.

Such activities are normally those required of students (at all levels) with the objective of providing them with exposure to research methods in their field of study such as interviewing techniques and community interaction.

Activities that are part of a student's own research shall be reviewed by the PCUREC. This includes theses or equivalent research projects involving human participants, as per Article 2.1, which shall be reviewed by the PCUREC.

The Terms of Reference of the PCUREC specify the procedures and criteria for determining which categories of research may be eligible for this type of review and responsibility for implementing and overseeing approval mechanisms.

To maintain oversight over the decisions made on its behalf and protect the interests of participants, the delegated review process operated by the PCUREC requires that the actions and decisions of delegated reviewers are well documented and formally reported to the full PCUREC in a timely and appropriate manner. Where the delegated review is conducted by non-voting members or non-members of the REB, this formal report shall be made through the Chair.

Research Exempt from PCUREC Review:

In accordance with the Tri-Council Policy Statement, research does not require ethics review and approval by PCUREC prior to the start of research when:

- a. the information is legally accessible to the public and appropriately protected by law;
- b. the information is publicly accessible and there is no reasonable expectation of privacy;
- c. the research involves the observation of people in public places where interaction or intervention is not staged by the researcher, individuals have no reasonable expectation of privacy, and any dissemination of results does not identify specific individuals; or
- d. the research relies exclusively on secondary use of anonymous information, or anonymous human biological materials, that does not generate identifiable information.



See TCPS2 articles 2.2, 2.3, and 2.4 for further details.

Other Activities Exempt from PCUREC Review

The Tri-Council Policy Statement recognizes that some activities may use the techniques and methods of research while not constituting research as defined above. Such activities do not require ethics review and approval when:

- a. the data collected is for quality assurance and quality improvement studies, program evaluation activities, performance reviews, or testing within the normal educational requirements when used exclusively for assessment, management or improvement purposes, unless the data is used for other research or scholarly purposes (see TCPS2 article 2.5);
- b. the data collected are for the purposes of conducting a needs assessment, provided the data are not also used for other research purposes; or
- c. it is a creative practice activity where an artist makes or interprets a work of art or studies how a work of art is generated, unless the research employs creative practice to obtain responses from participants that will be analyzed to answer a research question (see TCPS2 article 2.6).

PCUREC Appeal Process

The University has established a memorandum of agreement with Royal Roads University to serve as the appeal committee for PCUREC. When there is a request for an appeal of a decision of the PCUREC, the University will contact the Chair of the Ethics Review Committee of Royal Roads University who will conduct an appeal in accordance with the normal appeal procedures of that institution. See attached MOU.

Compliance

Pacific Coast University for Workplace Health Sciences requires that all faculty members, staff, and students adhere to this policy and the PCUREC Policies and Procedures derived from it. The University considers non-compliance and the inappropriate treatment of human participants to be a serious offence, subject to penalties, including, but not limited to, formal written notification and documentation, withdrawal of privileges to conduct research involving humans, and/or disciplinary action including dismissal from a program of study or termination of employment.

Approval and Responsibility

Approved by:Board of Governors, Dec 5, 2016Responsibility:Chief Academic Officer

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