



**INSTITUTIONAL REVIEW BOARD**  
**POLICIES AND PROCEDURES HANDBOOK**  
**Revised June 2014**

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## Policy on Research Involving Human Participants

City University of Seattle values the participation of students, faculty, and community members in research efforts that attempt to add to the body of knowledge in business, education, leadership and the social sciences. In so doing, the University adheres to the highest standards of integrity, accountability and responsibility. When student and/or faculty research efforts under the auspices of the University include human participants, City University of Seattle ensures adherence to the requirements of the U. S. Department of Health and Human Services regulations applicable to all human subject research. 45 CFR 46.101 et seq. Canadian students and faculty must also meet requirements for ethical review as outlined by the Tri-Council Policy Statement on *Ethical Conduct for Research Involving Humans* in Canada (1998, amended 2005).

City University of Seattle Institutional Review Board review is required prior to commencement of student and/or faculty research when that research meets all three of the following definitions:

**Research** means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

**Generalizable knowledge** refers to any systematically gathered data which is intended for dissemination beyond the institutional source of the data (e.g., program evaluation research for internal use does not usually need review), and which might reasonably be applicable beyond the research sample.

**Human subjects** are defined by HHS Regulations at 45 CFR 46.102(f) as “a living individual about whom an investigator conducting research; obtains (1) data through intervention or interaction with the individual; or 2) identifiable private information.” Intervention includes both the physical procedures by which data are gathered (e.g., venipuncture) and manipulations of the subject or the subject’s environment that are performed for research purposes. Interaction includes communication or interpersonal contact (e.g., questionnaires, interviews) between the investigator and the subject. Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

To ensure adherence to the above Policy, all research involving human subjects must be approved by the City University of Seattle Institutional Review Board before the research is begun.

For further details regarding US federal requirements, please refer to the following:

<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html>

The above site details requirements of valid informed consent, protections of human subject privacy in research and IRB oversight requirements. It is the policy of City University of Seattle to support and encourage student and faculty research that complies with these regulations.

Canadian students and faculty must also meet requirements for ethical review as outlined by the Tri-Council Policy Statement on *Ethical Conduct for Research Involving Humans in Canada* (1998, amended 2010).

[http://www.pre.ethics.gc.ca/pdf/eng/tcps2/TCPS\\_2\\_FINAL\\_Web.pdf](http://www.pre.ethics.gc.ca/pdf/eng/tcps2/TCPS_2_FINAL_Web.pdf)

City University of Seattle Institutional Review Board review is required prior to commencement of student and/or faculty research. In compliance with the above regulations, City University of Seattle requires as follows:

1. The research effort is in an established or commonly accepted educational setting and involves normal educational practices.
2. The research effort involves the use of educational or psychological tests, survey procedures, interview procedures, or observations of public behavior in such a way that participants cannot be identified directly or indirectly, and disclosure of participants' responses outside the research will not reasonably place them at risk of criminal or civil liability, or be damaging to the participants' financial standing, employability, or reputation.
3. Reasonably anticipated harms are not greater than the benefits of the research.
4. If proprietary educational or psychological tests are used, they are administered by a fully-qualified professional and the identities of subjects are completely protected.
5. The researcher reports data in such a manner that participants cannot be identified either directly or indirectly.

In addition, all research involving human participants at City University of Seattle must include documentation of the following:

1. Informed consent from all identifiable participants. (If any identifiable participants are minors, informed consent must be obtained from the appropriate parent or guardian.) As an exception, an alternative consent process may be used in certain Minimal Risk research studies as determined by the IRB and only with the permission of the IRB;
2. Approval from the agency, business, or school in which the research is being conducted;
3. For student research, approval by the research faculty supervisor. The Research Faculty supervisor serves as the initial review of both the appropriateness of the research protocol and methodology and the assessment of its ethical design.

If a student or faculty member has specific questions about whether a research project involving human participants meets the above criteria, he or she should consult the IRB.

## **Code of Good Practice in Research**

### **1. Introduction**

City University of Seattle focuses on practitioner excellence and development. Reflective practice is required of all faculty, research supervisors and students. To this aim, City University of Seattle seeks to encourage and foster an environment where relevant research practice, which furthers good practice and the knowledge base of the various disciplines, is embedded into the programs of study and the scholarly activities of the University community. All researchers have a duty to their profession, to their employer, and to those funding and/or participating in their research to conduct research in the most conscientious, responsible, ethical and accountable way possible.

### **2. Scope**

This Policy and Procedure applies to all employees, students and visiting researchers of City University of Seattle, conducting research within, or on behalf of, the institution, or as part of their related academic activities. Should an employee conduct research in partnership with others whose organization has in place a Human Subjects review policy and the research has been submitted to and approved under that organizations Policy, City University of Seattle's IRB will assure that said organization's policy is consistent with the protections incorporated into this Policy.

### **3. Professional Standards**

At all times, researchers under the auspices of City University of Seattle are expected to follow the highest standards of integrity, honesty and accountability to be observed in the pursuit of the research we support.

Where available, research students and employees should also observe the standards of research practice set out in guidelines published by scientific and learned societies, and other relevant professional bodies. This includes ethical codes and guidelines for the conduct of research in different disciplines.

### **4. Ethical Practice**

Course instructors, under guidance from the City University of Seattle Faculty, must approve all research involving human participants before submission to the IRB. The supervision of student research is conducted by Administrative Faculty and appointed Teaching Associate Faculty within the schools. All researchers must complete the approved City University of Seattle *Ethical Review Protocol* form prior to undertaking any research. This form must be signed by Faculty within the relevant school or division. This does not apply to projects that are being carried out by students within the City University of Seattle classroom setting, nor does it apply to surveys conducted for the sole purpose of internal City University of Seattle self-evaluation.

The principle role of this review is to ensure the interests of participants involved in research projects are ethically evaluated and protected. Additionally, it is important that the acquisition of informed consent from participants prior to the commencement of research is documented. Researchers should ensure the confidentiality of personal information relating to the participants in research, and that the research complies with any legal and good practice requirements for data compilation, storage, reporting as well as and privacy protection.

All staff and students involved in research projects, or staff involved in direct supervision of research projects, that involve groups of children and/or vulnerable adults as subjects or that take place on premises where children and/or vulnerable adults are present may require Criminal Records or background checks as required by the participating organization.

## **5. Submitting Research Proposals and Managing Research projects**

Where City University of Seattle employees are involved in research with other organizations or institutions, such activities may form part of the employee's work load upon agreement with their immediate supervisor. Any research that involves proposals for external funding of research programs, for whatever amount, including research projects, training, research leave and conference attendance, which are submitted by staff under the auspices of City University of Seattle must therefore be approved by the employee's supervisor, Dean or Principal, and the Provost.

## **6. Documenting Results and Storing Primary Data**

When completing the *Ethical Review Protocol* form the storage of data, samples used or created during the course, and the results of the research should be made clear.

Researchers are required to keep accurate and secure records throughout their work providing details of research procedures and results obtained. Primary data should be kept in paper or electronic form for a minimum of five years following the completion of the research project.

## **7. Publication Practice**

Students and employees may have their research published in a suitable form, usually as papers in refereed journals. Supervisors of student research will normally take on the role of editor (and second author) of such original work following the completion of the student's program of study with the University. City University of Seattle encourages these efforts.

City University expects anyone listed as an author on a paper to accept personal responsibility for ensuring that they are familiar with the contents of the paper and that they can identify their contributions to it. The practice of honorary authorship is unacceptable.

The contributions of formal collaborators and all others that directly assist or indirectly support the research must be properly acknowledged.

## **8. Conflict of Interest**

Anyone involved in any way in the conduct, management or administration of research must identify and make known any conflicts of interest, whether legal, ethical, financial, personal or of another nature.

## **9. Research Misconduct**

City University of Seattle takes seriously any allegation of research misconduct. A Research Misconduct Policy has been established and any allegation of misconduct will be promptly, fairly and thoroughly investigated.

## Policy on Informed Consent

- A. Research governed by the City University of Seattle Institutional Review Board may begin only if (1) prospective participants, or authorized third parties, have been given the opportunity to give free and informed (in a language understood by the participant) consent about participation, and (2) their free and informed consent has been given and is maintained throughout their participation in the research.
- B. Evidence of free and informed consent by the participant or authorized third party should ordinarily be obtained in writing. Where there are good reasons for not recording consent in writing, as determined by the IRB, the procedures used to seek free and informed consent will be documented.

When the research proposed involves online survey data collection where personally signed informed consent is not possible, the researcher may use an approved online survey program that provides for informed consent in the contents of the survey. City University of Seattle researchers must include the approved City University of Seattle consent form template at the start of the survey (not a consent template that may be available through the online program). All requirements for confidentiality, data collection, storage and destruction shall be followed as they are for paper or interview data collection.

When collecting data via online survey, the researcher must enable encryption features and ensure data collection mechanisms at the server site to protect participant confidentiality. Because there is no routine verbal communication between researcher and online participants, and to ensure voluntariness of the subject's participation, the online survey must include at the beginning, the end and after each question, an "opt out" or "withdraw" option as a response.

- C. The Institutional Review Board may approve a consent procedure that does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirement to obtain informed consent, provided that the IRB finds and documents that:
- The research involves no more than minimal risk to the participants;
  - The waiver or alteration is unlikely to adversely affect the rights and welfare of the participants;
  - The research could not practicably be carried out without the waiver or alteration;
  - Whenever possible and appropriate, the participants will be provided with additional pertinent information after participation; and
  - The waived or altered consent does not involve a therapeutic intervention.
- D. The requirement for free and informed consent should not disqualify research participants who are not proficient in the language used by the researchers from the opportunity to participate in potential research. Such individuals may give consent providing that one or more of the following are observed to the extent deemed necessary by the IRB, in the context of a proportionate approach to the harms envisaged in the research and the consent processes that are to be used:

- An intermediary not involved in the research study, who is competent in the language used by the researchers as well as that chosen by the research participant, is involved in the consent process.
- The intermediary has translated the consent document or approved an existing translation of the information relevant to the prospective participant.
- The intermediary has assisted the research participant in the discussion of the research study.
- The research participant has acknowledged in his or her own language, that he or she understands the research study, the nature and extent of his or her participation, including the risks involved, and freely gives consent (see exception in Article 5.3).

F. Informed Consent

Free and informed consent must be voluntarily given, without manipulation, undue influence or coercion.

G. In understandable language, researchers will provide to prospective participants or authorized third parties full and frank disclosure of all information relevant to free and informed consent. Throughout the free and informed consent process, the researcher must ensure that prospective participants are given adequate opportunities to discuss and contemplate their participation. At the commencement of the participation in a research project, researchers will provide prospective participants with the following:

- Information that the individual is being invited to participate in a research project;
- A comprehensible statement of the research purpose, the identity of the researcher, the expected duration and nature of participation, and a description of research procedures;
- A comprehensible description of reasonably foreseeable harms and benefits that may arise from research participation
- An assurance that prospective participants are free not to participate, have the right to withdraw at any time without prejudice to pre-existing entitlements, and will be given continuing and meaningful opportunities for deciding whether or not to continue to participate; and
- The presence of any apparent or actual or potential conflict of interest on the part of researchers or the institutions.

### **Research Misconduct Policy**

All members of the research community have a duty to conduct their research in the most conscientious, responsible, ethical and publicly accountable manner possible. It is the responsibility of the Faculty to convey clearly the standards for research and to ensure that observance of those standards is maintained.

1. This policy applies to all employees, students, and visiting researchers of the City University conducting research within, or on behalf of the University.
2. The University takes seriously any allegation of research misconduct. Any employee or student who suspects research malpractice should report it in confidence to their Program Coordinator and follow the guidelines for reporting such matters. Any student or member of staff raising genuine concerns can do so confidentially and without fear of suffering any disadvantage.

3. A checklist of some, but not all, examples of research misconduct follows this policy. Although a comprehensive definition of research misconduct is difficult, it is broadly defined under the following categories:
  - a. *Misrepresentation*
    - i. Conscious misrepresentation in the proposing, carrying out or reporting of the results of the research.
    - ii. Failure to reveal potential conflicts of interest involved in the research to the IRB and research sponsors, if any.
  - b. *Fabrication, falsification or plagiarism*
    - i. Misuse (unauthorized use or disposal) of research data, materials or funding.
    - ii. Conscious plagiarism, misquoting, misuse of information or falsification of data.
  - c. *Non-ethical practices*
    - i. Lack of adherence to federal, state, provincial or other regional regulations with regards to ethical research practices with human subjects.

Unless falsely reported, research lacking in academic rigor (i.e. 'poor quality' research) or honest mistakes and differences in the design, execution or evaluation of research are not considered potential cases of research misconduct.

5. Any practice or conduct by a member of the research community deemed to be in breach of ethical standards for proposing, conducting and publishing research constitutes research misconduct, a violation of University Policy, and renders the member liable to the University's disciplinary procedures.
6. In cases where an allegation implicates someone who is not subject to the University's disciplinary procedures City University of Seattle shall bring the matter to the attention of their employer or any other appropriate body.
7. Where the person responsible has published research to which the misconduct relates, City University of Seattle shall consider whether it is appropriate to inform journal editors or others of the finding.
8. Where the research is funded partially or entirely by an external grant, regard shall be given to the relevant guidance issued by the relevant funding body. The funding body will be provided appropriate information as to the initiation, progress and conclusion of an investigation.
9. If an allegation is found to have been malicious or mischievous in nature, the matter may result in disciplinary action being taken against the individual or group making the charge.
10. All allegations of research misconduct will be investigated fully, fairly and promptly.



### **Examples of research misconduct**

- ❑ refusal or failure to obtain permission to conduct research
- ❑ deception in relation to research proposals
- ❑ unethical behavior in the conduct of research
- ❑ unauthorized use of information which was acquired confidentially
- ❑ deviation from good research practice or health and safety standards, where this results in unreasonable risk of harm to humans, other animals or the environment
- ❑ fabrication, falsification or corruption of research data
- ❑ distortion of research outcomes, by distortion or omission of data that do not fit expected results
- ❑ dishonest misinterpretation of results
- ❑ publication of data known or believed to be false or misleading
- ❑ plagiarism, or dishonest use of unacknowledged sources
- ❑ misquotation or misrepresentation of other authors
- ❑ misappropriation of the intellectual property belonging to others
- ❑ inappropriate attribution of authorship
- ❑ fraud or other abuse of research funds or research equipment
- ❑ attempting, planning or conspiring to be involved in research misconduct
- ❑ inciting others to be involved in research misconduct
- ❑ collusion in or concealment of research misconduct by others

## Procedures for Review of Research Involving Human Participants

City University of Seattle's Policy on Research Involving Human Participants sets forth the permissible parameters of research that is allowed to be conducted by students, faculty, and staff. An Institutional Review Board ("IRB") has been appointed to review prospectively any proposed research involving human participants by a City University faculty member, staff member, or student to ensure compliance with this Policy.

In order to ensure compliance with the Policy, the following procedural steps must be followed by City University of Seattle faculty, staff, and students if they are proposing to engage in research that involves human participants:

1. The City University of Seattle *Ethical Review Protocol*, detailing the research to be conducted, the design to be followed, and the involvement of human participants must be filed with the IRB. For students proposing to do research involving human participants as part of their thesis, the Protocol must first be reviewed by the senior faculty member overseeing the program and approved by that faculty member who forwards the completed, dated and signed protocol to the IRB. The Research Faculty supervisor serves as the initial review of both the appropriateness of the research protocol and methodology and the assessment of its ethical design.
2. If the IRB determines that the research proposed in the Protocol is in compliance with the Policy on Research Involving Human Participants and all questions have been answered fully, the IRB will authorize the research to proceed. The IRB may require modifications to the Protocol as a condition of its approval.

Thus, the IRB will act upon protocols put before it by designating as follows:

- 1) Accepted with no revisions. The researcher is empowered to conduct the research as presented in the Protocol.
  - 2) Accepted with minor revisions, as specified. The student researcher and faculty research supervisor (or faculty researcher) complete the revisions prior to commencing research.
  - 3) Re-submit with major revisions, as specified. The student researcher and faculty research supervisor (or faculty researcher) complete the revisions and re-submit the *Ethical Review Protocol* to the IRB for review.
3. The IRB shall have the authority to deny the approval of any proposed research involving human participants if it believes that the research does not fit within the approved conditions of the Policy on Research Involving Human Participants. Denials may be reviewed by the Provost.
  6. The following types of research do not normally need to be submitted for review by the Institutional Review Board:
    - 1) City University of Seattle quality assurance studies and internal performance reviews, program evaluations, or City University of Seattle testing within normal educational requirements.

- 2) City University of Seattle class activities which involve human participants and which are conducted by students on other members of the class as exercises in learning provided that information is not disseminated outside the classroom.
- 3) Where a question arises as to the need for IRB review, it is the responsibility of the research faculty supervisor or faculty researcher to assure that a ruling is provided by the IRB.

A record of all reviews and their outcomes shall be maintained by the Institutional Review Board.

**END.**