

CCS Administrative Procedure

7.40.01-A Research Involving the Use of Human Subjects

Implementing Board Policy [7.40.01](#)

Contact: District Academic Services Officer, 434-5060

1.0 Purpose

This procedure establishes guidelines for review of all proposed research projects involving human subjects conducted by or with CCS faculty, staff or students when facilities, services, or personnel of CCS are used. This procedure does not supersede the educational unit's right to decline project participation communicated by the unit's president or CEO to the Institutional Review Board (IRB) chair.

The purpose of this procedure is to determine for all activities, as planned and conducted, whether the rights and welfare of all human subjects will be adequately protected as required by law and to assist researchers in conducting ethical research that complies with the law in a way that permits accomplishment of the research activity. All researchers and IRB members should consult Title 45, Part 46 of the Code of Federal Regulations (45 CFR 46) to ensure compliance with federal law.

2.0 Federal Law Requirements

All research involving the use of human subjects at CCS is guided by ethical principles developed by the scientific community. The manner in which these ethical principles are applied is prescribed in 45 CFR 46. To meet its legal and ethical responsibilities, a CCS Institutional Review Board (IRB) must review all proposed research projects involving human subjects unless legally exempt from doing so.

3.0 Institutional Review Board

- 3.1 The CCS chancellor will appoint the chairperson and members of the IRB.
 - 3.1.1 IRB members shall serve a three year term beginning on the 1st day of July through the 30th day of June.
 - 3.1.2 The IRB must have at least five members and shall be chosen without discriminatory intent.
 - 3.1.3 The IRB shall include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas. At least one member of the IRB shall have no affiliation with CCS.
 - 3.1.4 No member of the IRB may participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest.
- 3.2 The IRB shall determine if the research involving the participation of human subjects, as planned and conducted, will protect the rights and welfare of the people participating in the research. The IRB meets at the call of the chairperson to consider questions of policy and the individual research proposals which require full committee review.
- 3.3 The IRB shall review and have authority to approve, require modifications, or disapprove human subject research activities covered by this procedure. All IRB approved research is subject to continuing IRB review and must be reevaluated at least annually. The IRB shall have the authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements.

4.0 IRB Voting Requirements

- 4.1 **Quorum required:** A quorum of more than half of the voting membership is required to conduct business.
- 4.2 **Diversity requirements of quorum:** At least one member whose primary concerns are in non-scientific areas must be present.
- 4.3 **Full voting rights of all reviewing members:** Each member has one vote.
- 4.4 **No proxy votes:** No proxy votes are allowed. Members may attend the IRB meeting by video conference or by telephone. It is the responsibility of the member to contact the IRB chairperson to ensure the necessary equipment is available.
- 4.5 **Prohibition of conflict-of-interest voting:** IRB members who are an investigator on or have any other potential conflict of interest with any person or entity connected to an application must be recused from the vote and will not be counted as part of the voting quorum.

5.0 Research Exempted from Review

Any CCS faculty, staff, or student may apply to their departmental supervisor for a determination that their research proposal is exempt from IRB review. The Department supervisor may grant the exemption if the supervisor finds that the proposal does not qualify as “research” as defined in section 9.1, below, of this procedure, or finds that the research does not expose the research subjects to physical, social or psychological risks and falls under one of the following categories:

- 5.1 Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
- 5.2 Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.
- 5.3 Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph 5.2 of this section, if: (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
- 5.4 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.
- 5.5 Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

- 5.6 Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed, or (ii) if a food is consumed that contains a food ingredient at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

6.0 Expedited IRB Review

- 6.1 Under 45 CFR 46.110 an expedited review procedure may be carried out by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB. In reviewing the research, the reviewers may exercise all of the authorities of the IRB except that the reviewers may not disapprove the research. If a reviewer using the expedited process determines that research should be disapproved, federal regulations require that disapproval be formally determined by the entire IRB committee.
- 6.2 The Secretary of the United States Department of Health and Human Services has established and published as a Notice in the Federal Register an extensive list of research categories that may be reviewed by the IRB through an expedited review procedure. An IRB may use the expedited review procedure to review either or both of the following:
- 6.2.1 Some or all of the research appearing on the list found by the reviewer(s) to involve no more than minimal risk.
- 6.2.2 It involves minor changes in previously approved research during the period (of one year or less) for which approval is authorized.

7.0 IRB Review Criteria

The IRB will consider the following factors in determining project approval:

- 7.1 **Risk of Injury:** The risk to subjects must be minimized, by using procedures which are consistent with sound research design and which do not unnecessarily expose subject to risk, and, whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result.
- 7.2 **Equitable Selection of Subjects:** The IRB will take into account the purposes of the research and the setting in which the research will be conducted and will be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons. When some or all of the subjects are likely to be vulnerable to coercion or undue influence, additional safeguards will be required to be included in the study to protect the rights and welfare of these subjects.
- 7.3 **Voluntary and Informed Consent:** All subjects, adults or children, must be fully informed in advance of the degree of risk involved in their participation and, insofar as possible, given an explanation of the nature and consequences of the proposed research. Methods of securing cooperation of subjects should be specified in advance as clearly as possible. No coercion may be used to obtain or maintain cooperation. Adult subjects or their legal representatives must express consent to participate in writing. If a subject is under the age of 18, informed consent must be obtained in writing from the subject's parent or legal guardian. Subjects over seven years of age must give their consent as well. All subjects, adults and children alike, must be assured that they may choose to withdraw from the research program at any time without penalty.

- 7.4 **Confidentiality and Privacy:** All information provided by a human subject, including responses to questionnaires, tests, and interviews, must be kept confidential to those performing the research and, when feasible, anonymous. Published accounts of such data must not reveal the identity of the subject. Disclosure of records will be consistent with the Washington State Public Records Act (Chapter 42.56 RCW).
- 7.5 **Certificate of Confidentiality:** A Certificate of Confidentiality helps researchers protect the privacy of human research participants enrolled in biomedical, behavioral, clinical and other forms of sensitive research. These certificates are issued by the National Institute of Health (NIH). Certificates protect against compulsory legal demands, such as court orders and subpoenas, for identifying information or identifying characteristics of a research participant. Any research that collects personally identifiable, sensitive information and that has been approved by an IRB is eligible for a Certificate. Federal funding is not a prerequisite for Certificate. For more information see the [Certificates of Confidentiality Kiosk](#) on the NIH Office of Extramural Research web site.
- 7.6 **Adequate Provision to Ensure the Safety of the Subjects:** The IRB will stress risks to subjects in their review of research projects to ensure that the provision for physical and psychological safety is adequate and the risk involved in each study is as minimal as possible. The research plan must make adequate provision for monitoring the data collected and the data collection process to ensure the safety of the subjects.
- 7.7 **Codes and Standards:** In its review process, the IRB will consider the degree to which proposed research conforms to the prevailing social codes and moral standards of the community or cultural group involved.

8.0 IRB Approval

In order for the research to be approved, it shall receive the approval of a majority of those IRB members present at the meeting. The IRB shall notify investigators in writing of its decision to approve or disapprove the proposed research activity, or of modifications required to secure IRB approval of the research activity. If the IRB decides to disapprove a research activity, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing.

9.0 Definitions

- 9.1 **Research** means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Research includes all theses, dissertations, publications, and/or presentations. The term "research" designates an activity designed to test a hypothesis, permit conclusions to be drawn, and thereby to develop or contribute to generalizable knowledge (expressed, for example, in theories, principles, and statements of relationships). Research generally does not include operational activities such as practice activities in medicine, psychology, social work, and public health (e.g., routine outbreak investigations and disease monitoring) and studies for internal management purposes such as program evaluation, quality assurance, quality improvement, fiscal or program audits, marketing studies, or contracted-for services. It generally does not include journalism or political polls. However, some of these activities may include or constitute research in circumstances where there is a clear intent to contribute to generalizable knowledge.
- 9.1.1 If there is a plan to present or publish the work or otherwise share results of the study, it is probably research.
- 9.1.2 If there is a plan to present the data of the project on human subjects at an academic conference, publish the data in an academic journal, or use the human subjects research data in a master's thesis or doctoral dissertation, the project likely requires IRB approval.

- 9.2 **A Human Subject** is any living individual about whom an investigator conducting research obtains (i) data through intervention or interaction with the individual, or (ii) identifiable private information. This includes the use of written private information such as that contained in records. Examples of subjects/participants include:
- 9.2.1 Individuals who are asked to complete questionnaires, participate in interviews, or whose behavior is observed in daily activities.
 - 9.2.2 Oral history interviewees whose subjective perceptions are studied.
 - 9.2.3 Students and teachers observed in the classroom for the study of various teaching methods or development of curricula.
- 9.3 **Minimal Risk** means that the probability and the magnitude of harm or discomfort anticipated in the proposed research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.
- 9.4 **Generalized Knowledge** is knowledge that could be applied to populations outside of the population served by the covered entity. This definition can vary. Examples of activities that typically are not generalizable include:
- 9.4.1 biographies,
 - 9.4.2 oral histories that are designed solely to create a record of specific historical events,
 - 9.4.3 service or course evaluations, unless they can be generalized to other individuals,
 - 9.4.4 services, or concepts where it is not the intention to share the results beyond CCS or any agency supporting the research,
 - 9.4.5 classroom exercises solely to fulfill course requirements or to train students in the use of particular methods or devices,
 - 9.4.6 quality assurance activities designed to continuously improve the quality or performance of a department or program where it is not the intention to share the results beyond the CCS community.
- 9.5 **Directly or Indirectly Identifiable:** Identities of individual subjects are kept by the investigator. If subjects' identities are inseparable from data, then data is directly identifiable. If subjects' identities are kept separate from data, with information connecting them maintained by codes and a master list, then data is indirectly identifiable. In either case, the investigator must assure that confidentiality will be maintained, and must explain how subjects' identities will be protected.
- 9.5.1 *Direct identifiers:* Direct identifiers in research data or records include names; postal address information (other than town or city, state and zip code); telephone numbers, fax numbers, e-mail addresses; social security numbers; medical record numbers; health plan beneficiary numbers; account numbers; certificate /license numbers; vehicle identifiers and serial numbers, including license plate numbers; device identifiers and serial numbers; web universal resource locators (URLs); internet protocol (IP) address numbers; biometric identifiers, including finger and voice prints; and full face photographic images and any comparable images.
 - 9.5.2 *Identifiable data or records:* Contains information that reveals or can likely associate with the identity of the person or persons to whom the data or records pertain. Research data or records with direct identifiers removed, but which retain indirect identifiers, are still considered identifiable.

- 9.5.3 *In-direct identifiers*: Indirect identifiers in research data or records include all geographic identifiers smaller than a state, including street address, city, county, precinct, ZIP code, and their equivalent postal codes, except for the initial three digits of a ZIP code; all elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such age and elements may be aggregated into a single category of age 90 or older.

11.0 Projects from Other Institutions or Individuals outside of CCS

An application submitted for a project from another institution in which the other institution or individual outside of CCS has primary responsibility for the project may be approved by the IRB chairperson if the chairperson, in consultation with the appropriate CCS supervisory authorities, determines that the institution or individual adheres to federal guidelines and uses similar criteria to those of CCS in their project review.

11.0 Procedure for Application

All non-exempt projects involving the use of human research subjects must be submitted to the chairperson of the IRB for review using the CCS Human Subjects Activity Review form. Before research is approved the investigator must successfully complete human subjects protection training. The National Institutes of Health (NIH) on-line training course may be accessed at the NIH Office of Extramural Research web site.

12.0 IRB Records

The IRB shall prepare and maintain adequate documentation of IRB activities, including the following:

- 12.1 Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent documents, progress reports submitted by investigators, and reports of injuries to subjects.
- 12.2 Minutes of IRB meetings which shall be in sufficient detail to show attendance at the meetings; actions taken by the IRB; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution.
- 12.3 Records of continuing review activities.
- 12.4 Copies of all correspondence between the IRB and the investigators.
- 12.5 IRB records shall be retained for at least three years, and records relating to research which is conducted shall be retained for at least three years after completion of the research.

13.0 Reporting Problems

Any staff or student at Community Colleges of Spokane who is aware of any problems involving risks to subjects or others; serious or continuing noncompliance with the federal regulations or the requirements or determinations of the IRB must report the information to the IRB chair. The report can be made by contacting the chair directly. The chair will then alert the appropriate institutional officials, the head of the agency supporting the research, any applicable regulatory body, and the Office for Human Research Protections.

14.0 Related Information

- 14.1 CCS Institutional Review Board [web page](#)
- 14.2 IRB Application for Review, [CCS 2162](#)
- 14.3 IRB Application for Review Exemption, [CCS 2163](#)
- 14.4 Guidelines for Submitting Requests for Exemption from IRB Review, [CCS 2164](#)
- 14.5 [Protection of Human Subjects](#) – 45 CFR 46
- 14.6 [IRB Regulations and Policy Guidance](#) – U.S. Department of Health and Human Services, Office for Human Research Protections
- 14.7 [IRB Expedited Review Categories](#) – Office of Human Research Protections
- 14.8 [Human Subjects Projection Training](#) – NIH, Office of Extramural Research
- 14.9 [Certificates of Confidentiality Kiosk](#) – NIH, Office of Extramural Research
- 14.10 [Chapter 42.56 RCW](#) – Public Records Act
- 14.11 [Title 20 U.S. Code, Sec. 1232g](#) – Family Educational Rights and Privacy Act (FERPA)
- 14.12 [WAC 132Q-02-350](#) – Confidentiality of Student Records

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