CCS Administrative Procedure
7.40.01-A Research Involving the Use of Human Subjects

Implementing Board Policy 7.40.01
Contact: Chair, Institutional Review Board, 434-5120

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. CCS is committed to the ethical and responsible conduct of research, maintaining confidentiality and safeguarding data.

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. Researchers shall also follow all CCS policies and procedures

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 Definitions

3.1 **Assent:** Basically the same as consent yet involves minor children (under age 18) who are not authorized to give legally valid informed consent because of their age. Running Start students and some first year students might be considered minor children if they are under the age of 18.

3.2 **Benign Behavioral Intervention:** Interventions that are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing.

3.3 **Broad consent:** When a subject consents to an unspecified range of future research use of bio specimens or identifiable private information.

3.4 **Clinical Trial:** Research study in which one or more human subjects are prospectively assigned to one or more interventions to evaluate the effects of the intervention on biomedical or behavioral health related outcomes.

3.5 **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

3.5.1 **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.

3.5.2 **Identifiable private information**: Private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information

3.5.3 **In-direct 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.

3.6 **Generalized Knowledge:** 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:

3.6.1 biographies,

3.6.2 oral histories that are designed solely to create a record of specific historical events,

3.6.3 service or course evaluations, unless they can be generalized to other individuals,

3.6.4 services, or concepts where it is not the intention to share the results beyond CCS or any agency supporting the research,

3.6.5 classroom exercises solely to fulfill course requirements or to train students in the use of particular methods or devices,

3.6.6 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.

3.7 **A Human Subject:** Any living individual about whom an investigator (whether professional or student) conducting research (i) obtains information or bio specimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or bio specimens, or (ii) obtains, uses, studies, analyzes or generates identifiable private information or identifiable bio specimens. This includes the use of written private information such as that contained in records. Examples of subjects/participants include:

3.7.1 Individuals who are asked to complete questionnaires, participate in interviews, or whose behavior is observed in daily activities.

3.7.2 Students and teachers observed in the classroom for the study of various teaching methods or development of curricula.

3.8 **Limited Review**: A review by the IRB chair or by one or more experienced reviewers designated by the chair in order to ensure there are adequate privacy safeguards for identifiable private information and identifiable bio specimens in the proposed research.

3.9 **Minimal Risk: T**he 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. Examples of minimal risk studies included collection of data from voice, video, digital or image records made for research purposes and research on individual or group characteristics or behavior (e.g., focus groups, surveys, interviews). Research in which the identification of the subjects and/or their responses would reasonable place them at risk of criminal or civil liability or be damaging to their reputation or be stigmatizing is not considered minimal risk.

3.10 **Principle Investigator (PI):** The primary individual responsible for the preparation, conduct, and administration of a research grant, cooperative agreement, training or public service project, contract, or other sponsored project in compliance with applicable laws and regulations and institutional policy governing the conduct of sponsored research. Co-PIs also share the same responsibilities.

3.11 **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 that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public.

3.12 **Research:** 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 and may include class assignments and written work. 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).

3.12.1 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 does not include scholarly and journalistic activities that focus directly on the specific individuals about whom the information is collected (e.g., oral history, journalism, biography, literary criticism, legal research and historical scholarship), public health surveillance activities limited to those necessary to identify, monitor, assess, or investigate conditions of public health importance; collection and analysis of materials for criminal justice purposes and authorized operational activities for national security purposes. However, some of these activities may include or constitute research in circumstances where there is a clear intent to contribute to generalizable knowledge.

3.12.2 If there is a plan to present or publish the work or otherwise share results of the study, it is probably research.

3.12.3 If there is a plan is 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.

3.13 **Secondary Research**: Re-using for research purposes identifiable and non-identifiable information and bio specimens that are collected for some other primary or initial activity.

4.0 Institutional Review Board

4.1 The CCS chancellor will appoint the chair and members of the IRB.

4.1.1 IRB members shall serve a three year term beginning on the 1st day of July and ending on the 30th day of June three years later.

4.1.2 The IRB must have at least five members and shall be chosen without discriminatory intent. At least one faculty member from each college will serve on the IRB.

4.1.3 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.

4.1.4 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. Please also see section 5.5.

4.1.5 All IRB members must complete the NIH IRB or other appropriate training as deemed by the IRB within the past three years.

4.2 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 chair to consider questions of policy and the individual research proposals which require full committee review. The IRB will have scheduled meetings once per academic quarter.

4.3 The IRB shall review and have authority to approve, require modifications, or disapprove human subject research activities covered by this procedure. Full IRB approved research is subject to continuing IRB review and must be reevaluated at least annually except as noted in 4.4 below. 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 and CCS administrative procedures.

4.4 Continuing review of research is not required for (i) research eligible for expedited review; (ii) research reviewed with limited IRB review; or (iii) research that has progressed to the point that it is data analysis and/or accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care. The IRB will document the rationale for conducting continuing review of research that would otherwise not require continuing review.

5.0 IRB Voting Requirements

5.1 **Quorum required:** A quorum of more than half of the voting membership is required to conduct business.

5.2 **Diversity requirements of quorum:** At least one member whose primary concerns are in non-scientific areas must be present.

5.3 **Full voting rights of all reviewing members:** Each member has one vote.

5.4 **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 chair to ensure the necessary equipment is available.

5.5 **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. Please refer to CCS's Federal Conflict of Interest Guidelines and CCS Administrative Procedure 2.10.06-A General Ethics for Employees and Officers.

6.0 Research Never Considered Exempted from Review

6.1 If pregnancy is a prerequisite for serving as a subject

6.2 If fetuses in utero are subjects in the research

6.3 If any subjects are presumed not to be legally competent

6.4 If personal records (e.g., medical, academic) are used without written consent

6.5 If data are damaging to subjects' financial standing, employability or reputation

6.6 If material obtained at autopsy is to be used in the research

6.7 If subjects are to be asked sensitive questions about personal feelings, behavior, interactions or sexual experiences

6.8 If alcohol or other drugs will be ingested

6.9 If blood or body fluids will be drawn

6.10 If the subjects are children as defined by state law (in most instances)

7.0 Research Exempted from Review

7.1 Any CCS faculty, staff, or student may apply to the IRB chair for a determination that their research proposal is exempt from IRB review. The IRB chair may grant the exemption if the chair finds that the proposal does not qualify as "research" as defined in section 3.12 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:

7.1.1 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 so long as the research is not likely to adversely affect students′ opportunity to learn required educational content or the assessment of the instructors.

7.1.2 Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior (including visual or auditory recording) uninfluenced by the investigator, as long as the (i) recorded information is completely de-identified; or (ii) any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to their financial standing, employability, or reputation; or (iii) the information is recorded so that the subjects can be ascertained directly or through identifiers and the research procedures have been reviewed by the IRB for adequate privacy and confidentiality protection. This exemption applies to research with children if the research is limited to the use of educational tests or the observation of public behavior when the investigators do not participate in the activities being observed. Surveying and interviewing children may not be exempt. Obtaining and recording identifiable private information may not be applied to research involving children (i.e., video recordings and photographs).

7.1.3 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.

7.1.4 Research and demonstration projects which are conducted by or subject to the approval of federal 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.

7.1.5 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.

7.1.6 Research involving benign behavioral interventions with adults (not children) when (i) any information obtained is recorded so the identity of the subject cannot readily be ascertained directly or through identifiers linked to the subject, or (ii) any disclosures of information would not reasonably place the subjects at risk of criminal or civil liability or be damaging to their financial standing, employability, educational advancement or reputation, or (iii) the information is recorded so the subject can be ascertained, directly or through identifiers linked to the subject and the IRB conducts a limited review for privacy and confidentiality protection.

7.1.7 Secondary research and the storage and maintenance of identifiable private information or identifiable biospecimens when the subject or donor has (i) given broad consent; (ii) the broad consent was properly obtained, documented or waived; and (iii) the IRB determines the secondary research is within the scope of the broad consent. The IRB will review the appropriateness of the process proposed for obtaining broad consent, ensure the required elements of broad consent were appropriately included in the broad consent form and determine the consent is appropriately documented.

7.1.8 Secondary research use and identifiable private information or identifiable biospecimens for which consent is not required if (i) the identifiable private information or identifiable biospecimens are publically available, or (ii) information is recorded by the investigator in such a manner that the identity of human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects; or (iii) the research involves only information collection and analysis involving the investigator's use of identifiable health information for the purposes of “health care operations” or “research”; or (iv) the research is conducted by, or on behalf of, a federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the information originally involved a collection that adheres to the federal standards for safeguarding privacy**.**

7.2 If the IRB chair does not believe the research proposal is exempt from IRB review, the chair will have another IRB member review it for validation of that assessment.

7.3 If a modification occurs during the research process which might change the exemption status, a new IRB form must be submitted.

8.0 Expedited IRB Review

8.1 Under 45 CFR 46.110 an expedited electronic review procedure may be carried out by the IRB chair and one or more experienced reviewers designated by the chair 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.

8.2 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 the following:

8.2.1 Some or all of the research appearing on the list found by the reviewer(s) to involve no more than minimal risk. If the study involves more than minimal risk, the IRB must document the rationale for following the expedited review procedure.

8.2.2 It involves minor changes in previously approved research during the period (of one year or less) for which approval is authorized.

8.2.3 Research for which limited IRB review is a condition of exemption.

8.3 All protocol changes must be approved by the IRB prior to implementation.

8.4 Continued review is not needed for expedited review research unless the IRB determines it would enhance the protection of research subjects. The IRB will document the rationale for continued review in these circumstances.

8.5 Researchers are allowed to analyze study data after the research project has concluded without further review from the IRB.

9.0 IRB Review Criteria

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

9.1 **Risk of Injury:** The risk to subjects and researchers 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 and researchers are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result.

9.2 **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, individuals with impaired decision-making ability, 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.

9.3 **Voluntary and Informed Consent:** All subjects, adults or children, must be fully informed in advance of the degree of risk involved in their participation.

9.3.1 Key information must be provided in a concise way at the beginning of consent forms that will assist a prospective subject or legally authorized representative in understanding the reasons why they might or might not want to participate in the research. This information includes the purpose of the research, the risks and benefits, and appropriate alternative treatments that might be beneficial to the prospective subject.

9.3.2 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.

9.3.3 Adult subjects or their legally authorized representatives must express consent to participate in writing. The IRB may waive the requirement for signed informed consent if the subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained.

9.3.4 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 assent as well. Please note that Running Start and many first year students are under the age of 18.

9.3.5 All subjects, adults and children alike, must be assured that they may choose to withdraw from the research program at any time without penalty.

9.4 **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).

9.5 **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.

9.6 **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.

9.7 **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.

10.0 IRB Approval

10.1 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. The IRB may also give conditional approval, subject to the principle investigator changing the proposal to incorporate certain stipulations made by the IRB.

10.2 All protocol changes must be approved by the IRB prior to implementation.

11.0 Students Performing Research

11.1 Student projects that meet the federal definition of human subjects research require IRB review and approval.

11.1.1 Student research projects should present no more than minimal risk to human participants.

11.1.2 Subjects in most research projects about human beings must give voluntary, informed consent, even if the project does not require human subjects review.

11.2 Students involved in federally sponsored research activities must take the training specified in section 14.0.

11.3 Student projects that do not meet the federal definition of human subjects research, and involve no more than minimal risk to human participants, do not require IRB review and approval.

11.3.1 Projects embedded within academic programs and independent learning contracts are frequently designed to help students develop their understanding of the principles of sound research and practice research methods, but they are not intended to produce generalizable results. These projects may involve human participants, and they may employ systematic protocols for gathering information (i.e., surveys, interviews, behavioral observations in controlled environments, etc.)

11.3.2 If the results of the activity, however, will be used only for classroom instruction or for the student's own personal academic development (i.e., it will not be published or presented beyond the specific class or academic program), it does not require human subjects review.

11.3.3 No classroom-based project should present more than minimal risk to subjects.

11.4 Students collecting information through interaction with subjects must carefully consider the possible impact that those interactions might have on subjects, and the risk of harm that could result. Students are not permitted to conduct projects, in particular, where an interview, survey, focus group or other research interaction has the potential to evoke or reintroduce emotional harm to participants. Examples of projects to be avoided by students include but are not limited to:

- Any exploration of topics that could reasonably remind subjects of harm they suffered as a result of sexual assault, violent crime, war violence, domestic violence, state violence, terrorism, natural disaster, or other traumatic experiences.
- Tests or examinations that could bring to light personal information that could be troubling to subjects, such as IQ or some kinds of behavioral tests.
- Projects that ask for participant responses to potentially disturbing images, events, or reenactments of events, such as pornography, violence, or verbal abuse.

- Projects that involve deception of participants.

11.5 Students will not record or post audio or video of research activities online or through the use of any of type of electronic technology. Alleged violations will be handled according to the process outlined in the Standards of Conduct for Students Chapter 132Q-10 WAC.

11.6 If directly identifiable or indirectly identifiable data will be collected, please refer to section 6.0.

11.7 All student research projects should consider the criteria outlined in section 9.0 and pay particular attention to those in sections 9.3 and 9.4.

12.0 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 chair if the chair, 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. Applicants must include IRB exemptions or approvals from the other institution with their IRB exemption or application form. In the case of multi-institutional research studies, where each institution is located in the United States, a single IRB review may be appropriate.

13.0 Procedure for Application

All non-exempt projects involving the use of human research subjects must be submitted to the chair 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. The IRB may recommend other training options in lieu of the NIH training.

14.0 IRB Records

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

14.1 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.

14.2 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.

14.3 Records of continuing review activities.

14.4 Copies of all correspondence between the IRB and the investigators.

14.5 Rationale for justifications on why an expedited or limited reviewer determined the research activity was more than minimal risk.

14.6 Rationale for justifications on why the IRB determined a research activity that would not otherwise require continuing review is subject to continuing review.

14.7 IRB records shall be retained according to the CTC records retention schedule. There may also be records retention requirements (e.g., electronic records retention) for projects sponsored by the Federal government.

15.0 Training

All CCS employees who conduct human subjects research must complete required training as determined by the IRB. Employees who apply for Federal grants, which involve the use of human subjects, are required to show proof that they have completed the NIH Protections for Human Subjects or other equitable training as determined by the IRB within the last three years and prior to spending any grant funds. The IRB recommends employees complete the training prior to applying for Federal grants.

16.0 Reporting Problems

16.1 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 directly to the IRB chair or to the appropriate President or Chancellor. 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.

16.2 Any staff or student may report concerns regarding the IRB chair to the appropriate President or Chancellor.

16.3 Any current CCS employee may also report a suspected improper governmental action through CCS Administrative Procedure 2.10.06-B Complaint of Improper Governmental Action and Non-Retaliation.

16.4 No individual may be discriminated against or be subject to any reprisal for reporting violations of any regulations or standards.

17.0 Related Information

17.1 CCS Institutional Review Board web page

17.2 IRB Application for Review, CCS 2162

17.3 IRB Application for Review Exemption, CCS 2163

17.4 Guidelines for Submitting Requests for Exemption from IRB Review, CCS 2164

17.5 Protection of Human Subjects – 45 CFR 46

17.6 IRB Regulations and Policy Guidance – U.S. Department of Health and Human Services, Office for Human Research Protections

17.7 IRB Expedited Review Categories – Office of Human Research Protections

17.8 Human Subjects Projection Training – CITI Training Modules

17.9 Certificates of Confidentiality Kiosk – NIH, Office of Extramural Research

17.10 Chapter 42.56 RCW – Public Records Act

17.11 Title 20 U.S. Code, Sec. 1232g – Family Educational Rights and Privacy Act (FERPA)

17.12 WAC 132Q-02 – Confidentiality of Student Records

17.13 CCS Administrative Procedure 1.50.02-D Processing Grants

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