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| TITLE: | Institutional Review Board (IRB) and Protection of Human Subjects |
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**A. Purpose**

The following procedures are established to implement Whatcom Community College (WCC) Policy 318: Institutional Review Board (IRB) and Protection of Human Subjects. This document describes human subjects research, IRB membership, IRB review and approval procedures, cooperative research, and informed consent.

**B. Human subjects research definition**

*B1. Research*

*Research* means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this procedure and associated policy, whether or not they are conducted or supported under a program considered research for other purposes. For example, some demonstration and service programs may include research activities.

*B2. Human subjects*

*Human subjects* are living individuals about whom an investigator (whether a professional or student) conducting research: (1) obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (2) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens. Intervention includes both physical procedures by which information or biospecimens are gathered (e.g., blood samples) and manipulations of the subject or the subject's environment that are performed for research purposes. Interaction includes communication or interpersonal contact between investigator and 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 that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (for example, a medical record). Identifiable private information is private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information. An identifiable biospecimen is a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.

Only *human subject research* activities are subject to the procedures described here, and IRB approval or determination of exempt status is required before proceeding with human subject research. IRB approval may only be granted when all of the criteria functioning as guiding principles described in Policy 318 are met.

**C. IRB membership**

The IRB will be chaired by the vice president for instruction. IRB membership will consist of at least five members with varying backgrounds to promote and complete adequate review of research activities commonly conducted by the institution. According to federal policy, the IRB shall be sufficiently qualified through the experience, expertise, and the diversity of its members – including race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes – to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. In addition, the IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and

standards of professional conduct and practice. 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, as well as one member of the community. The IRB shall include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution. No IRB members may participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB. The IRB may, at its discretion, invite individuals with competence in special areas to assist in the review of issues that require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB.

**D. IRB review and approval procedures**

The IRB will follow procedures for conducting *exempt determination*, *expedited / minimal risk review*, and *regular IRB review* of human subjects research.

*D1. Exempt determination*

Research activities in which the only involvement of human subjects will be in one or more of eight federally-defined categories may be deemed *exempt* from meeting the requirements of the federal human subjects regulations. Although *exempt* means the research does not require IRB review or oversight, investigators still have the responsibility to conduct research ethically. Exempt activities still constitute *human subjects research.* These eight exemption categories apply to all research, whether federally funded or not.

Investigators who intend to perform human subjects research and seek an exempt determination must contact the IRB chairperson for consideration and submit a summary of the proposed project, including project title, brief overview, research aims, subject population, recruitment process, and research design and methods (including data collection instruments, if available). Determination, either issuing an exemption or requiring regular review, will be made in writing.

The following activities are considered exempt (note that limited IRB review may be required in some circumstances):

(1) Research conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

(2) Research that only includes interactions involving educational tests (e.g., cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording), if at least one of the criteria is met: (i) the information obtained is recorded in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects; (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 the subjects' financial standing, employability, educational advancement, or reputation; or (iii) the information obtained is recorded in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination of approval.

(3) (i) Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the same criteria under 2 (i-iii) is met. (ii) Benign behavioral interventions 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. (iii) If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to

participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

(4) Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met: (i) the identifiable private information or identifiable biospecimens are publicly available; (ii) information, which may include information about biospecimens, is recorded in such a manner that the identity of the 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; (iii) the research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated for the purposes of ''health care operations'' or ''research'' as those terms are defined for ''public health activities and purposes'' as described; 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.

(5) Research and demonstration projects conducted or supported by a federal department or agency, or otherwise subject to the approval of department or agency heads, and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs.

(6) Taste and food quality evaluation and consumer acceptance studies: (i) if wholesome foods without additives are consumed; or (b) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant 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) Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review and makes the determination of approval.

(8) Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met: (i) broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with informed consent requirements; (ii) documentation of informed consent or waiver of documentation of consent was obtained; (iii) an IRB conducts a limited IRB review and makes the determination that the research to be conducted is within the scope of broad consent; and (iv) the investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results.

*D2. Expedited / limited review*

The IRB chairperson, or one or more experienced reviewers designated by the chairperson from among members of the IRB, may follow an expedited review procedure for certain kinds of research involving no more than *minimal risk,* which means the probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. Expedited / limited review may also apply to minor changes in approved research or to research for which limited IRB review is a condition of exemption (research involving potentially identifiable information to ensure appropriate safeguards protecting privacy are in place before issuing an exempt determination). However, a research activity may only be disapproved through the regular IRB process, described below. In the event of an expedited / limited review that results in determination of an exemption, request for modification, or approval, all IRB members must be kept advised.

*D3. Regular IRB review*

Human subjects research that does not qualify for an exempt determination or expedited / limited review is assigned a regular IRB review. Review is required before beginning a project. Review materials, described below, are to be provided to the IRB chairperson at least one week before meetings, typically held twice per academic quarter or as necessary, for distribution to IRB members for consideration. Additional meetings may be scheduled on an as needed basis. Continuing review is required for any problems or relevant new information that develops during the research (e.g., adverse events), or as required by the IRB at intervals appropriate to the degree of risk determined through the regular IRB review process.

Required materials include a detailed description of the proposed project (i.e., research aims, subject population, recruitment process, research design, research methods, and data collection instruments). Where appropriate, relevant grant applications and contracts must be submitted. Where applicable, investigators must submit consent documents and any conflict of interest statements (financial or otherwise). In the event that some or all of the subjects are likely to be vulnerable to coercion or undue influence (such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons), additional safeguards must be included in the proposed project to protect the rights and welfare of these subjects. These projects will be subject to a higher level of scrutiny in accordance with federal regulations.

An IRB member will be identified as the primary reviewer for each item that requires review. The primary reviewer is typically the person with the most applicable expertise. The primary reviewer provides a brief summary of the item to the IRB; leads the discussion, including identification of any concerns; usually makes the first motion proposing specific actions; and may assist in writing or reviewing correspondence to the investigator that communicates the IRB's decisions, requirements, and questions. IRB must review proposed research at convened meetings at which a majority of the members of the IRB are present, including at least one member whose primary concerns are in nonscientific areas. A simple majority of the IRB members constitutes a quorum. Outcomes of IRB review are communicated in writing, including electronically.

Possible IRB review outcomes include

(1) Approval: All approved activities may be initiated. If the IRB requires continuing review, the reason and required interval must be provided to the investigator. Investigators must promptly report to the IRB proposed changes in research and must conduct the research approved in accordance with the terms of the IRB approval until any proposed changes have been reviewed and approved by the IRB. Investigators must promptly report to the IRB any unanticipated problems involving risks to subjects or others or any serious or continuing noncompliance with IRB requirements or determinations. The IRB will report these outcomes (as well as any suspension or termination of IRB approval) to appropriate institutional officials, the department or agency head, and the federal Office for Human Research Protections.

(2) Conditional approval: The IRB has determined the applicable criteria for IRB approval have been met, based on the assumption specific conditions will be met by the investigator and subsequently verified. As a condition of approval, the IRB requires the investigator (a) make specified changes; (b) confirm specific assumptions or understandings on the part of the IRB; or (c) provide additional or revised information or documents such that, based on the assumption the conditions are satisfied, the applicable criteria for approval would be met and required determinations would be made.

(3) Deferral: The IRB is unable to approve the research because it cannot make the determinations required for approval (i.e., the applicable criteria for IRB approval have not been met). The IRB defers the item for further review at a future date after modifications or additional information have been provided by the investigator. Modifications, clarification, revised documents or additional information are required from the investigator in order to determine the applicable criteria for IRB approval are met.

(4) Disapproval: The applicable criteria for IRB approval are not met and the IRB is not willing to re-consider the item. The disapproval action is not available as part of expedited / limited review.

(5) Suspension: The applicable criteria for IRB approval are not met and the IRB is not willing to re-consider the item. Suspension may be imposed at any time when research is not being conducted in accordance

with the IRB's requirements or has been associated with unexpected serious harm to subjects. Any suspension (or termination) of approval will include a statement of the reasons for the IRB's action and will be reported promptly to the investigator, appropriate institutional officials, and the federal agency.

(6) Termination: IRB approval for some or all parts of an approved research study is permanently withdrawn.

The IRB chairperson will be responsible for reporting the IRB's findings and actions to the investigator and the institution. The IRB must prepare and maintain adequate documentation of IRB activities, including (a) copies of all research proposals reviewed, approved sample consent forms, and reports of injuries to subjects; (b) minutes of IRB meetings, in sufficient detail to show attendance at the meetings, actions taken by the IRB, the vote on these actions, the basis for requiring changes in or disapproving research, and a written summary of the discussion of controverted issues and their resolution; (c) the rationale for an expedited / limited review determination; (d) copies of correspondence between the IRB and the investigators; (e) a list of IRB members, including membership characteristics; and other details as required. Records will be retained for at least three years, and records relating to research that is conducted shall be retained for at least three years after completion of the research. The IRB may maintain the records in printed form, or electronically.

**E. Cooperative research**

Cooperative research projects are those projects covered by this policy that involve more than one institution. In the conduct of cooperative research projects, each institution is responsible for safeguarding the rights and welfare of human subjects and for complying with this policy. Any institution located in the United States that is engaged in cooperative research supported or conducted by a federal department or agency must rely upon approval by a single IRB for that portion of the research that is conducted in the United States. Where appropriate, an institution participating in a cooperative project may enter into a joint review arrangement, rely upon the review of another IRB, or make similar arrangements for avoiding duplication of effort.

**F. Informed consent**

*F1. Procedure*

An investigator shall seek such consent for approved research only under circumstances that provide the prospective subject or the legally authorized representative sufficient opportunity to discuss and consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the legally authorized representative shall be in language understandable to the subject or the representative and must be free of jargon. Consent documents must present key information in a meaningful way and must not be unduly long. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence. For human subjects research occurring as part of an instructional activity, students who do not give their consent to be human subjects may be given alternative learning experiences. Students who do confirm consent are free to withdraw at any time. Note that while obtaining informed consent is not required by federal regulations for exempt research, the IRB may recommend or require a consent process if the investigator will interact with study subjects in order to ensure protection of study subjects' rights and welfare.

In seeking informed consent, the following information must be provided to each subject:

(1) A statement that the study involves research, an explanation of the purposes of the research, the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures that are experimental.

(2) A description of any reasonably foreseeable risks or discomforts to the subject.

(3) A description of any benefits to the subject or to others which may reasonably be expected from the research.

(4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.

(5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained.

(6) For research involving more than minimal risk, an explanation as to whether any compensation and medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained.

(7) An explanation of who to contact for answers to pertinent questions about the research and research subjects' rights, who to contact in the event of a research-related injury to the subject, and how to contact the IRB.

(8) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

(9) One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens: (i) a statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility; or (ii) a statement that the subject’s information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

Broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens (collected for either research studies other than the proposed research or nonresearch purposes) is permitted as an alternative to the informed consent requirements.

*F2. Documentation*

Informed consent shall be documented by the use of a consent form approved by the IRB and signed by the subject or the subject's legally authorized representative (including in an electronic format). A copy shall be given to the person signing the form.

The consent may be one of the following two options:

(1) A written consent document that embodies the elements of informed consent required. This form may be read to the subject or the subject's legally authorized representative, but in any event, the investigator shall give either the subject or the representative adequate opportunity to read it before it is signed.

(2) A short form written consent document stating the elements of informed consent required have been presented orally to the subject or the subject's legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Also, the IRB shall approve a written summary of what is to be said to the subject or the representative. Only the short form itself is to be signed by the subject or the representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the representative, in addition to a copy of the short form.