Central Oregon Community College (COCC) Institutional Review Board (IRB) Charter and Standard Operating Procedures

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INTRODUCTION

An Institutional Review Board (IRB) is a committee established by an institution to protect the rights and welfare of human subjects recruited to participate in research activities. Federal, state and university regulations require all human subjects research conducted by Central Oregon Community College (COCC) faculty, staff and students to be approved by the IRB before the research can be conducted.

Central Oregon Community College's Institutional Review Board (IRB) is recognized as a formal work group and is listed in the COCC Committee Matrix on the COCC website.

The COCC IRB reviews research proposals that involve human subjects. The IRB does not assume the role of evaluating the soundness of the proposed research study, the merits of the research design, or the potential contribution of the research to the scholarly literature. Rather, the IRB is charged with evaluating each project's compliance with ethical standards in regards to issues such as informed consent, confidentiality, and any risk to the participants. In short, the IRB acts to ensure that the individuals involved in the project are treated ethically.

Principal Investigators (PIs) seeking to conduct research involving human subjects may not solicit subject participation or begin data collection until they have obtained clearance by the Central Oregon Community College Institutional Review Board. Some federally supported research projects involving human subjects are exempt from IRB approval requirements, and others might only need an expedited, rather than a full review.

INSTITUTIONAL AUTHORITY

This Charter and Standard Operating Procedures establishes and empowers the Central Oregon Community College Human Subjects Protection Committee. Currently,
COCC has one committee, registered with the federal Office for Human Research Protections (OHRP) as Institutional Review Board:

- Institutional Review Board (IRB) # 00010217
- IRB Organization (IORG) # 0008531
- Federal Wide Assurance (FWA) # 00026087

This committee is herein after referred to as the IRB. The Signatory Official for the COCC IRB is the College President and the Human Protections Administrator is the IRB Chair (typically an Instructional Dean) as appointed by the College President.

IRB PURPOSE

The primary purpose of the IRB is to protect the rights and welfare of human subjects used in research. The IRB safeguards individuals involved in federally supported research by ensuring that:

1) risks have been considered and minimized;
2) the potential for benefit has been identified and maximized;
3) research-volunteers are provided with substantial information about the study and volunteer only after being provided with legally effective informed consent;
4) all private information will be handled with confidentiality; and
5) research is conducted in an ethical manner and in compliance with established standards.

IRB SCOPE

We are here to ensure that no human research takes place without the appropriate review process. We will either perform the review or act as a contact for a referral to the network of IRB offices.

IRB MEMBERSHIP

There will be a minimum of seven and maximum of eight voting members on the IRB with the make-up established in the bulleted list below. In the event that there are eight members and there is a tie vote, the Chair's vote will not count. A quorum (50% + 1) is necessary to make formal decisions at convened IRB meetings so that means five IRB members present. An alternate member may be appointed by the IRB Chair for long-term absence of a regular IRB member within the academic year. If one of the faculty forum appointed IRB member resigns or is no longer able to be on the committee, a faculty election will be run to fill in the vacancy as soon as possible.

- Presidential Appointment: Typically an Instructional Dean (IRB Chair)
- Science:
- Non-Science:
- Non-COCC, External:
- Faculty-Forum Elected 1:
- Faculty-Forum Elected 2:
- Director of Contracts & Risk Management: Automatic appointment
- Other: Optional

Membership terms are 3-year, staggered terms with the exception of the Director of Contracts & Risk Management who has an automatic appointment. All internal members are to be full-time faculty or staff members with an advanced degree (i.e. Masters, PhD, EdD, MD).

The IRB is composed of members with varying backgrounds and expertise in special areas to provide complete and adequate review of the research. Committee members should possess not only broad specific competence sufficient to comprehend the nature of the research, but also other competencies necessary for judgments as to acceptability of the research in terms of COCC regulations, relevant law, ethical standards, and standards of professional practice. The IRB may consult with specialists to review proposals for which additional expertise is needed, but the specialists may not vote.

The IRB must include both men and women, at least one member whose primary concerns are in the science, technology, engineering and math (STEM) areas, one whose primary concerns are nonscientific areas, and at least one member who is not otherwise affiliated (either directly or through immediate family) with COCC. No person shall be excluded from serving on the IRB based on age, disability, sex, marital status, national origin, ethnicity, color, race, religion, sexual orientation, gender identity, genetic information, citizenship status, veteran status or any other classes protected under Federal and State statues in any education program, activities or employment.

The College President is responsible for making her/his presidential appointment / IRB Chair. The IRB Chair (with discussion and consensus vote from the IRB) selects the science, non-science, and external members. The COCC Faculty Forum elects two faculty to the IRB. Whomever is in the position of Director of Contracts & Risk Management is automatically on the IRB. An additional IRB member may be added if the IRB feels it is in the best interest of the group.

IRB members may be removed from the IRB before their term is completed for reasons of poor attendance for which there is not reasonable justification, or for other manifestations of unwillingness or incapability to serve the committee adequately.
In either event, a replacement will be appointed as quickly as possible per the process above.

THE IRB'S FUNCTIONAL RELATIONSHIPS

The IRB functions administratively through the COCC Instructional Deans Office. The IRB works closely with the COCC Grants Office when reviewing any IRB protocol applications with associated grants requesting federal, state, or other funding.

DEFINITIONS

Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge (45 CFR 46.102 (d)).

Generalizable Knowledge: Investigations designed to develop or contribute to generalizable knowledge are those designed to draw general conclusions (i.e., knowledge gained from a study may be applied to populations outside of the specific study population), or inform policy. For

conclusions to be generalizable, they must actually be disseminated for research purposes (or be part of a program of investigation that will be disseminated).

Dissemination: Material will be shared beyond the local setting. Obvious examples of dissemination are publication in a scholarly journal, presentation at a professional conference, or placement of a report in a library. Examples that are not dissemination include oral presentation to a departmental group in fulfillment of a university requirement, sharing of results with an agency that cooperated in information collection, or internal presentation for utilization and review purposes.

Private Information: 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. (45 CFR 45.102(f))

Human Subjects Research: Research is considered to involve human subjects when an investigator conducting research obtains:

(1) Data through intervention or interaction with a living individual, or
(2) Identifiable private information about a living individual (45 CFR 46.102 (f)).

Human subjects research may include surveys and interviews, behavioral investigations, retrospective reviews of medical information, experiments with blood and tissue, and demonstration and service programs and clinical trials. In addition, the FDA includes under the definition of reviewable research, any use of a FDA regulated product except for use of a marketed product in the practice of medicine.

Minimal Risk: The probability and magnitude of harm or discomfort anticipated in the 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.

BASIC PRINCIPLES FOR RESEARCH INVOLVING HUMAN SUBJECTS

The basic principles that govern the IRB in assuring that the rights and welfare of subjects are protected are contained in Ethical Principles and Guidelines for the Protection of Human Subjects of Research (The Belmont Report) created by The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, April 18, 1979. Therefore, the following principles apply to all federally supported research involving human subjects at Central Oregon Community College to ensure that adequate safeguards are provided:

1) Subjects' legal rights will be respected; their rights to privacy, dignity, and comfort will also be considered in approving proposed research.
2) Risks to subjects must be reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result.
3) Adequate provision(s) must be made for all facilities, procedures, and professional attention necessary for the protection of the individual as a research subject.
4) Adequate provisions should be made for recruiting a subject population that is representative of the population base in terms of gender and minority representation unless scientifically justified.
5) Research involving human subjects must be supervised by qualified persons, including qualified clinicians for all study-related healthcare decisions.
6) Participation of a human subject in research must be voluntary, and the right to withdraw at any time must be provided. Information provided to gain subject consent must be adequate, appropriate, and presented in lay language appropriate to the subject population.
7) All research programs that involve human subjects must be reviewed by and must receive approval of a formally constituted review prior to their initiation or prior to initiating any changes to the project. Continuing research programs are subject to periodic review, to be carried out no less often than once a year. Primary investigators will receive this information on the application form.

AUTHORITY OF THE IRB

The IRB reviews all federally supported projects and programs involving human subjects in accordance with this Charter and Standard Operating Procedures, applicable federal regulations, and sponsor policies and guidelines. The IRB has the following authority:

1) All projects and programs involving human subjects (except for research exempted or waived in accordance with section 101(b) or 101(i) of the Common Rule) will be given full review by the majority of the IRB who will then either approve, require modifications in, or disapprove research activities.
2) The IRB provides continuing advice and counsel to personnel engaged in activities involving human subjects.
3) The IRB has approval authority of human subject protocols and can disapprove, modify, or approve studies based upon consideration of any issue it deems relevant to human subject protection. Research that has been approved by the IRB may be subject to further review to determine whether it is in compliance with college policies and procedures.
4) The IRB has authority to require progress reports from the investigators and oversee the conduct of the study.

5) The IRB has authority to suspend or terminate approval of a study or to place restrictions on a study when this is deemed to be in the best interests of the subjects in that study.
6) The IRB has authority to observe the informed consent process as practiced by any investigator or authorized person in any approved project especially in cases where the consentee is from a vulnerable population.
7) The IRB has the authority to access and to make copies of records related to any research approved by the IRB for any reason (or another body under an IRB Authorization Agreement), regardless of the location of those records. Where feasible, appropriate notice will be given of the need to review, copy, or duplicate records while being sensitive to causing the least inconvenience or disruption of ongoing research.

MANAGEMENT OF THE IRB

1) The IRB Chair is appointed by the College President, is typically an Instructional Dean, and has authority to sign all IRB action items.
2) An IRB Vice Chair (a current IRB member) can be appointed by the IRB Chair to preside over all convened IRB meetings in the absence of the IRB Chair. The Vice Chair is appointed by the IRB Chair and has authority to sign all IRB action items in the absence of the IRB Chair.
3) All IRB members are required to complete the NIH Protecting Human Research Participants web training at the time of their initial appointment. A copy of the NIH certificate of completion must be given to the IRB Chair.
4) IRB members do not receive compensation for their service.
5) Liability coverage for IRB members is provided through COCC's liability insurance coverage, whether the IRB member is an employee of COCC or not.
6) Consultants with competence in special areas may be used when deemed appropriate.

CONFLICTS OF INTEREST POLICY AND PROCEEDURE

Conflict of Interest for IRB Member

It is the responsibility of each IRB member to identify and avoid any situations in which he or she, either personally or by virtue of their position, might have a conflict of interest, or may be perceived by others as having a conflict of interest, arising in connection with a matter before an IRB of which they are a member. The PI shall not be involved in the selection of IRB members.

If assigned as a reviewer for a matter with which the IRB member feels that he or she may have a conflict of interest, the IRB member must notify the IRB Chair immediately so the matter may be reassigned to another reviewer. In order not to delay the review process, it is essential that potential reviewers peruse the matters to which they are assigned immediately upon receipt to

determine whether they have a conflict. An IRB member is said to have a conflicting interest whenever that IRB member, spouse, or dependent child of the member:

1) is an investigator or sub-investigator on the project;
2) has a significant financial interest in the sponsor or agent of the sponsor of a study being reviewed by the IRB, whereby the outcome of the study could influence the value of the financial interest;
3) acts as an officer or a director of the sponsor or an agent of the sponsor of a study being reviewed by the IRB; or
4) has identified him- or herself for any other reason as having a conflicting interest.

IRB member(s) who have a real or perceived conflict of interest may remain in the meeting room during the discussion of the matter at the discretion of the IRB Chair in order to provide answers to questions and to clarify research. However, said member must leave the meeting room for deliberations and actions/votes on the matter.

Minutes of IRB meetings will reflect the absence of a member (by name) when he or she leaves the meeting during deliberations and actions on matters for which they have, or may be perceived to have, a potential conflict of interest.

IRB REVIEW: GENERAL

All projects will first be reviewed through our "Does IRB Review Apply-COCC?" form. If it is determined that the project is indeed human research that requires IRB review, The IRB will encounter three types of applications for review: the Exempt Project Form, or Expedited/Board Review Form (same form, check different box). Any disagreement between the PI and the IRB Chair regarding the type of research must be resolved by the full IRB. PIs will be notified of the IRB decision by the Chair. Generally, for applications that do not fall under the exempt category, the IRB shall:

1) require that information given to subjects as part of informed consent is in accordance with the law and may add requirements as they deem necessary for the protection of the rights and welfare of subjects.
2) notify PIs and the institution in writing of its decision to approve or disapprove the proposed research activity, or of modifications required to secure IRB approval.
    a. If modifications are required, the IRB will detail the necessary changes and allow the PI to update application and resubmit for final approval.
    b. If the IRB disapproves a research activity, it shall give the reason for its decision and allow the PI an opportunity to respond in person or in writing.
3) conduct continuing review of research covered by this policy at intervals appropriate to the degree of risk, but not less than once per year.
4) The IRB will inform PIs via the application form that:
    a. changes in approved research may not be initiated without IRB review and approval except where necessary to eliminate apparent immediate hazards to subjects;
    c. any serious or ongoing problems are to be reported promptly to the IRB.

5) Determine which studies need verification from sources other than the investigators that no material changes have occurred since previous IRB review. The types of studies which will require outside source verification are:
   a. complex projects involving unusual levels or types of risk to subjects;
   b. projects conducted by investigators who previously have failed to comply with the requirements of the HHS regulations or the requirements or determinations of the IRB; and
   d. projects where concern about possible material changes occurring without IRB approval have been raised based upon information provided in continuing review reports or from other sources.
6) report any serious or continuing noncompliance by an investigator, or any suspension or termination of activities, promptly to the IRB Chair and the Human Protections Administrator who will take appropriate remedial action including, but not limited to:
   a. appropriate reporting to the granting agency in a timely fashion.
   b. suspension or termination of research project.

IRB REVIEW: EXEMPT RESEARCH

Under federal regulations, certain types of research are exempt from IRB review.
The IRB, not the investigator, shall make the determination as to whether a project is or is not exempt however on our website we do have an Exempt Category Screening Criteria form to assist the researcher in determining if it is likely exempt and which category it would fall into. To obtain an exemption, an investigator must submit an Exempt Protocol Application citing the specific exemption category and providing justification for the exemption. The IRB will review the form and either approve it as an exemption or will explain to the PI why the project is subject to expedited or full review instead.

Exempt types of research include the following:

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.
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.
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 (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.

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) 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.
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 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.

IRB REVIEW: EXPEDITED

The prospective PI will submit to the IRB Chair one (1) hardcopy original signed Expedited Protocol Application form as well as an electronic version of the completed application. The IRB Chair will distribute electronic copies to all IRB members.

Under federal regulations certain types of research qualify for an expedited review. These are activities that either:

1) present no more than minimal risk to human subjects and are on HHS's preapproved list (below).

NOTE: The expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, reputation, or stigmatizing unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.

2) Involve only minor changes in previously approved research during the period for which approval is authorized. PIs applying for expedited review must submit the Expedited Review Form to the IRB Chair or another member designated by the Chair. In reviewing the research, the Chair may exercise all the authorities of the IRB except he or she may not disapprove the research. A research activity may only be disapproved after full review by the IRB board. If the Chair believes full review is needed, he or she must

inform the PI promptly and have the PI complete the Full Board Protocol Application (Same for for expedited). If the Chair approves the research, he or she must send a copy of the approved form to each member of the IRB to keep them informed of expedited approvals.

Categorical Research Areas: The following is a list of categories of research that may be reviewed by the IRB through an expedited review when the specific circumstances of the proposed research involve *no more than minimal risk.*

(found at HHS's site http://www.hhs.gov/ohrp/humansubjects/guidance/expedited98.htm)

1) Clinical studies of drugs and medical devices only when condition (a) or (b) is met.
(a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)
(b) Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

3) Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
(a) from healthy, non-pregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8-week period and collection may not occur more frequently than 2 times per week; or
(b) from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

4) Prospective collection of biological specimens for research purposes by noninvasive means.
Examples: (a) hair and nail clippings in a non-disfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) un-cannulated saliva collected either in an unstimulated fashion or stimulated by chewing gum-base or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra-and sub-gingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

5) Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)
   Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subjects privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.
6) Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from federal regulations for the protection of human subjects. This list refers only to research that is not exempt.)
7) Collection of data from voice, video, digital, or image recordings made for research purposes.
8) Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from federal regulations for the protection of human subjects. This list refers only to research that is not exempt.)
9) Continuing review of research previously approved by the convened IRB as follows:
   (a) where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects;
   (b) where no subjects have been enrolled and no additional risks have been identified;
   (c) where the remaining research activities are limited to data analysis.

REVIEW OF RESEARCH: FULL-BOARD REVIEW

Forms for full-board (IRB) review should ideally be submitted four weeks prior to the deadline for the proposal or negotiated contract. The prospective PI will submit to the IRB Chair one (1) hardcopy original signed Full Board Protocol Application form as well as an electronic version of the completed application. The IRB Chair will distribute the electronic copies to all IRB members for their review. Copies of the form are available via the COCC IRB website. On the form, the investigator assures the IRB that he/she will follow the principles, procedures, and

guidelines established in the present document and agrees to allow the IRB access to pertinent records or research. In addition, the investigator should present any information that will aid in evaluating the proposal for compliance with this policy. Finally, the PI must be available to discuss the project and/or consent forms at the discretion of the IRB.

The IRB will have a quorum of members present when reviewing a proposal and must include at least one member whose primary concerns are in nonscientific areas. The IRB may take one of the following actions in regard to the proposed project and consent form - approve, require modifications in, or disapprove research activities.

Approved

In order for the research to be approved, it shall receive the approval of a majority of those members present at the meeting. Approval of the project will be based on the following:

1) Risks to subjects are minimized: (i) By using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk(i.e., adequacy of measures for minimizing of risk and the protection of the health, safety, comfort, and legal rights of the subject).
2) 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. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research).
3) Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should 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.
4) Informed consent will be sought from each prospective subject or the subject's legally authorized representative as defined in this document.
5) Informed consent will be appropriately documented.
6) When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.
7) When appropriate, there are adequate provisions to protect the privacy of subjects.

Requirement of Modifications

If the IRB requires modifications prior to approval, then the IRB Chair sends a memo to the PI outlining the necessary modifications. The PI then must respond to the modifications indicated by the IRB. Upon receipt and approval of the responses, the modifications are incorporated in the application; and it is processed as approved.

Disapproved

If the project is disapproved, the PI will be informed in writing of the reasons for disapproval. The PI may revise and resubmit his/her project for another review.

IRB RENEWAL

If the study is delayed for any reason or it is found that more time is needed to complete the project and it is over one year from the time of the project's approval, an IRB Renewal Form (found on the COCC IRB webpage) must be completed and signed by the PI and submitted to the IRB Chair as a scanned PDF electronically. The IRB Chair will share the document with all IRB members and a meeting will be called to determine if the renewal is approved, modified, or not approved.

ADVERSE EVENT (INCIDENT) REPORTING GUIDANCE

The Office of Human Research Protections (OHRP) recognizes that any adverse event in a trial is a potentially important occurrence because it may reflect additional risks to subjects. In accordance with their requirements, these regulatory bodies have charged Institutional Review Boards with the responsibility of conducting continuing review of research. Included in this review is the monitoring of adverse reactions and unexpected events (21 CFR 56.108 and 45 CFR 46.103).

If an adverse event or incident is noted by the PI, an IRB Incident Report Form (found on the COCC IRB webpage) must be completed, signed and turned into the IRB Chair electronically as a scanned PDF.

The IRB Committee must report to appropriate institutional officials, heads of any department or agency supporting the research, any applicable regulatory body, and the Office for Human Research Protections (OHRP) of any:

a. Unanticipated problems involving risks to subjects or others; and
b. Serious or continuing noncompliance with the federal regulations or the requirements or determinations of the IRB.

Upon receipt of such information, or if a research project is suspended or terminated by the IRB, the IRB Chair will make a written report to the Central Oregon Community College IRB committee, the President of Central Oregon Community College, the head of any department or agency conducting or supporting the research, any applicable regulatory body, and to OHRP.

IRB MODIFICATION

If the PI determines that the project needs to be modified in any way, he or she must complete an IRB modification Form (found on the COCC IRB webpage), sign, and submit to the IRB Chair as scanned PDF electronically. The IRB Chair will share the document with all IRB members and

a meeting will be called to determine if the modification is approved, modified, or not approved.

IRB FINAL REPORT

Once the study is complete, the PI completes the IRB Final Report Form (found on the COCC IRB website), signs, and sends as scanned PDF via email to the IRB Chair. The IRB Chair will share the document with all IRB members to determine if all has been handled properly. All IRB records will be kept for at least three years after the study is completed.

OPERATIONS OF THE IRB

1) IRB meetings are scheduled as required by the IRB Chair.

2) The place and time of meeting, agenda, and study material to be reviewed are distributed to IRB members at least seven (7) days prior to the meeting when possible. This may not always be possible.

3) Because the COCC IRB serves a relatively small population with infrequent protocol applications submitted, all IRB members read all applications and supporting materials. Perhaps in the future we will have enough volume of submissions that we will go to a system with primary and secondary reviewers but for now, we all read every submission.

4) Voting requirements

A. A quorum (50% + 1) of the IRB, duly convened through written notice, shall be a majority of voting members with varying backgrounds to promote complete and adequate review of research activities, including at least one member whose primary concerns are in nonscientific areas.

B. In order for the research to be approved, it shall receive the approval of a majority of those voting members present at the meeting. IRB meetings conducted via telephone conference call are permitted pursuant to OHRP guidelines.

C. PIs, including those who are also IRB members, may offer information and answer questions about their projects at a convened meeting but may not be present during voting (even if this means being unable to continue the meeting because of quorum requirements).

5) Appeals: The PI may appeal the decision of the IRB when a project has been disapproved or approved subject to restrictions and mutual agreement cannot be reached as to an acceptable alternative. Upon written notification of appeal from the PI, the IRB shall name an *ad hoc* committee of three or more faculty and/or consultants to review the project a second time.

The *ad hoc* committee members must be acceptable to both the PI and the IRB. The project will be reviewed in accordance with the guidelines established herein and the decision of the ad hoc committee will be referred to the IRB. The PI will be promptly notified of actions of the ad-hoc committee and final action by the IRB. Final disapproval of the IRB cannot be overridden by any institutional official.

6)Annual Reporting: The IRB Chair will provide an academic year report of activities each June to the COCC Shared Governance Committee.

7)Grievances: The IRB shall be informed of all grievances (e.g., of a research subject against a PI), and, if requested, the board will act in an advisory capacity.

COOPERATIVE ACTIVITIES

Cooperative activities relating to human subjects are those which involve Central Oregon Community College and another institution. Each institution is responsible for safeguarding the rights and welfare of human subjects and for complying with the law. With the approval of the funding agency, institutions can enter into joint review arrangements or rely upon the review of another IRB using an Authorization Agreement (or equivalent document) that stipulates the responsibilities of both parties. Furthermore, Central Oregon Community College may collaborate with another institution that does not have an FWA as long as the funding agency approves.

RECORD REQUIREMENTS

The IRB prepares and maintains adequate documentation of IRB activities, including the following:

1) Copies of all research proposals reviewed and accompanying documents including: scientific evaluations, approved sample consent documents, progress reports and reports of injuries to subjects.

2) Detailed minutes of IRB meetings that show the following:

- members present (any consultants/ guests/others shown separately).
- results of discussions on debated issues and record of IRB decisions, including the basis for requiring changes in or disapproving research;
- a written summary of the discussion of controverted issues and their resolution.
- record of voting (showing votes for, against, and abstentions).
- documentation on all four required findings when approving an informed consent modification/ waiver.

3) Records of continuing review activities.
4) Copies of all correspondence between IRB and the investigators.
5) List of IRB members as listed in the FWA.

6) A copy of the Charter/ Operating Procedure
7) Any statements of significant new findings (unanticipated risks or adverse reactions) provided to subjects.

These documents and records shall be retained for at least three (3) years after completion of the research, and the records shall be accessible for inspection and copying by authorized representatives of the Department of Health and Human Services, the Food and Drug Administration, the Department of Veterans Affairs, and other federal regulatory agencies, at reasonable times and in a reasonable manner.

All forms submitted or retained as evidence of informed consent must be preserved by the investigator indefinitely. Should the PI leave COCC, signed consent forms are to be transferred to the IRB Chair.

PRINCIPLES OF INFORMED CONSENT

Except as provided elsewhere in this policy, no investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to 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 representative shall be in language understandable to the subject or the representative. 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.

Basic elements of informed consent:

1) A statement that the study involves research, an explanation of the purposes of the research, and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which 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 an explanation as to whether any 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 whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and

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.

Additional elements of informed consent: when appropriate, one or more of the following elements of information shall also be provided to each subject:

1) A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant), which are currently unforeseeable;

2) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;

3) Any additional costs to the subject that may result from participation in the research;

4) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;

5) A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and

6) The approximate number of subjects involved in the study.

Modification or waiver of informed consent: An IRB may approve a consent procedure which 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 the IRB finds and documents that:

1) The research involves no more than minimal risk to the subjects;

2) The waiver or alteration will not adversely affect the rights and welfare of the subjects;

3) The research could not practicably be carried out without the waiver or alteration; and

4) Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

The IRB can also allow modifications, or even waive the informed consent requirement if:

1) The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is 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; and

2) The research could not practicably be carried out without the waiver or alteration.

DOCUMENTATION OF INFORMED CONSENT

Informed consent must be documented by the use of a written consent form approved by the IRB and signed by the subject or the subject's legally authorized representative. A copy shall be given to the person signing the form.

Informed consent can be presented to subjects in one of two ways:

1) Written: PIs may provide a written consent document that embodies the elements of informed consent above. 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) Read: A short form written consent document stating that the elements of informed consent 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.

Waiver of Documentation: An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either:

1) That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or

2) That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.

INSTRUCTIONS GIVEN TO PI

FOR SUBMITTING IRB PROTOCOL APPLICATIONS

The IRB is an administrative body established under federal requirements to protect the rights and welfare of human research subjects recruited to participate in research activities conducted under the auspices of the institution. The IRB has the authority to approve, require changes to, or disapprove all research activities that fall within its jurisdiction as specified by both the federal regulations and local institutional policy. Research protocols should be submitted before grants are funded and before *any* research data is collected.

Research is "a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalized knowledge" 45 CFR 46.102(d).

Research is considered to involve **human subjects** when an investigator conducting research obtains:

(3) Data through intervention or interaction with a living individual, or
(4) Identifiable private information about a living individual (45 CFR 46.102 (f)).

Human subjects research may include surveys and interviews, behavioral investigations, retrospective reviews of medical information, experiments with blood and tissue, and demonstration and service programs and clinical trials. In addition, the FDA includes under the definition of reviewable research, any use of a FDA regulated product except for use of a marketed product in the practice of medicine.

"Exempt" does not mean that your research is excluded from IRB review. All exempt studies are initially reviewed by the IRB. After its review, the IRB will determine a protocol application's exempt status. If a study qualifies as exempt, then it is exempt from expedited or full board IRB review.

If your research activities do not fall under one or more of the specified **EXEMPT CATEGORIES**, you will need to submit the "Expedited or Full Board Protocol Application" for IRB review.

Investigators are not permitted to make changes to the research without IRB review. You must notify the IRB to any changes in your study by completing a MODIFICATION FORM before they can be implemented.

INSTRUCTIONS FOR SUBMISSION

1. **TRAINING IS REQUIRED FOR ALL INVESTIGATORS**
   The IRB requires **all** investigators and key personnel (who will interact/intervene with participants or have access to identifiable data) listed on IRB protocol applications must successfully complete the online training program prior to submitting a protocol for consideration. You will need to create a password and login in order to access the tutorial. If a co-investigator has not completed the training by the time the protocol is ready to be approved, the principal investigator will be notified. The online training can be found at: https://phrp.nihtraining.com/users/login.php

2. **PRINCIPAL INVESTIGATOR ELIGIBILITY**
   Conducting research with humans is a privilege and carries with it ethical and legal responsibilities. The Principal Investigator (PI) is the individual responsible for writing an accurate protocol to utilize human subjects. Ultimately, the PI assumes the responsibility for the ethical conduct of the project and for the welfare of the human subjects. This responsibility includes the intellectual conduct of the project, fiscal accountability, administrative aspects, and the project's adherence to relevant policies and regulations. For these reasons, the IRB has determined that PIs must have a reasonable prospect of long-term employment at Central Oregon Community College.

   Eligible PIs include COCC faculty with the following titles:

   - Professor
   - Associate Professor
   - Assistant Professor (I and II)

   The IRB staff will confirm titles with the COCC directory when protocol applications are submitted.

   EXCEPTIONS

   If you are not eligible to be listed as a PI, you may still be listed as the PI if an eligible PI is listed as your Co-PI. Please note that the Co-PI must also complete the required online training. If you are not able to list an eligible PI as your Co-PI, you may request an IRB PI Exception which, if approved, will allow you to be listed as the sole PI on the IRB protocol application. This exception must be approved by the IRB Chair and Chair of the Department submitting the proposal. Contact the IRB Chair for additional information on how to obtain the IRB PI Exception form.

   NON-AFFILIATED INVESTIGATORS

   If you are not affiliated with COCC and you are seeking IRB review, the COCC IRB will review your research for approval, but you may be charged. See External Researchers for additional information.

3. **STUDENT INVESTIGATOR ELIGIBILITY**
   UNDERGRADUATE STUDENTS

The IRB does not permit undergraduate students to serve as principal investigators on protocol applications.

4. All supporting appendices **must** be included with the application for review and approval by the IRB. (See checklist below.)

5. **Submit completed application and ALL relevant materials to:** jdowning@cocc.edu

6. **Submit the signed investigator assurance and acknowledgement page.**
   - Scan and email PDF to jdowning@ cocc.edu

7. Within 5 business days of submission, the application will be scheduled for review.
   - **Allow up to THREE weeks for exempt review and approval.**
   - **Allow up to FOUR weeks for expedited review**
   - **Allow up to SIX weeks for full board review and approval.**

8. The IRB representatives are responsible for reviewing the protocol application. The IRB Chair will notify the PI if the IRB needs additional information or clarification about the research project. The IRB also has the authority to request that a protocol undergo a different review level than submitted. When the IRB has approved the application, appropriate online, IRB training is completed by all applicable personnel and signatures have been received, the IRB representative will send a Notification of Approval letter via e-mail to the principal investigator.

9. If the protocol application is not approved, the The IRB Chair will notify the principal investigator in writing.

10. **The investigators cannot begin their research until notification of approval from the IRB has been received.**

INVESTIGATOR SUBMISSION CHECKLIST

*For investigator use only; these pages **do not** need to be submitted with the protocol application.*

☐ Obtain all Principal Investigator Signatures

☐ Obtain Faculty Adviser/Co-Investigator Signature (if needed)

☐ Online IRB Training completed by ALL investigators and applicable key personnel

☐ IRB Application and ALL relevant materials emailed to jdowning@cocc.edu

☐ Signed Investigator Assurance and Acknowledgement Page submitted to the Office of Research Compliance

Appendices to be submitted with application (if applicable):

☐ Grant Proposal (if receiving or requesting external funding)

☐ Recruitment Materials

- ☐ Flyers
- ☐ Verbal Scripts
- ☐ Emails
- ☐ Letters

☐ Consent Documents

- ☐ Consent Form
- ☐ Assent Form
- ☐ Parent Permission Form
- ☐ Cover Letter
- ☐ Verbal Consent Script
- ☐ Debriefing Statement

- ☐ Research Tools
  - ☐ Questionnaire/Survey
  - ☐ Interview Questions and Scripts
  - ☐ Focus Group Questions and Scripts
  - ☐ Permission/Acknowledgement Letter from external site

ADDENDUM (12-17-2018)

While our SOP written content does not yet reflect changes required by the revised final rule as of the effective date (January 21, 2019), all revised final rule requirements will be applied in practice as of the effective date.