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

Updated 10-16-2017 by IRB, updated 4-17-18 by IRB Chair with IRB member edits, updated 3-6-2019 with 2018 revised rule edits by HRP/Downing/Andresen, updated 6-2-2020 by IRB Chair with IRB member edits, updated 11-30-2023 by IRB Chair with IRB member edits.

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1 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.

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 research projects involving human subjects are exempt from IRB approval requirements, and others might qualify for an expedited, rather than a full review.

2 INSTITUTIONAL AUTHORITY

This Charter and Standard Operating Procedures establishes and empowers the Central Oregon Community College Institutional Review Board. 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 as appointed by the College President.

3 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 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.

4 IRB SCOPE

We are here to ensure that no human research that COCC is engaged in 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. The COCC IRB does not review research that COCC is not engaged in. If uncertain of COCC engagement, please review OHRP's guidance on engagement and consult with the COCC IRB Chair prior to initiating any research activities.

5 IRB MEMBERSHIP

There will be a minimum of seven voting members on the IRB. The IRB is composed of members with varying backgrounds to provide complete and adequate review of research activities commonly conducted by COCC. The IRB must be sufficiently qualified through the experience and expertise of its members (professional competence), 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. 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 commitments (including policies and resources), regulations, relevant law, ethical standards, and standards of professional conduct and practice. If the COCC IRB regularly reviews research that involves a category of participants that is vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, consideration shall be given to the inclusion of one or more members who are knowledgeable about and experienced in working with these categories of participants. 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 at least one member whose primary concerns are in the scientific areas, at least one member whose primary concerns are in 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 of the IRB Chair. The IRB Chair (with discussion and consensus vote from the IRB) selects the scientific, non-scientific, and non-affiliated members. The COCC Faculty Senate elects two faculty members to the IRB. Whomever is in the position of Director of Contracts & Risk Management is automatically on the IRB. Additional IRB members may be added if the IRB feels it is in the best interest of the group (e.g., to provide expertise relevant to a type of research or a category of participants that is vulnerable to coercion or undue influence).

Membership terms are three-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). 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 two faculty-senate appointed IRB members 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.

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.

6 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.

7 DEFINITIONS

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 practice or policy.

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.

Human Subjects Research: Human Subjects Research means any activity that meets the definition of "research" and involves "human subjects" as defined by the Common Rule or other applicable regulations (e.g., FDA).

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.

Pre-2018 Common Rule Definitions:

Research: a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalized knowledge. Activities which meet this definition constitute research whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.

Human Subject: a living individual about whom an investigator (whether professional or student) conducting research obtains:

(1) Data through intervention or interaction with a living individual, or
(2) Identifiable private information about a living individual

Intervention: Intervention includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

Interaction: Interaction includes communication or interpersonal contact between investigator and subject. *Please note that per OHRP interaction includes indirect means of communication such as via completion of a web-based survey.*

Identifiable: information that is individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information).

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).

2018 Common Rule Definitions:

Clinical Trial: a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.

Research: a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalized knowledge. Activities which meet this definition constitute research whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.

The following activities are deemed not to be research:

(1) Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.
(2) Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).
(3) Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.
(4) Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.

Human Subject: a living individual about whom an investigator 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: Intervention includes both physical procedures by which information or biospecimens are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

Interaction: Interaction includes communication or interpersonal contact between investigator and subject. *Please note that per OHRP interaction includes indirect means of communication such as via completion of a web-based survey.*

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.

Identifiable Biospecimen: a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.

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).

Legally Authorized Representative: means an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research. If there is no applicable law addressing this issue, legally authorized representative means an individual recognized by institutional policy as acceptable for providing consent in the nonresearch context on behalf of the prospective subject to the subject's participation in the procedure(s) involved in the research.

Public Health Authority: means an agency or authority of the United States, a state, a territory, a political subdivision of a state or territory, an Indian tribe, or a foreign government, or a person or entity acting under a grant of authority from or contract with such public agency, including the employees or agents of such public agency or its contractors or persons or entities to whom it has granted authority, that is responsible for public health matters as part of its official mandate.

Written, or in writing: refers to writing on a tangible medium (e.g., on paper) or in an electronic format.

FDA Definitions:

Research: The FDA has defined "research" as being synonymous with the term "clinical investigation." A clinical investigation, as defined by FDA regulations, means any experiment that involves a test article and one or more human subjects, and that either must meet the requirements for prior submission to the Food and Drug Administration under section 505(i) or 520(g) of the Federal Food, Drug, and Cosmetic Act, or need not meet the requirements for prior submission to the Food and Drug Administration under these sections of the Federal Food, Drug, and Cosmetic Act, but the results of which are intended to be later submitted to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit. The terms research, clinical research, clinical study, study, and clinical investigation are synonymous for purposes of FDA regulations.

Experiments that must meet the requirements for prior submission to the Food and Drug Administration under section 505(i) of the Federal Food, Drug, and Cosmetic Act means any use of a drug other than the use of an approved drug in the course of medical practice.

Experiments that must meet the requirements for prior submission to the Food and Drug Administration under section 520(g) of the Federal Food, Drug, and Cosmetic Act means any activity that evaluates the safety or effectiveness of a device.

Any activity in which results are being submitted to or held for inspection by FDA as part of an application for a research or marketing permit is considered to be FDA-regulated research.

Human Subject: an individual who is or becomes a participant in a clinical investigation, either as a recipient of the test article or as a control. A subject might be either a healthy individual or a patient. For research involving medical devices a human subject is also an individual on whose specimen an investigational device is used or tested or used as a control (regardless of whether the specimens are identifiable).

Test Article: any drug (including a biological product for human use), medical device for human use, human food additive, color additive, electronic product, or any other article subject to regulation under the act or under sections 351 and 354-360F of the Public Health Service Act [42 U.S.C. 262 and 263b-263n].

8 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. These principles are:

1) **Respect for Persons**, which involves the acknowledgment and support of autonomy, and protection of those with diminished autonomy
2) **Beneficence**, which involves ensuring that possible benefits of research are maximized, and possible harms are minimized
3) **Justice**, which involves the fair distribution of the benefits and burdens of research through the equitable selection of subjects

The following principles derived from the above apply to all 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. Primary investigators will receive this information on the application form.

9 AUTHORITY OF THE IRB

The IRB reviews all research involving human subjects in accordance with this Charter and Standard Operating Procedures, applicable federal regulations, state and local law (including tribal laws passed by the official governing body of an American Indian or Alaska Native tribe), and sponsor policies and guidelines.

The IRB applies the principles of the Federal Policy for the Protection of Human Subjects (the Common Rule) to all research except for research that is solely regulated (i.e., research that is not also regulated by the Common Rule) by another federal rule such as those of the FDA or the Department of Justice (DOJ). The Common Rule was updated in 2018. Research approved or determined exempt by the COCC IRB before January 21, 2019 will be subject to the pre-2018 Common Rule requirements through the close of the study. Research approved or determined exempt on or after January 21, 2019 will be subject to the revised Common Rule (the 2018 requirements). Where applicable, the variations in the pre-2018 and 2018 rules will be noted in this manual.

The IRB has the following authority:

1) All research activities involving human subjects (except for research waived in accordance with section 101(i) of the Common Rule) will be given full review by the

majority of the IRB who will then either determine exempt, 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, require modifications, or approve studies, including exempt studies with a limited IRB review requirement, based upon federal standards and 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 the study is not being conducted in accordance with the IRB's requirements, the study has been associated with unexpected serious harm to subjects, or when deemed to be in the best interests of the subjects in the study.
6) The IRB has authority to observe or have a third party 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 observe or have a third party observe the research it oversees. This includes 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.
8) The IRB has the authority to require all Principal Investigators (PI) and Co-PIs complete the PHRP or Citi human research subjects training prior to any data collection and if the PI submits future research applications, records must be sent to the IRB Chair that identify the training was completed within the past five years.

10 MANAGEMENT OF THE IRB

1) The IRB Chair is appointed by the College President 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 will send successful completion documentation of PHRP or Citi human subject research training every five years to the IRB Chair. New IRB members should have completed this training prior to attending their first IRB meeting.
4) IRB members do not receive compensation for their service.

5) IRB members receive reimbursement for training costs.
6) Liability coverage for IRB members is provided through COCC's liability insurance coverage, whether the IRB member is an employee of COCC or not.
7) Consultants with competence in special areas may be used when deemed appropriate.

11 CONFLICTS OF INTEREST POLICY AND PROCEDURE

Conflict of Interest for IRB Member

It is the responsibility of each IRB member to identify and avoid any situations in which they, 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 they 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 they leave the meeting during deliberations and actions on matters for which they have, or may be perceived to have, a potential conflict of interest. Members with a conflict cannot be counted towards quorum on the agenda item(s) for which they are conflicted.

12 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 two types of applications for review: the Exempt Project Form, or Expedited/Full Board Review Form. Any disagreement between the PI and the IRB Chair regarding whether IRB review applies or the type of research (e.g., exempt vs. expedited/full) 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 the application and resubmit for review.
    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 (except as permitted by the revised Common Rule and noted in this manual)
4) The IRB will inform PIs that:
    a. research activities must be conducted in accordance with the terms of the IRB approval until any proposed changes have been reviewed and approved by the IRB, except where necessary to eliminate apparent immediate hazards to subjects (in which case the change(s) and reason must be immediately reported to the IRB);
    b. Any unanticipated problems involving risks to subjects or others, any known or suspected noncompliance with applicable regulations or the requirements of the IRB, and any problems relevant to the protection of subjects, are to be reported promptly to the IRB.
    c. Research protocol application approval time can be reduced by submitting concise, well-written, proof-read documents for review. Typos and poorly written documents that detract from the IRB's ability to clearly understand the content will be sent back for revision. It is not the IRB's role to line edit documents. We encourage PIs to have a colleague proof-read their work prior to submission.
5) Determine which studies need verification from sources other than the investigators that no material changes have occurred since previous IRB review. For example:
    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

c. 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, unanticipated problems involving risks to subjects or others, and any suspension or termination of IRB approval promptly to the IRB Chair and the Human Protections Administrator who will take appropriate action which may include, but is not limited to:
   a. when applicable, reporting to the regulating body (e.g., OHRP) and granting agency in a timely fashion.
   b. suspending IRB approval of some or all activities until the matter can be reviewed by the convened IRB.

13 IRB REVIEW: EXEMPT RESEARCH

Under federal regulations, certain types of research are exempt from certain federal and IRB requirements. At COCC, the IRB, not the investigator, shall make the determination as to whether a project is or is not exempt. To obtain an exemption, an investigator must submit an Exempt Protocol Application citing the specific exemption category and providing justification for the exemption.

The convened IRB will review the information provided and either approve it as an exemption, require modifications for the project to qualify for exemption, or will explain to the PI why the project is subject to expedited or full review instead. Exempt research must still be conducted in accordance with the principles of the Belmont Report and COCC (see the Basic Principles for Human Subjects Research section of this manual). The IRB may require modifications to exempt research to ensure consistency with these principles. There is a regulatory requirement under the revised Common Rule for IRBs to conduct a limited IRB review of the adequacy of the provisions to protect the privacy of subjects and to maintain the confidentiality of data for certain exempt research. The COCC IRB performs this limited IRB review for all research eligible for exemption.

A determination of exemption at COCC is valid for no more than 5 years after which time the exemption approval is terminated and a new application is required for extension. Based upon the specifics of the study (e.g., the anticipated timeline for completion), the IRB may determine that a shorter determination period (e.g., 3 years) is appropriate for a given study. Submission of a Final Report is required when the study is completed. The Final Report Form is available on the COCC IRB website.

The categories of research eligible for exemption under the **pre-2018 Common Rule** are listed below. The exemptions are not applicable to research involving prisoners.

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) the information obtained is recorded by the investigator 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.

Exemption of research involving survey or interview procedures or observation of public behavior is not permissible for research involving children, except for research involving observations of public behavior when the investigators do not participate in the activities being observed.

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 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.
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.

The categories of research eligible for exemption under the **2018 Common Rule** are listed below. The exemptions are not applicable to research involving prisoners, unless the research is aimed at involving a broader subject population that only incidentally includes prisoners.

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 educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:
    (i) The information obtained is recorded by the investigator 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 by the investigator 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 required by .111(a)(7): *When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data*.

The exemptions noted in 2(i) and 2(ii) may only be applied to research involving children when the research involves educational tests or the observation of public behavior when the investigators do not participate in the activities being observed. The exemption at 2(iii) may not be applied to research involving children.

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 following criteria is met:

    A. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;
    B. 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
    C. The information obtained is recorded by the investigator 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 required by .111(a)(7): *When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data*.

(ii) For the purpose of this provision, 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. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

(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 they will be unaware of or misled regarding the nature or purposes of the research.

Exempt Category 3 may not be applied to research involving children.

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 by the investigator 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 under 45 CFR parts 160 and 164, subparts A and E, for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b); 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 non-research activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy

Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq.

5) Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including 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. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.
    (i) Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal website or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.
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.

NOTE: COCC has chosen not to adopt federal exempt categories 7 & 8 (for storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens using broad consent) at this time. Likewise, COCC will not accept an exempt determination using these categories from an outside organization or IRB.

14 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:

1) Present no more than minimal risk to human subjects and are on HHS's preapproved list (below);
2) Involve only minor changes in previously approved research (research that required convened IRB review) during the period for which approval is authorized; or
3) When limited IRB review is required as a condition of an exemption (discussed in prior section).

NOTE: The expedited review procedure may not be used for classified research nor for research 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.

PIs applying for expedited review must submit the Expedited/Full Board Application, or the Modification Form for previously approved research, to the IRB Chair or another member designated by the Chair. At COCC, initial applications are always reviewed by the convened IRB. Reviews of minor modifications may be performed by the convened IRB or by the IRB Chair or another experienced IRB member designated by the Chair. In reviewing the research, the Chair may exercise all the authorities of the IRB except they may not disapprove the research. A research activity may only be disapproved after full review by the IRB board. If the Chair approves the research, they 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.* The 2018 Common Rule includes a presumption that the activities on the expedited list are minimal risk. If the IRB determines that the study involves more than minimal risk, the research is not eligible for expedited review. The IRB will document its rationale for the determination that the research involves more than minimal risk in the IRB records.

(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.

2) 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.
3) 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.
4) 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.
5) 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.)

6) Collection of data from voice, video, digital, or image recordings made for research purposes.
7) 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.)
8) 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; or
   (b) where no subjects have been enrolled and no additional risks have been identified; or
   (c) where the remaining research activities are limited to data analysis.
9) Continuing review of research not conducted under an IND or IDE where categories (2) through (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

15 REVIEW OF RESEARCH: FULL-BOARD REVIEW

Applications for full-board (IRB) review should ideally be submitted four weeks prior to the deadline for the proposal or negotiated contract. Turnaround time of submitted applications is dependent on completeness of application, availability of reviewers, responsiveness of investigators, training of reviewers, and committee meeting scheduling. 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 they 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 research that requires full-board review. A quorum of the IRB consists of a majority (50%+1) of the voting membership, including at least one member whose primary concern is in a non-scientific area. At meetings of the IRB, a quorum must be established and maintained for the deliberation and vote on all matters requiring a vote. IRB members are considered present and participating at a duly convened IRB meeting when either physically present or participating through electronic means

(e.g., teleconferencing or video conferencing) that permits them to listen to and speak during IRB deliberations and voting. When not physically present, the IRB member must have received all pertinent materials prior to the meeting and must be able to participate actively and equally in all discussions.

Opinions of absent members may be considered by the attending IRB members but may not be counted as votes or to satisfy quorum requirements for convened meetings.

The IRB may take one of the following actions in regard to the proposed project, the consent form, and other relevant materials - 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. For non-exempt research to receive IRB approval, the IRB must determine that the following criteria are satisfied:

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, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.
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). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.
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 subjects vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, 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 and to maintain the confidentiality of data.
8) When 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 have been included in the study to protect the rights and welfare of these 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. The IRB will review the responses to determine whether the criteria for approval outlined above are satisfied.

Disapproved

A project may be disapproved when the convened IRB determines that the proposed research activity does not satisfy the criteria for approval and that it cannot be modified to render it approvable (or the sponsor or investigator will not make necessary modifications that would render the research approvable).

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

16 IRB RENEWAL

For research subject to the **pre-2018 Common Rule** requirements and any research where continuing review is required by applicable regulations, policy, or other requirements: The IRB must conduct continuing review of research at intervals appropriate to the degree of risk but not less than once per year. The IRB will determine the period of approval when it initially approves research and at continuing review. The date by which continuing review must occur will be recorded in IRB records and on initial and continuing review approval letters.

For research subject to the **2018 Common Rule** requirements: The IRB must conduct continuing review of research requiring review by the convened IRB at intervals appropriate to the degree of risk of the research, but not less than once per year, except as described below. When applicable, the date by which continuing review must occur will be recorded in IRB records and on initial and continuing review approval letters.

Unless an IRB determines otherwise, continuing review of research subject to the **2018 Common Rule** is not required in the following circumstances:

- Research eligible for expedited review;
- Research reviewed by the IRB in accordance with the limited IRB review requirement;
- Research that has progressed to the point that it involves only one or both of the following, which are part of the IRB-approved study:
    - Data analysis, including analysis of identifiable private information or identifiable biospecimens, or

- Accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care.

The COCC IRB may determine that continuing review is required for any research protocol that falls within the above criteria. For example, the IRB may determine that continuing review is required when:

- Required by other applicable regulations (e.g., FDA);
- Required by the terms of a grant, contract, or other agreement;
- Recommended by Federal guidance (e.g., OHRP recommends that IRB's require continuing review of research that falls within expedited categories 8(b) and 9);
- The research involves topics, procedures, or data that may be considered sensitive or controversial;
- The research involves particularly vulnerable subjects or circumstances that increase subjects' vulnerability;
- An investigator has minimal experience in research or the research type, topic, or procedures; and/or
- An investigator has a history of noncompliance.

When the COCC IRB determines that continuing review is required for such research, it will document the rationale in the IRB record and communicate the requirement for continuing review to the investigator in the IRB determination letter.

Regardless of whether continuing review is required, the IRB Chair will send annual reminders out to all PIs with active research reminding them of IRB requirements and where to find any necessary forms.

When continuing review is not required, projects will generally be granted a 5-year period of approval after which time the IRB approval is terminated and a new application is required for extension. Based upon the specifics of the study (e.g., the anticipated timeline for completion), the IRB may determine that a shorter determination period (e.g., 3 years) is appropriate for a given study. Submission of a Final Report is required when the study is completed. The Final Report Form is available on the COCC IRB website.

When continuing review is required, the IRB will document the expiration date of approval in the IRB records and the letter to the investigator. Investigators must submit an IRB Renewal Form prior to the expiration date of the study in sufficient time (generally 4-6 weeks) for the IRB to be able to review it prior to expiration.

Generally, research requiring continuing review will receive a one-year period of approval, but the IRB may determine that a study requires review more frequently than annually. The IRB will consider the following factors when determining which studies require review more frequently than annually:

1) The probability and magnitude of anticipated risks to subjects;
2) The likely medical/psychological/social/legal/educational condition of the proposed subjects;
3) The overall qualifications of the investigator and other members of the research team;
4) The specific experience of the investigator and other members of the research team in conducting similar research;
5) The nature and frequency of adverse events observed in similar research at this and other institutions;
6) The novelty of the research making unanticipated adverse events/unanticipated problems more likely;
7) The involvement of especially vulnerable populations likely to be subject to undue influence or coercion (e.g., terminally ill);
8) A history of serious or continuing noncompliance on the part of the investigator; and
9) Any other factors that the IRB deems relevant.

In specifying an approval period of less than one year, the IRB may define the period with either a time interval or a maximum number of enrolled subjects. If a maximum number of subjects is used to define the approval period, it is understood that the approval period in no case can exceed one year unless the study does not require continuing review. If an approval period of less than one year is specified by the IRB for research that is subject to continuing review, the reason for more frequent review must be documented in the minutes or elsewhere in the IRB records.

Federal regulations do not provide for a grace period or approval extension after expiration of IRB approval. If reapproval does not occur prior to the study expiration date, all research activities must stop until IRB approval to continue is obtained. When temporarily ceasing research activities may be harmful to already enrolled subjects (e.g., when the research intervention holds out the prospect of direct benefit to subjects or when withholding interventions or safety monitoring would place subjects at increased risk), the investigator should, at the earliest opportunity, contact the IRB Chair and submit a request to continue those research activities that are in the best interests of subjects. Such a request should specify the research activities that should continue, provide justification, and indicate whether the request applies to all or only certain subjects. The IRB Chair or designee will review the request and provide a determination regarding what activities, if any, may continue during the lapse. Such a determination may include a time limit or other conditions or restrictions.

17 INTERIM REPORTS

The IRB Interim Report Form (found on the COCC IRB webpage) must be promptly completed, signed and turned into the IRB Chair electronically as a scanned PDF whenever any of the following occur:

- Adverse events
- Changes made to research without prior IRB approval
- Hold or suspension of a study or certain study activities initiated by an investigator, collaborator, sponsor, or others
- Incarceration of a subject in a protocol not approved for enrollment of prisoners
- Known or potential issues impacting subject privacy or confidentiality (e.g., lost laptop)
- Known or potential noncompliance with the regulations or the requirements of the IRB
- Known or suspected Unanticipated Problem Involving Risks to Subjects or Others (UAP)
- New information that may impact participants' health, rights, welfare, or willingness to continue in the research
- Subject complaints
- Any other information relevant to the rights and welfare of research subjects.

The IRB will review such reports and determine whether any additional actions are needed to ensure the protection of human subjects. When appropriate, the IRB will consider whether an Unanticipated Problem Involving Risks to Subjects or Others and/or serious or continuing noncompliance with the regulations or the requirements of the IRB has occurred.

An *Unanticipated Problem Involving Risks to Subjects or Others* (UAP) means any incident, experience, or outcome that meets all of the following criteria:

(1) Unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document and (b) the characteristics of the subject population being studied;
(2) Related or possibly related to participation in the research; and
(3) Suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

Noncompliance is defined as the failure to follow federal, state, or local regulations governing human subject research or the requirements or determinations of the IRB. Noncompliance may be minor or sporadic or it may be serious or continuing.

Serious Noncompliance is defined as noncompliance that, in the judgment of the convened IRB, creates an increase in risks to subjects, adversely affects the rights, welfare, or safety of subjects, or adversely affects the scientific integrity of the study. Willful violation of policies and/or federal regulations may also constitute serious noncompliance.

Continuing Noncompliance is defined as a pattern of noncompliance that, in the judgment of the convened IRB, suggests a likelihood that instances of noncompliance will continue unless the IRB or institution intervenes.

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

(1) Unanticipated problems involving risks to subjects or others;
(2) Serious or continuing noncompliance with the federal regulations or the requirements or determinations of the IRB; and
(3) Suspensions or terminations of IRB approval

Upon determination that an UAP or serious or continuing noncompliance occurred, 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, and any applicable regulatory body such as OHRP. When appropriate, a preliminary report may be made to allow the IRB sufficient time to gather additional information and take any necessary actions.

18 IRB MODIFICATION

Investigators must obtain IRB approval before making any changes, no matter how minor, to approved research unless the change is necessary to eliminate an apparent immediate hazard to the subject(s) (in which case the change(s) and reason must be immediately reported to the IRB). If the PI determines that a research project needs to be modified in any way, they 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.

When the IRB reviews a modification, it must determine that the research, as modified, would continue to meet the criteria for IRB approval. The IRB will also consider whether information about the modification might impact already subjects' welfare or willingness to continue to take part in the research, and, if so, whether and how subjects should be informed.

19 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.

20 OPERATIONS OF THE IRB

1) IRB meetings are scheduled as required by the IRB Chair, typically monthly during the academic year. Normally, no IRB meetings are scheduled in July or August.

2) The place and time of meeting, agenda, and study material to be reviewed are distributed to IRB members at least four (4) days prior to the meeting when possible. This may not always be possible, but IRB members will always be provided with sufficient time to review materials and prepare for meeting discussion.

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 of the IRB, duly convened through written notice, shall be a majority of voting members (50% +1) 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 or video conference 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 the IRB's final deliberations and 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 and provide recommendations to the IRB.

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 recommendation of the ad hoc committee will be referred to the IRB. The PI will be promptly notified of the final action by the IRB. Final disapproval of the IRB cannot be overridden by the ad hoc committee or 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. The IRB may also take action when a grievance or complaint is received to ensure the protection of the rights and welfare of subjects.

21 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.

In June 2016, the National Institutes of Health (NIH) released a final policy requiring domestic awardees and domestic sites of NIH-funded multi-site research to use a single IRB (sIRB) for review of non-exempt human subject research unless there is justification for an exception. The policy does not apply to career development, research training, or fellowship awards, nor to sites that are not conducting the same protocol as the other sites (e.g., sites providing statistical support or laboratory analysis only) or to foreign sites.

Exceptions to the policy are automatic when local IRB review is required by federal, tribal, or state law/regulation/policy and when the proposed research is the "child" of a grant that predates the requirement for sIRB review. Other exceptions will be considered by NIH when there is compelling justification.

Beginning on January 20, 2020, cooperative research conducted or supported by a Common Rule Department or Agency is subject to the revised Common Rule requirement for single IRB review. Under the revised Common Rule, any institution located in the United States that is engaged in cooperative research must rely upon approval by a single IRB for that portion of the research that is conducted in the United States. The reviewing IRB will be identified by the Federal department or agency supporting or conducting the research or proposed by the lead institution subject to the acceptance of the Federal department or agency supporting the research. The following research is not subject to this provision: (i) Cooperative research for which more than single IRB review is required by law (including tribal law passed by the official governing body of an American Indian or Alaska Native tribe); or (ii) Research for which any Federal department or agency supporting or conducting the research determines and documents that the use of a single IRB is not appropriate for the particular context.

Investigators should consult with the IRB Chair in advance when reliance on another IRB is proposed or required. The IRB Chair, in consultation with others as appropriate, will determine

whether the proposed IRB reliance is acceptable and will ensure that the necessary documentation for agreement and division of responsibilities is in place.

22 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:
    a. Members present (any consultants/ guests/others shown separately).
    b. Actions taken by the IRB
    c. The votes on these actions including the number of members voting for, against, and abstaining
    d. The basis for requiring changes in or disapproving research;
    e. A written summary of the discussion of controverted issues and their resolution.
    f. Record of voting (showing votes for, against, and abstentions).
(3) Documentation on any specific findings required by the regulations (e.g., for waivers or alterations of consent, for inclusion of vulnerable populations)
(4) Records of continuing review activities
(5) Copies of all correspondence between IRB and the investigators
(6) A list of IRB members (the IRB roster) identified by name, earned degrees, representative capacity, indications of experience such as board certifications or licenses sufficient to describe each member's chief anticipated contributions to IRB deliberations, and any employment or other relationship between each member and COCC (e.g., full-time employee, part-time employee, member of governing panel or board, paid or unpaid consultant)
(7) A copy of the IRB Charter/ Operating Procedures
(8) Statements of significant new findings provided to subjects
(9) For research subject to the 2018 Common Rule requirements:
    a. Documentation of the rationale for a determination that research appearing on the expedited review list is more than minimal risk
    b. Documentation of the rationale for conducting continuing review of research that otherwise would not require it per federal regulations
    c. When COCC is relying upon another IRB to serve as the IRB of record for research that takes place at COCC, or when the COCC IRB serves as the IRB of record for external research: documentation, such as an IRB Authorization Agreement,

specifying the responsibilities that the relying institution and the organization providing the IRB review each will undertake to ensure compliance with the regulations and the requirements of the IRB of record

These documents and records shall be retained for at least three (3) years after completion of the research, and records related to the research that is conducted (e.g., investigator records) shall be retained for at least 3 years after the completion of the research. All 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.

23 PRINCIPLES OF INFORMED CONSENT

General Requirements:

For research subject to the pre-2018 Common Rule requirements:

Except as provided elsewhere in these SOPs, 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.

For research subject to the 2018 Common Rule requirements:

Except as provided elsewhere in these SOPs:

1) Before involving a human subject in research, an investigator shall obtain the legally effective informed consent of the subject or the subject's legally authorized representative

2) An investigator shall seek informed consent 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
3) The information that is given to the subject or the legally authorized representative shall be in language understandable to the subject or the legally authorized representative
4) The prospective subject or the legally authorized representative must be provided with the information that a reasonable person would want to have in order to make an informed decision about whether to participate, and an opportunity to discuss that information
5) Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension
6) Informed consent as a whole must present information in sufficient detail relating to the research, and must be organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates the prospective subject's or legally authorized representative's understanding of the reasons why one might or might not want to participate
7) No informed consent may include any exculpatory language through which the subject or the legally authorized 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.

These informed consent requirements are not intended to preempt any applicable federal, state, or local laws (including tribal laws passed by the official governing body of an American Indian or Alaska Native tribe) that have additional requirements for informed consent to be legally effective.

<u>Basic elements of informed consent</u>: In seeking informed consent, the following elements of information shall be provided to each subject or legally authorized representative:

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.
9) For research subject to the **2018 Common Rule** requirements: One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:
    a. 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
    b. 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.
10) For clinical trials with NIH support:
    a. A statement informing subjects that information about the clinical trial is available on ClinicalTrials.gov.
11) For FDA-regulated studies:
    a. A statement that notes the possibility that the FDA may inspect the records
    b. For applicable FDA-regulated clinical trials, the following statement must be included verbatim: *"A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time."*

Additional elements of informed consent: As applicable, the following additional elements of information must also be provided to each subject or the legally authorized representative:

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 or legally authorized representative'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;
6) The approximate number of subjects involved in the study; and
7) For research subject to the **2018 Common Rule** requirements:
    a. A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit;
    b. A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions; and
    c. For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).

General Waiver or Alteration of informed consent:

For research subject to the pre-2018 Common Rule requirements:

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.

For research subject to the 2018 Common Rule requirements:

An IRB may waive the requirement to obtain informed consent, provided the IRB finds and documents that the below criteria are satisfied. An IRB may not waive or alter broad consent, nor may it waive consent for the storage, maintenance, or secondary research use of

identifiable biospecimens if an individual was asked to provide broad consent in accordance with 45 CFR 46.116(d) and refused.

Likewise, an IRB may approve a consent procedure that omits some, or alters some or all, of the basic and additional elements of informed consent (an "alteration"), provided that the IRB finds and documents that the below criteria are satisfied. An IRB may not omit or alter any of the general requirements for informed consent. If a broad consent procedure is used, an IRB may not omit or alter any of the required elements of broad consent described at 45 CFR 46.116(d).

1) The research or clinical investigation involves no more than minimal risk to the subjects;
2) The research or clinical investigation could not practicably be carried out without requested waiver or alteration;
3) If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format;
4) The waiver or alteration will not adversely affect the rights and welfare of the subjects; and
5) Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation.

Public Benefit or Service Programs Waiver or Alteration:

For research subject to the pre-2018 Common Rule requirements:

The IRB may also approve a consent procedure that does not include, or that alters, some or all of the elements of informed consent; or waive the requirements to obtain informed consent, provided the IRB finds and documents that:

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.

For research subject to the 2018 Common Rule requirements:

An IRB may waive the requirement to obtain informed consent, provided the IRB finds and documents that the below criteria are satisfied. An IRB may not waive or alter broad consent, nor may it waive consent for the storage, maintenance, or secondary research use of identifiable biospecimens if an individual was asked to provide broad consent in accordance with 45 CFR 46.116(d) and refused.

Likewise, an IRB may approve a consent procedure that omits some, or alters some or all, of the basic and additional elements of informed consent (an "alteration"), provided that the IRB finds

and documents that the below criteria are satisfied. An IRB may not omit or alter any of the general requirements for informed consent. If a broad consent procedure is used, an IRB may not omit or alter any of the required elements of broad consent at 45 CFR 46.116(d).

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:
    a. Public benefit or service programs;
    b. Procedures for obtaining benefits or services under those programs;
    c. Possible changes in or alternatives to those programs or procedures; or
    d. 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.

Screening, recruiting, or determining eligibility:

For research subject to the 2018 Common Rule requirements:

An IRB may approve a research proposal in which an investigator will obtain information or biospecimens for the purpose of screening, recruiting, or determining the eligibility of prospective subjects without the informed consent of the prospective subject or the subject's legally authorized representative, if either of the following conditions are met:

1) The investigator will obtain information through oral or written communication with the prospective subject or legally authorized representative, or
2) The investigator will obtain identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens.

This provision does not apply to research subject to the pre-2018 Common Rule requirements. A waiver of consent must be obtained for the use of information or biospecimens prior to consent for participation in research.

DOCUMENTATION OF INFORMED CONSENT

Unless the requirement is waived by the IRB, informed consent must be documented by the use of a written consent form approved by the IRB.

1) Informed consent is documented by the use of a written consent form approved by the IRB and signed (including in an electronic format) and dated by the subject or the subject's legally authorized representative at the time of consent;
2) For research conducted in facilities subject to Joint Commission requirements, the name of the person who obtained consent and the date they did so is documented on the written consent form;

3) A written copy of the signed and dated consent form must be given to the person signing the form. The investigator should retain the signed original in the research records.

The consent form may be either of the following:

For research subject to the pre-2018 Common Rule requirements:

a. A written consent document that embodies the basic and required additional elements of informed consent. The consent form may be read to the subject or the subject's legally authorized representative, but the subject or legally authorized representative must be given adequate opportunity to read it before it is signed;

For research subject to the 2018 Common Rule requirements:

a. A written consent document that embodies the basic and required additional elements of informed consent. The investigator shall give either the subject or the subject's legally authorized representative adequate opportunity to read the informed consent form before it is signed; alternatively, this form may be read to the subject or the subject's legally authorized representative;

or

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 (For research subject to the **2018 Common Rule** requirements: and that the key information required by 45 CFR 46.116(a)(5)(i) was presented first to the subject, before other information, if any, was provided). When this method is used:

b. The oral presentation and the short form written document should be in a language understandable to the subject; and
c. There must be a witness to the oral presentation; and
d. The IRB must approve a written summary of what is to be said to the subject (the approved full consent document may serve as this summary); and
e. The short form document is signed by the subject;
f. The witness must sign both the short form and a copy of the summary; and
g. The person actually obtaining consent must sign a copy of the summary; and
h. A copy of the summary must be given to the subject or representative, in addition to a copy of the short form.

When the short form procedure is used with subjects who do not speak or read English, or have Limited English Proficiency (LEP), (i) the oral presentation and the short form written document should be in a language understandable to the subject; (ii) the IRB-approved English language informed consent document may serve as the summary; and (iii) the witness should be fluent in

both English and the language of the subject. When the person obtaining consent is assisted by an interpreter, the interpreter may serve as the witness.

The IRB must receive all foreign language versions of the short form document as a condition of approval. Expedited review of these versions is acceptable if the protocol/research plan, the full English language informed consent document, and the English version of the short form document have already been approved by the convened IRB.

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 any of the following:

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 (or legally authorized representative) 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; or
3) For research subject to the **2018 Common Rule** requirements: 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.

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.

POSTING OF CLINICAL TRIAL CONSENT FORM

Applicable only to research subject to the **2018 Common Rule** requirements:

For each clinical trial conducted or supported by a Federal department or agency, one IRB approved informed consent form used to enroll subjects must be posted by the awardee or the Federal department or agency component conducting the trial on a publicly available Federal Web site that will be established as a repository for such informed consent forms.

If the Federal department or agency supporting or conducting the clinical trial determines that certain information should not be made publicly available on a Federal Web site (e.g. confidential commercial information), such Federal department or agency may permit or require redactions to the information posted.

The informed consent form must be posted on the Federal Web site after the clinical trial is closed to recruitment, and no later than 60 days after the last study visit by any subject, as required by the protocol.

At this time, two publicly available federal websites that will satisfy the consent form posting requirement have been identified: ClinicalTrials.gov and a docket folder on Regulations.gov (Docket ID: HHS-OPHS-2018-0021). Additional federal websites that would satisfy the revised Common Rule's clinical trial consent form posting requirement might be identified in the future.

24 RESEARCH INVOLVING PREGNANT WOMEN, HUMAN FETUSES AND NEONATES

Research Not Conducted or Supported by DHHS:

For research not conducted or supported by DHHS, where the risk to the pregnant women and fetus is no more than minimal, no additional safeguards are required by policy and there are no restrictions on the involvement of pregnant women in research. However, the IRB may determine that additional safeguards or restrictions are warranted for a specific study.

When research involves greater than minimal risk, the DHHS standards outlined below will apply except that the purpose of the research is not restricted only to the development of important biomedical knowledge which cannot be obtained by other means (see criterion #2 below); rather, for non-DHHS research, the purpose of the research is for the development of important knowledge which cannot be obtained by any other means.

Research Conducted or Supported by DHHS:

Pregnant women or fetuses may be involved in research if all of the following conditions are met:

1) Where scientifically appropriate, pre-clinical studies, including studies on pregnant animals, and clinical studies, including studies on non-pregnant women, have been conducted and provide data for assessing potential risks to pregnant women and fetuses.
2) The risk to the fetus is caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus; or, if there is no such prospect of benefit, the risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge which cannot be obtained by any other means;
3) Any risk is the least possible for achieving the objectives of the research;

4) If the research holds out the prospect of direct benefit to the pregnant woman, the prospect of a direct benefit both to the pregnant woman and the fetus, or no prospect of benefit for the woman nor the fetus when risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge that cannot be obtained by any other means, then the consent of the pregnant woman is obtained in accord with the provisions for informed consent.
5) If the research holds out the prospect of direct benefit solely to the fetus then the consent of the pregnant woman and the father is obtained in accord with the provisions for informed consent, except that the father's consent need not be obtained if he is unable to consent because of unavailability, incompetence, or temporary incapacity or the pregnancy resulted from rape or incest.
6) Each individual providing consent under paragraph 4 or 5 of this section is fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate;
7) For children who are pregnant, assent and permission are obtained in accord with the provisions of permission and assent described elsewhere in this manual;
8) No inducements, monetary or otherwise, will be offered to terminate a pregnancy;
9) Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy; and
10) Individuals engaged in the research will have no part in determining the viability of a neonate.

Research Involving Neonates of Uncertain Viability or Nonviable Neonates:

Neonates of uncertain viability and nonviable neonates may be involved in research if all of the following conditions are met:

1) Where scientifically appropriate, preclinical and clinical studies have been conducted and provide data for assessing potential risks to neonates.
2) Each individual providing consent is fully informed regarding the reasonably foreseeable impact of the research on the neonate.
3) Individuals engaged in the research will have no part in determining the viability of a neonate.
4) The requirements of Neonates of Uncertain Viability or Nonviable Neonates (see below) have been met as applicable.

Neonates of Uncertain Viability: Until it has been ascertained whether a neonate is viable, a neonate may not be involved in research unless the following additional conditions have been met:

1) The IRB determines that:
    a. The research holds out the prospect of enhancing the probability of survival of the neonate to the point of viability, and any risk is the least possible for achieving that objective, or

b. The purpose of the research is the development of important biomedical knowledge which cannot be obtained by other means and there will be no added risk to the neonate resulting from the research; and

2) The legally effective informed consent of either parent of the neonate or, if neither parent is able to consent because of unavailability, incompetence, or temporary incapacity, the legally effective informed consent of either parent's legally authorized representative is obtained in accord with the provisions of permission and assent, except that the consent of the father or his legally authorized representative need not be obtained if the pregnancy resulted from rape or incest.

Nonviable Neonates: After delivery, nonviable neonates may not be involved in research unless all of the following additional conditions are met:

1) Vital functions of the neonate will not be artificially maintained;
2) The research will not terminate the heartbeat or respiration of the neonate;
3) There will be no added risk to the neonate resulting from the research;
4) The purpose of the research is the development of important biomedical knowledge that cannot be obtained by other means; and
5) The legally effective informed consent of both parents of the neonate is obtained in accord with the provisions of permission and assent, except that the waiver and alteration of the provisions of permission and assent do not apply.

However, if either parent is unable to consent because of unavailability or incapacity, the informed consent of one parent of a nonviable neonate will suffice to meet the requirements of this paragraph, except that the consent of the father need not be obtained if the pregnancy resulted from rape or incest. The consent of a legally authorized representative of either or both of the parents of a nonviable neonate will not suffice.

Research Involving Viable Neonates:

A neonate, after delivery, that has been determined to be viable may be included in research only to the extent permitted by and in accord with the requirements for research involving children (i.e., a viable neonate is a child for purposes of applying federal research regulations and COCC policies).

Research Involving, After Delivery, the Placenta, the Dead Fetus, or Fetal Material:

Research involving, after delivery, the placenta; the dead fetus; macerated fetal material; or cells, tissue, or organs excised from a dead fetus, must be conducted only in accord with any applicable federal, state, or local laws and regulations regarding such activities.

If information associated with material described above in this section is recorded for research purposes in a manner that living individuals can be identified, directly or through identifiers

linked to those individuals, those individuals are research subjects and all pertinent sections of these policies and procedures are applicable.

Research Not Otherwise Approvable:

Research Not Conducted or Supported by DHHS:

If the IRB finds that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of pregnant women, fetuses or neonates; and the research is not approvable under the provisions described previously in this section, the IRB will consult with a panel of experts in pertinent disciplines (for example: science, medicine, ethics, law). Based on the recommendation of the panel, the IRB may approve the research based on either:

1) That the research in fact satisfies the conditions detailed above, as applicable; or
2) The following:
    a. The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of pregnant women, fetuses or neonates;
    b. The research will be conducted in accord with sound ethical principles; and
    c. Informed consent will be obtained in accord with the requirements for informed consent described in this manual.

Research Conducted or Supported by DHHS:

DHHS-conducted or supported research that falls in this category must be approved by the Secretary of Health and Human Services. If the IRB finds that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of pregnant women, fetuses or neonates; and the research is not approvable under the above provisions, then the research will be sent to OHRP for DHHS review.

25 RESEARCH INVOLVING PRISONERS

For research not conducted or supported by DHHS, where the risk to prisoners is no more than minimal (as defined below, no additional safeguards are required under these policies and procedures. However, the IRB may determine that additional safeguards or restrictions are warranted for a specific study.

For research involving more than minimal risk, and for research conducted or supported by DHHS (unless the research is subject to the revised Common Rule, qualifies for exemption, and only incidentally includes prisoners), the requirements outlined in this section apply.

As applicable, investigators must obtain permission from and abide by the requirements of correctional authorities and federal, state, or local law.

Prisoner: Prisoner means any individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures that provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing

Minimal Risk**:** Minimal risk, in studies involving prisoners, means the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons.

Composition of the IRB:

In addition to satisfying the general membership requirements detailed in other sections of these policies and procedures, when reviewing research involving prisoners, the IRB must also meet the following requirements:

1) A majority of the IRB (exclusive of prisoner members) must have no association with the prison(s) involved, apart from their membership on the IRB;
2) At least one member of the IRB must be a prisoner, or a prisoner representative with appropriate background and experience to serve in that capacity, except that where a particular research project is reviewed by more than one IRB, only one IRB need satisfy this requirement; and
3) The prisoner representative must be a voting member of the IRB. A comment may be added to the roster indicating that the prisoner representative will only count towards quorum when s/he is in attendance and reviewing studies involving prisoners.

Initial IRB Review of Research Proposal:

1) The prisoner representative must review research involving prisoners, focusing on the requirements outlined in Subpart C and these policies;
2) The prisoner representative must receive all review materials pertaining to the research (same as primary reviewer); and
3) The prisoner representative must be present at a convened meeting when the research involving prisoners is reviewed. If the prisoner representative is not present, research involving prisoners cannot be reviewed or approved. The prisoner representative may attend the meeting by phone, video-conference, or webinar, so long as the representative is able to participate in the meeting as if they were present in person at the meeting.
4) The IRB must be familiar with the specific conditions in the local prison(s) or jail site(s) that are pertinent to subject protections, before approving the proposal for the local site (45 CFR 46.107(a)).

Modifications to Research and Continuing Review:

Modifications to and Continuing Review of research will be performed by the convened board with the participation of the prisoner representative. In addition to the regular criteria for approval, the IRB will consider whether the conditions that permit inclusion of prisoners in research continue to be satisfied.

Additional Duties of the IRB:

In addition to the responsibilities of the IRB described in other sections of this manual, the IRB will review research involving prisoners and approve such research only if it finds that:

1) The research falls into one of the following permitted categories [45 CFR 46.306(a)(2)]:
    a. Study of the possible causes, effects, and processes of incarceration, and of criminal behavior, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;
    b. Study of prisons as institutional structures or of prisoners as incarcerated persons, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;
    c. Research on conditions particularly affecting prisoners as a class (for example, research on diseases or social and psychological problems much more prevalent in prisons) provided that the study may proceed only after the DHHS Secretary has consulted with appropriate experts in penology, medicine, and ethics, and published notice in the Federal Register of their intent to approve the research;
    d. Research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject. In cases in which those studies require the assignment of prisoners in a manner consistent with protocols/research plans approved by the IRB to control groups which may not benefit from the research, the study may proceed only after the DHHS Secretary has consulted with appropriate experts in penology, medicine, and ethics, and published notice in the Federal Register of their intent to approve the research; or
    e. The research qualifies under the HHS Secretarial waiver that applies to certain epidemiological research (68 FR 36929, June 20, 2003). The criteria for this category are that the research must have as its sole purpose (i) to describe the prevalence or incidence of a disease by identifying all cases, or (ii) to study potential risk factor associations for a disease.
2) Any possible advantages accruing to the prisoner through his or her participation in the research, when compared to the general living conditions, medical care, quality of food, amenities and opportunity for earnings in the prison, are not of such a magnitude that his or her ability to weigh the risks of the research against the value of such advantages in the limited choice environment of the prison is impaired;
3) The risks involved in the research are commensurate with risks that would be accepted by non-prisoner volunteers;

4) Procedures for the selection of subjects within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners. Unless the investigator provides to the IRB justification in writing for following some other procedures, control subjects must be selected randomly from the group of available prisoners who meet the characteristics needed for that particular research proposal;
5) The information is presented in language which is understandable to the subject population;
6) Adequate assurance exists that parole boards will not take into account a prisoner's participation in the research in making decisions regarding parole, and each prisoner is clearly informed in advance that participation in the research will have no effect on his or her parole; and
7) Where the IRB finds there may be a need for follow-up examination or care of subjects after the end of their participation, adequate provision has been made for such examination or care, taking into account the varying lengths of individual prisoners' sentences, and for informing subjects of this fact.

Certification to DHHS:

Under 45 CFR 46.305(c), the institution responsible for conducting research involving prisoners that is conducted or supported by DHHS shall certify to the Secretary (through OHRP) that the IRB has made the seven findings required under 45 CFR 46.305(a) and receive OHRP authorization prior to initiating any research involving prisoners. Certifications, and requests for DHHS Secretarial consultation, do not need to be submitted to OHRP for research not conducted or supported by DHHS.

For all DHHS-conducted or supported research, COCC will send to OHRP a certification letter to this effect, which will also include the name and address of the institution and specifically identify the research study in question and any relevant DHHS grant application or protocol/research plan. DHHS-conducted or supported research involving prisoners as subjects may not proceed until OHRP issues its authorization in writing to COCC on behalf of the Secretary.

Under its authority at 45 CFR 46.115(b), OHRP requires that the institution responsible for the conduct of the proposed research also submit to OHRP a copy of the research proposal so that OHRP can determine whether the proposed research involves one of the categories of research permissible under 45 CFR 46.306(a)(2), and if so, which one.

The term “research proposal” includes:

1) The IRB-approved protocol; any relevant DHHS grant application or proposal;
2) Any IRB application forms required by the IRB; and
3) And any other information requested or required by the IRB to be considered during initial IRB review.

OHRP also encourages the organization to include the following information in its prisoner research certification letter to facilitate processing:

1) The OHRP Federal-wide Assurance (FWA) number;
2) The IRB registration number for the designated IRB; and
3) The date(s) of IRB meeting(s) in which the study was considered, including a brief chronology that encompasses:
    a. The date of initial IRB review; and
    b. The date of Subpart C review, if not done at the time of initial IRB review.

Incarceration of Already Enrolled Subjects:

If a subject becomes a prisoner while enrolled in a research study that was not reviewed according to these procedures, the investigator must promptly notify the IRB and the IRB shall:

1) Confirm that the subject meets the definition of a prisoner;
2) Consult with the investigator to determine if it is in the best interests of the subject to continue participation in the study, in part or in full, and if so, if there are specific study activities which are in the best interests of the subject that should continue until the IRB is able to review the research applying the standards and requirements for research involving prisoners.
3) If the subject should continue on study, the research will be reviewed applying the standards and requirements for research involving prisoners. If some of the requirements cannot be met or are not applicable (e.g., procedures for the selection of subjects within the prison), but it is in the best interests of the subject to remain in the study, keep the subject enrolled and, if the research is DHHS-conducted or supported, inform OHRP of the decision along with the justification.
4) If a subject is incarcerated temporarily while enrolled in a study:
    a. If the temporary incarceration has no effect on the study (i.e., there is no need for study activities involving the prisoner subject to take place during the temporary incarceration), keep the subject enrolled.
    b. If the temporary incarceration has an effect on the study, follow the guidance outlined above.

26 RESEARCH INVOLVING CHILDREN

The following applies to all research involving children, regardless of funding source. The requirements in this section are consistent with Subpart D of 45 CFR 46, which applies to DHHS-funded research and Subpart D of 21 CFR 50, which applies to FDA-regulated research involving children.

Allowable Categories:

In addition to the IRB's normal duties, non-exempt research involving children must be reviewed by the IRB to determine if it fits within and is permissible under one or more federally-defined categories (OHRP/FDA). Each procedure or intervention that the child will undergo for the research must be taken into consideration, and, if the research includes more than one study group assignment (e.g., placebo vs. active, investigational agent vs. comparator) the category determination must be made for each group assignment. In other words, a component analysis must be conducted by the IRB. The categories are as follows:

1) Research/Clinical Investigations not involving greater than minimal risk [45 CFR 46.404/21 CFR 50.51]. Research determined to not involve greater than minimal risk to child subjects may be approved by the IRB only if the IRB finds and documents that adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians as set forth below.
2) Research/Clinical Investigations involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects [45 CFR 46.405/21 CFR 50.52]. Research in which the IRB finds that more than minimal risk to children is presented by an intervention or procedure that holds out the prospect of direct benefit for the individual subject, or by a monitoring procedure that is likely to contribute to the subject's well-being, may be approved by the IRB only if the IRB finds and documents that:
    a. The risk is justified by the anticipated benefit to the subjects;
    b. The relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative options; and
    c. Adequate provisions are made for soliciting the assent of children and the permission of their parents or guardians as set forth below.
3) Research/Clinical Investigations involving greater than minimal risk and no prospect of direct benefit to the individual subject, but likely to yield generalizable knowledge about the subject's disorder or condition [45 CFR 46.406/21 CFR 50.53]. Research in which the IRB finds that more than minimal risk to children is presented by an intervention or procedure that does not hold out the prospect of direct benefit for the individual subject, or by a monitoring procedure which is not likely to contribute to the well-being of the subject, may be approved by the IRB only if the IRB finds and documents that:
    a. The risk represents a minor increase over minimal risk;
    b. The intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations;

c. The intervention or procedure is likely to yield generalizable knowledge about the subjects' disorder or condition which is of vital importance for the understanding or amelioration of the subjects' disorder or condition; and
d. Adequate provisions are made for soliciting the assent of children and the permission of their parents or guardians as set forth below.

4) Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate serious problems affecting the health or welfare of children [45 CFR 46.407/21 CFR 50.54]. When the IRB does not believe that the research meets the requirements of any of the above categories, and the IRB finds and documents that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children, the IRB shall refer the research for further review as follows:

   a. DHHS-conducted or supported research in this category will be referred for review by the Secretary of Health and Human Services. However, before doing so the IRB must determine that the proposed research also meets all of the requirements of the Common Rule.
   b. FDA-regulated research in this category will be referred for review by the Commissioner of Food and Drugs.
   c. For research that is not DHHS conducted or supported and not FDA-regulated, the IRB will consult with a panel of experts in pertinent disciplines (for example: science, medicine, ethics, law). Based on the recommendation of the panel, the IRB may approve the research based on either:
      i. That the research in fact satisfies the conditions of the previous categories, as applicable; or
      ii. The following:
         1. The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children;
         2. The research will be conducted in accord with sound ethical principles; and
         3. Adequate provisions are made for soliciting the assent of children and the permission of their parents or guardians as set forth in below.

Parental Permission:

The IRB must determine that adequate provisions have been made for soliciting the permission of each child's parent or guardian.

Parents or guardians must be provided with the basic elements of consent and any additional elements the IRB deems necessary, as described in elsewhere in this manual.

The IRB may find that the permission of one parent is sufficient for research to be conducted under Categories 1 [45 CFR 46.404/21 CFR 50.51] & 2 [45 CFR 46.405/21 CFR 50.52] above. The IRB's determination of whether permission must be obtained from one or both parents will be documented in the reviewer's notes when a study receives expedited review, and in meeting minutes when reviewed by the convened committee.

Permission from both parents is required for research to be conducted under Categories 3 [45 CFR 46.406/21 CFR 50.53] & 4 [45 CFR 46.407/21 CFR 50.54] above unless:

1) One parent is deceased, unknown, incompetent, or not reasonably available; or
2) When only one parent has legal responsibility for the care and custody of the child.

The IRB may waive the requirement for obtaining permission from a parent or legal guardian if:

1) The research meets the provisions for a waiver of consent as described elsewhere in this manual; or
2) For research that is not FDA-regulated, if the IRB determines that the research is designed to study conditions in children or a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects (for example, neglected or abused children) provided that an appropriate mechanism for protecting the children who will participate as subjects in the research is substituted, and that the waiver is not inconsistent with Federal, State, or local law. The choice of an appropriate mechanism would depend upon the nature and purpose of the activities described in the protocol/research plan, the risk and anticipated benefit to the research subjects, and the child's age, maturity, status, and condition.

Permission from parents or legal guardians must be documented in accordance with and to the extent described elsewhere in this manual.

<u>Assent from Children:</u>

The IRB is responsible for determining that adequate provisions are made for soliciting the assent of the children, when in the judgment of the IRB the children are capable of providing assent. This judgment may be made for all children to be involved in the study, or for each child, as the IRB deems appropriate.

If the IRB determines that the capability of some or all of the children is so limited that they cannot reasonably be consulted or that the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research, the assent of the children is not a necessary condition for proceeding with the research. Even where the IRB determines that the subjects are capable of assenting, the IRB may still waive the assent requirement under circumstances in which consent may be waived for research that meets the provisions for a general waiver described elsewhere in this manual.

Because “assent” means a child’s affirmative agreement to participate in research, the child must actively show his or her willingness to participate in the research, rather than just complying with directions to participate and not resisting in any way.

The IRB should take into account the nature of the proposed research activity and the ages, maturity, and psychological state of the children involved when reviewing the proposed assent procedure and the form and content of the information conveyed to the prospective subjects. For research activities involving adolescents whose capacity to understand resembles that of adults, the assent procedure should likewise include information similar to what would be provided for informed consent by adults or for parental permission. For children whose age and maturity level limits their ability to fully comprehend the nature of the research activity, but who are still capable of being consulted about participation in research, it may be appropriate to focus on conveying an accurate picture of what the actual experience of participation in research is likely to be (for example, what the experience will be, how long it will take, whether it might involve any pain or discomfort). The assent procedure should reflect a reasonable effort to enable the child to understand, to the degree they are capable, what their participation in research would involve.

Parents and children will not always agree on whether the child should participate in research. Where the IRB has indicated that the assent of the child is required in order for him or her to be enrolled in the study, dissent from the child overrides permission from a parent. Similarly, a child typically cannot decide to be in research over the objections of a parent. There are individual exceptions to these guidelines but in general, children should not be forced to be research subjects, even when permission has been given by their parents.

Documentation of Assent:

When the IRB determines that assent is required, it also is also responsible for determining whether and how assent must be documented. When the research targets the very young child or children unable or with limited capacity to read or write, an oral presentation accompanied perhaps by some pictures with documentation of assent by the person obtaining assent in a research note is likely more appropriate than providing the child a form to sign. In this case, the investigator should provide the IRB with a proposed script and any materials that they intend to use in explaining the research.

When the research targets children who are likely able to read and write, investigators should propose a process and form that is age appropriate and study specific, taking into account the typical child's experience and level of understanding, and composing a document that treats the child respectfully and conveys the essential information about the study. The assent form should:

1) Tell why the research is being conducted;
2) Describe what will happen and for how long or how often;
3) Say it's up to the child to participate and that it's okay to say no;

4) Explain if it will hurt and if so for how long and how often;
5) Say what the child's other choices are;
6) Describe any good things that might happen;
7) Say whether there is any compensation for participating; and
8) Ask for questions.

Whenever possible, the document should be limited to one page. Illustrations might be helpful, and larger type and other age appropriate improvements are encouraged when they have the potential to enhance comprehension. Studies involving older children or adolescents should include more information and may use more complex language.

Children Who are Wards

Children who are wards of the State or any other agency, institution, or entity can be included in research approved under 45 CFR 46.406/21 CFR 50.53 or 45 CFR 46.407/21 CFR 50.54, only if such research is:

1) Related to their status as wards; or
2) Conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as subjects are not wards.

If the research meets the condition(s) above, an advocate must be appointed for each child who is a ward (one individual may serve as advocate for more than one child), in addition to any other individual acting on behalf of the child as legal guardian or in *loco parentis.*

The advocate must be an individual who has the background and experience to act in, and agrees to act in, the best interests of the child for the duration of the child's participation in the research and who is not associated in any way (except in the role as advocate or member of the IRB) with the research, the investigator(s), or the guardian organization.