

## EXPEDITED OR FULL BOARD PROTOCOL APPLICATION



### SECTION A: General Information

Project Title:

Anticipated Start Date:

Anticipated End Date:

Has this protocol previously been considered by Central Oregon Community College's IRB?

NO

YES

IRB Number:

Date Approved:

### SECTION B: Investigators

Principal Investigator Name:

Department:

Email:

Phone:

Title:

Full Professor

Associate Professor

Assistant Professor

*For any titles below, a full/associate/assistant professor must be listed as the co-principal investigator.*

Adjunct Faculty

Part Time Faculty

Staff

Roles and Responsibilities in Study:

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Title:

Full Professor

Associate Professor

Assistant Professor

Adjunct Faculty

Part Time Faculty

Staff

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*For additional investigators and/or key personnel, send an attachment with a listing of additional personnel, titles, contact information, and affiliations.*

### SECTION C: Funding

Funding Source:

Not Applicable

Internal Funding

External Funding

External Funds, attach grant project summary.

*Please contact the IRB Chair if the research is supported by the Department of Justice/National Institute of Justice/Office of Justice Programs.*

**SECTION D: Review Category**

Any research or training project involving the use of human participants which does not fall into an exempt or expedited review category must be submitted for full board IRB review. Research involving more than minimal risk requires full board review even when the procedures fall within the expedited categories. Indicate the applicable review category for your research:

FULL BOARD Review

EXPEDITED Review (Indicate category(ies) below)

**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 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, nonpregnant adults who weigh at least 110 pounds. For these participants, 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 participants, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these participants, 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: hair and nail clippings in a nondisfiguring manner; deciduous teeth at time of exfoliation or if routine patient care indicates need for extraction; permanent teeth if routine patient care indicates need for extraction; excreta and external secretions (including sweat); uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase/wax or by applying a dilute citric solution to the tongue; placenta removed at delivery; amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; mucosal and skin cells collected by buccal scraping or swab or mouth washings.

**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/effectiveness of a device are not generally eligible for expedited review, including studies of cleared devices for new indications. Examples: physical sensors applied 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 subject's privacy; weighing/testing sensory acuity; magnetic resonance imaging; moderate exercise/strength testing 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 nonresearch purposes (such as medical treatment or diagnosis).**

NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human participants. 45 CFR 46.101(b)(4). This listing 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/behavior or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.**

NOTE: Individual or group characteristics/behavior includes, but is not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior. Some research in this category may be exempt from the HHS regulations for the protection of human participants. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.

**SECTION E: Purpose**

Provide a summary of the purpose of your project. Include information about the background and rationale for the study and goal(s) of the proposed study. Use language understood by a person unfamiliar with this area of research. Specific jargon should be avoided or explicitly explained.

What is your research question? State your hypothesis.

What will you do with the results of your study (e.g., contributing to generalizable knowledge, publishing, sharing at conference, etc.)? If this project is only for internal evaluation or to complete a class assignment, IRB may not be required.

## SECTION F: Participant Population

Provide a description of the participant population. Describe the characteristics of the participant population such as gender, age ranges, ethnic background and health status, as applicable to the research.

Will your research involve vulnerable populations such as children or adolescents under the age of 18, pregnant women, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged participants?

NO	YES	If yes, describe the population and additional safeguards planned to protect the rights and welfare of this population(s):
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Are you using students from a class that you teach?

NO	YES	If yes, explain why this population is necessary and how you will ensure participants do not feel coerced to participate.
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Are you using employees who report to you?

NO	YES	If yes, explain why this population is necessary and how you will ensure participants do not feel coerced to participate.
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Indicate any inclusion and/or exclusion criteria for participants.

How many participants do you anticipate are needed for this research?

## SECTION G: Recruitment and Informed Consent

*Attach copies of all applicable recruitment materials.*

Recruitment Scripts (what will be said to participants during recruitment)

Recruitment Emails

Cover Letters

Flyers

Advertisements

Other:

Will information or biospecimens be obtained for the purpose of screening, recruiting, or determining the eligibility of prospective participants without first obtaining informed consent?

NO

YES

If yes, explain how one (or both) of the following conditions is met:

- a) Information will be obtained through oral or written communication with the prospective participant or the legally authorized representative, or
- b) Identifiable private information or identifiable biospecimens will be obtained by accessing records or stored identifiable biospecimens.

Who will recruit potential participants?

Describe how, when, and where individuals will be first contacted about their interest in participating in the study (e.g., face-to-face, email, flyers, advertisements, phone call, etc.).

Attach copies of all applicable informed consent materials:

Informed Consent Form

Cover Letter

Web-based Cover Letter

Assent Form

Parent/Guardian Informed Consent Form

Verbal Consent Script

Debriefing Statement

Are you requesting an alteration or waiver to any informed consent requirements, including documentation of informed consent (signed consent)?

**NO, skip SECTION G PARTS A and B**

YES, I am requesting to waive the required documentation of informed consent (i.e. waive obtaining the signature for anonymous internet-based survey, telephone survey, mailed survey, etc.). **COMPLETE SECTION G PART A**

YES, I am requesting to waive or alter the required elements of the informed consent process. **COMPLETE SECTION G PART B**

## SECTION G PART A

Check the box next to the condition that best fits your research study and justify how your research study meets that condition. If waiving the signature, you must still submit a verbal script or cover letter for participants that addresses the eight required elements of consent as stated in 45 CFR 46.116 (a)(1-8).

**CONDITION 1:** The only record linking the participant and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each participant will be asked whether the participant wants documentation linking the participant with the research, and the participant's wishes will govern.

*Justify why your study meets this condition:*

**CONDITION 2:** The research presents no more than minimal risk to the participant and involves no procedures for which written consent is normally required outside the research context (i.e. no questions are being asked that could result in potential embarrassment, personally or professionally).

*Justify why your study meets this condition:*

**CONDITION 3:** The participants or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, the research presents no more than minimal risk of harm to participants, and there is an appropriate alternative mechanism for documenting that informed consent was obtained. Note: This option is not applicable to research regulated by the FDA or Department of Justice.

*Justify why your study meets this condition:*

**SECTION G PART B**

To request to waive the informed consent process or for an alteration to the informed consent process, describe which elements of consent will be altered an/or omitted.

You must justify your request to waive or alter the informed consent process in accordance with each of the following criteria established under 45 CFR 46.116 (f)(3)(i-v).

The research involves no more than minimal risk to the participants. *Justification:*

The waiver or alteration will not adversely affect the rights and welfare of the participants. *Justification:*

The research could not practicably be carried out without the waiver or alteration. *Justification:*

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.

Note: if this is not applicable to your study, write N/A. This criterion is not applicable to research regulated by the FDA or Department of Justice. *Justification:*

Whenever appropriate, the participants will be provided with additional pertinent information after participation. If a debriefing statement is used, submit a copy with this application. *Justification:*

**SECTION H: Informed Consent Process**

Describe the consent **process**. Do not answer, “see attached consent form,” as this does not describe the **process** of obtaining informed consent. Describe **how, when, and where** the informed consent process will take place **and who** will obtain informed consent. [Review Federal regulations \(45 CFR 46.116\(a 1-6\)\)](#) and be sure to address the general requirements for informed consent, whether written or oral.

If the participants are not able to give legal consent (e.g., minors), explain how assent will be secured. If assent will not be sought, from some or all participants, explain and provide justification.

If consent will be sought from legally authorized representatives instead of the participants (e.g., for adults with impaired decision-making capacity), explain. Be sure to address whether use of legally authorized representatives applies to some or all participants, why consent from legally authorized representatives is necessary, and how the proper legally authorized representative will be determined.

If any, please indicate into what languages will these documents be translated? *Note: A copy of the English and translated consent documents must be submitted for IRB review. Translated consent documents must be reviewed and approved by the IRB prior to use.*

If your research involves collecting a combination of demographic data (e.g., a combination of gender, age, race, and ethnicity) that may make a participant identifiable, you must inform the participants the following: “For this research project, the researchers are requesting demographic information. Due to the make-up of Oregon’s population, the combined answers to these questions may make an individual person identifiable. The researchers will make every effort to protect your confidentiality. However, if you are uncomfortable answering any of these questions, you may leave them blank.” *If applicable, indicate where and how participants will be informed of this.*



**SECTION I: Data Collection**

Check all applicable data collection tools and methods to be used:

Questionnaire/Survey ( <i>attach questions</i> )	Videotaping
Observation	Photographing
Interviews ( <i>attach questions and scripts</i> )	Audiotaping
Focus Groups ( <i>attach questions and scripts</i> )	Using direct quotes
Reviewing Medical/Education Records	Deception
Other:	

***Attach copies of all data collection tools and methods to be used.***

Indicate all biomedical procedures that apply to your research:

Physical Activity	Collection of blood samples
Venipuncture	Body Mass Index
Magnetic resonance imaging (MRI)	X-rays
Electrocardiograms (EKGs)	Anthropomorphic evaluations
Other:	Intravenous catheter insertion

If applicable, describe the procedures being performed already for diagnostic or treatment purpose.

What are you going to ask participants to do? Provide a step-by-step description of each procedure, including the frequency and duration of each procedure.

Does your study fall within the definition of a clinical trial? *Per federal regulations (45 CFR 46.102(b), clinical trial means 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.*

NO YES

If YES, registration of the study on a platform such as ClinicalTrials.gov may be required and, if the research is supported by a Federal department or agency, an IRB-approved consent form may need to be posted on a Federal website. Please consult with the IRB Chair prior to submitting your application.

Where will the study take place (i.e., explain where you are distributing surveys, conducting interviews, etc.)?

Does your study include plans to conduct research at an external site (e.g., school, hospital, prison)?

NO YES

If YES, indicate the external site(s) and you must attach an acknowledgment (letter or email) indicating you have permission to use their facility, records, or personnel. If applicable, does your study include plans to conduct research at external sites that are engaged in the research? If so, will that site’s IRB approve this research or will it rely upon the COCC IRB?

Will monetary or other compensations be offered to the participants (e.g., gift certificates, raffle, cash payment, or class extra credit)?

NO YES

If YES, identify the amount of compensation and method of payment. Explain how participants would earn compensation if their participation is anonymous. If students are offered extra credit, you must provide other options to fulfill the research component if they do not wish to participate.

## SECTION J: Participant Privacy

*Privacy refers to persons during research interactions such as recruitment and data collection. It is the control over the extent, timing, and circumstances of sharing oneself (physically, behaviorally, or intellectually) with others (e.g., surveys are completed in the privacy of their own home; interviews will be done in a location of their choosing where it is unlikely they will be overheard).*

Describe the provisions to protect the privacy of the participants during the research.

## SECTION K: Confidentiality of Data

*Confidentiality refers to how data is handled after collection. It is the treatment of information already revealed and states that there is an expectation that it will not be divulged to others in ways that are inconsistent with the understanding of the original disclosure without permission (e.g., data is secured on a password-protected computer or locked file cabinet, data is de-identified or coded, only the researchers have access to the data). Note: Please review COCC's Data Security recommendations found on the IRB Intranet for guidance.*

Provide details as to how you plan to protect the data while on site and during travel (e.g. from data collection site back to the office). When traveling (especially overseas) or just with portable devices, data security is vital, especially if the device or data is lost or stolen. Address the storage and security of electronic data as well as any physical data, such as paper consent forms or surveys, during travel.

Describe how you will maintain confidentiality of the data after it has been collected, including measures to protect the identity of the participants and their responses.

Where will you store the data? A copy of the data must be kept within the campus departmental area, not stored at home. In what format will the data be stored (e.g., paper or electronic copy)?

Who will have access to the data?

## SECTION L: Risks and Benefits

What are the risks and inconveniences to the participants? Describe all known anticipated psychological, physical, sociological, financial, economic risk to participants, examples include but are not limited to loss of confidentiality, identifiable links to individual participants, feeling guilty for lying in study requiring deception, emotional stress or discomfort, physical injury or discomfort, etc.

How will you minimize these risks and their impact to the participants?

Describe how you are able to identify and handle the risks above. Provide a brief description of all relevant training, experience, education, and credentials.

Describe your plan for an emergency situation. Even if you feel this situation is unlikely, please have a plan in case of emergency (e.g., the researcher will carry a cell phone, etc.).

What are the potential direct benefits to the research participants? (This may not be applicable to your research)

What are the potential broader benefits of the study?

## SECTION M: Unanticipated Problems/Adverse Events

**An unanticipated problem** includes any information that is unexpected, related or possibly related to the research, or indicates that participants or other individuals may be placed at greater risk of harm than initially anticipated by the IRB.

**An adverse event** is any untoward or unfavorable medical occurrence in a human participant, including any abnormal sign (for example, abnormal physical exam), symptom, or disease, temporally associated with the subject's participation in the research, whether or not considered related to the subject's participation.

***If an unanticipated problem or adverse event should occur, immediately complete and submit the IRB Interim Report Form to [irb@cocc.edu](mailto:irb@cocc.edu).***

## SECTION N: Principal Investigator Assurance and Acknowledgment

*I certify that the information provided in this application is complete and accurate. As the principal investigator, I have ultimate responsibility for the conduct of this study, the ethical performance of the project, the protection of the rights and welfare of human participants, and strict adherence to any stipulations designated by the IRB. I accept and will conform to all federal, state, and institutional provisions concerning the protection of human participants in research. I will ensure all personnel involved in the research will be appropriately trained for all procedures used in this project.*

*I agree to conduct the research involving human participants as presented in this protocol application as approved by the Central Oregon Community College Institutional Review Board (IRB), and am qualified to perform the procedures described herein. I will submit any proposed changes/modifications for review and approval before they are implemented. I agree to notify the IRB Chair of any adverse events that may occur during the study. I also assure that I will follow through with the storage and destruction of data as outlined in the protocol. I understand that Central Oregon Community College owns the research data. If I choose to transfer to another institution, I will need departmental approval to take the data with me.*

***I understand that data collection (including recruitment) is not permitted until this application has been reviewed and approved by the IRB.***

**Principal Investigator (PRINT)**

**Signature**

**Date**

## SECTION B: Co-Principal Investigator Assurance and Acknowledgment

*I certify I have read this protocol application and that the information is complete and accurate. I ensure the principal investigator is qualified to perform the procedures described. I understand that I will be included in all email correspondence related to the protocol application including questions from the IRB committee and approval notifications.*

*I further agree to meet with the principal investigator on a regular basis to monitor the progress of the study. I agree to be available and to personally supervise the principal investigator in solving problems as they arise. I will arrange for an alternate Co-PI to assume responsibility if I become unavailable, as when on sabbatical leave or vacation, and will notify the IRB of this change. I assure that the principal investigator will follow through with the storage and destruction of data as outlined in the protocol.*

*Please note, if the principal investigator is an adjunct faculty, part time faculty, temporary faculty or staff, the co-principal investigator's signature must be received before the protocol application will move forward to the IRB for review. Otherwise, Co-PI signature is not required.*

**Co-Principal Investigator (PRINT)**

**Signature**

**Date**

**Signatures must be received before final approval can be given. Submit a signed, scanned PDF of this application and appendices to [irb@cocc.edu](mailto:irb@cocc.edu).**