

EXEMPT PROTOCOL APPLICATION



CENTRAL OREGON
community college

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

For 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: - empty Research Category

Indicate the applicable empty category 1-6:

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 such as:

research on regular and special education instructional strategies; or

research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

This applies only to normal educational research in regular educational settings.

Research that only includes interactions involving 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:

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; or 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

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 .111(a)(7) determination that "when appropriate there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data."

This category of exemption does not apply to research involving interventions. The exemptions at 2.a) and 2.b) may only be applied to research involving children when the research involves educational tests or the observation of public behavior when the investigator(s) do not participate in the activities being observed.

3. 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; or
- 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 is recorded by the investigator in such a manner that the identity can readily be ascertained, directly or through identifiers, and an IRB conducts a limited IRB review to make the .111(a)(7) determination that "when appropriate there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data."

7 the purposes of this exemption 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. Examples include but are not limited to having subjects play an online game, having subjects solve puzzles under various noise conditions,

or having subjects decide how to allocate a nominal amount of received cash between themselves and someone else. If the research involves deceiving subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research. This category of exemption does not apply to research involving children.

4. Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:

- a) the identifiable private information or identifiable biospecimens are publicly available; or
- b) 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; or
- c) 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 ("HIPAA"), 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
- d) the research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the 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 conducted by or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research), 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.

- a) Each Federal department or agency conducting or supporting the research must establish, on a publicly accessible Federal Web site or other such manner, a list of the research that the Federal department or agency conducts or supports under this provision. The research must be published on this list prior to commencing the research involving human subjects.

This exemption is reserved for Federal research and is rarely applied to research at COCC. When submitting for this exemption, the location of the list referenced in 5.a) must be provided.

6. Taste and food quality evaluation and consumer acceptance studies, if at least one of the following criteria is met:

- a) if wholesome foods without additives are consumed; or
- b) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the USDA.

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

Does the intended participant population include prisoners?

NO	YES	If YES, exemptions do not apply to biomedical or behavioral research involving prisoners, except for research aimed at involving a broader subject population that only incidentally includes prisoners.
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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.

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:

Describe the recruitment process. How, where, and when will you contact potential research participants?

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 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.*

Attach copies of all applicable informed consent materials.

Informed Consent Form

Cover Letter

Web-based Cover Letter

Verbal Consent Script

Other:

SECTION H: Data Collection

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

Questionnaire/Survey (*attach questions*)

Observation

Interviews (*attach questions and scripts*)

Focus Groups (*attach questions and scripts*)

Existing Data

Other:

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

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.

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?

SECTION I: 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 J: Confidentiality

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).

Describe how you will maintain confidentiality of the data once it has been collected, including measures to protect the identity of the participants (if applicable) 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.) Who will have access to the data? If the data will be shared or transferred, describe the recipients, the purpose, and how the data will be protected during transfer and upon receipt.

Indicate what will happen to the identifiable data at the end of the study. Research related records must be retained for at least three years after the research has been completed per federal regulations.

Identifiers permanently removed from the data and destroyed (de-identified)

Identifiable/coded data retained, explain why and whether data will be made available for other purposes:

Identifiable data not collected

Other:

SECTION K: Risks and Benefits

Describe the potential research risks to participants.

Describe the potential benefits of this research to participants (if any) as well as the potential broader benefits to society.

Will participants receive compensation or other incentives (e.g., gift certificates, extra credit, etc.) to participate in the research study?

NO

YES

If YES, describe the incentive, including the amount and timing of payment. If offering extra credit, an equal alternative must be provided.

SECTION L: 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 that 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@cooc.edu.