INSTRUCTIONS FOR SUBMITTING IRB PROTOCOL APPLICATIONS

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

Prior to submitting a research protocol to the IRB, review the "Does IRB Review Apply—COCC" form to determine if your activity meets the definition of research [45 CFR 46.102(l)] involving human subjects [45 CFR 46.102 (e)(1)].

Determine if your research meets the definition of Exempt to decide which protocol application to submit. Exempt does not mean that your research is excluded from IRB review. All exempt studies are initially reviewed by the IRB. After its review, the IRB will determine a protocol application's exempt status and any requirements that apply.

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

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

INSTRUCTIONS FOR SUBMISSION

1. TRAINING IS REQUIRED FOR ALL INVESTIGATORS

The IRB requires **all** investigators and key personnel (who will interact/intervene with participants or have access to identifiable data) listed on IRB protocol applications to successfully complete a Human Subjects Research Online Training prior to submitting a protocol for consideration (typically PHRP Training). You will need to create a password and login as well as pay a fee in order to access the training. It takes approximately 1-2 hours to complete. Upon completion of the course, users will receive a downloadable, printable certificate of accreditation showing the user's name and date of completion that should be included with the protocol application. If a co-investigator has not completed the training by the time the protocol is ready to be approved, the principal investigator will be notified.

2. PRINCIPAL INVESTIGATOR ELIGIBILITY

Conducting research with humans is a privilege and carries with it ethical and legal responsibilities. The Principal Investigator (PI) is the individual responsible for writing an accurate protocol to utilize human subjects. Ultimately, the PI assumes the responsibility for the ethical conduct of the project and for the

welfare of the human subjects. This responsibility includes the intellectual conduct of the project, fiscal accountability, administrative aspects, and the project's adherence to relevant policies and regulations. For these reasons, the IRB has determined that PIs must have a reasonable prospect of long-term employment at Central Oregon Community College.

Eligible PIs include COCC faculty with the following titles:

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

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

EXCEPTIONS

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

NON-AFFILIATED INVESTIGATORS

If you are not affiliated with COCC and you are seeking IRB review, you must find another IRB of Record as currently the COCC IRB does not review external research.

3. STUDENT INVESTIGATOR ELIGIBILITY

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

4. SUBMISSIONS

All supporting appendices must be included with the application for review and approval by the IRB. (See checklist below.) Submit completed application and ALL relevant materials to: irb@cocc.edu. Scan and email the **signed** investigator assurance and acknowledgment page to irb@cocc.edu.

Allow up to **SIX** weeks for review and approval. The committee schedules meetings as needed during the academic year. The committee does not meet during summer term.

The IRB committee members are responsible for reviewing the protocol application. The IRB Chair will notify the PI if the committee needs additional information or clarification about the research project. The IRB also has the authority to request that a protocol undergo a different review level than submitted. When the IRB has approved the application and all required documentation has been received, the IRB chair will send a Notification of Approval letter via e-mail to the PI.

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

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

SUBMISSION CHECKLIST

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

- ☐ Obtain all Principal Investigator Signatures
- ☐ Obtain Faculty Adviser/Co-Investigator Signature (if needed)
- ☐ Online IRB Training completed by ALL investigators and applicable key personnel
- ☐ IRB Application and ALL relevant materials emailed to irb@cocc.edu
- ☐ Signed Investigator Assurance and Acknowledgment Page submitted to the IRB Chair

Appendices to be submitted with application (if applicable):

- ☐ Grant Proposal (if receiving or requesting external funding)
- ☐ Recruitment Materials (i.e., flyers, verbal scripts, emails, letters, etc.)
- ☐ Consent Documents, be sure to review the "Informed Consent Requirements form" (i.e., consent form, assent form, parent permission form, cover letter, verbal consent script, debriefing statement, etc.)
- ☐ Research Tools (i.e., questionnaire/survey, interview questions/scripts, focus group questions/ scripts, permission/acknowledgment letter from external site, etc.)
- ☐ Privacy Considerations, be sure to review the "Data Security" form (i.e., data privacy protocols, etc.)