OWENS COMMUNITY COLLEGE

Institutional Review Board

GUIDANCE FOR EXEMPT HUMAN SUBJECTS PROTOCOL FORM COMPLETION

Before completing the Exempt Human Subjects Protocol Form, read **Activities Exempt from IRB Review** (Page 3 of the form). Choose a category that qualifies your research as exempt from human subjects review by the IRB. Document the category in **Q10** on the form.

IRB Log # , Date Submitted, and Date Approved - Leave blank. These fields will be completed by the IRB Administrator.

Q1. Provide a project title

Q2. For research not conducted by a student, provide the name of the Principal Investigator/Project Director (PI/PD) who will oversee the research activities along with his/her institution name, office telephone number, and e-mail address.

Q3. Provide the names of Co-PI/PD: Two spaces are provided for anyone who has a significant role in the project, for example, assisting with data analysis. In cases where students are involved in course activities such as questioning, participation in minimally physically stressing classroom exercises, observing, and/or interacting with other individuals, the student is the Co-PI/PD.

Q4. Sub investigators are persons assisting with the research but not playing a significant role, for example, assist with the distribution of consent forms or surveys. This term does not include human subjects participating in the research.

Q5. For student research, provide the name of the student's Faculty Advisor and his/her institution name, office telephone number, and e-mail address, the student's name and address, and the type of research being conducted.

Q6. Your research may or may not be funded. If it is, please check the appropriate box. If your research is not funded, check **Non-funded research**. If you check **"Other:"** please provide an explanation.

Q7. The IRB wants to confirm that the protocol is consistent with a grant proposal. Provide the date the proposal was submitted and include a copy with the protocol form. If the proposal is not yet due, provide the date it is due and submit it as soon as it is complete.

Q8. Provide the projected dates of your research. Determine these dates carefully. You cannot start your project prior to the stated date. If you need to extend it beyond the stated end date, you will need to submit a **Modification Request**.

Q9. List any collaborators that are part of this project: schools, community organizations, churches, etc. This includes places where you will solicit research subjects.

Q10. The federal government has approved six categories of research that may be exempt from human subjects review. On Page 3 of the **Exempt Human Subjects Protocol Form**, read and select the criterion that you think applies to your research. Check the box that corresponds to that criterion. The IRB may determine that your research meets a different criterion or that it is NOT exempt from review.

Q11. The SUMMARY ABSTRACT is a short narrative describing the **"who, what, why, where, and how"** of your project. See Page 2 of the **Exempt Human Subjects Protocol Form**. Include your professional qualifications to do the research, a summary of the research to be conducted, the purpose of the study, the study design, location(s) of the project, a description of the subjects, how you'll recruit them and that participation is voluntary, procedures to be used for data collection and storage, how you will protect the confidentiality of the subject, and who will have access to the data while it is stored. And finally, explain the benefit of this project to Owens State Community College.

Keeping data confidential and secure is important in all research projects. The IRB has concerns about data security and disposal. Please address the following in the abstract.

- **Paper consent forms and surveys:** These should be kept in a locked file within a locked office. Access should be limited to the PI and one other designated research associate.

- **Online surveys:** When establishing a survey on Zoomerang, SurveyMonkey, or other online sites, the PI must determine how the survey site protects data. All survey sites can provide a security certificate that indicates how confidentiality is protected. ***Provide a copy of this document with the protocol.***

- **Data collection on a PC or laptop:** Personal computers can be hacked into, laptops can be stolen, and flash drives can be lost. Encrypting of data is encouraged so that only the PI can read it. Encryption software such as TrueCrypt and SafeHouse are available online; some downloads are free. ***In the protocol, indicate how any computer-stored data will be encrypted.***

- **Disposal:** Federal regulations require that data is stored for three years. The protocol should state how data will be destroyed at the end of that time. Options include shredding paper, audio tapes, and CDs. Data on hard drives can be deleted using software such as Eraser and SureDelete. To find software, search online for "free secure file deletion". Flash drives can be cleared using a right click of the mouse and choosing to delete.

Writing tips for the Abstract:
You are writing a scholarly document that supports a research project. The document is reviewed by the IRB chair that is knowledgeable about research and the protection of human subjects.

- Write the protocol as you would any academic or professional paper.
- Proofread the abstract for grammatical and typographical errors.
- Give sufficient details so that the IRB chair can determine whether or not the project is exempt.
- If you are supervising a student's research, read the protocol before it is submitted to the IRB.

Q12. INFORMATIONAL LETTER OR SCRIPT

An informational letter or script is **required** to introduce a survey or other research instrument, provide instructions, and explain options to a research participant. For surveys conducted online this information should be provided at the beginning of the survey. Please provide the script you will be using with the protocol form.

Q13. SIGNATURES

Sign the protocol form and obtain signatures for all persons named in items ❷ through ❺.

SUBMIT THE PROTOCOL

Send or deliver the signed protocol to the IRB Administrator, located in the Office of Institutional Research, Administration Hall 227. If you have questions about completing the protocol, e-mail the IRB Administrator or call 567-661-7116.

UPON RECEIVING THE PROTOCOL

The IRB Administrator will conduct a preliminary review of the completed protocol. If it does not follow the guidelines, is unsigned, is incomplete, or contains a number of typos or grammatical errors, it will be returned to you for revision.

The IRB Chair will review the protocol and determine one of the following: that the project is not research as defined by the IRB, is exempt from review, or will be referred to the full committee for review.