OWENS COMMUNITY COLLEGE

Institutional Review Board

GUIDANCE FOR FULL HUMAN SUBJECTS PROTOCOL FORM COMPLETION

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. Provide evidence of training in human subjects protection.

Q7. 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.

Q8. 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.

Q9. 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**.

Q10. List any collaborators that are part of this project: schools, community organizations, churches, etc. This includes places where you will solicit research subjects.

Q11. PROJECT INFORMATION

A. Choose one box that describes the activity status.
B. Indicate whether or not your study involves students and/or employees
C. Check the box(es) which indicate the population(s) to be included in the study.
D. Based on your methodology, estimate how many subjects are needed for the study.

Q12. Certification and Signatures - Sign the protocol form and obtain signatures for all persons named in Q2 through Q5.

Protocol Narrative

I THROUGH IV.
Place the project title and PI's name on each page.
Number all the pages of the narrative.

The narrative addresses **all** the points listed for these sections. In writing the narrative, you are providing details as well as describing and explaining the rationale for the research methodology. As you write, consider the following:

- The IRB will have no knowledge about your project except what you provide. Give them context and good information.
- The IRB makes no assumptions about your research abilities. Tell them how you will handle confidentiality, how you will store data, etc.
- The role of the IRB is to protect human subjects. Members engage in thoughtful debate about what you write in the narrative. They will not routinely approve or dismiss any protocol.

V. ATTACH 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.

VI. ATTACH CONSENT FORM
Create and provide a *Consent Form.* Use the Informed Consent Guidelines as an additional guide in drafting your form.

VII. ATTACH PERMISSION FOR DATA COLLECTION FOR A RESEARCH PROJECT FORM
Complete the form and obtain the signature of the person authorized to grant permission to grant access to data/resources/participants necessary to complete the research for the organization where the data will be collected. At Owens State Community College, the authorized agent is the Vice President/Provost.

VIII. RESEARCH PROPOSAL
Provide an electronic copy of your research proposal to IRB Administrator.

Writing Tips for the Research Proposal
You are writing a scholarly document that supports a research project. The document is reviewed by IRB members knowledgeable about research and the protection of human subjects.

- Write the protocol as you would any academic or professional paper.
- Proofread the proposal for grammatical and typographical errors.
- Give sufficient detail so that the IRB members can understand what you plan to do and how the welfare of the human subjects is protected.
- If you are supervising a student's research, read the protocol before it is submitted to the IRB.

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, 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 or refer the protocol to the full committee for review.