OWENS COMMUNITY COLLEGE

Institutional Review Board

IRB Log #

Date Submitted:

Date Approved:

FULL HUMAN SUBJECTS PROTOCOL FORM

1 Title of Research Project:

	Name	OSCC Department or Other institution	Office Phone	E-mail
2 PI/PD				
3 Co-PI/PD				
Co-PI/PD				
4 Sub Investigator				
Sub Investigator				
Sub Investigator				
Sub Investigator				

5 For Student Research

Faculty Advisor

Student Name

Student Address

Type of Research: ☐ Dissertation ☐ Thesis ☐ Class Project ☐ Other - please describe below

6 **Evidence of training in human subjects protection:** Any PI/PD, Co-PI/PD, Sub Investigator, Faculty Advisor, or Student must be trained. See the **OSCC IRB Website** . If you have documentation of IRB training from another resource, **please attach**.

7 **Project Funding Source** (Check all that apply)

☐ External Grant / Sponsor Name:

☐ OSCC Grant

☐ Non-funded Research

☐ Other:

8 **If grant funded, provide the following dates:**

Proposal Due Date

Proposal Submission Date:

(IRB requires one copy of the grant proposal as soon as it is available.)

9 Projected Dates of Research

Data Collection Start Date: _____ Data Collection End Date: _____

10 Collaborators: (List any other organizations/agencies involved in the study.)

_____

11 Project Information

A. Project Activity Status:

- ☐ New Project
- ☐ Periodic Review of Continuing Project
- ☐ Revision to Previously Approved Project

B. This project involves Owens State Community College **students**

☐ Yes ☐ No

This project involves Owens State Community College **employees (faculty, staff, or administration)**

☐ Yes ☐ No

C. Human Subjects from the following populations will be involved in this study:

- ☐ Minors
- ☐ High School Students
- ☐ Intellectually Disabled
- ☐ Prisoners
- ☐ Elderly
- ☐ None of the above

D. Total number of subjects to be studied: _____

12 Certification and Signatures:

Investigator's Assurance: By submitting this protocol, I attest that I am aware of the applicable principles, policies, regulations, and laws governing the protection of human subjects in research and that I will be guided by them in the conduct of this research.

Investigator's Certification: I certify that the protocol and method of obtaining informed consent as approved by the Owens State Institutional Review Board will be followed during the period covered by this research project. Any future changes to the research project will be submitted to the IRB for review and approval prior to implementation.

	Signature	**Date**
PI/PD	_____	_____
Co-PI/PD	_____	_____
Co-PI/PD	_____	_____
Sub Investigator	_____	_____
Sub Investigator	_____	_____

Certification and Signatures cont....

	Signature	Date
Sub Investigator		
Sub Investigator		
Sub Investigator		
Sub Investigator		

Note: Approval of an IRB protocol implies that the PI/PD will carry out the research **as described** in the approved protocol. If changes are needed to any part of the research protocol, the researcher must complete a **Modification Request** and submit it to the IRB.

FOR IRB USE ONLY

IRB DETERMINATION

☐ Not Research ☐ Approved ☐ Approved Subject to Conditions (see attached memo)

☐ Tabled (see attached memo) ☐ Not Approved (see attached memo)

Signature: _____ **Date:** _____

PROTOCOL NARRATIVE

In a separate document, in addition to pages 1, 2, and 3 of the protocol, write a narrative that provides the information requested in items I through VIII.

See Guidance for Full Human Subjects Protocol Form Completion

Number the pages and put the project title and PI name on each page.

I. PURPOSE, RESEARCH VARIABLES, AND POPULATION

1. Purpose of study: State concisely and realistically what the study is intended to accomplish, what the benefits are expected to be, and how risks are reasonable in relation to benefits. State the benefit of this project to Owens State Community College.

2. Background: Briefly state the background of the study, including relevant references and identify the main questions the current study is intended to address.

3. Characteristics of the Subject Population: The following information should be provided:
    a. Age Range - What is the age range and why was it chosen?
    b. Sex - What is the sex of the subject? If there is a restriction, provide the rationale.
    c. Number - What is the estimated number of subjects?
    d. Inclusion Criteria - What are the specific inclusion criteria?
    e. Exclusion Criteria - What are the specific exclusion criteria? Clear rationale should be provided for the exclusion of any particular population group, unless the title of the study reflects the restricted population range.
    f. Vulnerable Subjects: If vulnerable subjects will be included (children, pregnant women, fetuses, prisoners, intellectually disabled persons), provide justification of the need to use these subjects in research.

II. METHODS AND PROCEDURES

1. Method of Subject Selection: Describe the study's method(s) of identification and recruitment of prospective subjects. Provide a copy of any planned advertisements.

2. Study Site: State the location(s) where the study will be conducted. Include letters of approval to conduct the study from all non-OSCC sites.

3. Methods and Procedures Applied to Human Subjects: Describe in detail the study design and all procedures (sequentially) to be applied to subjects. Include provisions for managing adverse reactions. Attach copies of any instruments to be used, such as surveys, ratings scales, or questionnaires as well as copies of brochures or advertisements that may be provided to the subject.

4. 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. Attach this to the protocol form.

III. RISKS/BENEFITS

1. Potential Risks: identify the potential risks of the study. Specify the types and levels of risks.

2. Protection Against Risks: For all studies involving greater than minimal risk, specify the procedures for preventing or minimizing any potential risks.

3. Potential Benefits: Describe any potential non-monetary benefits of the study, both for subjects and for society in general.

4. Compensation for Participation: Describe any monetary or other forms of compensation which will be provided to subjects, and any conditions which must be fulfilled to receive compensation, including compensation for injury .

5. Alternative to Participation: Describe any alternatives to participation in the study which might be advantageous to the subject. If the subjects are to receive academic credit for research participation, describe the alternatives available to earn equivalent academic credit.

6. Information Withheld: Identify the nature of any information to be purposely withheld from subjects, and provide justification for the non-disclosure.

7. Debriefing: Describe the procedure for post-study debriefing of subjects.

IV. CONFIDENTIALITY - PROTECTION OF PRIVACY

Describe explicitly how confidentiality of data will be maintained. If any information with subject identifiers will be released, specify the recipients. Include a statement that all data will be retained for at least three years in compliance with federal regulations. Refer to Securing Research Data.

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

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 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.

V. 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.

VI. CONSENT

Describe the procedures for documenting informed consent, including any procedures for obtaining assent from minors. Attach a copy of the consent form to the protocol.

VII. PERMISSION FOR ACCESS TO DATA/RESOURCES/PARTICIPANTS

Obtain permission for access to data/resources/participants necessary to complete the study from the organization where the data will be collected. Please provide the signed permission form with your protocol materials.

VIII. RESEARCH PROPOSAL/GRANT APPLICATION

Append a copy of the research proposal and grant application to the protocol or attach as an e-mail to the IRB Administrator.

IX. MAILING ADDRESS

Send all documents to:

IRB Administrator
Office of Institutional Research
Owens Community College
P. O. Box 10,000
Toledo, Ohio 43699-1947