Institutional Review Board

Exempt Human Subjects Protocol Form

IRB Log # _____

Date Submitted: _____

Date Approved:_____

Guidance for Exempt Human Subjects Protocol Form Completion is available on the IRB website. Before completing this form, read **Activities Exempt from IRB Review** (page 3 of this form). Choose one category that applies to your research. Document that category in item 10 on this form.

1. Title of Research Project: _____

	Name	Owens Departments/ Other Institution	Office	Email Address
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 Project: ☐ Dissertation ☐ Thesis ☐ Class Project ☐ Other - please describe below

6. Project Funding Source (Check all that apply)

☐ External Grant / Sponsor Name: _____

☐ OSCC Grant

☐ Non-funded Research

☐ Other: _____

7. If grant funded, provide the following

Proposal Due Date : _____ Proposal Submission Date: _____

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

8.. Projected Dates of Research

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

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

10. Exemption Code: (See definitions on Page 3) (Check only one)

☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6

11. **ATTACH a Summary Abstract:** Write a short narrative describing the "who , what , when, where, and how" of the project. For guidance on what to include, see *Guidance for Exempt Human Subjects Protocol Form Completion* - oscc.edu/IRB/forms.htm

12. **ATTACH a copy of the Informational Letter or Script** that will be used in the project to introduce the research instrument, provide instructions, and explain options to the research participant. See *Guidance for Exempt Human Subjects Protocol Form Completion* - oscc.edu/IRB/forms.htm

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 as submitted to 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.

13. Signatures:

PI/PD _____ Date _____

Co-PI/PD/Student _____ Date _____

Co-PI/PD/Student _____ Date _____

FOR IRB USE ONLY

☐ Not Research ☐ Exempt from Review ☐ Referred for Full Committee Review

Signature of IRB Chair: _____

Date: _____

ACTIVITIES EXEMPT FROM IRB REVIEW

Research activities involving human subjects in the following categories may be exempt from review by Owens State's Institutional Review Board. The principal investigator/project director is authorized to make the first determination of eligibility for exemption; however, the College bears the responsibility for concurring in that determination based on notice provided by the principal investigator to the Institutional Review Board.

The following exemptions do **NOT** apply when:

(a) deception of subjects may be an element of the research;
(b) subjects are under the age of eighteen;
(c) the activity may expose the subject to discomfort or harassment beyond levels encountered in daily life; or
(d) fetuses, pregnant women, human in vitro fertilization, children, individuals involuntarily confined or detained in penal institutions, or vulnerable individuals with special needs, illnesses, etc. are subjects of the activity.

EXCEPT FOR THE ABOVE EXCLUSIONS, the federally-approved Categories of Exemption are:

1. Research conducted in established or commonly accepted educational settings involving 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. This includes most research on regular and special education instructional strategies and research on the effectiveness of or the comparison among instructional techniques curricula, or classroom management methods.

2. Research that only includes interactions involving the use of 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:: (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; (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 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 determination that there are adequate privacy and confidentiality protections in the study.

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; (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 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 determination that there are adequate privacy and confidentiality protections in the study.

    - For the purpose of this provision, 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. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

    - If the research involves deceiving the 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.

4. Secondary research for which consent is not required: 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; (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; (c) The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under HIPPA as "health care operations", "research" or "public health"; 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 federal privacy standards.

5. Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), 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. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.

6. Taste and food quality evaluation and consumer acceptance studies: (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 U.S. Food and Drug Administration or approved by the U.S. Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

7. Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review and makes the determination that there are adequate privacy and confidentiality protections in the study.

8. Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met: (a) Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained; (b) Documentation of informed consent or waiver of documentation of consent was obtained; (c) An IRB conducts a limited IRB review and makes the determination that the research to be conducted is within the scope of the broad consent as well as privacy and confidentiality protections; and (d) The investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results.

Exempting an activity from review does not absolve the investigator(s) of the activity from ensuring that the welfare of subjects in the activity is protected and that methods used and information provided to gain subject consent are appropriate to the activity.

Questions about whether a research activity may be exempt from human subjects review can be directed to the IRB Administrator in the Office of Institutional Research.