EXEMPT REVIEW APPLICATION

HUMAN SUBJECTS RESEARCH - OBLATE SCHOOL OF THEOLOGY INSTITUTIONAL REVIEW BOARD

IDENTIFYING INFORMATION

Researcher: _____ Telephone Number: _____

Address: _____ Program: _____

_____ Research Director: _____

Email Address: _____ (IRB disposition letter will be electronically emailed)

Research Title: _____

☐ If Checked, The student ensures that the proposed research has not yet begun, but this application is written in the past tense as directed by the Graduate Program Director.

I. CRITERIA

Place an X next to the criterion or criteria under which you are seeking Exempt review:

☐ The project is not "research" as defined by the federal guidelines. (See the Common Rule (45 CFR 46 subpart A))

☐ Research which does not utilize human subjects.

☐ Research involving the collection or study of existing data, documents, or records from publicly available sources or if the information is recorded in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects such as in content or secondary data analyses.

☐ Research on normal educational practices, such as research on regular or special education instructional strategies that are not likely to adversely affect students' opportunity to learn required educational content or the assessment of educators who provide instruction, including research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods in established or commonly accepted educational settings.

☐ Research involving the use of educational tests (cognitive, diagnostic, aptitude, or achievement), survey procedures, interview procedures or observation of public behavior (including visual or auditory recording), and one of the following criteria is met: the information obtained is recorded by the investigator in such a manner that the identity of subjects cannot readily be ascertained, directly or through identifiers linked to the subjects, or any disclosure of the human subjects' response outside the research would not reasonably place the subject at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement or reputation, or 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 indirectly through identifiers linked to the subjects and IRB will conduct a limited IRB review.

☐ Taste and food quality evaluation and consumer acceptance studies where wholesome foods without additives are consumed, or in which 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 Food and Drug Administration, or approved by the Environmental Protection Agency, or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

☐ Storage or maintenance of identifiable private information or identifiable biospecimens for secondary research? If yes, broad consent is required.

☐ Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research? If yes, broad consent is required.

☐ Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

☐ Secondary research uses of identifiable private information or identifiable biospecimens (for which no consent is required) if at least one of these are met: the identifiable private information or identifiable biospecimen are publicly available information (which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of 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, or the research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under HIPAA, or the research is conducted by, or on behalf of a federal department or agency using government-generated or government-collected information obtained for non-research activities if certain other requirements are met as outlined in Section 7 of the Exempt Categories section of this *Guidebook*.

EXEMPT REVIEW APPLICATION

II. DESCRIPTION

Summarize specifically but concisely the purpose, source(s) of data, and HOW the planned research meets the above criteria (attach additional pages as needed).

III. SIGNATURES

The researcher's signature indicates that during all phases of the conduct of this research he or she will ensure the practical application of the general ethical principles identified by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, including respect for persons, beneficence, and justice. The researcher will respect the confidentiality of information obtained from or about subjects in this research and will protect all subjects' privacy by not disclosing any information in a way in which an individual may be identified.

The Program Director's signature indicates that all IRB application materials have been reviewed and approved by him/her prior to submission to the IRB.

Researcher's Signature	**Date**	**Graduate Program Director's Signature**

Note: The proposed research may NOT begin until a formal Letter of IRB Approval has been issued.