

I. Abstract Describing Project and Purpose: Briefly describe (a) the project or study, and (b) what human participants will experience during the proposed study or project. Describe all strategies or experimental methods to be used, design and program activities. Indicate what data, measures, or observations will be collected and used in the study or for the project. If any questionnaires, tests or other instruments are to be used, include a brief description and one copy of the instruments. **Special note to Grant Projects Directors:** In the case of educational or training grants, data collected about the participants served, assessment testing, pre and post testing and other aspects of project evaluation plans are critical.

II. Methodology: Specify who the project participants or research subjects will be. Indicate how they will be solicited, recruited, or contacted. Include any recruitment letters and materials with this document. State how much time will be required of each participant or subject. Describe procedures to which individuals will be subjected. Use additional pages if necessary.

III. Voluntary Participation: Specify the steps that will be taken to insure that each individual's participation is voluntary. State what, if any, inducements will be offered for their participation.

IV. Confidentiality of Data and Privacy Protection: Describe the methods to be used to safeguard the privacy of your participants, ensure the confidentiality of data obtained, including plans for publication, disposition and destruction of data, including that of computer, print, videotape and audio materials. Include a security plan for web based or online survey data.

V. Informed Consent: Attach a copy of all consent forms to be signed by the participants and/or any statements to be read to or provided to the participant.

VI. Risks to Participants: Describe a) any potential risks to participating individuals– physical, psychological, social, legal, or other; b) Include all known and anticipated risks to the participants such as side effects, risks of placebo (inert) treatments, etc.; and c) In research that proposes substantial risk to human participants, list emergency backup procedures that are in place such as medical or counseling interventions.

VII. Benefits: (a) Describe the benefits /or any compensation that the participating individuals can expect, and (b) describe the gains in knowledge that may result from the project or research study.

VIII. Human Subjects Research Protection Exemption Categories: Federal law 45 CFR 46.101(b) identifies the six (6) EXEMPT categories listed below using the language found in the legislation... *Check all that apply to your project or study and explain why your proposed project or study falls into the category.*

NOTE: The exemptions at 45 CFR 46.101(b) do not apply to research involving prisoners, fetuses, pregnant women, or human in vitro fertilization. The exemption at 45 CFR 46.101(b)(2), for research involving survey or interview procedures or observation of public behavior, does not apply to research with children, except for research involving observations of public behavior when the investigator(s) do not participate in the activities being observed.

Special Note to Grant Project Directors:

In most cases, your grant projects are not what we traditionally think of as research studies. Nevertheless, the participant data, pre and posttests of student learning, and other information you generate, compile, analyze, and report on in carrying out project activities and project evaluation are now considered Human Subjects Research by federal funding agencies. As you review the exemption categories listed below, think about the data you are collecting and reporting for the participants you serve and other data you will be using for project evaluation purposes.

(1.) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

Please provide an explanation as to how your research falls into this category:

(2.) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) Information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; AND (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

Please provide an explanation as to how your research falls into this category:

(3.) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if: (i) The human subjects are elected or appointed public officials or candidates for public office; or (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

Please provide an explanation as to how your research falls into this category:

(4.) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

Please provide an explanation as to how your research falls into this category:

(5.) 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: a) Public benefit or service programs; b) procedures for obtaining benefits or services under those programs; c) possible changes in or alternatives to those programs or procedures; or d) possible changes in methods or levels or payment for benefits or services under those programs.

Please provide an explanation as to how your research falls into this category:

(6.) Taste and food quality evaluation and consumer acceptance studies, a) if wholesome foods without additives are consumed or b) if a good 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 Inspective Service of the U.S. Department of Agriculture.

Please provide an explanation as to how your research falls into this category:

Attachments: Attach all that apply to your proposal. (Check the ones you've included with proposal.)

- Informed Consent Form(s): first page (s) on letterhead
- External support proposal or award letter
- Letters of approval from cooperating entities
- Research methods (research design, data source, sampling strategy, etc)
- Questionnaires, surveys, or other data gathering forms
- Letters, flyers, questionnaires, etc. which will be distributed to the study subjects

- Copy of thesis/dissertation approved proposal or prospectus
- If the research is part of a research proposal submitted for federal, state or external funding, submit a copy of the FULL proposal.
- If this is dissertation research, attach the IRB approval from the sponsoring University (that awards the doctoral degrees).

Notes:

- 1) The information should be in sufficient detail to allow the IRB to make a determination under Federal Regulations 45 CFR 46.101(b).

Certification and Signatures

In making this application, I certify that:

- 1) I have successfully completed the IRB Required Tutorial through CITI. Date completed (A current certificate of completion is attached. Successful completion requires an 80% pass rate on each section.)
- 2) I intend to comply with the directives and spirit of WWCC IRB.
- 3) I agree to comply with federal, state, and local laws regarding the protection of human participants in research.
- 4) I will submit any future changes to my research project to the IRB for review and approval prior to implementation, as these may alter the status of the project.
- 5) I agree that any new findings that develop during the course of this study that may affect the risks and benefits to participants will be promptly reported to the IRB in writing.
- 6) I agree that any adverse events that occur in the course of this study will be promptly reported to the IRB in writing.
- 7) I also agree and understand that records of the participants will be kept for at least six (6) years after the completion of the research.
- 8) I may begin research when the IRB gives notice of its approval.

Signature of Principal Investigator: _____ **Date:** _____ **Email:** _____

Printed Name:

Co-Investigator (Name): _____ **Email:** _____

Student Investigator (Name): _____ **Email:** _____

Approval by Faculty Sponsor (e.g., dissertation, thesis, special project) or Project Director. I confirm the accuracy of this application. I accept responsibility for the conduct of this research, the supervision of human participants, and the maintenance of informed consent documentation as required by the IRB.

Signature of Faculty Sponsor or Project Director: _____ **Date:** _____

Printed Name: _____ **Email:** _____

College Approvals

Before submitting the proposal to the IRB for review, the Principal Investigator will need to obtain approval to perform the research at each college specified in the application. The approval must be from the College Vice President of Academic Affairs (VPAA) or their Designee, and their signature affixed to the Investigator's application.

Approval by Nursing Program if your research involves the nursing program

(If nursing program is not involved, leave this section blank.)

I approve of this project, subject to WWCC IRB review for risks to human subjects.

Nursing Department Chair Signature: _____ Date: _____

Approval by the College Vice President of Academic Affairs (VPAA) or Designee:

I approve of this project, subject to WWCC IRB review for risks to human subjects. I reserve the college right not to participate in the project, or to withdraw participation from the project at any time. (Note: 1. VPAA approval does not commit the college to provide resources or data collection for the investigators. 2. IRB approval does not commit the college to participate in the project or to provide resources or data collection for the investigators. 3. If the IRB disapproves the study, the Investigators cannot conduct the study. However, they may revise and resubmit their proposal to the IRB.)

Vice President Academic Affairs (or Designee)

Signature: _____ Date: _____

For IRB OFFICE Use Only:

Year:

ID#:

This application has been reviewed by the WWCC IRB:

- Approved, Categories:**
- Approved, Subject to Restrictions:**
- Tabled (insufficient information for IRB to make a final decision)**
- Disapproved:**

Determination:

- Exempt: Criteria number:**
- Expedited: Criteria number:**
- Full board review:**

Authorizing Signature: _____

Date:

Printed Name: