Request for Study Exemption from IRB Review

Complete this form to request an exemption from IRB review. Only studies that fit into one or more eligible categories listed under **45 CFR 46.1010(b)** may be considered for an exemption. Studies that include the collection of sensitive information[1] or include special subject populations[2] are generally not eligible for an exemption. These studies require IRB review. Please complete an **IRB Application For Initial Review and Approval** form.

The UNE Assurance for the Protection of Human Subjects prohibits the start of any research (including recruitment of subjects or advertising) that has not been reviewed and approved or exempted by the IRB or its designee. Please sign this form and include a brief description of the research. Return these materials to the Research Compliance Office via email (irb@une.edu) for official assessment. The Primary Investigator and all key personnel, including Faculty Advisors, must complete the CITI Training module as a condition of IRB Approval or Exemption. Please submit a copy of your CITI completion certificate or report (http://www.citiprogram.org/) and those of key personnel, with your application (please see the section captioned "Additional Documentation" below).

Date of Review:	Principal Investigator:	College and Program:
Phone:	Email:	
Faculty Mentor:	Phone:	Email:
Title of Study or Project:		
Estimated Project Duration:	Start Date:	End Date:

To determine whether the research is eligible for exempt status or expedited review, complete this checklist. **If any of the answers are 'Yes", the research is not eligible** for either exempt status, or expedited review.

The research activities present more than minimal risk to human participants.	☐ Yes. ☐ No.
The research employs deception of research participants.	☐ Yes. ☐ No.
The research involves fetuses, pregnant women or human in vitro fertilization.	☐ Yes. ☐ No.
Identification of the participants or their responses may place them at risk of criminal or civil liability or may be damaging to their financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.	☐ Yes. ☐ No.

Is this research eligible for exemption from further IRB review?

1 **"Sensitive information" includes:**
   1. **Genetic information or**
   2. **Information that relates to**
      a. **sexual attitudes, preferences or practices; or**
      b. **the use of alcohol, drugs or other addictive products or**
      c. **illegal conduct; or**
   3. **Information that if released, could reasonably damage an individual's financial standing, employability, or reputation within the community; or**
   4. **Information that would normally be recorded in a patient's medical record and the disclosure of which could reasonably lead to social stigmatization or discrimination or**
   5. **Information that pertains to an individual's psychological well-being or mental health.**

2 **"Special subject population" includes:**
   1. Minors (under eighteen years of age).
   2. Fetuses or products of labor and delivery;
   3. Pregnant women (in studies that may influence maternal health);
   4. Prisoners;
   5. Individuals with a diminished capacity to give informed consent.

The research must involve ***only*** procedures listed in one or more of the following categories to be exempt from further IRB review. Select the category(ies) that apply to the research study, and include a brief explanation in the comment box(es).

Exempt Category 1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as: • Research on regular and special education instructional strategies, • Research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods. • If the research does not involve prisoners as subjects. • And, If the research is not FDA-regulated.	☐ Yes. Comment:
Exempt Category 2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, *unless*: • Information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and, • 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. • If the research involves prisoners as subjects. • And, if the research is FDA-regulated. NOTE: Category 2 DOES NOT APPLY to research involving survey or interview procedures or observation of public behavior when individuals under the age of 18 are subjects of the activity. *Except* for research involving observations of public behavior when the investigator(s) do not participate in the activities being observed.	☐ Yes. Comment:
Exempt 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 Category 2, if: • The human subjects are elected or appointed public officials or candidates for public office, or • Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter. • If the research does not involve prisoners as subjects. • And, if the research is not FDA-regulated.	☐ Yes. Comment:
Exempt 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. • If the research does not involve prisoners as subjects. • And, if the research is not FDA-regulated.	☐ Yes. Comment:

Checklist For Exempt Research, cont'd

Exempt Category 5. Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, andwhich are designed to study, evaluate, or otherwise examine: 1. Public benefit or service programs; 2. Procedures for obtaining benefits or services under those programs; 3. Possible changes in or alternatives to those programs or procedures; or 4. Possible changes in methods or levels of payment for benefits or services under those programs. • If the research will be conducted pursuant to specific federal statutory authority. • If the research has no statutory requirements for IRB review. • The research does not involve significant physical invasions or intrusions upon the privacy interests of participant. • The research has authorization or concurrence by the funding agency. • If the research does not involve prisoners as subjects. • And, if the research is not FDA-regulated.	☐ Yes. Comment:
Exempt Category 6. Taste and food quality evaluation and consumer acceptance studies, if • Wholesome foods without additives are consumed, or • 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 orenvironmental 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. • If the research does not involve prisoners as subjects. **Note: Any other (non-emergency) research subject to FDA regulation cannot be exempt.**	☐ Yes. Comment:

Note: If none of the exempt categories apply to this research, IRB review is required. In that case, please complete the **IRB Application For Initial Review and Approval**

Additional Documentation

11. Please attach a brief summary (2-3 pages maximum) of your research proposal. Be sure to include copies of the instruments used for data collection such as questionnaires and consent forms. Use the headings listed below and provide a separate document, labeled as Research Proposal Summary.

A. Introduction
B. Specific Aims
C. Methods of Data Collection and Analysis (Qualitative and Quantitative)
D. Description of the subject population, research setting, subject recruitment procedures
E. Informed Consent
F. Provisions for subject and data confidentiality
G. Statement of potential research risks to subjects (e.g. breach of confidentiality, treatment complications)
H. Statement of potential research benefits to subjects (Monetary compensation is not a benefit of participation)
I. Investigator experience – attach a current copy of your C.V. or resume. We do not keep copies on file