Request for Exemption from IRB Review

**Proposals must be typed: No Handwritten proposals will be accepted.**

1. Title of Project

2. Contact information

   Principal Investigator (PI)
   Name
   Email address
   College/Division
   Department/Unit

   Choose Status

   ___Undergraduate Student
   ___Graduate Student
   ___Faculty
   ___Staff

3. Co-Principal Investigator and members of the research team:

   Name
   Email
Part 2 - Exemption Category Self-Assessment

While IRB is ultimately responsible for deciding if research qualifies for exemption, investigators are asked to make an initial determination of the appropriate exemption category. Please select all the categories that apply from the list below.

Note: Research projects involving prisoners or the collection of biological samples cannot be granted exemption.

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

____(2) Research involving one or more of the following:

i. Educational tests (cognitive, diagnostic, aptitude, achievement):
   a. If the information is recorded in a manner that individuals cannot be identified (directly or through identifiers linked to the individual), OR
   b. If the information may be recorded in a manner that individuals can be identified (directly or through identifiers linked to the individual), but disclosure of the information could NOT reasonably place the participants at risk of criminal or civil liability or be damaging to their financial standing, employability, or reputation.*

ii. Survey or interview procedures (this exemption category does not apply to research activities with minors/children):
   a. If the information is recorded in a manner that individuals cannot be identified (directly or through identifiers linked to the individual), OR
   b. If the information may be recorded in a manner that individuals can be identified (directly or through identifiers linked to the individual), but disclosure of the information could NOT reasonably place the participants at risk of criminal or civil liability or be damaging to their financial standing, employability, or reputation.*

iii. Observation of public behavior:
For minors/children: Observation of public behavior of minors is eligible for exemption only if the researcher does not participate in the activities being observed.

For non-minors: Generally considered exempt from IRB review as follows:

a. If the information is recorded in a manner that individuals cannot be identified (directly or through identifiers linked to the individual), OR

b. If the information may be recorded in a manner that individuals can be identified (directly or through identifiers linked to the individual), but disclosure of the information could NOT reasonably place the participants at risk of criminal or civil liability or be damaging to their financial standing, employability, or reputation.*

Note: Risks of criminal or civil liability or of damage to financial standing, employability, or reputation can be dependent on the context of the research and are determined by the IRB staff based on experience, past precedent and bench marked best practices. The IRB staff welcomes the input of investigators in determining the possibility of such risks, but if there is reasonable doubt about whether or not criteria b. applies, the research is not exempt.

Note: Exemption category #2 does not apply to research with children, unless the research is exclusively limited to activities described in 2.i (educational tests) and/or 2.iii (observation of public behavior and the investigators do not participate in or manipulate the activities being observed).

(3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior, but is not eligible for the above exemption (2), can be exempted if the research participants are elected or appointed public officials or candidates for public office, or federal statute requires that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

(4) Research involving the collection or study of existing (i.e., existing before the request for exemption is submitted to determine whether the research is exempt) data, documents, records, pathological specimens, or diagnostic specimens:

i. If these sources are publicly available;

OR
ii. If the sources are not publicly available, but the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.**

_(5) Research and demonstration projects that are conducted by or subject to the approval of federal department or agency heads, and are designed to study, evaluate, or otherwise examine public benefit or service programs, 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._

_(6) Taste and food quality evaluation and consumer acceptance studies:_

i. If wholesome foods without additives are consumed, OR

ii. 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 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.

**Part 3 - Study Design, Methods and Procedures**

1. Type of project/study: Please select ALL of the categories of work that apply to this proposed project.

- [ ] Active collection of data (not human biological materials or biomedical procedures).
- [ ] Use of existing data (not human biological materials)
- [ ] Use of existing human biological materials

2. Please provide a summary of the study, including the purpose and the research questions and hypothesis to be evaluated.

3. Please describe briefly how this study will contribute to existing knowledge in the field.

Active collection of data (not human biological materials or biomedical procedures). Please select ALL the methods of data collection that will be employed in this study (select all that apply)

- [ ] In person interviews
- [ ] Paper surveys
- [ ] Telephone surveys
___ Internet surveys (including online and email based data collection)
___ Use of Social Networking Sites
___ Data collected using other communication/electronic devices (e.g., cell phones, pagers and texting devices)
___ Observation
___ Cognitive or behavioral measures, including daily diaries (Note- if surveys will also be administered, please select the appropriate option above.)
___ Focus groups
___ Audio/Video recording
___ Anthropometric measures (e.g., height, weight, waist circumference, etc.)
___ Self health monitoring (e.g., pedometers, food diaries, etc.)
___ Other activities or interventions

Please provide details of all the procedures selected above. If none are selected, enter N/A.

Please select ALL the geographical locations where data will be collected (select all that apply)
___ Ohio
___ Other US territories and states, specify
___ International location, specify

Please select ALL the specific locations where data will be collected (select all that apply)
___ Participants’ homes
___ Elementary, secondary or high school, specify_________________________________________
___ Lake Erie College campus, specify location______________________________________________
___ Other university campuses, specify_____________________________________________________
___ Hospitals, specify___________________________________________________________
___ Community clinics, specify____________________________________________________________
___ Prisons/halfway houses, specify________________________________________________________
___ Nursing homes, specify________________________________________________________________
___ Other locations, specify________________________________________________________________

**Part 4 - Participants, Recruitment and Compensation**
1. Please indicate the estimated number of participants you plan to recruit.
2. Please provide the age range of the participants.
3. Please select all the categories of participants that will be included in your study.
___ Adult Volunteers
Children under 18
Lake Erie College students
Lake Erie College employees
None of the above, specify

4. Please select all of the tools that you plan to use to recruit your participants.

Flyers
Notices
Mailers (U.S. Post)
Online Advertisements
Email
Use of Internet social media or online networking sites
TV, radio, print advertisements
Face to face public intercept
Presentations at meetings
Other (Please describe below)

5. Please describe each recruitment method to be used.

6. Describe the inclusion or exclusion criteria for participants as applicable in this study.

7. Will participants be compensated for their participation? Yes No

If yes, describe

8. Please describe the tasks that the participants will be asked to perform for each phase of the study.

9. Please provide an estimate of the time commitment from each participant for each phase of the study.

Part 5 - Privacy and Confidentiality
1. Will you or any member of your research team collect or have access to any of the personal identifiers listed below? Select all that apply.

Name
Date of birth
Mailing or email address
Phone or fax numbers
Social Security number: Why is this needed?

Medical records
License, certificate or Vehicle ID
Biometric identifiers
Photos/images/audio recording
Signatures, handwriting samples
Any unique identifiers not mentioned above, specify.

No member of the research team will have access to any personal identifiers.

**This option is valid only if none of the other options in this question are selected.

Part 6 - Informed Consent Process
Please indicate the informed consent process(es) and/or document(s) to be used in the study. Click here for a Consent Template that you can modify to use for your study. Check all that apply. Provide copies of documents, as applicable.

Not Applicable (existing data or specimens)
Informed Consent – form Informed Consent – oral script/online/unsigned
Assent (participants under 18) – form Assent – oral script/online/unsigned
Parental Permission – form Parental Permission – oral script/online/unsigned
Translated Consent/Assent – form(s), script(s), Other – please explain below
Debriefing script

Describe the consent process. Explain when and where consent will be obtained:

You have now completed this form. Please review it to ensure that it is filled out completely and accurately.
This page is to be signed by the principal investigator. If the principal investigator is an undergraduate or graduate student, the faculty supervisor must also sign.

Principal Investigator,

I certify that the information I provide in this application is correct and complete. I also pledge that I will not change any of the procedures, forms, or protocols used in this study without first seeking review and approval from the Institutional Review Board for Human Participants.

__________________________________________________________________
Student Signature                                                                 Date
__________________________________________________________________
Faculty Signature                                                                 Date

For IRB Committee Use Only:

_____Proposal is exempt from IRB review

_____Proposal is NOT exempt from IRB review for the following reasons:

_____IRB Research Proposal Form must be submitted and approved before any research can be conducted.