UA IRB EXEMPTION REQUEST: PROCEDURES AND APPLICATION INSTRUCTIONS

Research activities in which the only involvement of human subjects will be in one or more specified categories are exempt from the Federal Policy for the Protection of Human Subjects. **Please review the Screening Questions, available on the IRB website or in the IRB Applicant Manual, to determine if your study falls into one of these exempt categories.**

Although certain research activities are exempt from review, the Institutional Review Board (IRB) still must certify that the research meets the exemption criteria requirements. Consequently, the IRB has developed the exemption request mechanism to facilitate the approval process for qualifying projects.

The preliminary determination that a research project is eligible for exemption is made by the investigator. This judgment should be made with care, after reviewing the Screening Questions. If the IRB reviews the Exemption Request and determines that exemption is not appropriate, a full application will be required. Questions of interpretation may be directed to the Office of Research Administration at (330) 972-7666 or at irb@uakron.edu.

0nce a research study has been certified as "exempt," continuing review is not required, unless changes are made that would disqualify the study for exemption. It is the investigator's responsibility to notify the IRB if any changes or modifications are made in the study's design, procedures, etc. which do not fall within one of the categories exempted from the regulations.

Exempting an activity from review does not absolve the investigator(s) from ensuring that the welfare of the subjects participating in the research is protected and that methods used and information provided to gain subject consent are appropriate to the activity. Furthermore, exempt studies may still need to comply with guidelines and ethics codes of academic disciplines.

All researchers and faculty advisors must either have an Investigator Certification on file with the IRB or complete the on-line CITI investigator training. All researchers must complete the CITI training before research with human subjects at any level will be approved.

Below are instructions for preparing an IRB Exemption Request:

1. Complete and submit the form electronically to irb@uakron.edu . **THIS FORM MUST BE TYPED.**

2. The Exemption Request must be signed by the investigator. If the research is being conducted by a student, the student's faculty advisor must also sign the Exemption Request.

3. A complete application will include the Exemption Request Form with attachment that provides the information requested in item 1, and the materials listed below, as applicable, and collated in the following order:

   a) Subject recruitment materials
   b) Copies of any questionnaires, interview questions or assessment scales given to participants
   c) Informed consent form(s) or information about study involvement to be given to participants
   d) Documentation of approval from off-campus sites
   e) If the research is supported by an external or internal funding agency or program, a copy of the grant proposal or contract must also be submitted with the exemption request.

4. The IRB Administrator will review the exemption request and either approve or request submission of a full IRB application. If exemption is not approved, the researcher will be informed of the reason(s).

5. If exemption is not approved, submit the IRB application for review.

6. The Office of Research Administration will notify the investigator of the outcome of the review.

(DO NOT SUBMIT THIS PAGE)

IRB # _____

THE UNIVERSITY OF AKRON
EXEMPTION REQUEST FORM

Title of Research Project:	
Principal Investigator:	**Co-Investigator**:
Address*: *Students – provide complete home address	**Address***: *Students – provide complete home address
UA Department & +4Zip:	**UA Department & +4Zip**:
College:	**College**:
Phone:	**Phone**:
Email:	**Email**:
Status: Select One	**Status**: Select One

Advisor (if student PI):	**Advisor Phone:**
Advisor Department & +4Zip:	**Advisor e-mail**:
Sponsor/Funding Agency (if funded):	
If this protocol is for a consortium program class, thesis, dissertation, etc. (e.g. joint MSW, MPH, Nursing, Au.D. or Sociology), please indicate the program and collaborating university(ies):	
Anticipated Start date:	**Anticipated End date:**

1. On a separate sheet, answer the following questions. Number your responses 1a, 1b, etc.

a. Provide a brief description of the purpose of the proposed project and the procedures to be used. What will research subjects be asked to do? How long will it take?

Do not answer 1b – 1h if you are applying for Exemption 4 (secondary data).

b. Provide the process by which individuals will be recruited. Describe any qualifying characteristics of the subject population such as gender, age ranges, ethnic background and health status. Indicate any special classes of subjects that might be included in the study population (e.g., socially or economically disadvantaged, minors, mentally disabled.) Estimate the number of subjects to be recruited.

c. Where will data collection take place (e.g. university, outside agency, school district, hospital, etc) and who will collect the data? Attach letter(s) of authorization to perform the research from all off-campus sites.

d. Describe any potential risks - physical, psychological, economic, social, legal or other. Indicate how you will eliminate or reduce any potential risks to subjects. ***Only minimum risk research is eligible for exemption***.

e. Describe any potential benefits of the research to subjects or to society.

f. Explain how individual privacy will be protected. For example, if interviewing, where will that be conducted?

g. Explain how individual confidentiality or anonymity will be protected. What kind of information will be recorded and how will it be protected? Who will have access to the data and where will it be kept? Will any identifying information be included in publications or presentations of the research?

h. Describe your consent procedures. Provide justification if you do not plan to collect a signed consent from each participant. (Provide a copy of the consent form or information sheet you will provide to participants.)

Answer 1i – 1l only if you are applying for Exemption 4 (secondary data).

i. Describe the database or data to be analyzed (e.g., national database; publicly available information; medical, educational or research records; video or audiotapes.) If publicly available, please give name of database and identify the holder of the data. If not, provide documentation that you have permission to access the data.

j. Briefly describe how and when these data were originally collected, including the sampling strategy and number of cases. If unknown, please state. ***All data must have been collected prior to the start of the research in order for it to qualify for exemption 4.***

k. How many cases will be analyzed in the current study?

l. Will analysis involve sub-groupings so that the responses of individuals or small groups of individuals are potentially identifiable?

Check the exemption category for which you are applying:

☐ **Exemption 1**
Research conducted in established or commonly accepted educational settings, involving normal educational practices.

☐ **Exemption 2**
Research involving the use of **educational tests** (cognitive, diagnostic, aptitude, achievement), **survey** procedures, **interview** procedures or **observation** of public behavior.

☐ **Exemption 3**
Research not exempt under Exemption 2, if the subjects are elected or appointed public officials or candidates for public office; or federal statute requires without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

☐ **Exemption 4**
Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens (secondary data).

☐ **Exemption 5**
Research and demonstration projects which are conducted by or subject to the approval of department or agency heads.

☐ **Exemption 6**
Taste and food quality evaluation and consumer acceptance studies.

ATTACHMENTS - Please include as applicable:

☐ Instruments to be used for data collection (surveys, interview questions, scales, etc.)
☐ Scripts of verbal instructions
☐ Informed consent and assent form(s)
☐ Grant proposal
☐ Permissions to use/collect data from off campus sites

Investigator Assurance:

I certify that the information provided in this application is complete and correct. I understand that as Principal Investigator, I have ultimate responsibility for the protection of the rights and welfare of human research participants, the conduct of the study, and the ethical performance of the project.

I agree to comply with all University of Akron policies and procedures, as well as with all applicable federal, state and local laws regarding the protection of human research participants. I also certify that I have completed the CITI Core Training as well as any additional required modules.

_____ _____

Principal Investigator Date

Co-Investigator / Research Staff Assurance

All co-investigators & research staff who will interact with participants and/or have access to identifiable private data must also complete training and sign this assurance.

I agree to comply with all University of Akron policies and procedures, as well as with all applicable federal, state and local laws regarding the protection of human research participants. I also certify that I have completed the CITI Core Training as well as any additional required modules.

_____ _____

Co-Investigator /Staff Date Co-Investigator /Staff Date

Advisor Assurance:

By my signature below, as advisor to the student(s) performing research with human participants, I certify that I:

- will consult with the student investigator on a regular basis to monitor study progress;
- will be available to assist the student investigator should problems arise in the study;
- will forward to the IRB in writing any information related to an adverse event immediately upon my knowledge of the event;
- have completed the CITI Core Training for social & behavioral research, as well as any additional required modules.

_____ _____

Advisor Date

FOR IRB USE ONLY

☐ Exemption Request Approved under category _____ ☐ Exemption denied

Revisions / Additional Information Required:

_____

Reviewer signature: _____ Date: _____ ☐ Consent form