IRB # _____

THE UNIVERSITY OF AKRON INSTITUTIONAL REVIEW BOARD

APPLICATION FOR RESEARCH INVOLVING HUMAN SUBJECTS

Please check all attachments that are included with this application:

Mandatory:
- ☐ Short summary of project (1-2 pages)
- ☐ Copies of any information to be presented to participants

As applicable:
- ☐ Informed consent and assent forms (on department letterhead)
- ☐ Surveys, questionnaires, interview or focus group questions
- ☐ Testing and experimental scenarios and materials
- ☐ Script(s) of verbal instructions and debriefing information

All materials must be submitted electronically to irb@uakron.edu.

If you have any questions about this form, please contact the IRB at 330-972-7666 or irb@uakron.edu. If your responses will not fit in the space allotted, please use additional sheets as needed.

Title of Research Project:

Principal Investigator

Name:		
Status: Select One	**Email**:	
Address: *Students: provide complete home address; faculty: provide office location (building/room)*		
College:	**Department**:	
Phone:	**Fax**:	**+4 zip:**

Co-Investigator #1 – use additional sheets if more than 1 co-investigator

Name:		
Status: Select One	**Email**:	
Address: *Students: provide complete home address; faculty: provide office location (building/room)*		
College:	**Department**:	
Phone:	**Fax**:	**+4 zip:**

Advisor – if PI is a student

Name:		**Phone:**
Department:	**+4 zip:**	**Email:**
Advisor's Institution, if not UA:		

Is this protocol being developed for a consortial program class, thesis, dissertation, etc. (e.g. the joint MSW with Cleveland State University; MPH with other NE Ohio universities; joint PhD in Nursing with Kent State University; Doctor of Audiology (Au.D) with Kent State University)? ☐Yes ☐No

If yes, provide the program and collaborating universities:

Protocol Funding Status: Select One

If funded, is it federal? Select One

If externally funded, agency:

Please answer all of the following questions – if not applicable to your project, write in "NA", if repeated in a previous answer write "see #___."

Section I: Research Methodology

1. Describe the purpose and significance of the research, including your specific aims and research question. Please summarize the major hypotheses only.

2. Identify the basic design of the study (i.e. randomized-controlled trial, experiment, quasi-experiment, survey, secondary analysis of data, ethnographic study, grounded theory, etc.).

3. Describe the characteristics of your study population and your recruitment procedures. **Give the desired sample size** and provide a justification for it.

4. Describe all procedures that you will use. What will you ask participants to do?

5. For each variable included in the research questions and hypotheses, please list the measurement instrument(s).

Section II: Risks and Benefits

6. Identify the risks and/or discomforts (current and potential) to the participants and describe the expected frequency, degree of severity, and potential reversibility of the risks. Be sure to consider physical, psychological, social, legal and economic risks.

7. Describe the precautions taken for protecting against and/or minimizing these risks. Describe procedures for ensuring necessary intervention in the event of negative reactions by participants. If including vulnerable populations, describe the methods you will use to provide the special protections to which these groups may be entitled under federal regulations. See 45 CFR 46 Subparts B (pregnant women), C (prisoners) and D (children). (Counseling referral information should be provided to subjects if the research could provoke a disturbing response.)

8. List the anticipated benefits to the participants of this research project. If none, state that here and in your consent form. Please note: provision of compensation or course credit should not be considered a benefit of participation. Also, if you are evaluating a program or intervention, do not include the benefits of participation that would have occurred anyway.

9. Does the research involve (check all that apply):

☐ Use of private records (***check type(s) to be used***: ☐ medical ☐ educational ☐ financial)
☐ Possible invasion of privacy of subject or subject's family (such as medical, financial, sexual information)
☐ Deprivation of physiological requirements such as nutrition or sleep
☐ Collection of sensitive information in surveys or interviews (such as illegal activities, sexuality)
☐ Presentation of materials that subjects might consider offensive, threatening or degrading
☐ Changes in diet or exercise
☐ Infectious or hazardous materials
☐ Potential risk to employability or financial standing
☐ Invasive medical procedures other than blood draw
☐ Blood draw (cc will be drawn)
☐ Other risks. Please specify:

10. Vulnerable populations to be targeted in the research (check all that apply):

☐ Minors under 18
☐ Pregnant women
☐ Fetuses; use of fetal tissue
☐ Prisoners/arrestees
☐ Traumatized or comatose
☐ Other (please specify):
☐ Economically disadvantaged
☐ Cognitively/mentally impaired
☐ Institutionalized
☐ Seeking emergency treatment
☐ Terminally ill

11. Does the research involve deception? ☐ Yes ☐ No
If yes, please provide the rationale and describe debriefing procedures. Attach debriefing information. If not providing debriefing, please give rationale.

Section III: Subject Selection

12. Age Range:
    - ☐ 0-7 years
    - ☐ 8-17 years
    - ☐ 18-64 years
    - ☐ 65+ years

13. Source of participants *(check all that apply)*:
    - ☐ UA students, staff, faculty
    - ☐ Volunteers not affiliated with UA
    - ☐ Other; please specify:

14. Does the research require inclusion or exclusion of subjects based on their gender, ethnicity or some other criterion? ☐ Yes ☐ No
    If Yes, describe the scientific rationale for including or excluding these subjects:

15. Where will data collection take place (e.g. university, agency, school district, hospital, etc) and who will collect the data? (Attach letter of authorization from the agency to perform research if location is off campus. In addition, please forward a copy of IRB approval from the agency if it has an IRB.)

Section IV: Informed Consent Process

16. Describe the process you will use to recruit participants, inform them of their role in the study, and obtain their informed consent. See the UA IRB Applicant Manual and sample consent forms online for guidance. Please attach a copy of your informed consent form(s) with this application. Make sure the forms you are using contain the correct IRB contact information and are printed on your UA Department letterhead.

17. If applicable, describe the procedures you will use to obtain and document (a) informed consent from parents/guardians and (b) assent for children between 7 years of age and up to 18 years of age or persons of any age who have a legal guardian. Please attach copies of all forms.

18. Describe any compensation (money, gift certificates, course credit, gifts) that will be offered to participants including how the compensation will be prorated for participants who discontinue participation prior to completion. Include information on when the compensation will occur (at end of the study, after each interview, etc.) and how it will be delivered.

19. Are you going to collect a signed consent form from each participant? ☐ Yes ☐ No

If you checked "No", the IRB must approve a waiver of documentation of informed consent. Please indicate which of the following justifications is being used to request approval for this waiver.

☐ The only record linking the subject and the research would be the signed consent document and the principal risk or harm of the research would be a breach of confidentiality.

☐ The research involves no more than minimal risk or harm to the subject and involves no procedures for which written consent is normally required outside of the research context.

If waiver of documentation of informed consent is requested, the investigator must provide subjects with a written statement regarding the research, which contains all required elements of informed consent – unless waiver or alteration is requested and approved under #20 below. A copy of this statement must be provided with your application.

20. Are you requesting a waiver or alteration of some or all of the required elements of informed consent (**other than waiver of documentation**)? ☐ Yes ☐ No

If yes, you must provide protocol specific justification for **all** of the following four criteria. A waiver may be requested for the entire study, or for a portion of the research.

a. Please explain why you believe the proposed research (or portion of the research) will present no more than minimal risk to the participants:

b. Please explain whether or not a waiver of written informed consent would adversely affect the rights and welfare of participants:

c. Please explain whether or not it would be possible to conduct this research without a waiver or alteration of written informed consent:

d. Please explain your plans, if appropriate, for providing any pertinent information about the research to the subjects at a later date:

Section V: Privacy and Confidentiality

21. Will this study require the use or disclosure of protected health information from a covered entity as defined in the HIPAA Privacy Rule? Please check the applicable box below and attach the appropriate document if protected health information will be used:

☐ Not Applicable
☐ Applicant will use a HIPAA Authorization
  ☐ Form provided by covered entity ☐ Form created by applicant using UA HIPAA guidelines
☐ Applicant requests an IRB waiver of Authorization
☐ Applicant will use a limited data set & data use agreement

Please contact the Office of Research Administration (330-972-7666) if you are unsure if HIPAA regulations apply to your project.

22. Will the results of this study be publicly disseminated (public presentation, masters thesis, doctoral dissertation, publication)? ☐ Yes ☐ No If yes, please indicate form of dissemination below:

23. Describe provisions made to maintain anonymity and/or confidentiality of subject responses and data. Consider where data will be kept and for how long. How will data be secured and who will have access to the data? How will you dispose of the data? (Subject identifiable information may include audiotapes, videotapes, a match list of subject names and code numbers, etc.)

24. Will responses or data **that identify subjects** be made available to anyone other than the principal investigator and the research team (such as the sponsor of the research, school district personnel, consultants, Food and Drug Administration)? ☐ Yes ☐ No

    If Yes, please identify and explain the rationale for this disclosure:

25. Do you intend to follow subjects after the end of the project? ☐ Yes ☐ No If Yes, please explain: (If follow-up contact is planned, be sure to include that information in your consent form)

Section VI: Conflict of Interest

26. Do the researchers conducting this protocol have any potential conflicts of interest? A potential conflict of interest may arise if you anticipate financial rewards such as additional employment (i.e. second job), gifts, consultant agreements, stock options, ownership or equity in a company, royalties, etc. to be offered based on the research outlined in this application. ☐ Yes ☐ No

    If yes, please explain:

Principal 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 certify that:

- No changes will be made to the protocol or consent form unless approved by the UA IRB.
- Legally effective informed consent will be obtained from human research participants unless a waiver has been approved by the IRB.
- Adverse events will be reported to the UA IRB in writing within 48 hours of the event.
- 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

_____ _____ _____ _____

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 agree:

- to consult with the student investigator on a regular basis to monitor study progress;
- to be available to assist the student investigator should problems arise in the study;
- to forward to the IRB in writing any information related to an adverse event immediately upon my knowledge of the event.

I also certify that I have completed the CITI Core Training for social & behavioral research, as well as any additional required modules.

_____ _____

Advisor Date