

IRB Number _____

Please Do Not Staple

OHIO UNIVERSITY
INSTITUTIONAL REVIEW BOARD (IRB)
PROJECT OUTLINE FORM

Title of Research Proposal _____

Investigator(s) Information

Primary Investigator

Name _____ Department _____

Address _____

(If off-campus, include city, state and zip code)

Email _____ Phone _____

Training Module Completed? Yes No (Attach Certificate as Appendix H)

(<http://cscwww.cats.ohiou.edu/research/compliance/citiprogram.html>)

Co-investigators

Name _____ Department _____

Address _____

(If off-campus, include city, state and zip code)

Email _____ Phone _____

Training Module Completed? Yes No (Attach Certificate as Appendix H)

Attach sheets for additional co-investigators if necessary, and check here

Advisor Information (if applicable)

Name _____ Department _____

Address _____ Phone _____

Email _____

Please refer to Guidelines for assistance in completing the form.

Training Module Completed? Yes No

(Attach Certificate as Appendix H)

Please refer to Guidelines for assistance in completing the form.

Anticipated Starting Date _____ Duration _____ mos _____ yrs
(Work, including recruitment, **cannot** begin prior to IRB approval. This date should **never** precede the submission date)

Funding Status

Is the researcher receiving or applying for external funding? Yes No
(Note - This refers to funding from entities outside of Ohio University)

If yes, list source _____
(NOTE - If an application for funding has been submitted, a FULL copy of the funding application must accompany this form as APPENDIX G)

If yes, describe any consulting or other financial relationships with this sponsor.

Is there a payment of any kind connected with enrollment of participants on this study that will be paid to persons other than the research participants?
 Yes No

(If yes, describe.)

Review Level

Based on the definition in the guidelines, do you believe your research qualifies for:
____ Exempt Review Category _____
____ Expedited Review Category _____
____ Full Committee Review

Final determination of review level will be determined by Office of Research Compliance in accordance with the categories defined in the Code of Federal Regulations

Prior Approval

If this or a similar protocol been approved by OU IRB or any other, please attach copy of approval and label as Appendix E.

Recruitment/Selection of Subjects

Estimated Number of Human Participants _____

Characteristics of subjects (check as many boxes as appropriate).

- ___ Minors ___ Physically or Mentally Disabled ___ Elementary School Students
- ___ Adults ___ Legal Incompetency ___ Secondary School Students
- ___ Prisoners ___ Pregnant Females ___ University Students
- ___ Others (Specify) _____

Briefly describe the criteria for selection of subjects (inclusion/exclusion). Include such information as age range, health status, etc. Attach additional pages if necessary.

Please refer to Guidelines for assistance in completing the form.

How will you identify and recruit prospective participants? If subjects are chosen from records, indicate who gave approval for the use of the records. If records are "private" medical or student records, provide the protocol, consent forms, letters, etc., for securing consent of the subjects for the records. Written documentation for cooperation/permission from the holder or custodian of the records should be attached. (Initial contact of subjects identified through a records search must be made by the official holder of the record, i.e. primary physician, therapist, public school official.)

Please describe your relationship to the potential participants, i.e. instructor of class, co-worker, etc. If no relationship, state no relationship.

Attach copies of all recruitment tools (advertisements, posters, etc.) and label as APPENDIX B

Performance Sites

List all collaborating and performance sites, and provide copy of IRB approval from that site and/or letters of cooperation or support.

Please refer to Guidelines for assistance in completing the form.

Project Description

Please provide a brief summary of this project, using non-technical terms that would be understood by a non-scientific reader. Attach an additional page, if needed, but please limit this description to no more than one typewritten page.

Please describe the specific scientific objectives (aims) of this research and any previous relevant research.

Please refer to Guidelines for assistance in completing the form.

Methodology: please describe the procedures (sequentially) that will be performed/followed with human participants.

Please refer to Guidelines for assistance in completing the form.

Describe any potential risks or discomforts of participation and the steps that will be taken to minimize them.

Describe the anticipated benefits to the individual participants. If none, state that. (Note that compensation is **not** a benefit, but should be listed in the compensation section on the next page.)

Describe the anticipated benefits to society and/or the scientific community. There must be some benefit to justify the use of human subjects.

Please refer to Guidelines for assistance in completing the form.

Describe procedures in place to protect confidentiality. Who will have access to raw data? Will raw data be made available to anyone other than the Principal Investigator and immediate study personnel (e.g., school officials, medical personnel)? If yes, who, how, and why? Describe the procedure for sharing data. Describe how the subject will be informed that the data may be shared.

Will participants be: Audiotaped?

- Yes
- No

Videotaped?

- Yes
- No

If so, describe how/where the tapes will be stored (i.e. locked file cabinet in investigator office), who will have access to them, and at what point they will be destroyed.

Provide details of any compensation (money, course credit, gifts) being offered to participants, **including** how the compensation will be prorated for participants who discontinue participation prior to completion.

Please refer to Guidelines for assistance in completing the form.

Instruments

List all questionnaires, instruments, standardized tests below, with a brief description, and provide copies of each, labeled as APPENDIX C.

How will the data be analyzed? State the hypothesis and describe how the analysis of the data will test that hypothesis.

Please refer to Guidelines for assistance in completing the form.

Informed Consent Process

Attach copies of all consent documents or text and label as

APPENDIX A.

Informed consent is a process, not just a form. Potential participants/representatives **must** be given the information they need to make an informed decision to participate in this research. How will you provide information/obtain permission?

How and where will the consent process occur? How will it be structured to enhance independent and thoughtful decision-making? What steps will be taken to avoid coercion or undue influence?

Will the investigator(s) be obtaining all of the informed consents? Yes No

If not, identify by name and training who will be describing the research to subjects/representatives and inviting their participation?

Will all adult participants have the capacity to give informed consent? If not, explain procedures to be followed.

If any participants will be minors, include procedures/form for parental consent and for the assent from the minor.

Are you requesting a waiver or alteration of Informed Consent? Yes No

An IRB may approve a consent that does not include, or alters, some or all of the elements of *Please refer to Guidelines for assistance in completing the form.*

Will participants be deceived or incompletely informed regarding any aspect of the study?

Yes

No

If so, provide rationale for use of deception.

Attach copies of post-study debriefing information and label as APPENDIX D.

Please refer to Guidelines for assistance in completing the form.

Investigator Assurance

I certify that the information provided in this outline form is complete and correct.

I understand that as Principal Investigator, I have ultimate responsibility for the protection of the rights and welfare of human subjects, conduct of the study and the ethical performance of the project.

I agree to comply with Ohio University policies on research and investigation involving human subjects (O.U. Policy # 19.052), as well as with all applicable federal, state and local laws regarding the protection of human subjects in research, including, but not limited to the following:

- The project will be performed by qualified personnel, according to the OU approved protocol.
- No changes will be made in the protocol or consent form until approved by the OU IRB.
- Legally effective informed consent will be obtained from human subjects if applicable, and documentation of informed consent will be retained, in a secure environment, for three years after termination of the project.
- Adverse events will be reported to the OU IRB promptly, and no later than within 5 working days of the occurrence.
- All protocols are approved for a maximum period of one year. Research must stop at the end of that approval period unless the protocol is re-approved for another term.

I further certify that the proposed research is not currently underway and will not begin until approval has been obtained. A signed approval form, on Office of Research Compliance letterhead, communicates IRB approval.

Principal Investigator Signature _____ **Date** _____

Co-Investigator Signature _____ **Date** _____

Please refer to Guidelines for assistance in completing the form.

Faculty Advisor/Sponsor Assurance

By my signature as sponsor on this research application, I certify that the student(s) or guest investigator is knowledgeable about the regulations and policies governing research with human subjects and has sufficient training and experience to conduct this particular study in accord with the approved protocol. In addition:

- I agree to meet with the investigator(s) on a regular basis to monitor study progress.
- Should problems arise during the course of the study, I agree to be available, personally, to supervise the investigator in solving them.
- I assure that the investigator will report significant or untoward adverse events to the IRB in writing promptly, and within 5 working days of the occurrence.
- If I will be unavailable, as when on sabbatical or vacation, I will arrange for an alternate faculty sponsor to assume responsibility during my absence.

I further certify that the proposed research is not currently underway and will not begin until approval has been obtained. A signed approval form, on Office of Research Compliance letterhead, communicates IRB approval.

Advisor/Faculty Sponsor Signature _____ **Date** _____

*The faculty advisor/sponsor must be a member of the OU faculty. The faculty member is considered the responsible party for legal and ethical performance of the project.

Please refer to Guidelines for assistance in completing the form.

Checklist:

- Completed and Signed IRB-1 (this form)
- Appendix A - copies of all consent documents (in 12 pt. Font) including
 - ___ Informed Consent to Participate in Research (adult subjects)
 - ___ Parental Permission/Informed Consent (parents of subjects who are minors or children)
 - ___ Assent to Participate in Research (used when subjects are minors or children)
- Appendix B - copies of any recruitment tools (advertisements, posters, etc.)
- Appendix C - copies of all instruments (surveys, standardized tests, questionnaires, interview topics, etc.).
- Appendix D - Copies of debriefing text
- Appendix E - Approval from other IRB, School District, Corporation, etc.
- Appendix F - Any additional materials that will assist the Board in completing its review
- Appendix G - Copies of any IRB approvals
- Appendix H - Copies of Human Subjects Research Training Certificates (for all key personnel involved in non-exempt research)

All fields on the form must be completed, regardless of review level. If a field is not applicable, indicate by inserting n/a. Incomplete forms will result in delayed processing. Forward this completed form and all attachments to:

Human Subjects Research
Office of Research Compliance
RTEC 117

Questions? Visit the website at www.ohio.edu/research/compliance/ or email compliance@ohio.edu

Please refer to Guidelines for assistance in completing the form.

Ohio University Consent Form Template (must be in 12 point font)

Title of Research: _____

Principal Investigator: _____

Co-Investigator: _____

Department: _____

Federal and university regulations require signed consent for participation in research involving human subjects. After reading the statements below, please indicate your consent by signing this form.

Explanation of Study

- Purpose of the research
- Procedures to be followed
- Duration of subject's participation
- Identification of specific procedures that are experimental

Risks and Discomforts

Benefits

Alternative Treatments (if applicable)

Confidentiality and Records

Compensation

Contact Information

If you have any questions regarding this study, please contact **(Researcher/Advisor & email/phone number)**.

If you have any questions regarding your rights as a research participant, please contact Jo Ellen Sherow, Director of Research Compliance, Ohio University, (740)593-0664.

I certify that I have read and understand this consent form and agree to participate as a subject in the research described. I agree that known risks to me have been explained to my satisfaction and I understand that no compensation is available from Ohio University and its employees for any injury resulting from my participation in this research. I certify that I am 18 years of age or older. My participation in this research is given voluntarily. I understand that I may discontinue participation at any time without penalty or loss of any benefits to which I may otherwise be entitled. I certify that I have been given a copy of this consent form to take with me.

Signature _____ Date _____

Printed Name _____

Please refer to Guidelines for assistance in completing the form.