

**Eastern Michigan University
College of Education
Request for Approval of Student Research
Involving Human Subjects**

Date Submitted

Principal Investigator (Faculty Advisor)

Department

Telephone #

e-mail address:

Address:

Co-PI (Student Investigator)

Telephone #

e-mail address:

Address:

Title of Project

From what sources are funds expected for this project?

Please note that all Human Subjects Proposals need to be submitted well in advance of scheduled solicitation of potential participants and that no data involving human subjects should be collected prior to approval.

Please submit a brief synopsis (400 words or less) of the proposed project. DO NOT submit your thesis or dissertation proposal, grant application, etc. These can not be processed by the Human Subject Review committee (HSRC) and will be returned to you.

CERTIFICATION / SIGNATURE

I certify that the information contained in this Human Subject Review application and all attachments are true and correct. If this proposal is approved by the Human Subjects Review Committee, I agree to conduct the research according to the approved protocol. I agree not to implement any changes in the protocol until such changes have been approved by HSRC. If, during the course of the research, unanticipated risks or harm to subjects are discovered, I will report them to HSRC immediately.

Principal Investigator / Faculty Advisor Signature

Date

Co-Principal Investigator / Student Investigator Signature

Date

I. Application Status

New

Renewal

Modification

If Renewal or Modification:

Date of last approval by this Committee:

Principal Investigator of previous research:

Describe any modifications in the previously approved research protocols.

Were any human subjects problems encountered in previous research? If yes, how were they handled?

II. Numbers, Types, and Recruitment of Subjects

A. Numbers and characteristics of subjects (e.g., age ranges, sex, ethnic background, health status, handicapping conditions, etc.):

B. Special Classes. Explain the rationale for the use of special classes of subjects such as pregnant women, children, prisoners, mentally impaired, institutionalized, or others who are likely to be particularly vulnerable.

C. How are individual subjects to be recruited for this research? How is it clear to the subjects that participation is voluntary and without any negative consequences?

III. Informed Consent

It is required that you attach a copy of the written “Informed Consent Form” or a written statement of the oral consent documenting the voluntary nature of participation; procedures for protection of subjects; and the right of subjects to withdraw without penalty.

If your study is such that you must obtain informed consent, you should prepare a letter that contains the following basic elements where applicable:

- A. A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject’s participation, a description of the procedures to be followed, and identification of any procedures that are experimental.
- B. A description of any reasonable foreseeable risks or discomforts to the subject.
- C. A description of any benefits to the subject or to others that may reasonably be expected from the research.
- D. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.
- E. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained.
- F. For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or whether further information may be obtained.
- G. An explanation of whom to contact for answers to pertinent questions about the research-related injury to the subject, including Dr. Michael Bretting, College of Education, Human Subjects Research chair.
- H. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

Consent Forms for Children.

Parent /Guardian Consent is required for any Human Subjects Research involving Minors.

Children’s *assent* is also required and a separate consent form must be submitted that is written in clear, understandable, and developmentally appropriate language so that children understand what they are *assenting* to in terms of a research project.

The following age-appropriate guidelines should be followed:

Young Children (under six) and Children who cannot read

Oral protocol must be read to the children in the presence of a neutral adult observer who will sign the protocol as a witness

Children and Adolescents 6-18

Consent Form must be written to the appropriate developmental/grade level of the child/Adolescent. Language must be carefully chosen so that children are not confused by unfamiliar terminology. Children will sign a consent form that is separate from the parent consent form. Basic guarantees of anonymity and confidentiality must be included with assurance of no penalty for withdrawal or non-participation.

IV. Specific Risks Involved in the Research

Does the research involve any of the following procedures: (Please check correct answer.)

	Yes	No
Deception of the subject		
Punishment of the subject		
Use of drugs in any form		
Electric shock		
Deliberate production of anxiety or stress		
Materials commonly regarded as socially unacceptable		
Use of radioisotopes		
Use of chemicals		
Drawing of blood		
Any other procedure that might be regarded as inducing in the subject any altered state or condition potentially harmful to her/his personal welfare.		
Any procedure that might be considered as an invasion of privacy.		
Disclosure of name of individual subjects participating in the research.		
Any other physically invasive procedure.		

A. If the answer to any of the above is “Yes”, please explain this aspect of the research procedure in detail.

B. Describe the procedures for protecting against or minimizing any potential risks.

VI. Describe any anticipated benefits to subjects from participation in this research.

VII. Please describe instrumentation and protocol to be used.

VIII. Submit Form

Submit this form by mail or in person to the COE HSRC:
c/o Dr. Michael Bretting
310 Porter Building
Ypsilanti, MI 48197