



Application to Conduct Research with Human Subjects

Initial Review

DIRECTIONS: All research involving data collection or other investigations using human subjects must be reviewed and approved by the University's Institutional Review Board for the Protection of Human Subjects (IRB), prior to beginning any such research. In order to obtain approval, complete and submit this application electronically to irb@uu.edu. **In addition to the application, the IRB requires that the researcher complete the Human Subject Assurance Training found on the IRB website at <http://www.uu.edu/programs/irb/> and submit the certificate of completion with the application.** Please allow up to 4 weeks for a response from the IRB. The review process will cease if there are gross grammatical errors and the protocol will be returned. For questions or further information, call the IRB Office at (731) 661-5580.

Applying for: Exempt Review Expedited Review Full Board Review

Name _____ Phone _____ E-mail _____

Home address _____

Department _____ Faculty advisor _____

Proposed Starting Date and Duration of Study _____

Project title _____

List any research grants you have received _____

Sponsoring agency _____

If project is being submitted for external funding, attach any proposal that has been or will be submitted to sponsor.

Please submit the following materials:

- This Initial Review application (all pages)
- Assurances page signed by the investigator and the advisor (not typewritten)
- Copy of consent document, cover letter, or script
- Copies of any survey, questionnaire, or interview instruments
- Copy of OHRP Training Certificate of Completion
- Copies of any recruitment advertisements
- Website addresses, if applicable
- School of Education Research Review Committee approval (if applicable)

PROJECT DESCRIPTION: Describe your project in terms of the following items. If any item is not applicable this should be so stated. Please include sufficient information to facilitate an efficient IRB review.

1. **PURPOSE OF THE STUDY.** Provide a description of the project that includes a statement, grounded in the pertinent body of research literature, that describes the purpose and importance of the proposed research project.

2. **METHODS AND PROCEDURES.** Describe the study design (e.g., randomized, blinded, placebo controlled, etc.) and all procedures, step by step, to be applied to subjects. Clearly indicate which procedures and treatments are research and those which are not.

3. HUMAN SUBJECTS

Anticipated number of subjects _____

- a. Characteristics. Describe the characteristics of the subject population. Include the anticipated number of subjects to be studied, age range(s), gender, ethnicity, health status, any physical, mental, cognitive or emotional limitations, and any other relevant variables. Also indicate if subjects are to include students, prisoners, pregnant women or any other class of subjects that might be especially vulnerable and require special consideration. If subjects are students, describe the relationship between students and researcher. If using vulnerable populations, provide rationale for doing so.
 - b. Recruitment. Describe how subjects will be identified and recruited. Attach all materials to be used in recruitment (advertisements, posters, scripts for radio/TV, other electronic ads, etc.)
 - c. Selection. Describe criteria for inclusion and exclusion of subjects in the study.
 - d. Compensation or Incentives. Describe any economic or other incentives for participation. Payments must be pro-rated over the course of the study. List alternative ways for subjects to earn credit if participation is part of a school course.
4. POTENTIAL RISKS. Describe all potential risks: physical, psychological, social, legal or other associated with each procedure. Assess the probability, severity, potential duration and reversibility of each risk. Identify those risks which are minimal and those which are more than minimal. Describe the procedures used to minimize any potential risks. If there are no identifiable risks this should be so stated.
5. POTENTIAL BENEFITS. Describe the potential benefits that may accrue directly to the subject. If there are none this should be so stated. Describe the potential societal benefits of the study in terms of human health/welfare, the advancement of knowledge or the good of society.
6. ASSESSMENT. Justify the research study based on your evaluation of the risk/benefit assessment.
7. CONFIDENTIALITY. Describe how confidentiality of data and privacy of subjects' participation will be maintained. If project involves drugs or medical devices, records must be open to FDA inspection, and the subjects must be informed of this provision. Confidentiality can only be maintained within the limits allowed by law and should be stated as such. Do not promise strict confidentiality unless participation is anonymous.

8. **INFORMED CONSENT.** Informed consent to participate in the research project is required of all research involving human subjects and must include the elements listed below. Such consent must be given by the subject and/or parent/guardian if the subject is under 18. Informed consent is usually obtained using a written consent form but other presentation methods may be utilized depending on the nature of the research and/or the characteristics of the subjects. **The IRB requires that the investigator use the consent form templates provided on the IRB webpage. These templates can be downloaded at <http://www.uu.edu/programs/irb/>.** If a written, signed consent form will not be obtained, explain why not and attach a description of how informed consent will be obtained and documented.

Simply giving a consent form to a subject does not constitute informed consent. Researchers are cautioned that consent forms should be written in simple declarative sentences. The forms should be jargon-free. Foreign language versions should be prepared for any applicable research. Describe the informed consent process in terms of the following questions:

- a. Will all adult subjects have the capacity to give informed consent?
- b. What will be said to the subjects to explain the research?
- c. How will subjects' understanding be assessed? What questions will be asked to assess the subjects' understanding; will there be written responses; will understanding be assessed at other points in time?

Required elements of informed consent are listed below:

- (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 (include exact dates of study if possible), a description of the procedures to be followed, and identification of any procedures which are experimental;
- (b) a description of any reasonably foreseeable risks or discomforts to the subject;
- (c) a description of any benefits to the subject or to others which 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 (Note: due to the Open Records Act, confidentiality can only be maintained within the limits allowed by law and should be stated as such. Do not promise strict confidentiality unless participation is anonymous);
- (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 where further information may be obtained (Note: a statement must be included that Union University does not have any funds budgeted for compensation for injury, damages, or other expenses);
- (g) an explanation of whom to contact for answers to pertinent questions about the research and whom to contact in the event of a research-related injury to the subject;
- (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; and
- (i) for an explanation for answers to questions regarding the research subjects' rights, the Chair of the Institutional Review Board should be contacted at (731) 661-5580.

INVESTIGATOR'S ASSURANCE

I certify that the information provided in this initial review 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 subjects and the ethical conduct of this research protocol.

I agree to comply with all Union University policies and procedures, 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 research protocol,
- I will maintain a copy of all questionnaires, survey instruments, interview questions, data collection instruments, and information sheets for human subjects,
- I will promptly request approval by the Union University IRB if any changes are made to the research protocol
- I will report any adverse events that occur during the course of conducting the research to the IRB within 10 working days of the date of occurrence.
- I will file a Notice of Completion report with the IRB Office before the expiration date of the study.

Principal Investigator

Date

FACULTY ADVISOR'S ASSURANCE

By my signature as advisor on this research application, I certify that the student 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 student investigator 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 principal investigator in solving them.
- I understand that as the faculty advisor, I will be responsible for the performance of this research project.

Faculty Advisor (if principal investigator is a student)

Date

*A new signed assurances page must be included with each revised submission.