Guidelines for Class Projects

These guidelines are intended to assist instructors in determining when class projects meet the definition of research with human subjects and require review by the Edgewood University Institutional Review Board.

For clarification, the following are NOT class projects; they are considered research and must be reviewed and approved by the IRB:

- Senior research projects conducted within the framework of the senior capstone experience
- Master's theses
- Doctoral dissertations

Review Procedures

- Class projects that involve systematic collection of data and for which the design or objective is to develop or contribute to generalizable knowledge are considered research. **In other words, if the student (or instructor) plans to use the data outside of the class, the project is considered research and requires IRB review.**

- Class projects that are designed solely with the objective of providing students with training about and experience with research methods are not considered research. In cases in which data will not be used outside of the classroom context and data will be destroyed upon completion of the project, these projects are not considered research and do not require IRB review. **HOWEVER, if the instructor allows a student to design a class project that involves protected populations or sensitive information (as defined below) IRB review and approval are required.**

Instructors' Responsibilities

- Instructors should meet with students as soon as possible and go over these guidelines to determine if the proposed class project could be considered research.
- If there is even a remote possibility that a class project may fall under the definition of research, instructors are advised to submit an application with the student to the IRB. **Remember, class projects that involve protected populations or sensitive information require IRB review and approval.**

Protected Populations/Sensitive Information

*Protected Populations – Examples include, but are not limited to:
- Children/Minors (under the age of 18) (**Exception** – projects conducted in established or commonly accepted educational settings involving normal educational practices. Contact IRB office for guidance.)
- Prisoners (now includes non-publicly available secondary data)
- Pregnant women
- People with diminished capacity to give consent
- Mentally or physically challenged individuals

*Sensitive Information – Examples include, but are not limited to:
- Information relating to an individual's psychological well-being or mental health
- Information relating to sexual attitudes, preferences, or practices
- Information relating to the use of alcohol or drugs
- Information relating to illegal behavior
- Information that if released could reasonably place the individual at risk of criminal or civil liability or be damaging to the individual's financial standing, employability, or reputation
- Information that would normally be recorded in a patient's medical record and the disclosure could reasonably lead to discrimination, stigmatization, etc.

If the class project <u>meets</u> the definition of research:

- The instructor and the student should both register for IRBNet, complete the IRBNet tutorial, complete the NIH online ethics tutorial, and prepare the IRB research proposal application.

If the class project <u>does not meet</u> the definition of research:

- It is the responsibility of the instructor to ensure that the student project does not meet the definition of research.
- It is the responsibility of the instructor to ensure that the class project is conducted according to the ethical standards of the relevant discipline. To this end the IRB encourages that all students complete the free IRB Online Tutorial sponsored by the U.S National Institutes of Health at http://phrp.nihtraining.com.
- Remember that from the participant's viewpoint, giving out personal information does not differ for a class assignment or a research project. Personal information is personal information. Instructors should advise students to identify the project to participants as a class assignment and be sensitive to the personal nature of the obtained information. Labeling the class project as "research" is inaccurate and misleading to participants.
- Students should inform participants that data will be destroyed after their assignment or class project is completed.
- Instructors are advised to tell students that data from human subjects should not contain any personal, identifying information whenever possible.
- All class projects must include informed consent language that closely follows the guidelines. Information on what to include in a consent form/script is described below. For an on-line survey, this would be the first page of the survey or in the email post.
- The IRB is available to give feedback on any proposed class project not meeting the definition of research, even though the IRB would not officially act on the project.

Information to Include in an Informed Consent for Class Projects

When information is collected for a class project that does not meet the definition of research (as defined by the federal regulations) and does not require approval by the IRB, it is still important to "inform" the participants about the class project. Make sure the participant is told:

- The identity of the student (introduce yourself!). (This may not always be necessary, as many students enlist the help of friends or family to collect data for a class project.)
- They must be at least 18 years of age to participate.
- It is a class project. (Give a little information, e.g., This is for my business class, I am trying to see if there is a relationship between X and Y.)
- What they will be asked to do ("I would like to ask you some questions about why you chose to attend Edgewood College. If there are any questions you don't want to answer, it is fine to skip them.").
- How long the interview, survey, etc., may take to complete.
- What will happen to the information collected ("The information will be used to write my paper for the class, and I will give a presentation in class. All of my notes, surveys, etc., will be destroyed when the project is completed.")
- If they will be identified: examples: "I will not write your name on my notes"; "Do not write your name on the survey;" "I will not use your name in my paper."
- The student's and instructor's contact information if they have any questions (provide phone number/email).