



PROCEDURE

Policy Name:	Use of Human Subjects
Policy Number:	5329
Applicable Code/Law:	Code of Federal Regulations, Title 45 Part 46

Procedural Guidelines

This procedure is intended to address participation by individuals as human subjects in such activities as training procedures, demonstrations and experiments where subjects may be exposed to situations which may be embarrassing, injurious or dangerous to them or to which they are not ordinarily exposed or accustomed in their normal daily lives as students or non-students.

1. All activities that use human subjects shall be conducted only under the direct supervision of the instructor who has been assigned to teach the course (or is the instructor of record) that has received the appropriate prior approval.
2. Before involvement as a human subject, a subject must give informed consent. If under the age of 18, informed consent must be obtained from the parent or the legal guardian unless the participant is determined to be an emancipated minor. The consent is to be freely given, obtained from the subject, parent, or legal guardian without undue inducement or any element of constraint or coercion. The following *prescribed language* will be used to obtain informed consent from all human subjects in a training procedure, demonstration, and/or experiment required for student learning. This statement will be provided to participants before the activities begin, with adequate time for review before the beginning of the activity:

You are invited to take part in [description of activity or activities]. These activities are part of the educational experience in [name of course(s) and/or program] and will further the skills and knowledge of students in [course(s)/program], by providing [description of relevant learning outcomes]. As a participant in [name of activities], you will [description of procedures].

In the course of [activities], the following steps will be taken to ensure confidentiality of your identity and any personal information. [Include a description of how confidentiality will be maintained and under what conditions it may not.]

During the activities, you may be at risk of experiencing [description of the attendant risks and/or discomforts]. If you experience [description of risks/discomfort], you can contact [description of resources available to address risks/discomfort].

You can withdraw from [activity] at any point without penalty. If you have any questions about any aspect of your participation in [activities], please [feel free to inquire in person before the activities begin] or contact [name, email, and phone number].

3. Students in courses involving human subjects in educational activities will be provided with information about their use of human subjects in these activities, as well as their own participation as a human subject. The following *prescribed language* will be included in the course syllabus and will be used as informed consent for students in courses that require the use of human subjects in educational activities.

In this course, you [may/will] be required to engage in educational activities that involve the use of human subjects. It is necessary to use human subjects to gain [description of critical competency to be gained].

In addition, you will be asked to serve as a human subject in these activities.

During the activities, you may be at risk of experiencing [description of the attendant risks and/or discomforts]. If you experience [description of risks/discomfort], you can contact [description of resources available to address risks/discomfort].

Serving as a human subject is part of the educational experience in this course, and will contribute to [description of critical competency to be gained through participation]. You are expected to participate as a human subject in these activities, but if there are exceptional circumstances preventing you from participating, you may request permission to opt out by [description of procedures used and any alternative educational experience, if applicable]. Where feasible, such permission will be granted.

4. An Institutional Review Board (IRB) shall be convened, as necessary, to review and approve training procedures, demonstrations, and/or experiments that use human subjects as part of those training procedures, demonstrations, and/or experiments which may place an individual "at risk". "At risk" means that as a consequence of participating in an activity, an individual may be exposed to the possibility of injury, including physical and/or psychological, which increases the ordinary risks of daily life.

- a. Appointment
 - i. The IRB shall be appointed by the President, in consultation with each unit administrator. The IRB shall be chaired by the Executive Vice President or designee.
- b. Composition
 - i. The IRB shall consist of the Executive Vice President, two (2) members from health occupations, two (2) members from science, one (1) member from counseling, one (1) member representing one of the academic divisions not already represented, as well as the College's risk manager.
- c. Review and Approval Procedures
 - i. No activity within the purview of these procedures shall be initiated until it has been reviewed and approved by the IRB.
 - ii. Before beginning an activity using human subjects, it shall be the responsibility of the instructor and the unit administrator to submit a description of the proposed activity and an informed participant consent form to the IRB for review and approval. When a training activity, demonstration or experiment is modified, it shall be the responsibility of the instructor and the unit administrator to request such re-evaluation, review and approval prior to the initiation of the modification.
 - 1. The IRB is responsible for completing the review and approval process expeditiously.
 - 2. All previously approved activities shall be reviewed prior to any changes being made or at the discretion of the IRB.
 - iii. The IRB shall incorporate the principles of research outlined in the Nuremberg Code.
 - iv. Written records of IRB activity shall be maintained.

5. Appeal Procedures

- a. The instructor shall advise the unit administrator of any individuals who are unwilling to participate in an approved activity. The unit administrator, in consultation with the instructor, shall review the objections and may make appropriate adjustments, or refer the matter to the IRB for resolution.
- b. All appeals shall be reported in writing to the IRB.