Ethical Review Guidelines for Research Involving Students, Employees and/or Normal Volunteers as Research Participants.

The involvement of students, employees, and normal (i.e. healthy) volunteers in research may present special concerns, but the federal regulations do not provide explicit protections for subjects in these categories. The following is a guideline; requests for variance will be considered by the HPRO based on individual circumstances.

ISSUES TO CONSIDER:

(I) COERCION: The good faith of the Principal Investigator (PI) is mandatory to avoid any semblance of coercion of potential research participants, or of any special treatment [either favorable or unfavorable] based upon the subject's willingness or unwillingness to participate.

1. Students/Employees: Teacher/researchers should ordinarily not use as research subjects students whom they currently supervise in a teaching situation, and researchers/employers should ordinarily not use as research participants employees whom they currently supervise in a work situation, when that teacher (or employer) has any prerogative or opportunity for grading, evaluating or influencing that student's (or employee's) past, present, or future performance.

Nevertheless, under certain circumstances, there may be a justification for a researcher to approach such students or employees regarding research participation. These students/employees must then be treated as a vulnerable population, and investigators should consider in good faith whether the students/employees may feel pressured, or may be pressured to participate in research because of their relationship with the investigator and fear of undesirable consequences of their non-participation. Should such pressure be sensed, these vulnerable subjects may not be recruited.

Participation in studies may be offered for credit in a class, but students should be given other options for fulfilling the research component that are comparable in terms on time, effort, and educational benefit. To fulfill the research component, students could either participate in research, write a brief research paper, or attend faculty research colloquia. The paper should not be graded, and students who attend colloquia should only have to show up. If students do choose to participate in studies, they should be given several studies from which to choose.
2. Normal Volunteers: Normal participants who volunteer to participate in studies are usually compensated for their time and discomfort, but the compensation offered must be commensurate with the time, discomfort, and risk involved. When a research procedure involves serious discomfort and/or the real, though slight, possibility of serious harm, one can easily imagine that the motivation of persons who volunteer to participate may be monetary. Therefore, investigators should pay particular attention to the subject population.

(II) CONSENT: Valid informed consent must be voluntary. The potential participant “should be so situated as to be able to exercise free power of choice without the intervention of any element of force, fraud, deceit, duress, overreaching, or other ulterior form of constraint or coercion.”

Students/Employees: Because of the imbalance of power in relationships between students and teachers in the formal education context, or between employees and their supervisors in the context of employment, it may be difficult or impossible to ensure that students who are potential participants in a researcher/teacher's class, or employees in the researcher/supervisor's employment responsibility, are in a position to give consent freely, without fear of potential or actual reprisal.

Normal Volunteers: The consent processes must be free from elements of coercion or undue inducement to participate. In research involving normal volunteers, particularly where the research involves more than minimal risk, monetary payments to subjects should not be so great as to constitute an undue inducement.

A. CONFIDENTIALITY
1. Students/Employees: Loss of a student's or employee's confidentiality may be the most significant risk if a researcher/teacher, or researcher/employer gains access from the research process to private information regarding the student or employee that might conceivably effect the subjects’ grading, evaluation or good standing. The researcher must make every effort to avoid any breach of confidentiality, by use of anonymous, unidentified, or coded information whenever possible, and the participants should be so informed.

Should it not be possible to de-identify research data, participants and employees must be assured that their confidentiality will be maintained to the greatest extent possible, and that divulgence of private information to the teacher or employer will occur, but will have no impact upon students’ grades, employees working conditions or rewards, or any other form of favorable or unfavorable consequence.

Reasons for inability to de-identify research information should be provided to the HPRO in the research application.
B. THERAPEUTIC BENEFIT:

1. Students/Employees: Recruitment by researchers of specific students/employees into research protocols involving their potential or actual therapeutic benefit will be considered by the HPRO depending upon individual circumstances. In these situations, the possibility of individual benefit may outweigh other risks discussed above.

2. Normal Volunteers: The Belmont Report states the two general rules that describe beneficent actions as: (1) do not harm; and (2) maximize possible benefits and minimize possible harms. Volunteers for whom no therapeutic benefit can result from participation in research should, therefore, be exposed to risks that are minimized to the greatest extent possible. While the minimization of risks is an important requisite for any research involving human participants, the altruistic motivation of the normal volunteer's agreement to participate (i.e., of contributing to scientific knowledge for the benefit of society) heightens the concern for the risks to which such participants should ethically be exposed.

C. RISKS: All of the above requirements apply whether the proposed research is classified as minimal risk or greater-than-minimal risk.

(III) RECRUITMENT TECHNIQUES: Students, employees, and normal volunteers should be recruited through general announcements or advertisements, rather than through individual solicitations. In the absence of perceived coercion, acceptable recruitment techniques may include: (1) Public posting of HPRO-approved flyers and advertisements; (2) sending written notices or invitations to individuals who have agreed to receive such solicitations, particularly individuals registered in the Volunteer for Health Program. Such solicitations may not be in person or by telephone.

1. Students/Employees: If a researcher requests HPRO's consideration of recruitment of students or employees whose evaluation is at risk of being influenced as a result of research participation or non-participation, the HPRO may suggest use of a disinterested third party to recruit participants, including distribution and collection of information and consent documents. In such instances, the HPRO will ordinarily require that informed consent documents and/or processes should explicitly assure participants that their decision to participate or not to participate will have no direct or indirect influence upon their grades, assessments or any other outcomes. Investigators should consider asking students or employees currently involved in research if they would be willing to receive invitations for future studies.

Other precautionary measures may include curtailing of data collection until the researcher/teacher-student interaction is complete (i.e., when the course is finished) or curtailing of analysis of data until the course is over.
2. **Normal Volunteers:** When recruiting Normal Volunteers the HPRO encourages investigators to employ the following standards for enrollment in the studies that offer considerable monetary remuneration.
   a. enroll participants with a permanent address
   b. enroll participants with a source of income
   c. have an unaffiliated witness involved with the consent process
   d. ask potential subjects about previous clinical trial experience (avoid enrollment of “career participants”)

**REFERENCES:**

1. Nuremberg Code – 1946

2. “Ethical review guidelines for research involving students or other individuals related to the researcher as research participants.” Athabaska University Research Ethics Board.


Developed January 31, 2005 by Task Force Members:
Philip A. Ludbrook, M.D.
Sarah Frankel, PhD,
Melissa Torres, MSW
John Csernansky, M.D.
Dorothy Edwards, Ph.D.
Patricia Scannell, BA
Judge Lloyd Jack Vasquez