Subject: Procedure for Recruitment of Students and Employees as Research Participants

Procedure:
This procedure outlines the responsibilities of the Human Research Protections Program and Investigators when recruiting students and employees as participants in research conducted under the HRPP's jurisdiction.

I. Investigator Responsibilities.
The Investigator must take into consideration the following when recruiting students and employees as participants in human subjects research.

A. Recruitment of students by Investigators who are also faculty members or instructors at VU or VUMC.
   1. Investigators are to advertise and recruit student participants generally, rather than recruiting individual students directly.
   2. An exception to this rule may be allowed when the use of one’s own students is integral to the research. For example, research into teaching methods may be allowed by the IRB when sufficient precautions have been taken to protect the student-participant (e.g., using a third party to obtain informed consent).

B. Student Participation as a Class Component.
   1. The IRB may approve the giving of course credit or extra credit to students who are expected to participate in research activities as part of a class curriculum only when alternative means of obtaining course credit or extra credit is made available to students who do not wish to volunteer as research participants. Students must be given other options for fulfilling the research participation component that are comparable in terms of time, effort, and educational benefit. For example, short papers, special projects, book reports, and brief quizzes on additional reading may be offered in lieu of research participation.
   2. These research studies may not involve more than minimal risk and students must be told that they can withdraw from the study at any time without losing the extra credit.
   3. The use of extra credit points for participation in research studies should be limited as a reward, used only when the research is closely tied to the course subject matter, and should not raise the student’s grade by more than one-half of a letter grade (e.g., B to B+).
   4. Students should be recruited through general announcements, bulletin board postings or advertisements, rather than individual solicitations.
   5. Research interventions should not be conducted during class time.
   6. Students should not be recruited into research of a sensitive nature e.g. drug use, alcoholism, sexual preferences, etc.

C. Medical School Students.
   1. Medical school students may participate in research however recruitment activities must be general and cannot target individual students directly.
   2. Medical students of a particular Investigator or laboratory should not be directly recruited for participation in any study by that Investigator or laboratory.
   3. The IRB has the authority to review and approve research involving medical students. However, any IRB concerns regarding the use of medical students...
shall be promptly forwarded to the Associate Dean for Medical Students for review.

4. Medical students should not be recruited into research of a coercive or sensitive nature, e.g. drug use, alcoholism, sexual preferences, etc.

D. Student Recruitment.

Although IRB approval is granted, research activities that are targeted for or designed specifically to address students from a particular Department or School may require the approval of the appropriate Dean before the study may commence.

E. Student Records.

1. Vanderbilt University is subject to the provisions of federal law known as the Family Educational Rights and Privacy Act (also referred to as the Buckley Amendment or FERPA). This act affords matriculated students certain rights with respect to their educational records.

2. Generally, students have the right to consent to disclosures of personally identifiable information contained in the student's education records to third parties (such as researchers). Therefore, Investigators must obtain student's consent to access personally identifiable information in the student's educational records, even if consent to participate in the research may have been waived by the IRB.

E. Employees.

1. Investigators should minimize the likelihood that employees who participate in research programs perceive that the decision will affect performance evaluations or job advancement.

2. Employees should be recruited through general announcements or advertisements, rather than individual solicitations.

3. Employees of a particular Investigator or laboratory should not be directly recruited for participation in any study conducted by that Investigator or laboratory, although such employees may, on their own, volunteer to participate.

4. Investigators who include colleagues or subordinates as research participants should be able to provide a rationale other than convenience for selecting those individuals and should show that the recruitment methods do not lead colleagues to think that they will be compromised by not participating.

II. IRB Committee Responsibilities.

A. The IRB should exercise oversight with the use of faculty, instructors, students, medical students, and employees as the targeted population in research.

B. The IRB will review the proposed involvement of faculty, instructors, students, medical students, and employees as the targeted population in research activities and when making its final determination assure that:

1. Consent for participation is sought only under circumstances which minimize the possibility of coercion or undue influence, which, clearly identify methods used to maintain confidentiality;

2. There are genuinely equivalent alternatives to participation available;

3. The selection of participants is equitable;

4. The risk of coercion is minimized; and

5. If applicable, added protections for vulnerable populations have been assured.

C. Any concerns regarding the use of students should be promptly forwarded to the Dean of the appropriate school or department.

D. Any concerns regarding the use of medical students should be promptly forwarded to the Associate Dean for Medical Students.

III. Regulatory Compliance Analyst (RCA) Responsibilities.

A. The RCA will conduct a pre-review of all initial applications or amendments that propose the use of students, medical students, or employees as a targeted population.
B. The RCA will assure that the IRB Committee is aware of the inclusion students, medical students, or employees as a targeted population.
C. If necessary, the RCA will facilitate communication between the IRB Committee and the Dean of the appropriate school or department or the Associate Dean for Medical Students.

References:
45 CFR 46.111