

**Department:** UAMS Institutional Review Board  
**Policy Number:** 17.10  
**Section:** Special Populations  
**Effective Date:** July 31, 2002  
**Revision Date:** August 25, 2004

**SUBJECT: Students, Employees and Healthy Volunteers**

**Healthy Volunteers.** Special concerns surround the involvement of healthy persons who volunteer to participate in research. Primarily, the principles involved are beneficence and respect for persons. In the *Belmont Report*, the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research stated 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 healthy 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.

The principle of respect for persons requires that research participants be, where capable of doing so, allowed to act autonomously and to express their right of self-determination. These principles are effectuated through the process of informed consent, which involves providing subjects with all relevant information about the study, including the risks and benefits involved, in clear and simple language, and ensuring that the information is understood and appreciated. In research involving healthy volunteers, particularly where the research involves more than minimal risk, the IRB must ensure that any monetary payments to subjects are not so great as to constitute an undue inducement. The IRB should seriously scrutinize the payment schedules to ensure that any compensation offered is commensurate with the time, discomfort, and risk involved. Where a research procedure involves serious discomfort and/or the real, though slight, possibility of serious harm, the IRB should pay particular attention to the proposed study population and whether it may comprise persons who are likely to be vulnerable to coercion or undue influence, such as persons who are educationally or economically disadvantaged. The federal regulations require that the IRB employ special safeguards under such circumstances [45CFR 46.111(b)].

One area where healthy volunteers are employed in research is in Phase 1 drug trials. The justification for the involvement of healthy subjects is the need for volunteers whose experience with the trial materials is more easily analyzed because of the existence of fewer confounding factors. While Phase 1 trials are the first use of experimental drugs and devices in humans, preliminary studies involving animals provide investigators with data indicating a high likelihood of safe use in humans. Studies have indicated that the risk of injury from participating in Phase 1 studies is small, about the same as the risk of being injured while working as an office secretary [Levine, Robert J. *Ethics and Regulation of Clinical Research*, 2d ed. Baltimore: Urban and Schwarzenberg, 1986, p. 42.]. The likelihood of risk, including the availability of animal data, should be scrutinized by the IRB.

Healthy volunteers, like students and employees, should be recruited through general announcements or advertisements, rather than through individual solicitations. Personal solicitations increase the likelihood that participation will be the result of undue influence, either because of the relationship between the recruiter and the prospective subject, or methods of communication employed by the recruiter that may act to persuade prospective subjects to participate, thus compromising the voluntariness of the agreement to participate.

Investigators and the IRB should carefully consider what will happen if and when a healthy volunteer should become sick or be injured during the research. As with any research involving human subjects, such issues should be clearly spelled out in the informed consent document, and should be reviewed carefully with the prospective subject. For example, subjects should be told: whether any medical treatments will be made available should injury occur and, if so, what they consist of; whom to contact should a research-related injury occur; and that they may discontinue participation at any time without penalty or loss of benefits to which they would otherwise be entitled [45CFR 46.116(a)(6-8)]. In addition, where appropriate subjects should be told whether they will be dropped from the study in the event of injury or illness, and whether they will be required to pay for treatment of research-related injuries or illness [45CFR46(b)(2-3)]. Where illness in healthy volunteers does occur, particularly during a drug study, investigation by an independent physician may be warranted. [See Fazackerley, Randall, and Pleuvry (1987).]

The issues raised by the involvement of healthy subjects in genetic research are discussed in Guidebook Chapter 5, Section H, "Human Genetic Research."

**Students.** Two questions that have been posed are whether students -- medical students, in particular -- should be allowed to participate in biomedical research (and whether special protections should be adopted to restrict their participation), and whether participation in research can appropriately be included as a course component for course credit. The problem with student participation in research conducted at the university is the possibility that their agreement to participate will not be freely given. Students may volunteer to participate out of a belief that doing so will place them in good favor with faculty (e.g., that participating will result in receiving better grades, recommendations, employment, or the like), or that failure to participate will negatively affect their relationship with the investigator or faculty generally (*i.e.*, by seeming "uncooperative," not part of the scientific community).

**Consent must state that students are allowed to refuse participation or withdraw early from a study without affecting their academic standing at UAMS.** Prohibiting all student participation in research, however, may be an overprotective reaction. An alternative way to protect against coercion is to require that faculty-investigators advertise for subjects generally (e.g., through notices posted in the school or department) rather than recruit individual students directly. As with any research involving a potentially vulnerable subject population, the IRB should pay special attention to the potential for coercion or undue influence and consider ways in which the possibility of exploitation can be reduced or eliminated.

Confidentiality is a concern raised by the involvement of students as subjects in research. The IRB should be aware that research involving the collection of data on

sensitive subjects such as mental health, sexual activity, or the use of illicit drugs or alcohol presents risks to subjects of which they should be made aware and from which they should be protected, to the greatest extent possible. The close environment of the university amplifies this problem.

**Employees.** The issues with respect to employees as research subjects are essentially identical to those involving students as research subjects: coercion or undue influence, and confidentiality. Employee research programs raise the possibility that the decision will affect performance evaluations or job advancement. It may also be difficult to maintain the confidentiality of personal medical information or research data when the subjects are also employees, particularly when the employer is also a medical institution [Meyers (1979)]. For issues regarding compensation each Institution may have policies that apply. The investigator is responsible for following those policies.