Department: UAMS Institutional Review Board

Policy Number: 17.10

Section: Special Populations

Effective Date: July 31, 2002

Revision Date: August 25, 2004; February 15, 2016; July 15, 2020

SUBJECT: Students, Employees and Healthy Volunteers

POLICY

It is incumbent upon both investigators and the IRB to ensure that the special considerations involved in recruiting healthy volunteers, students, and/or employees are adequately addressed in protocol submissions to the IRB. While concerns for justice, beneficence, and respect for persons apply to all human subject research, these considerations are heightened when the populations involved are not likely to derive any therapeutic benefit from participation or who may be asked to participate in research by someone who may be evaluating their academic or professional performance.

PROCEDURE

- A. When proposing research that involves students, employees, and/or healthy volunteers, investigators shall address:
 - 1. The rationale for including these participants
 - 2. The steps to be taken to protect these participants' rights and to uphold the principles described in the Belmont Report.
- B. When reviewing research involving volunteers, students, and/or employees, the IRB shall consider the following elements related to the criteria for approval:
 - 1. Whether risks to subjects are minimized. While the minimization of risks is an important requisite for any research involving human participants, the altruistic motivation of the healthy volunteer's/student's/employee'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. In addition, the assessment of the risk/benefit ratio should take into account the fact that these populations may not derive any personal benefit from participation.
 - 2. Whether subject selection is equitable. Students and employees in particular may feel compelled to participate in research presented to them by people who may be evaluating either their academic or professional performance. The IRB shall consider whether these populations are appropriate for the proposed research.
 - Appropriateness of the recruitment process, to ensure the possibility of undue influence is minimized.
 - 4. Appropriateness of the proposed informed consent process. The process should involve providing subjects with all relevant information about the study, including a description of possible risks and benefits, in clear and simple language and in a manner appropriate to the research. When appropriate, the consent process shall also make clear that neither a decision whether or not to participate or to continue in the study, nor their individual study results (e.g. survey responses) will have any bearing on the participants' academic or employment or on any future relationship with the institution.

- 5. Any monetary payments or other compensation are not so great as to constitute an undue influence. The IRB should scrutinize proposed payment schedules to ensure that any compensation is commensurate with the time, discomfort, and inconvenience involved. The IRB shall generally not allow the awarding of extra academic credit or professional benefit in exchange for participating in research.
- 6. The provisions for providing care or otherwise compensating subjects if they are injured as a result of their participation are adequate, and that these issues are adequately addressed in any informed consent materials.

REFERENCE

AAHRPP Element II.4.A