

UNIVERSITY RULE

15.99.01.M1 Human Subjects in Research

Approved October 5, 1999

Next Scheduled Review: June 13, 2011

Supplements [System Regulation 15.99.01](#)

1. GENERAL

1.1 Texas A&M University complies with regulations of the Department of Health and Human Services (DHHS) for the protection of human subjects involved in research (45 CFR 46 as amended and published in the Federal Register). These regulations, as defined by DHHS, are applicable to all research involving human subjects for which the University is responsible regardless of the source of funding or whether the research is funded. In the case of conflict between regulations of the funding or regulatory agency and DHHS the more restrictive regulations shall prevail.

2. INSTITUTIONAL REVIEW BOARD (IRB)

All research done under the auspices of Texas A&M University, including cooperative research conducted with one or more public or private entity or entities, in which human subjects are involved must be reviewed and approved by the [Institutional Review Board \(IRB\)](#) appointed by the [Vice President for Research](#) and Associate Provost for Graduate Studies.

3. HUMAN SUBJECT REVIEW AND APPROVAL

The IRB review and approval process shall be conducted in accordance with all Federal, State, System and University rules, policies, regulations and laws that govern the use of human subjects in research. The requirement for IRB review and approval applies to all studies in all locations, whether funded or not funded, and whether conducted by faculty, students, or staff. It also applies to persons unaffiliated with the University who wish to investigate subjects who are under the protection of the University, such as students or patients. No such study may begin before it has been approved. (<http://researchcompliance.tamu.edu/irb/welcome>)

3.1 Texas A&M University recognizes the ethical principles, considerations, and concerns expressed in the report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research entitled [Ethical Principles and Guidelines for the Protection of Human Subjects of Research \(The Belmont Report\)](#).

3.2 The IRB will review research at intervals appropriate to the degree of risk, but not less than once per year.

4. HUMAN SUBJECTS ASSURANCE

Texas A&M University is committed to a policy of safeguarding the rights and welfare of human subjects and hereby gives assurance that it will comply with the Department of Health and Human Services (DHHS) regulations.

5. HUMAN SUBJECTS RESEARCH POPULATIONS

5.1 Research involving human subjects must employ a study design with gender and/or minority representation appropriate to the scientific objectives of the research. It is not an automatic requirement for the study design to provide statistical power to answer the questions posed for men and women and racial/ethnic groups separately; however, whenever there are scientific reasons to anticipate differences between men and women, and racial/ethnic groups separately, with regard to the hypothesis under investigation, the researcher must include an evaluation of these gender and minority group differences in the proposed study.

5.2 If adequate inclusion of one gender and/or minorities is impossible or inappropriate with respect to the purpose of the research because of the health of the subjects, or other reasons, or if in the only study population available, there is a disproportionate representation of one gender or minority/majority group, then the rationale for the study population must be well explained and justified. This rationale must be strong, particularly if the study has a high potential benefit, risk or high compensation for those selected to participate.

5.3 Additional and special precautions will be taken to protect the rights and welfare of subjects when research involves vulnerable populations. The nature of such precaution will depend upon the type and extent of vulnerability but shall be based upon respect for persons and concern for their welfare and be in accordance with Federal, State, and University regulations.

5.3.1. Dependent Subjects: Dependent subjects include such individuals as the mentally or physically disabled, pregnant women, fetuses, children, prisoners, parolees, addicts, and others in conditions of dependency.

5.3.2. University Students as Subjects: University students are vulnerable populations when a decision to participate as subjects is perceived to be required to prevent discrimination either in determination of course grades or in other activities of the academic department. Efforts must be made to avoid coercion.

5.3.3 Foreign Cultures: When research takes place involving foreign culture, the ethical principles and cultural traditions of that society will be respected, including use of the native language when providing information which may lead subjects to agree to participate in the program.

5.3.4 Laboratory Personnel: By virtue of their dependent positions, laboratory personnel represent a vulnerable population with regard to acting as research subjects. The principal investigator(s) should be sensitive to the need to avoid even subtle coercion and to ensure that all personnel who participate in even minimal risk activities do so entirely voluntarily. Compensation of individuals who are members of the University academic staff or regular exempt staff is governed by System Policies and Regulations, and University Standard Administrative Procedure [21.01.99.M0.03: Payment of Research and Survey Participants](#).

6. STUDENT RESEARCH INVOLVING HUMAN SUBJECTS (NON-MEDICAL)

Student research projects are reviewed using the same principles and guidelines followed by the IRB for the protection of human subjects in general. Any student-initiated and/or student-conducted research, leading to generalize results, which uses human subjects, requires clearance by the IRB. This includes graduate theses and dissertation research and honors theses. Responsibility for obtaining the IRB approval for student research resides equally with the student and the faculty advisor. (<http://researchcompliance.tamu.edu/irb/welcome>)

OFFICE OF RESPONSIBILITY: [Office of the Vice President for Research](#)