

**THE TEXAS A&M UNIVERSITY SYSTEM  
HEALTH SCIENCE CENTER INTERNAL POLICY**

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**15.99.01.Z1.01 Human Subjects in Research**

*Approved August 15, 2006*

Supplements HSC Rule 15.99.01.Z1

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**1. GENERAL**

The Texas A&M University System Health Science Center (HSC) 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 HSC 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 the Health Science Center in which human subjects are involved must be approved by an Institutional Review Board (IRB) that is approved by the Vice President for Research and Graduate Studies. Each individual project involving human subjects must be reviewed and approved by an IRB prior to its initiation.

**3. HUMAN SUBJECT REVIEW AND APPROVAL**

The IRB review and approval process shall be conducted in accordance with all Federal, State, TAMU System, and HSC 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. This includes cooperative research conducted with one or more private or public entities. It also applies to persons unaffiliated with the HSC who wish to investigate subjects who are under the protection of the HSC, such as students or patients. No such study may begin before it has been approved by an IRB.

The Health Science Center 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* (also known as The Belmont Report).  
[<http://ohsr.od.nih.gov/guidelines/belmont.html>]

## **4. HUMAN SUBJECTS RESEARCH POPULATIONS**

4.1 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, women, and racial/ethnic groups, with regard to the hypothesis under investigation, the research must include an evaluation of these gender and minority group differences in the proposed study.

4.2 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.

4.3 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, TAMU System, and HSC rules.

4.3.1 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.

4.3.2 Students as Subjects: Health Science Center 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.

4.3.3 Foreign Cultures: When research takes place involving a 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.

4.3.4 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 staff members of the Health Science Center must be provided in compliance with TAMU System policies and regulations.

## **5. STUDENT RESEARCH INVOLVING HUMAN SUBJECTS**

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 that uses human subjects requires clearance by the IRB. This includes graduate theses and dissertation research. Responsibility for obtaining the IRB approval for student research resides equally with the student and the faculty advisor.

## **6. REVIEW AND APPROVAL OF PROJECTS USING HUMAN SUBJECTS**

6.1 The following IRB has been established by the HSC to oversee projects using human subjects by HSC research programs primarily at the Baylor College of Dentistry in Dallas. This IRB reports directly to the Vice President for Research and Graduate Studies, who is the Institutional Official for the HSC.

6.1.1 The Baylor College of Dentistry, Texas A&M University System HSC IRB#1 in Dallas (Federal-wide Assurance No. 00005869).

6.1.2 The HSC-Baylor College of Dentistry IRB may also be used by other HSC components with the approval of the Vice President for Research and Graduate Studies.

6.2 The HSC has established a memorandum of understanding (MOU) with Scott & White Hospital and Clinic (S&W) that recognizes that these two institutions are best served by a single IRB for the Temple campus of the HSC.

6.2.1 Protocols involving human subjects in research by HSC personnel at Scott & White Hospital and Clinic must utilize the Scott & White Memorial Hospital/SS & BF IRB#1 (FWA No. 00003358).

6.3 The HSC has an MOU with Texas A&M University (TAMU) that permits cooperative use of a TAMU IRB [<http://researchcompliance.tamu.edu/irb>] for review and approval of protocols involving human subjects in research by HSC personnel based in College Station and Houston. Other components of the HSC also may use the TAMU IRB with the approval of the HSC VPRGS and the TAMU Director of Compliance.

6.3.1 The TAMU Institutional Official (IO) shall be responsible for all appropriate compliance reports to local, State, and Federal agencies covering human subjects in research as described within the boundaries of the MOU.

6.3.2 The TAMU IO shall promptly report any problems and concerns about human subjects in research by HSC faculty to the VPRGS.

## **7. RESPONSIBILITIES OF THE PRINCIPAL INVESTIGATOR**

7.1 Principal investigators, department heads, and component deans or designates are responsible for assuring that human subject research is appropriately reviewed and approved prior to initiation of any work.

7.2 Regardless of funding sources, research protocols involving the use of human subjects must be prepared by the principal investigator and must be reviewed and approved by the appropriate IRB.

7.2.1 Written approval must be obtained from the IRB prior to making changes in the research project.

7.2.2 If research is collaborative or involves other institutions, approval must be obtained from each institution.

7.3 Principal Investigators must take responsibility for the appropriate training of their research staff in human subjects research, ensuring that they are qualified to perform their duties, and that they understand their obligations to comply with all relevant regulations and the specifics of the approved protocol. Documentation of this training may be requested by regulatory and accrediting agencies, and by the HSC.

## **OFFICE OF RESPONSIBILITY**

**Office of the Vice President for Research and Graduate Studies**