

THE TEXAS A&M UNIVERSITY SYSTEM
HEALTH SCIENCE CENTER RULE

15.99.01.Z1 Human Subjects in Research

Approved August 16, 2006

Supplements System Regulation 15.99.01

1. OVERVIEW

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).
[\[http://ohsr.od.nih.gov/guidelines/belmont.html\]](http://ohsr.od.nih.gov/guidelines/belmont.html)

4. HUMAN SUBJECTS ASSURANCE

The HSC 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.

5.2 Additional and special precautions will be taken to protect the rights and welfare of subjects when research involves vulnerable populations including dependent subjects, students as subjects, subjects in foreign countries, and laboratory personnel.

OFFICE OF RESPONSIBILITY

Vice President for Research and Graduate Studies