15.99.01 Use of Human Subjects in Research

Approved August 24, 2001
Revised June 6, 2013
Next Scheduled Review: June 6, 2015

Regulation Statement

The Texas A&M University System, including its members and employees, shall comply with the applicable laws relating to human subject research.

Reason for Regulation

This regulation provides guidance in complying with federal law relating to research on human subjects, including upholding the ethical principles and guidelines set forth in The Belmont Report, April 18, 1979, for the protection of human subjects of research.

Procedures and Responsibilities

1. ADMINISTRATIVE REQUIREMENTS

   1.1 Procedures for safeguarding the rights of individuals shall be consistent regardless of sources of funding.

   1.2 The chief executive officer or designee of each member that is involved with research on human subjects shall develop an Institutional Review Board (IRB) or enter into a Memorandum of Understanding with another member with a registered IRB. Each IRB shall meet the requirements set out in the federal regulations and register with the Office for Human Research Protections (OHRP) of the U.S. Department of Health and Human Services. All research on human subjects, whether funded or unfunded, must be approved by the member's IRB before the initiation of the research project.

   1.3 Each member that conducts research involving the use of human subjects shall obtain a Federalwide Assurance (FWA) from OHRP. Requirements for the FWA and sample forms, as well as controlling documents (such as The Belmont Report, 45 CFR 46, etc.), may be obtained from the official website of OHRP.

   1.4 Each member that conducts research involving the use of human subjects shall develop written IRB procedures, including procedures relating to the review of human subject research protocols and reporting guidelines. A specific protocol shall be developed for each project. Each protocol shall be approved by the member's IRB for human subjects before the initiation of the research project.

2. GENERAL GUIDELINES

2.1 Principal investigators (PIs) and department heads (or equivalent) are responsible for ensuring that all research involving human subjects (including protocols which may be exempt, as defined in the federal regulations) is submitted to the member's respective IRB for review and approval.

2.2 PIs shall submit continuing reviews to their respective IRBs, as directed by the IRB, but not less than annually.

2.3 For research projects involving more than one member, all respective IRBs must approve the protocol, unless there is:

(a) a joint review arrangement;

(b) reliance upon the review of another qualified IRB; or

(c) similar arrangements for avoiding duplication of effort.

If the research involves federal funding and (a), (b) or (c) is utilized, the review process must be approved by OHRP and, as applicable, the funding agency.

2.4 Each member involved with research on human subjects shall establish a rule for carrying out this regulation.

Related Statutes, Policies, or Requirements

45 C.F.R. Part 46

21 C.F.R. Part 50 and Part 56

5 U.S.C. 301

42 U.S.C. 289

The Belmont Report, April 18, 1979

Federal Policy for the Protection of Human Subjects ('Common Rule')

Additional U.S. Food and Drug Administration Regulations

Contact Office

System Office of Research
(979) 458-6052