15.99.01 Use of Human Subjects in Research

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Regulation Summary

This regulation provides guidance to The Texas A&M University System, including its members and employees, in complying with federal regulations 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.

Regulation

1. ADMINISTRATIVE REQUIREMENTS

   1.1 Procedures for the protection of human subjects in research must be consistent regardless of sources of funding.

   1.2 Each member that is involved with research on human subjects must develop an Institutional Review Board (IRB) or enter into a Memorandum of Understanding with another member with a registered IRB. Each IRB must 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 must obtain a Federalwide Assurance from OHRP.

   1.4 Each member that conducts research involving the use of human subjects must develop written IRB procedures, including procedures relating to the review of human subject research protocols and reporting guidelines.

2. GENERAL GUIDELINES

   2.1 Principal investigators 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 The Institutional Officer (IO) is responsible for the human research protection program and ensuring compliance with relevant policies and procedures.

2.3 The IRB reports to the IO. The IRB is charged with reviewing and approving any research activities involving the use of human subjects and is responsible for safeguarding the rights and welfare of human subjects in research.

2.4 Each member involved with research on human subjects must 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

Member Rule Requirements

A rule is required to supplement this regulation. See Section 2.4.

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