

15.03.01 Human Subjects in Research

Revised [October 27, 2026](#)

Next Scheduled Review: October 27, 2031

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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 with human subjects, including upholding the ethical principles and guidelines set forth in The Belmont Report, published in 1979, a foundational document outlining ethical principles and guidelines for the protection of human subjects in research and serves as a basis for US government requirements; in addition to, federal regulations, and other applicable standards for the protection of human subjects of research.

Regulation

1. ADMINISTRATIVE REQUIREMENTS

- 1.1 All research involving human subjects, whether funded or unfunded, must be reviewed and, when necessary, approved by an appropriate Institutional Review Board (IRB) before the initiation of the research project.
 - 1.1.1 Each member involved with human subjects research must identify an Institutional Review Board (IRB) or enter into a formal agreement with an IRB external to the member (e.g., a Memorandum of Understanding with another member with a registered IRB, contract with an independent IRB, or other appropriate reliance arrangement consistent with single IRB) for the review of human subjects research projects. Each IRB must meet the requirements set out in the federal regulations, including submitting and maintaining any necessary registrations and assurances.
 - 1.1.2 The IRB is responsible for safeguarding the rights and welfare of human subjects in research.
 - 1.1.2.1 Each member that conducts research involving human subjects and maintains its own IRB must develop written IRB procedures that are consistent regardless of funding, including procedures relating to the review of human subject research protocols and reporting guidelines.

2. GENERAL GUIDELINES

- 2.1 Principal investigators are responsible for ensuring that all research involving human subjects is submitted to the designated IRB for review.
- 2.2 A member's IRB reports to the IO. Each member's Institutional Officer (IO) is responsible for the oversight of human subjects research and ensuring compliance with

relevant federal regulations and other requirements. In the event that an IO is not named (for example, when there is no IRB), the member's Chief Research Officer will be responsible for ensuring that no human subjects research is occurring and for initiating a mechanism for IRB review should human subjects research be initiated at the member.

- 2.3 Each member engaged in human subjects research must establish a rule for carrying out this regulation.

Related Statutes, Policies, or Requirements

21 C.F.R. [Part 50](#) and [Part 56](#)

[eCFR :: 45 CFR Part 46 -- Protection of Human Subjects](#)
[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 2.3.

Contact Office

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