

15.99.05 Research Compliance

Reviewed [May 2, 2017](#)
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Regulation Statement

This regulation establishes the framework for coordinating research compliance programs within and between members of The Texas A&M University System (system), and establishes mechanisms to ensure that each member develops, implements and maintains an appropriate research compliance program.

Reason for Regulation

This regulation provides a framework for (a) achieving the highest level of compliance with applicable ethical, legal, regulatory and system standards and requirements in the research performed throughout the system, and (b) promoting an organizational culture that encourages ethical conduct and a commitment to compliance with federal and state laws and regulations and other applicable requirements by all members.

Procedures and Responsibilities

1. RESEARCH COMPLIANCE

- 1.1 It is the responsibility of the system and each member to take appropriate action that promotes an organizational culture of ethical conduct in research and commitment to compliance with federal and state laws and regulations and other applicable requirements, including, but not limited to, system policies and regulations and member rules and procedures.
- 1.2 Areas of research compliance covered by this regulation include, but are not limited to, the following:
 - (a) human subjects
 - (b) vertebrate animals
 - (c) recombinant DNA biosafety and controlled substances
 - (d) export controls
 - (e) responsible conduct of research

2. SYSTEM RESEARCH COMPLIANCE

- 2.1 For purposes of this regulation, a system research compliance program refers to administrative oversight designed to (a) ensure that each member develops, implements and maintains an appropriate research compliance program, and (b) facilitate and coordinate research compliance programs within and between members.
- 2.2 The chief research officer (CRO) for the system shall appoint a chief research compliance officer (CRCO) who shall report to the CRO.
- 2.3 The CRCO shall be responsible for working with members to establish and maintain an effective system-wide research compliance program designed to ensure that appropriate research compliance rules, procedures and related activities are present at each member.
- 2.4 The chief executive officer (CEO) or designee of each member shall appoint a research compliance officer (RCO).
 - 2.4.1 The RCO shall be a senior administrative official, such as the member's CRO and, typically, shall be the official responsible for research compliance at the member.
 - 2.4.2 The RCO is responsible for developing, implementing and monitoring appropriate research compliance programs at the member.
- 2.5 Research Compliance Advisory Committee
 - 2.5.1 The CRCO shall establish a Research Compliance Advisory Committee (Committee) for the purpose of sharing information and best practices regarding system-wide and member-specific research compliance and discussing and/or participating in research compliance developments, reporting requirements, inspections, training, education and other tasks deemed appropriate by the Committee.
 - 2.5.2 The Committee shall be chaired by the CRCO and will be comprised of all member RCOs. Additional members may be added to the Committee as deemed appropriate by the CRCO. The Committee will meet periodically, but not less than twice per year.
 - 2.5.3 The CRCO may form subject matter subcommittees, the membership of which may be recommended by the Committee.
- 2.6 As part of the system research compliance program, the CRCO, with the advice and support of the Committee, shall undertake the following activities:
 - (a) Ensure all members have an appropriate program for research compliance;
 - (b) Develop, implement and monitor a system-wide research compliance program;
 - (c) Assist in the development, implementation and/or review of each member's research compliance plan, as appropriate;

- (d) Develop or enhance research compliance education and training opportunities throughout the system;
- (e) Serve as a source of research compliance information for the system;
- (f) Assist members to overcome barriers to achieve the highest level of research compliance;
- (g) Collaborate with members to develop innovative and effective ways to mitigate research compliance risks; and
- (h) Make recommendations for policies, regulations and rules to the CRO.

3. SHARED SERVICES

- 3.1 The system and its members are encouraged to share resources (subject matter experts, equipment, training, etc.) and best practices to facilitate research compliance across the system.
- 3.2 In consultation with the Committee, the CRCO shall work with the RCOs to design and implement effective research compliance that maximizes cost-sharing and best practice opportunities (including, but not limited to, the development of system-wide subject matter expertise, training and education) for compliance services by and between members and across the system.

4. REPORTING OBLIGATIONS

- 4.1 Each member shall be responsible for complying with all applicable federal or state reporting requirements. The reporting obligations set forth below are to fulfill the purposes of this regulation, to enable the system and each member to do a risk assessment to determine if additional resources should be allocated, and to assist the member to respond as needed. The reporting obligations set forth below do not replace, change or modify reporting requirements or any other action required of a member under federal or state laws or regulations.
- 4.2 Each member shall implement a plan for faculty, staff, students or the public to report suspected research compliance violation(s) of federal, state, system or member requirements and standards in research conducted at that member (the “suspected violation”). Each member’s plan shall be approved by the member’s RCO and CEO and the CRCO with approval for legal sufficiency by the Office of General Counsel.
- 4.3 Each member is responsible for reporting research compliance violations to federal and state agencies as prescribed by law and in accordance with the member’s established internal reporting requirements. In addition, members must report violations requiring reporting to federal or state agencies to the CRCO as soon as possible. The CRCO will promptly notify appropriate system officials, including the CRO, the system ethics and compliance officer and the general counsel of such violations, and is responsible for preparing and submitting an annual report on system research compliance to the CRO.
- 4.4 The Committee shall determine the types of events that require internal reporting pursuant to this regulation and make recommendations to the CRCO as to the need for

additional policies, regulations and/or rules pertaining to reporting suspected violations. The Committee will review existing research compliance policies and regulations and make recommendations to the CRCO as to the need for modifications and additional reporting obligations.

Related Statutes, Policies, or Requirements

[Animal Welfare Act, as amended \(7 U.S.C. §§ 2131 et. seq.\)](#)

[Public Health Security and Bioterrorism Preparedness and Response Act of 2002 \(PL 107-188\)](#)

[USA PATRIOT Act of 2001 \(PL 107-56\)](#)

[7 CFR 331 Possession, Use, and Transfer of Select Agents and Toxins](#)

[9 CFR 2.31 Institutional Animal Care and Use Committee \(IACUC\)](#)

[9 CFR 121 Possession, Use, and Transfer of Select Agents and Toxins](#)

[42 CFR 73 Select Agents and Toxins](#)

[45 CFR 46 Protection of Human Subjects](#)

[Tex. Educ. Code § 51.971 Compliance Program](#)

[Federal Sentencing Guidelines Chapter 8 – Part B2 - Effective Compliance and Ethics Program](#)

[NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules](#)

[Public Health Service \(PHS\) Policy on Humane Care and Use of Laboratory Animals](#)

[Biosafety in Microbiological and Biomedical Laboratories \(BMBL\), 5th Edition
System Policy 15.01, Research Agreements](#)

[System Regulation 15.01.01, Sponsored Agreements – Research and Other](#)

[System Regulation 15.01.02, Federal Procurement Integrity Act](#)

[System Regulation 15.01.03, Financial Conflicts of Interest in Sponsored Research](#)

[System Policy 15.02, Export Controls](#)

[System Regulation 15.99.01, Use of Human Subjects in Research](#)

[System Regulation 15.99.02, Classified Information](#)

[System Regulation 15.99.03, Ethics in Research, Scholarship and Creative Work](#)

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[System Regulation 15.99.06, Use of Biohazards in Research, Teaching and Testing](#)

[System Regulation 15.99.07, Use of Vertebrate Animals](#)

[System Policy 24.01, Risk Management](#)

[System Regulation 24.01.01, Risk Management Programs](#)

This regulation supersedes:
System Policy 15.03, *Research Compliance*

Member Rule Requirements

A rule is not required to supplement this regulation.

Contact Office

Research Compliance
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