

15.03 Research Compliance

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Policy Statement

The Board of Regents (board) of The Texas A&M University System (system) is committed to the highest standards of integrity in all areas of research and resolves that such activities undertaken by system faculty, staff, and students should be conducted in accordance with strict ethical principles and in compliance with federal and state laws and regulations, and other applicable requirements.

Reason for Policy

This policy 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 within 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.

Procedures and Responsibilities

1. RESEARCH COMPLIANCE

- 1.1 It is the responsibility of the system and each system 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 and institutional policies, regulations and rules.
- 1.2 Areas of research compliance covered by this policy include, but are not limited to, the following: human subject testing, animal use and care, biosafety, radiation safety, export controls, handling of controlled or regulated substances, and research misconduct.

2. SYSTEM RESEARCH COMPLIANCE

- 2.1 The chancellor shall appoint a system compliance officer (SCO). The SCO shall be responsible for working with the Office of the Vice Chancellor for Research (OVCR) and system members to establish and maintain an effective system-wide research compliance program, coordinating research compliance activities within the system,

and reporting to the board and the chancellor regarding the status of such activities. For purposes of this policy, a system research compliance program means a program to ensure that each system member develops, implements and maintains an appropriate research compliance program. The coordination of system-wide research compliance will be supported by the Office of General Counsel (OGC) and the OVCR.

2.2 The SCO shall undertake the following activities:

- (a) Develop, implement and monitor the system-wide research compliance program;
- (b) Assist in the development, implementation and/or monitoring of each member's research compliance plan;
- (c) Develop or enhance research compliance education and training opportunities throughout the system;
- (d) Serve as a source of research compliance information for employees, management and the System Internal Audit Department;
- (e) Assist system member research compliance officers and functionally responsible offices in overcoming barriers to achieve the highest level of research compliance;
- (f) Collaborate with system members to develop innovative and effective ways to mitigate research compliance risks;
- (g) In consultation with the System Research Compliance Committee (Committee), make recommendations for policies, regulations and rules; and
- (h) Independently investigate and act on matters related to research compliance as deemed appropriate.

2.3 The chief executive officer (CEO) or designee of each system member shall designate an employee who will serve as that member's research compliance officer (RCO). The CEO or designee shall also ensure that the RCO is provided with an adequate amount of time, staff and/or resources necessary to implement effective research compliance at that system member. The CEO shall report the name of the RCO to the chancellor and SCO. An individual may serve as the RCO for more than one system member.

2.4 System Research Compliance Committee. A Committee shall be formed and, at a minimum, be comprised of the SCO, OVCR, and RCOs 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. The Committee shall be chaired by the SCO and meet periodically, but no fewer than twice per fiscal year. The Committee may form subject matter subcommittees, the membership of which shall be determined by the Committee.

3. SHARED SERVICES

The system and system members should seek to share resources (subject matter experts, equipment, training, etc.) and best practices to facilitate research compliance across the system. In consultation with the Committee, the SCO shall work with the CEOs or designees 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 system members and across the system.

4. REPORTING OBLIGATIONS

- 4.1 Each system 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 policy, to enable the system and each system member to do a risk assessment to determine if additional resources should be allocated, and to assist the member to respond as needed. These requirements do not replace, change or modify these applicable reporting requirements or any other action required of a member under federal or state laws or regulations.
- 4.2 Each system 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 system member (the “suspected violation”). Each member’s plan shall be approved by the SCO and that member’s RCO.
- 4.3 In addition to fulfilling the above reporting requirements after receiving a report of a suspected violation, the RCO shall conduct a preliminary inquiry into the nature and scope of the suspected violation. The RCO shall report to the CEO and SCO any suspected violation that has caused or poses an imminent risk of injury or harm to persons, property or the surrounding community as soon as possible but no later than twenty-four (24) hours after discovering or receiving the report of the suspected violation. In coordination with the SCO, the RCO will (a) conduct a more substantive investigation or (b) monitor the investigation conducted by an appropriate member entity of the suspected violation(s) and, as appropriate, will make written findings and recommendations to the member’s CEO or designee, SCO, and, as appropriate, grant management.
- 4.4 The Committee shall determine the types of events that require internal reporting pursuant to this policy and make recommendations to the SCO 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 SCO 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 Biological Agents and Toxins](#)

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

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

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

[Federal Sentencing Guidelines - Chapter 8](#)

[NIH Guidelines for Research Involving Recombinant DNA Molecules](#)

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

[Biosafety in Microbiological and Biomedical Laboratories \(BMBL\), 5th Edition](#)

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

[Higher Education Code Chapter 51.971 Compliance Program](#)

[System Policy 15.01, *Research Agreements*](#)

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

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

[System Regulation 15.01.03, *Conflict of Interest in the Design, Conduct and Reporting of Sponsored Research and Educational Activities*](#)

[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 and Scholarship*](#)

[System Regulation 15.99.04, *State Review of Federal Grants and Loans*](#)

[System Policy 24.01, *Risk Management*](#)

[System Regulation 24.01.01, *Supplemental Risk Management Standards*](#)

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