

## 15.99.05 Research Compliance Office

Revised [February 17, 2025](#)

Next Scheduled Review: February 17, 2030

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### Regulation Summary

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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.

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### Regulation

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#### 1. RESEARCH COMPLIANCE

- 1.1 It is the responsibility of the system and each member to take appropriate action that promotes a commitment to compliance with federal, state, and local 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) biohazards, including recombinant and synthetic nucleic acids
  - (d) controlled substances
  - (e) research misconduct
  - (f) responsible conduct of research/responsible and ethical conduct of research training
  - (g) financial conflict of interest in research

#### 2. SYSTEM RESEARCH COMPLIANCE

- 2.1 For purposes of this regulation, the system research compliance program refers to administrative oversight designed to (a) ensure that the system and 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 must appoint a chief research compliance officer (CRCO) who reports to the CRO and collaborates with the system chief compliance officer.
- 2.3 The CRCO is responsible for working with members to establish and maintain an effective systemwide research compliance program designed to ensure that appropriate research compliance rules, procedures and related activities are present at each member. Additionally, the system Research Compliance Office (RCO), undertakes the following activities:
  - 2.3.1 Serves as a source of research compliance information for members.
  - 2.3.2 Assists and approves system member annual research compliance plans, including reviews of major areas of research compliance risk on at least an annual basis.
  - 2.3.3 Advises and assists members in research compliance activities including reporting non-compliance and adverse events to oversight agencies as applicable, including but not limited to assistance in developing processes, advising on risk mitigation strategies, providing research compliance programmatic assessments, and supporting research compliance incident reviews.
  - 2.3.4 Supports and trains system member CROs and institutional officials (IOs).
  - 2.3.5 Communicates with federal regulatory agencies and oversight bodies to resolve regulatory questions, concerns, or interpretations that impact system members.
  - 2.3.6 Provides educational and training opportunities for system members research compliance leadership and staff, and coordinates professional development activities.
  - 2.3.7 Assists, as needed, with system member research oversight accreditation, assurance and registration efforts.
- 2.4 The chief executive officer (CEO) or designee of each member must appoint an IO who is the individual responsible for research compliance at the member. The IO must be a senior administrative official, such as the member's CRO, who is the ultimate authority responsible for developing, implementing, and monitoring research compliance programs at the member as defined in this regulation.

### 3. SHARED SERVICES

- 3.1 As a shared service entity, members will work closely with the RCO in exercising the office's available resources including but not limited to subject matter expertise, communications with regulatory agencies, and training.
- 3.2 The CRCO will work primarily with the CRO for each member, who will typically also serve as the member's IO for research compliance programs, and other research compliance leads as designated by the CRO.

### 4. REPORTING OBLIGATIONS

- 4.1 Each member is 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, enable the system and each member to do a risk assessment to determine if

additional resources should be allocated, and 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 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 incidents, both noncompliance and adverse events, to the system RCO as established by the CRCO. The system RCO will promptly notify appropriate system officials, including the CRO, the system ethics and compliance officer, and others as appropriate. The system RCO must maintain a systemwide mechanism to gather and evaluate incidents of research non-compliance and adverse events, with reporting guidelines established by the vice chancellor for research and CRCO.

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## **Related Statutes, Policies, or Requirements**

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

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

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

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

[System Policy 24.01, Risk Management](#)

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## **Member Rule Requirements**

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A rule is not required to supplement this regulation.

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## **Contact Office**

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Research  
(979) 458-5598

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