



Research Compliance and Regulatory Affairs Program Charter

MISSION STATEMENT:

The mission of the Emory University Office of Research Compliance and Regulatory Affairs (RCRA) is to support Emory's research enterprise in understanding and complying with requirements and regulations for the conduct of ethical research by implementing compliance processes and policies and providing education.

To accomplish this mission, RCRA works closely with the Emory research community to obtain their input and to incorporate their needs and ideas into our work.

RCRA conducts processes and initiatives with integrity and maintains the confidentiality, as much as possible, of all parties and information for adequate management of noncompliance processes and investigations.

PURPOSE:

RCRA promotes Emory's research mission by ensuring compliance with US state and federal regulations and Emory policies related to financial conflicts of interest, animal subjects research, export controls, research security, research misconduct, and others.

RCRA facilitates the development and implementation of policies and procedures needed for the Emory academic and research enterprise to succeed in their goals and, at the same time, stay compliant with current laws, policies and regulations.

RCRA is composed of five offices:

- Export Controls
- Conflict of Interest and Commitment
- Institutional Animal Care and Use Committee
- Research Integrity and Compliance
- Research Security

Each office is responsible for different academic and research compliance aspects but shares the goals of serving the Emory community and promoting ethical research. The offices collaborate but also work independently to achieve our shared goals.

ROLES AND RESPONSIBILITIES

RCRA is responsible for creating and maintaining an effective research compliance program in accordance with US Federal Sentencing Guidelines to oversee research compliance and regulatory activities. RCRA accomplishes this goal by:

- Developing effective lines of communication with university partners;
- Providing effective training, education, and outreach to researchers and research administrators;
- Developing, maintaining, and revising policies and procedures for research compliance issues;
- Conducting research compliance monitoring, investigations, and reviews;

- Responding promptly to detected and/or reported issues of concern and ensuring appropriate corrective actions are in place for resolution;
- Promoting and enforcing standards through education, awareness and training as well as via disciplinary guidelines when applicable; and
- Routinely evaluating research compliance program effectiveness.

RCRA serves as a consultative guidance resource for the Emory research workforce to navigate the application of Emory policies and state and federal regulations that apply to their research activities. To that goal, these are some of the services provided by RCRA:

- Performs risk assessments and creates or modifies existing programs to address identified risks
- Performs gap analyses to ensure compliance with current state and federal regulations and Emory policies
- Performs audits and evaluations of ORA compliance plans to ensure compliance with current state and federal regulations and Emory policies.
- Manages research misconduct allegations, including the assessment process, Inquiry, and Investigation proceedings
- Manages ORA policies to ensure compliance with Emory policies and federal regulations
- Supports compliance with the Export Control regulations and policies
- Facilitate and support the following faculty-led committees:
 - Institutional Animal Care and Use Committee
 - Research Compliance Committees for research security, investigation management, and regulatory reporting, ORA policy approval
 - Conflict of Interest and Commitment Committee
 - Embryonic Stem Cell Committee
- Fulfills internal reporting obligations as part of the research compliance plan
- Serves as a resource to the University in matters involving research compliance at Emory
- Serves as a resource to the University in matters involving Controlled Substances and FDA Regulated Research
- Ensures compliance with all research data protection policies
- Provides research compliance-related training
- Collaborates with Emory offices to support the onboarding of the research workforce, to ensure adequate training and awareness of current state and federal regulations and Emory policies.
- Partners with Emory offices to address research compliance risks and implement new processes and policies as needed

To meet RCRA's responsibilities and maintain independence, RCRA is authorized to access university records, documents, facilities, and personnel necessary to conduct research compliance assessments, training, audits, monitoring, and investigations and fulfill reporting requirements. University leaders must ensure personnel under their oversight cooperate with RCRA during compliance audits and activities.

Reports generated from RCRA assessments, audits, monitoring, and investigations will be provided to leaders in research administration, appropriate university administrative personnel, and legal counsel. When specific findings or issues of non-compliance, unmitigated compliance risks, or other deficiencies are identified, the research administrative personnel with authority over the activities reviewed shall be responsible for implementing necessary corrective action plans.

REPORTING STRUCTURE:

The RCRA programs and offices are part of the Office of Research Administration, reporting to the Vice President of the Research Administration (VPRA) and ultimately to the Office of the Senior VP of Research.

PARTNERS ACROSS EMORY:

RCRA strives to collaborate with Emory offices to reduce the burden on our research workforce and ensure communication between our compliance partners. We coordinate our efforts with various units, including but not limited to the following (in alphabetical order):

- Emory Healthcare Compliance
- Emory Investment Management, Advancement, and Alumni Engagement
- Emory Police Department
- Global Health Institute
- Human Resources
- Information Security
- Internal Audit
- Office of Diversity, Equity, and Inclusion
- Office of Enterprise Risk Management
- Office of Ethics and Compliance
- Office of Global Strategy and Initiatives
- Office of Information Technology
- Office of the General Counsel
- Office of the Provost
- Research Administration offices in ORA
- Schools and Other Academic Offices

Charter Review and Effective Date: November 14, 2022

Signatures

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