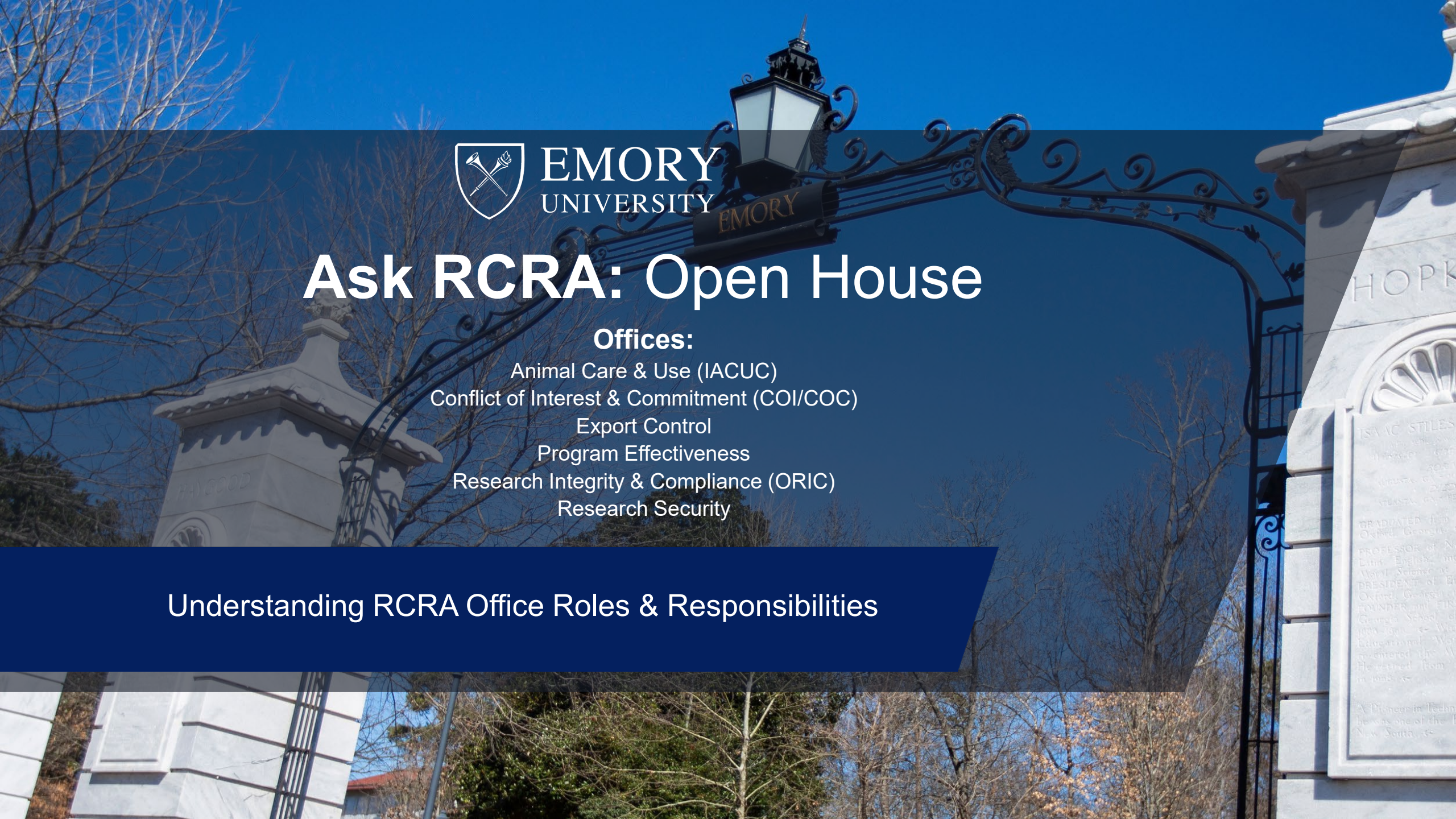


EMORY UNIVERSITY

Ask RCRA: Open House

Offices:

Animal Care & Use (IACUC)
Conflict of Interest & Commitment (COI/COC)
Export Control
Program Effectiveness
Research Integrity & Compliance (ORIC)
Research Security

Understanding RCRA Office Roles & Responsibilities

OFFICE OF RESEARCH COMPLIANCE AND REGULATORY AFFAIRS (RCRA)





Institutional Animal Care & Use Committee

Conflict of Interest & Committment

Export Controls

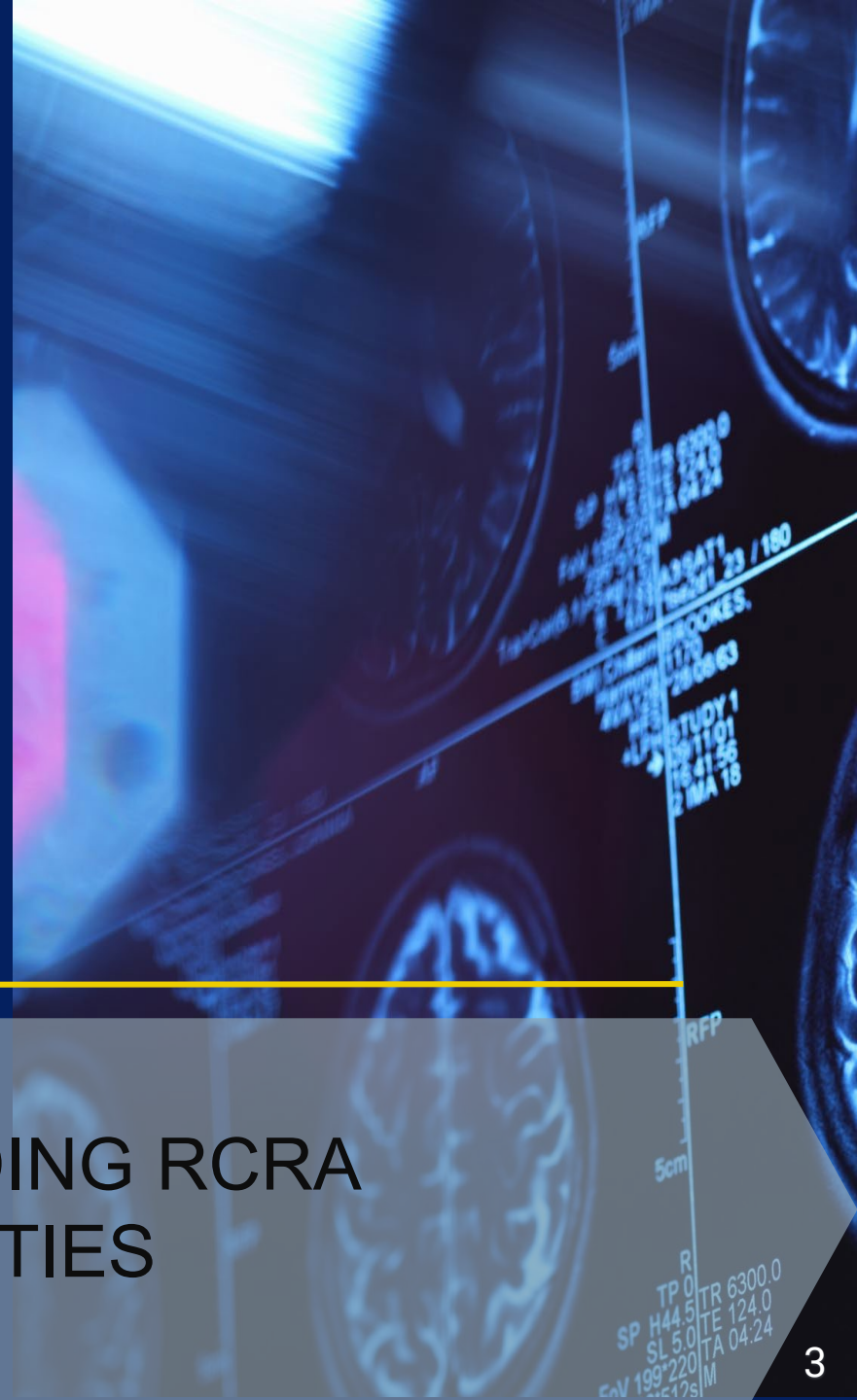
Program Effectiveness

Research Integrity and Compliance

Research Security

Dr. Sarah Thompson, a respected neuroscientist, is leading a groundbreaking study on the effects of a new chemical compound (NeuroDex) on cognitive function in rats. The research aims to develop new treatments for Alzheimer's disease. The study is conducted at a leading research university.*

* This case was generated with the help of Microsoft Copilot



EMORY UNIVERSITY

Research Compliance and Regulatory Affairs

Research Administration

CASE SCENARIO: UNDERSTANDING RCRA OFFICE ROLES & RESPONSIBILITIES

CASE SCENARIO: UNDERSTANDING RCRA OFFICE ROLES & RESPONSIBILITIES

The study involves the use of 100 rats, which are genetically modified to exhibit symptoms of Alzheimer's disease.

- What pre-approvals are needed before starting animal work?
  - Dr. Thompson reached out to EHSO to submit biosafety and chemical registrations for NeuroDex
  - IACUC protocol approval
- What post-approval activities are needed?
  - Review approved IACUC procedures
  - Review applicable IACUC Policies
  - Training of personnel handling animals
  - Meet with the Post-Approval Monitoring team
  - Dr. Thompson is processing their GBP and DEA licenses

CASE SCENARIO: UNDERSTANDING RCRA OFFICE ROLES & RESPONSIBILITIES

- Is partnering with other ORA departments necessary? If so, which departments?
  - EHSO
  - DAR
  - Office of Research Integrity and Compliance
  - Office of Technology Transfer
  - Conflict of Interest
- Is partnering with other schools necessary?
  - No other collaborations related to animal work are needed
- Rats will need to be shipped to GA State for imaging, what is needed?
  - A Memorandum of Understanding needs to be signed between IACUCs

CASE SCENARIO: UNDERSTANDING RCRA OFFICE ROLES & RESPONSIBILITIES

The NeuroDex mechanism of action was developed partially at an institution in China. Dr. Thompson would like to bring in a visiting scholar expert to assist with research.

- Who does Dr. Thompson need to contact in RCRA for guidance?
  - This introduces an international collaboration aspect to the project, requiring involvement of Export Controls and Research Security Offices.
- What is the approval process for a visiting scholar in Dr. Thompson's lab?
  - Visiting Scholars Policy 7.12 and Export Control Policy 7.11.
  - A Visitor Application form must be completed and submitted via OnBase, along with supporting documentation.
  - Export Controls reviews for deemed export, trade and economic related sanctions, restricted/prohibited parties.
  - Research Security reviews for affiliations (red flags), collaborations, foreign funding, publications, co-authors, disclosures, patents, ORCID, SOW, lab restrictions.

CASE SCENARIO: UNDERSTANDING RCRA OFFICE ROLES & RESPONSIBILITIES

The compound NeuroDex is classified as a controlled item under export control regulations due to its potential dual-use (civilian and military applications).

- What Export control concerns should Dr. Thompson be aware of?
  - Physical security of material
  - International shipping
  - Use of proprietary/unpublished technology

CASE SCENARIO: UNDERSTANDING RCRA OFFICE ROLES & RESPONSIBILITIES

In order to push the science behind NeuroDex further, Dr. Thompson creates a new company called, NeuroMND. NeuroMND licenses the IP from Emory and applies for awards outside of Emory.

- How would we review and/or manage such a relationship?
  - Work with a variety of partners: IRB, IACUC, OTT, Export, OSP, RAS, and Research Security
  - Is this a domestic or international company?
  - Send to COI Committee
- What obstacles exist?
  - How to manage objectivity
  - Safeguarding Emory and its resources
- What is the best way we would begin to mitigate the conflict?
  - Disclosure to Research Team and Participants

CASE SCENARIO: UNDERSTANDING RCRA OFFICE ROLES & RESPONSIBILITIES

NeuroDex is classified as a controlled substance, schedule I, due to its psychoactive properties. Neurodex has not been approved in the US for research, and Dr. Thompson is in communication with the drug pharmaceutical company in the US to secure its use in animals.

- What RCRA office should Dr. Thompson contact?
  - Office of Research Integrity and Compliance (ORIC) at oric@emory.edu.
- What type of permits Dr. Thompson needs to start the study?
  - Institutional approval (IRB/IACUC/RCRA); Georgia Board of Pharmacy and DEA licenses (Emory Policy 7.25).

CASE SCENARIO: UNDERSTANDING RCRA OFFICE ROLES & RESPONSIBILITIES

Dr. Thompson has received all the approvals pressure and has started the grueling part of doing the research. She is under a lot of pressure and is trying to ensure the research team reaches the milestones to prevent falling behind. She has a new team member who is bringing great work, but it is only on the weekends when she is alone in the lab. Dr. Thompson finds that some of the graphics and data results cannot be found in the lab's raw data repository.

- What should Dr. Thompson be worried about?
  - She should be worried about possible research misconduct. Dr. Thompson should look for data to ensure the issue is credible and specific (Emory Policy 7.8)
- Who should Dr. Thompson contact?
  - The Emory RIO and team at rio@emory.edu. The Emory RIO is Deepika Bhatia.

CASE SCENARIO: UNDERSTANDING RCRA OFFICE ROLES & RESPONSIBILITIES

A high schooler (age 16) reached out to Dr. Thompson and expressed that he is interested in developing research skills and asks if he can volunteer in Dr. Thompson's lab. Dr. Thompson is excited about the idea of having a volunteer in her lab and immediately tells the student that he can start next week. The student starts in the lab the following Monday and while working in the lab, Dr. Thompson leaves the student alone. While unsupervised, the student drops chemicals and the chemicals splash in the student's eye, and he experiences redness and irritation.

- What should have been Dr. Thompson's first step when she decided she wanted to host the minor in her lab?
    - Dr. Thompson should have reached out to RCRA at researchcompliance@emory.edu to obtain the Minors Registration Form and the required trainings. Dr. Thomspon should not have had the minor in her lab until RCRA provided final approval.
- What other issues can you identify?
    - Dr. Thompson should not have left the minor unsupervised. Minors must be always supervised by the Principal Investigator/Sponsor or by another responsible adult Emory faculty or full-time Emory staff member to whom the Principal Investigator/Sponsor has specifically delegated this responsibility.
- Applicable Emory policy?
    - Policy 7.21 - Minors Participating in Research Activities at Emory University

Contact Us

- COI/COC: edisclose@emory.edu
- Export Control: exportcontrol@emory.edu
- IACUC: iacuc@emory.edu
- ORIC: oric@emory.edu
- Research Security: researchsecurity@emory.edu
- Program Effectiveness: researchcompliance@emory.edu

Resources

- RCRA Offices: Fact Sheet
- Policy Handbook