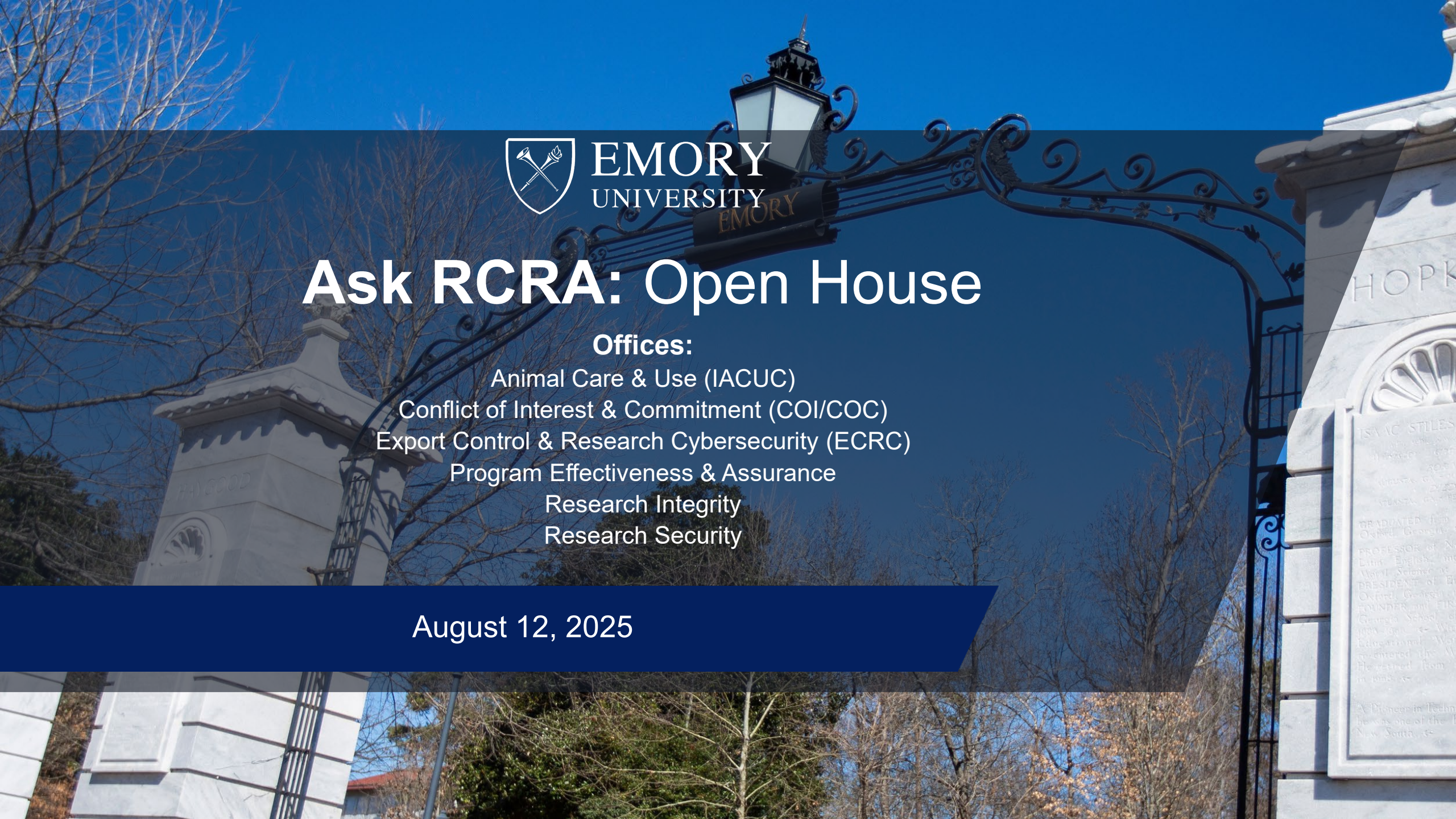


EMORY UNIVERSITY

Ask RCRA: Open House

Offices:

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

August 12, 2025

OFFICE OF RESEARCH COMPLIANCE AND REGULATORY AFFAIRS (RCRA)





Institutional Animal Care & Use Committee

Conflict of Interest & Committment

Export Control & Research Cybersecurity

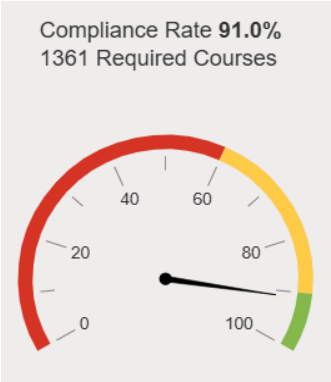
Program Effectiveness & Assurance

Research Integrity

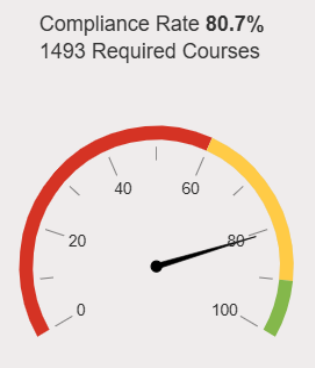
Research Security

INSTITUTIONAL ANIMAL CARE & USE COMMITTEE (IACUC)

- **FY25 ACCOMPLISHMENTS**
  - Training – Continuing Education



OHS compliance program



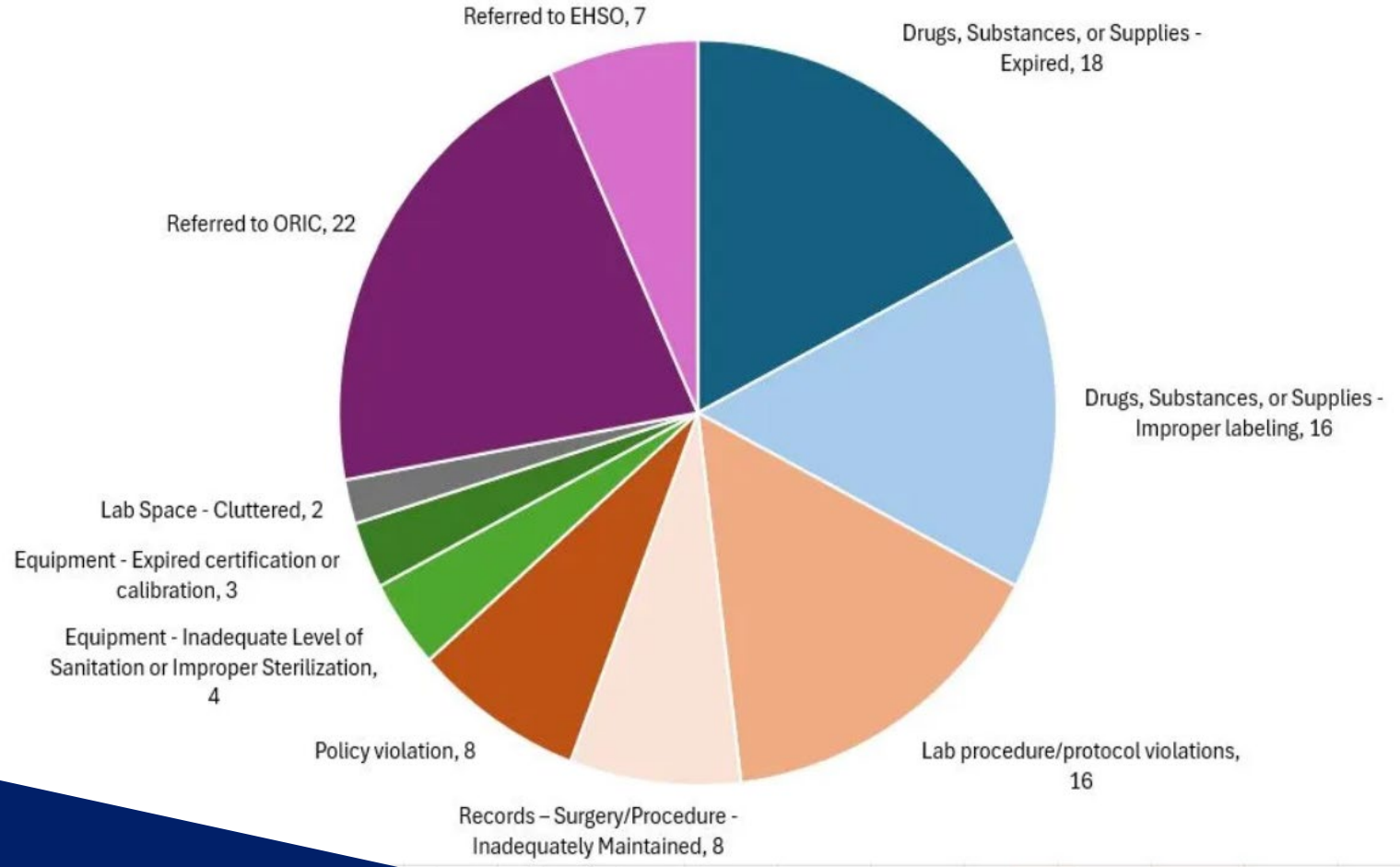
- **GOALS FOR FY26**
  - Preparation for AAALAC International re-accreditation site visit – Spring 2026
  - Review of spaces outside the animal facility used for animal care and use
  - QA of protocols during pre-review
  - Post-noncompliance monitoring

IACUC website:
https://emory.sharepoint.com/sites/eIACUC

INSTITUTIONAL ANIMAL CARE & USE COMMITTEE (IACUC)

COMPLIANCE TOPIC:

- Current cycle: June – November 2025
- Most frequent site inspection deficiencies



CONFLICT OF INTEREST & COMMITMENT (COI/COC)

- **FY25 ACCOMPLISHMENTS**
  - Annual Certification #s 99.9%, over 1700 proposals reviewed for Conflicts
  - Development of Disclosures in the upcoming Online Submission Platform (Insight)
  - Research COI/COC Training Module in Brainer with Integration to Insight

- **GOALS FOR FY26**
  - 100% completion rate for the Annual Certification Cycle (Dec-Feb)
  - Improve the functionality of Insight
  - Update governance documents to support the goal and mission of the Research COI/COC Office (QA/QI process, COI/COC Charter)

CONFLICT OF INTEREST & COMMITMENT (COI/COC)

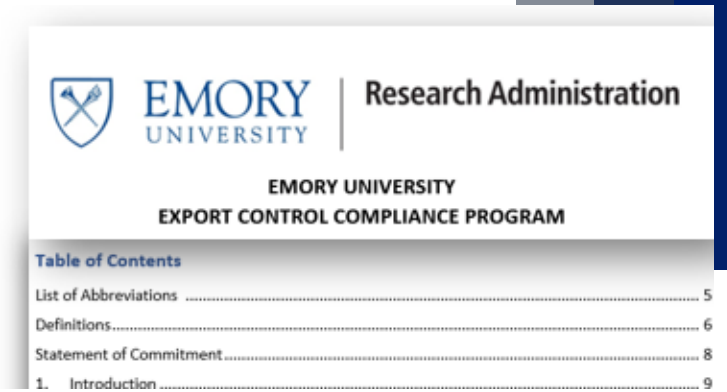
- **COMPLIANCE TOPIC: Insight Navigation**

EXPORT CONTROL & RESEARCH CYBERSECURITY (ECRC)

FY25 ACCOMPLISHMENTS

Program Maturity Assessment

- Program maturity assessed against 8 Elements of effective export compliance program


EMORY UNIVERSITY | Research Administration

EMORY UNIVERSITY
EXPORT CONTROL COMPLIANCE PROGRAM

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Expanded responsibilities : Research cybersecurity

- Controlled Unclassified Information (CUI),
- Cybersecurity Maturity Model Certification (CMMC) for protecting sensitive unclassified information
- Other sensitive research information/data


Develop programmatic components for new responsibilities related to Research Cybersecurity

- Written Policies and Procedures
- Compliance Oversight
- Training and Education
- Internal Monitoring

Office Rebranding and Updated website to include information on CUI and research cybersecurity resources

Export Control and Research Cybersecurity Office (ECRC)

EXPORT CONTROL & RESEARCH CYBERSECURITY (ECRC)

FY26 GOALS

ECRC module in INSIGHT

Customized configuration and workflows

Research cybersecurity program development

Secure Enclave Solution for CUI and other sensitive data

Breakout Room Compliance Topic:
Expanded responsibilities of Export Control & Research Cybersecurity (ECRC)
- Focus on CUI

PROGRAM EFFECTIVENESS & ASSURANCE

FY25 ACCOMPLISHMENTS

- Minors Participating in Research Activities
  - The new **Minors in Research Form** is now available on the **Research Portal**.
    - All researchers must complete and submit this form **before** minors participate in any research activities.
    - **Minors may not begin participation** until the form has been reviewed and approved.
  - Restructuring: For an enhanced and robust compliance with CSDD, on the basis on an external assessment, we have a dedicated program and support for Research Controlled Drugs Compliance (RCDC) now managed under Program Effectiveness & Assurance

- Policy Updates
  - Policy 2.126 - Effort Reporting (Approved)
  - Policy 7.28 - Payments to Human Subjects Research Participants (Pending Approval)
  - Policy TBA – Research Data Protection Policy (Pending Approval)
  - Policy 7.30 - Authorship (Pending Approval)
  - Policy 7.8 - Research Misconduct (Pending Approval)
  - Policy 7.11 - Export Control (Pending Approval)
  - Policy 7.6 - Intellectual Property (Pending Approval)

PROGRAM EFFECTIVENESS & ASSURANCE

- **GOALS FOR FY26**
  - RCDC:
    - **System Integration**: Migrating Georgia Board of Pharmacy (GBP) and DEA license management into EHS Assist for centralized tracking and oversight.
    - **Update to Policy 7.25:** to meet the needs to federal/state regulations
    - **Training Material:** All Emory forms and training will be updated
    - **QA/QI reviews:** Provide enhanced support to Researchers through Annual QA/QI reviews
    - **Technology Enhancement**: Leveraging an existing vendor to implement an electronic drug management system at no cost to the institution.

PROGRAM EFFECTIVENESS & ASSURANCE

- **GOALS FOR FY26**
  - Program Effectiveness
    - **Emerging Compliance Topics (e.g., Research Security, AI Use, Data Sharing)** - Address compliance with newly evolving federal priorities (e.g., NSPM-33, AI governance).
    - **CAT Planning: Policy Updates & Communication:** Increase awareness of policy changes via consistent education.
    - **Approval Process Optimization and Enhancement** - Streamline the research policy approval process through governance reform

RESEARCH INTEGRITY

- **FY25 ACCOMPLISHMENTS**
  - Support of research staff during GDNA audits
  - New CS/DD forms and processes
  - Continuing support to researchers during FDA audits
  - Research misconduct prevention training sessions
  - RCR training expansion to include training in Humanities fields.

- **GOALS FOR FY26**
  - Restructuring
    - CS/DD program requires additional support
    - Program is moving under Program Effectiveness and Assurance
  - Refocusing
    - Our Team will be rebranded from ORIC to Research Integrity (RI)
    - We will continue to support the RIO during research misconduct and research noncompliance reviews, as well as supporting the ESCRO committee, researchers submitting to FDA, and the RCR training program. We will also continue with compliance audits.

ESCRO committee submission requirement

You must submit your study for review to the ESCRO (human embryonic stem cell oversight) committee in the following scenarios:

- Non-integrated stem cell-based embryo models
- In vitro culture of chimeric embryos (human cells into non-human embryos)
- In vitro gametogenesis without fertilization or generation of embryos
- Genetic alteration of embryos or gametes
- Integrated stem cell-based embryo models
- Procurement of embryos, or gametes for the creation of embryos, for in vitro Research
- Derivation of cell lines from human embryos
- In vitro culture of human embryos for Research for up to 14 days
- Transferring human embryos following Mitochondrial replacement techniques into a human uterus

Submit your application using the MS Form located at https://rcra.emory.edu/oric/stem-research.html

RESEARCH INTEGRITY

You are exempt for review to the ESCRO committee in the following scenarios:

- Research involving the use of adult stem cells
- Use of human cord blood
- Transplantation of stem cells as part of recognized and accepted medical treatment for a disease or condition
- Human Induced pluripotent stem cell line (hiPSC) generation or use in research, excluding the above research applications
- Most in vitro organoid research, excluding the above research applications
- Transfer of non-embryonic human stem cells into postnatal animal hosts

RESEARCH INTEGRITY

The ESCRO committee **will not approve research** that is conducting the following activities:

- Germline genome editing
- Transferring Mitochondrian DNA (mtDNA)-modified (not including MRT) embryos into a uterus
- Using gametes differentiated from human stem cells for reproduction
- Gestating Human stem cell-based embryo models
- Human reproductive cloning
- Breeding human-animal chimeras where there may be human germ cells
- Transferring human-animal chimeric embryo(s) to a human or ape uterus
- Transferring human embryo(s), irrespective of origins, to an animal uterus

What about Fetal Tissue Use in Research?

Fetal tissue use in research does not need to be reviewed by the ESCRO committee; however, it needs to be reviewed by:

- RCRA office
- In some cases, Office of General Counsel
- Other offices as applicable

If you plan to use fetal tissue for research, please contact us at researchcompliance@emory.edu.

RESEARCH SECURITY

- **FY25 ACCOMPLISHMENTS**
  - Travel Registry
    - Past effort stalled
    - Revived initiative with budget commitment and stakeholder inclusion
    - Timeline
      - Gather requirements summer 2025
      - Identify potential vendors Summer 2025
      - RFP release end of summer 2025
      - Award end of year 2025

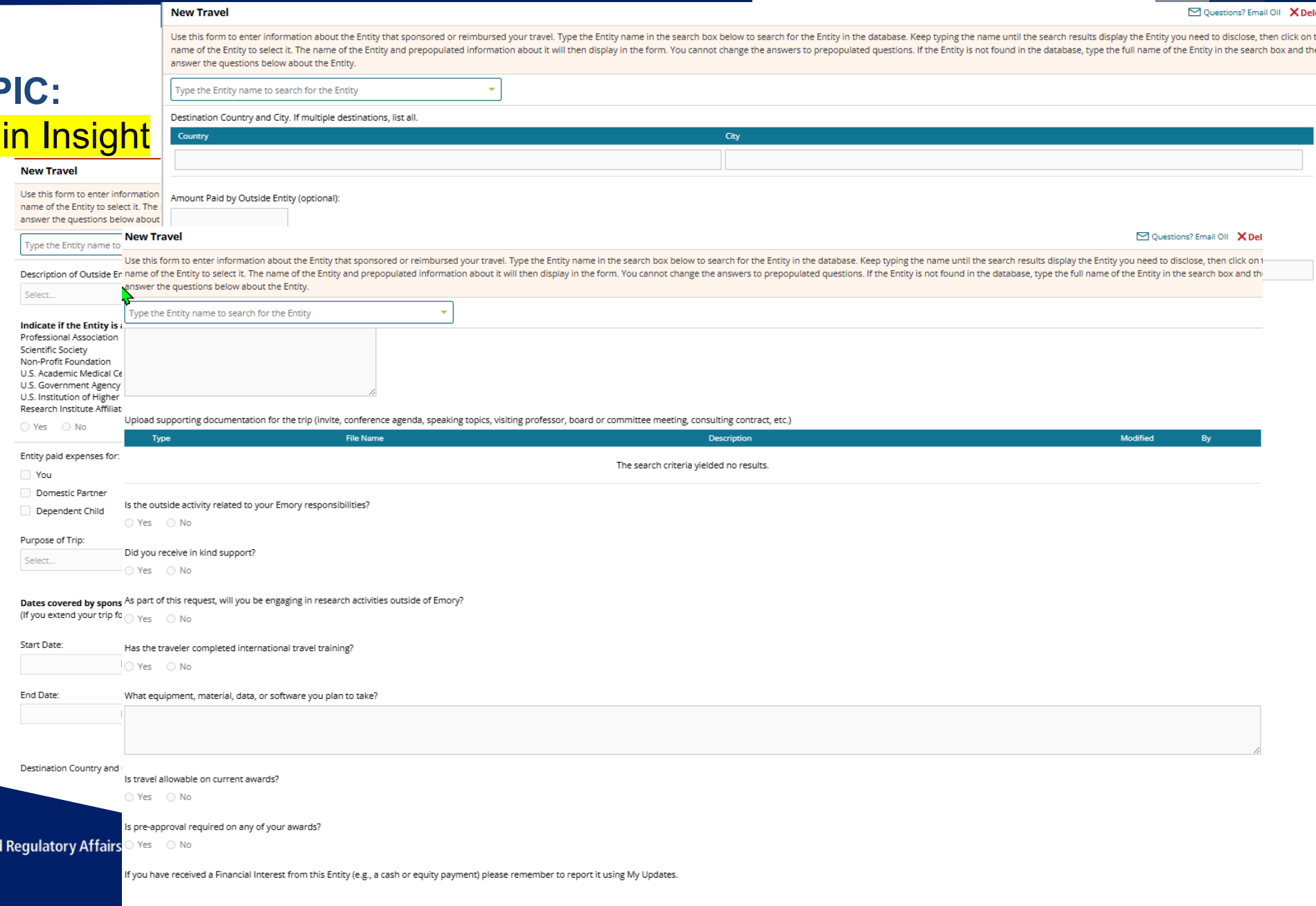
  - NSF SECURE SE
    - 5 year award September 2024
    - Hire Staff September 2024-January 2025 (fully staffed)
    - Stakeholder input
    - Develop solutions to challenges
    - Launch MVP on internet

RESEARCH SECURITY

- **GOALS FOR FY26**
  - Travel Registry
    - Implementation
    - Training
    - Rollout summer 2026
  - SECURE SE
    - Solutions use, feedback, refine
    - New solutions to address stakeholder challenges
  - Loaner laptop program
    - Program expansion
    - Configuration standardization
    - Awareness/use

RESEARCH SECURITY

- **COMPLIANCE TOPIC:**
  - MyTravel Form in Insight
  - Loaner
  - Travel Matrix



RESEARCH SECURITY

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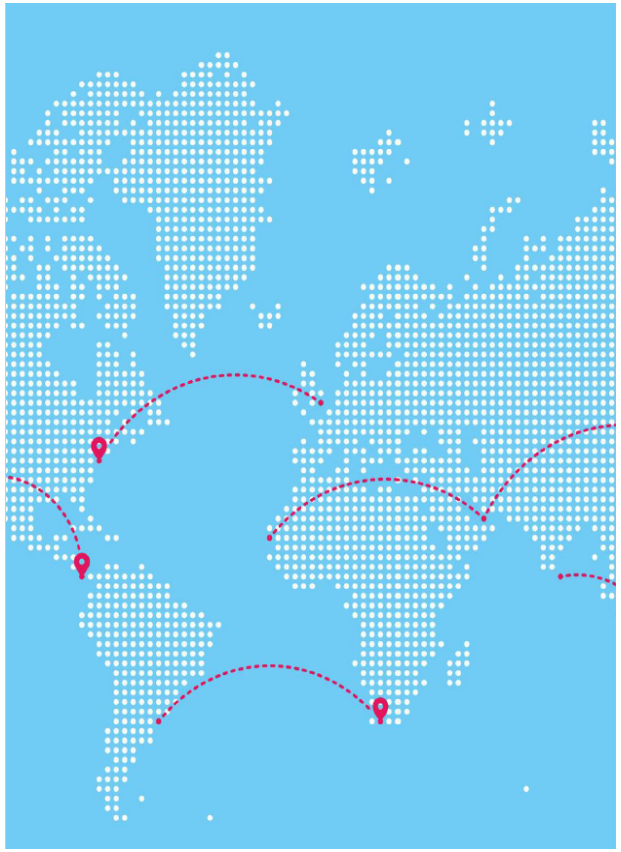


International Travel Loaner Laptop Program

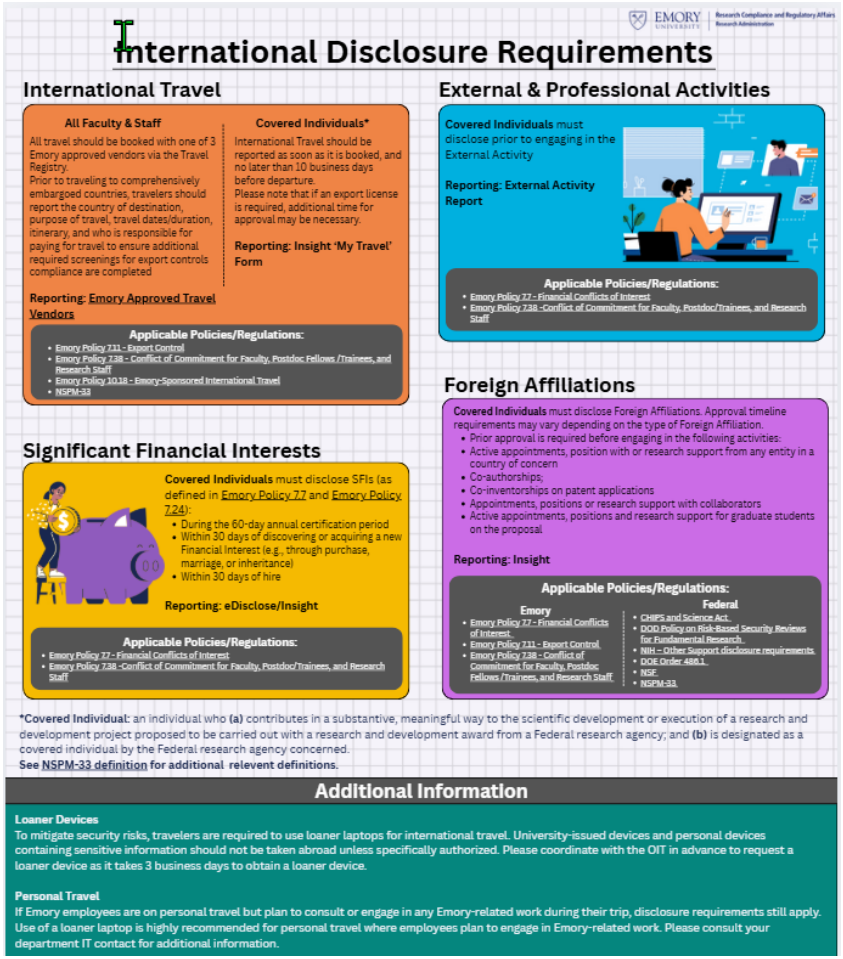
- Available to faculty, staff, and student employees conducting Emory University-sponsored international travel
- No cost to borrow a laptop. However, travelers are responsible for any damage or loss of the laptop or peripheral items.
- Available devices: Dell Latitude 14 inch; MacBook Pro 14 inch
- Limited availability under pilot program, with preference for travel to high-risk destinations of Cuba, Iran, North Korea, Syria, and regions in Ukraine under Russian control (Crimea, Luhansk and Donetsk), as well as any destination on the State Department Travel Advisory website listed as a level 3 or 4 travel advisory
- Request a loaner through ServiceNow Service Portal

Please see the full loaner laptop website for more details.

Rev 7

RESEARCH SECURITY

- **COMPLIANCE TOPIC:**
  - MyTravel Form in Insight
  - Loaner
  - Travel Matrix



International Disclosure Requirements

International Travel

All Faculty & Staff

All travel should be booked with one of 3 Emory approved vendors via the Travel Registry.
Prior to traveling to comprehensively embargoed countries, travelers should report the country of destination, purpose of travel, travel dates/duration, itinerary, and who is responsible for paying for travel to ensure additional required screenings for export controls compliance are completed

Covered Individuals*

International Travel should be reported as soon as it is booked, and no later than 10 business days before departure.
Please note that if an export license is required, additional time for approval may be necessary.

Reporting: Insight 'My Travel' Form

Reporting: Emory Approved Travel Vendors

Applicable Policies/Regulations:

- Emory Policy 7.11 - Export Control
- Emory Policy 7.38 - Conflict of Commitment for Faculty, Postdoc Fellows /Trainees, and Research Staff
- Emory Policy 10.18 - Emory-Sponsored International Travel
- NSPM-33

External & Professional Activities

Covered Individuals must disclose prior to engaging in the External Activity

Reporting: External Activity Report

Applicable Policies/Regulations:

- Emory Policy 7.7 - Financial Conflicts of Interest
- Emory Policy 7.38 -Conflict of Commitment for Faculty, Postdoc/Trainees, and Research Staff

Significant Financial Interests

Covered Individuals must disclose SFIs (as defined in Emory Policy 7.7 and Emory Policy 7.24):

- During the 60-day annual certification period
- Within 30 days of discovering or acquiring a new Financial Interest (e.g., through purchase, marriage, or inheritance)
- Within 30 days of hire

Reporting: eDisclose/Insight

Applicable Policies/Regulations:

- Emory Policy 7.7 - Financial Conflicts of Interest
- Emory Policy 7.38 -Conflict of Commitment for Faculty, Postdoc/Trainees, and Research Staff

Foreign Affiliations

Covered Individuals must disclose Foreign Affiliations. Approval timeline requirements may vary depending on the type of Foreign Affiliation.

- Prior approval is required before engaging in the following activities:
- Active appointments, position with or research support from any entity in a country of concern
- Co-authorships;
- Co-inventorships on patent applications
- Appointments, positions or research support with collaborators
- Active appointments, positions and research support for graduate students on the proposal

Reporting: Insight

Applicable Policies/Regulations:

Emory

- Emory Policy 7.7 - Financial Conflicts of Interest
- Emory Policy 7.11 - Export Control
- Emory Policy 7.38 - Conflict of Commitment for Faculty, Postdoc Fellows /Trainees, and Research Staff

Federal

- CHIPS and Science Act.
- DOD Policy on Risk-Based Security Reviews for Fundamental Research.
- NIH – Other Support disclosure requirements
- DOE Order 486.1
- NSF
- NSPM-33

***Covered Individual:** an individual who **(a)** contributes in a substantive, meaningful way to the scientific development or execution of a research and development project proposed to be carried out with a research and development award from a Federal research agency; and **(b)** is designated as a covered individual by the Federal research agency concerned.
See NSPM-33 definition for additional relevent definitions.

Additional Information

Loaner Devices
To mitigate security risks, travelers are required to use loaner laptops for international travel. University-issued devices and personal devices containing sensitive information should not be taken abroad unless specifically authorized. Please coordinate with the OIT in advance to request a loaner device as it takes 3 business days to obtain a loaner device.

Personal Travel
If Emory employees are on personal travel but plan to consult or engage in any Emory-related work during their trip, disclosure requirements still apply. Use of a loaner laptop is highly recommended for personal travel where employees plan to engage in Emory-related work. Please consult your department IT contact for additional information.

Contact Us

- COI/COC: edisclose@emory.edu
- Export Control & Research Cybersecurity: exportcontrol@emory.edu
- IACUC: iacuc@emory.edu
- Research Integrity: rio@emory.edu
- Research Security: researchsecurity@emory.edu
- Program Effectiveness & Assurance: researchcompliance@emory.edu

Resources

- RCRA Offices: Fact Sheet
- Policy Handbook