



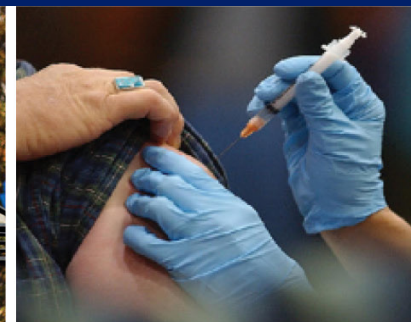
EMORY
UNIVERSITY

Research Compliance
and Regulatory Affairs

Community Forum

ASK RCRA

Learn what is the latest in Research Compliance and
have a chance to interact with our Research
Compliance Experts!



Know the Audience

POLL



Session Agenda

**RCRA System
Updates**

1

2

Research Key Risks

NASA Forms

3

4

**Controlled
Substances**

RCRA Office Spotlight

5

6

Q&A



RCRA System Updates

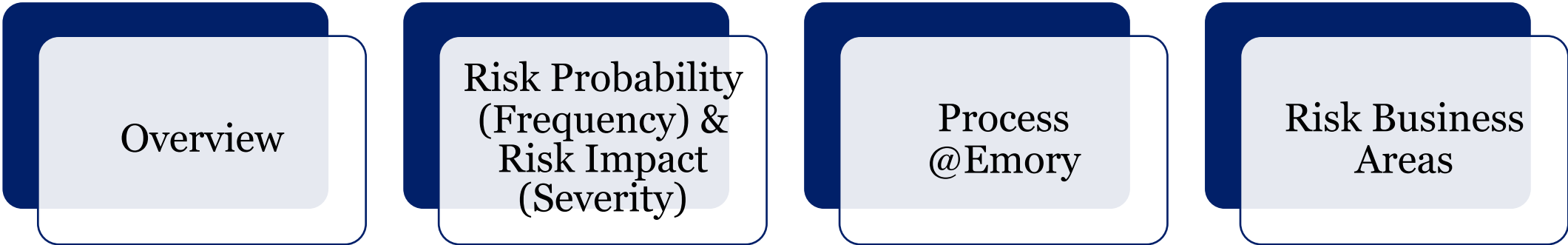
eDiscloseComing Soon!



- *eDisclose Town Hall in June 2022.*
- *Check the [eDisclose](#) site for information and resources.*
- *Visit the [FAQs](#) link to learn more about the system and the transition from eCOI to eDisclose.*



Enterprise Risk Assessment



| | | |
|---------------------------|-----------------------------|---------------------|
| AA - Academic Affairs | HC - Healthcare | PL - Physical Plant |
| CS - Campus Safety | HR - Human Resources | |
| FI - Finance & Investment | IT - Information Technology | |
| R - Research | ST - Student Affairs | |



ERM RISK INVENTORY

EU Key Risks

Key Research Risks

- R1 – Research ‘Misconduct’/Research Integrity/Finance Compliance
- R2 – Research Security/Export Controls



RISK MANAGEMENT & MITIGATION



ROOT
CAUSE



TRENDS



TRIGGER
POINTS



RISK
INDICATORS



MITIGATION
STRATEGIES



RISK INDICATORS

| ERM RISK R1 Research Misconduct & Research Integrity | | | | | | | |
|--|--|---|-------------------------------------|----|----|----|----|
| CATEGORY | KPI | Indicator Type | Research Compliance Program Element | Q1 | Q2 | Q3 | Q4 |
| INVESTIGATIONS | Number of Allegations Received | N/A *Not KPI, metric for correlation with substantiated cases | Open Communication | | | | |
| | Intake Method | | | | | | |
| | Type of Allegation | | | | | | |
| | Number Substantiated | Lagging | | | | | |
| | Number Leading to Inquiry | | | | | | |
| | Number leading to Investigation | | | | | | |
| | Schools > 3 substantiated cases | | | | | | |
| | Departments > 5 substantiated cases | | | | | | |
| TRAININGS | RCR Trainings Offered | Leading | Training & Education | | | | |
| | School | | | | | | |
| | Department | | | | | | |
| | Training Attendance/Completion | Leading | | | | | |
| | School | | | | | | |
| | Department | | | | | | |
| | Title/Position of attendees | | | | | | |
| NONCOMPLIANCE | External Disclosures/Notifications | Lagging | Enforcement | | | | |
| | IRB | | | | | | |
| | IACUC | | | | | | |
| | Grants Management | | | | | | |
| | For Cause Audits/Investigations | Lagging | | | | | |
| | FDA | | | | | | |
| | USDA | | | | | | |
| | Other | | | | | | |
| | NSF/NASA (Other federal or private sponsors) | | | | | | |
| | External Program Assessments | Leading | | | | | |
| | Business Area | | | | | | |
| | | | | | | | |
| | Program Audits (Internal QA) | Leading | | | | | |
| | Trending Observations | | | | | | |
| Corrective Actions Completed | | | | | | | |



PROACTIVE RISK MITIGATION

COI/COC External Program Assessment

Policies/ Procedures

- Conflict of Commitment
- COI Research
- ICOI
- Faculty/
Administrator/Staff
disclosure
requirements

Training/ Education

- Comprehensive
Training Program
- New Hire
- Refresher
- Dept Chair/
Administrator

Disclosure Processes

- eDisclose
- Management Plans
- Committee
operations
- Monitoring

Stakeholder Partnerships

- IRB, IACUC, Tech
Transfer
- University
Compliance, OGC
- Faculty Affairs
- Schools



NASA Restrictions on Funding Activities With China

NASA is prohibited from funding any work that involves the bilateral participation, collaboration, or coordination with China or any Chinese-owned company or entity, at the prime recipient level or at any subrecipient level, whether funded or performed under a no-exchange-of funds basis.

“China or Chinese-owned Company” means the People’s Republic of China (PRC), any company owned by the PRC, or any company incorporated under the laws of the PRC. Includes Universities.

Disclosure Requirements:

- Project involves bilateral collaboration with, or participation of, the Chinese government or any company incorporated under the laws of China.
- Project involves persons or entities associated with or receiving support from the Chinese government or Chinese-owned companies.
- Project involves any Chinese national (i.e., non-U.S. citizens) such as students, fellows, researchers, faculty, or principal and/or co-principal investigators.



Process Updates

Updated Electronic Disclosure Form

Project Team- Signed off by PI AND all research personnel sourced from NASA award

School - Dean & CBO

OSP – Award Set Up & Semi-annual Monitoring

RCRA – Annual Audits, TCPs

