HAVEN'T SEEN A CONFLICT THAT DIDN'T INTEREST US

HCCA Research Compliance Conference June 11, 2023

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EMORY UNIVERSITY Research Compliance and Regulatory Affairs Research Administration

AGENDA

- Emory University
- Emory's Research Enterprise
- Research Compliance & Regulatory Affairs
- Research Security @ Emory
- 101 COI/COC

NIVERSITY

- Challenges and Solutions
- Program Enhancements
- COI/COC @ Emory
- ICOI
- Monitoring & More...



ICE BREAKER

Which of the following best describes your Institution?

- Public University
- Private University
- Academic Medical Center
- Hospital
- Public Research University
- Private Research University
- Liberal Arts College
- Other



What is your role at your Institution?

- Research Faculty
- Research Administration
 Staff
- Academic Leadership
- Research Administration Leadership
- Medical Professional
- Hospital Administrator
- Other

3

What is your level of experience with research compliance?

- I am an expert!
- I am familiar with research compliance requirements from my experience as a researcher
- I am transitioning to a research compliance role from the side of research
- I am beginning a research compliance role and coming from another industry



COLLEGES AND SCHOOLS

- Emory College of Arts and Sciences
- Oxford College
- School of Medicine
- Nell Hodgson Woodruff School of Nursing
- Candler School of Theology
- School of Law
- Roberto C. Goizueta Business School
- James T. Laney School of Graduate Studies
- Rollins School of Public Health



NIVERSITY PRESIDENT

DIVERSITY

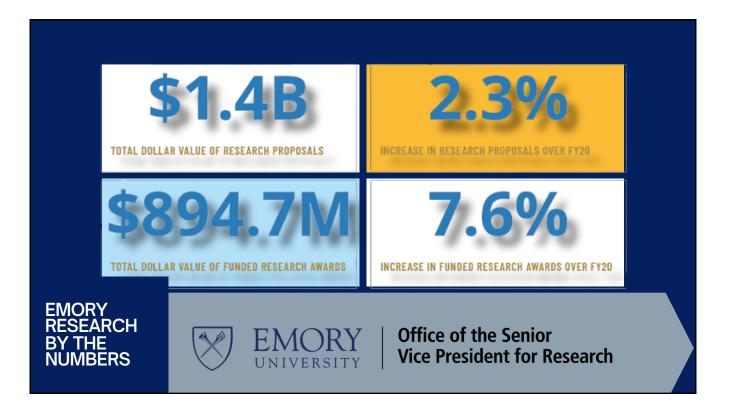
ARTS

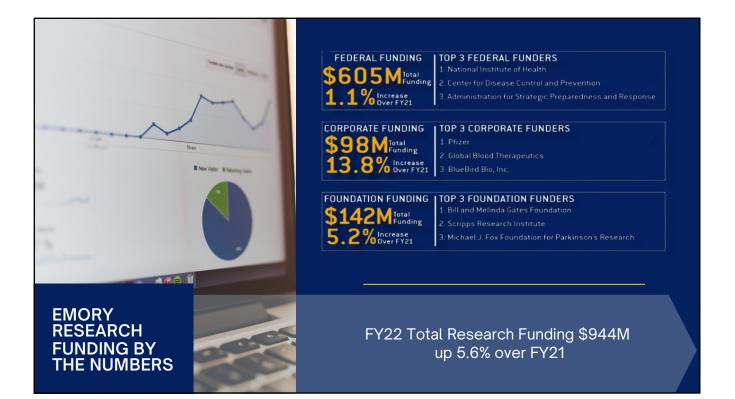
IFACT

DIVERSITY a leader in diversity, to a culture of debate and believing that we have a urpose in bettering the world.



ATLANTA A progressive, global city, Atlanta is partner in our mission of empowering community and makin a real difference.





Emory's Past: Dr. Charles

If an institution that is a recipient of federal awards fails to provide effective oversight, such agencies/federal sponsors like the National Institutes of Health (NIH) has the power to suspend its entire portfolio of grants for said institution:

 In 2005, Dr. Nemeroff was Principal Investigator of a 5-year, \$3.9 million grant, sponsored by the National Institute of Mental Health that utilized drugs provided by GSK

As a result, Dr. Nemeroff:

- Voluntarily stepped down as chairman of the department and eventually left Emory
- Was prohibited from applying for NIH grants for two years

(



Office of the Senior Vice President for Research (SVPR)

Emory is world-renowned for its research excellence and is home to some of the most talented scientists and scholars worldwide. Our research enhances the lives of millions, solving real problems through a vast network of partnerships and collaborations. The extent of our research and the community connections drive advancement in knowledge, understanding, innovation, and creativity.

"To Grow and Protect Research"

Provide strategic and operational support to advance Emory's eminence as a leading research university. The SVPR office supports this by using Emory's strategic framework and the strategic priorities of the schools and units to align research strategy and support priority

ORA MISSION, VISION

The Office of Research Administration (ORA) provides collaborative administrative support, efficient systems, and technical expertise to facilitate scholarship, research, and discovery within the Emory community. Our priority is to aid our researchers in driving high impact discoveries and facilitating worldclass research through collaboration, communication, and transparency.

OFFICE OF RESEARCH ORG CHART



Research Compliance & Regulatory Affairs

Research Compliance and Regulatory Affairs Research Administration

OFFICE OF RESEARCH COMPLIANCE AND REGULATORY AFFAIRS (RCRA)



EMORY

UNIVERSIT

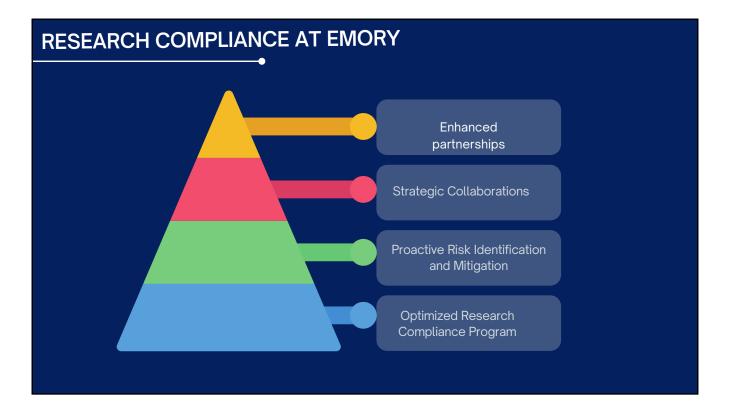
To support the Emory research community by implementing processes and policies and providing training to comply with requirements and regulations



To become recognized as institutional leaders who enable research compliance by anticipating risk in an ethically driven environment.

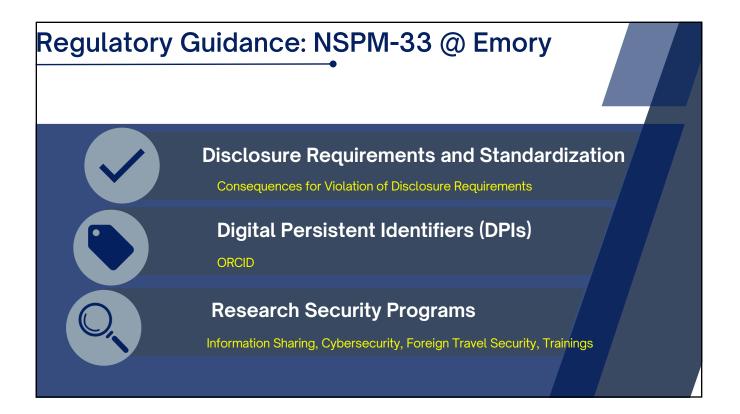
Goals

To initiate the development and implementation of a proactive, comprehensive, and integrated compliance strategy that supports the success of Emory's entire academic research enterprise.

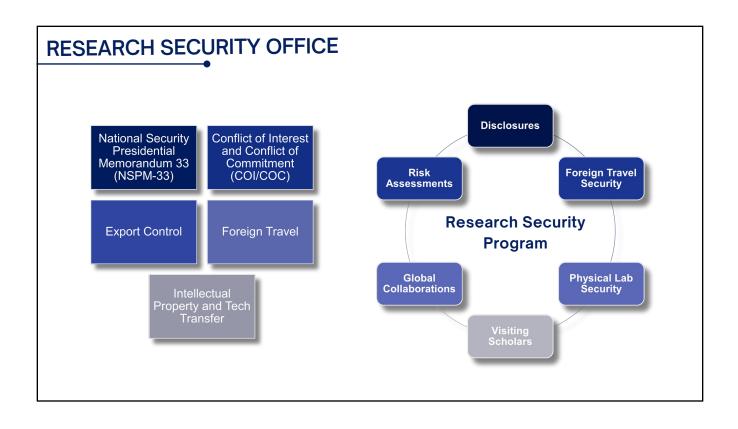


OFFICE OF RESEARCH COMPLIANCE AND REGULATORY AFFAIRS (RCRA)











Audience Poll: Research COI

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How much do you know about Conflicts of Interest?

- A lot. I work on Conflicts of Interest as part of my role at my Institution. I implement the policy/process.
- Somewhat. I am familiar with the concept, but I do not engage with the topic as part of my role.
- Not at all. I am new to the topic.



Does your institution have a COI policy and/or process?

- Yes
- No
- I am not sure

How would you rate your institution's COI policy and/or process?

- Excellent! Call us for best practices.
- Good. We have made progress, but there is room for improvement.
- Fair. We have a policy, but we are still figureing out how to implement it.
- We don't have one, but we need one.

What is a Conflict of Interest in Research?

A financial or other personal consideration that may compromise – or have the appearance of compromising — an Investigator's professional judgment in the conducting or reporting research.

Examples:

- •An Investigator who is gainfully employed by the sponsor of research study.
- •An Investigator with Intellectual Property being utilized in the research study.
- •An Investigator who owns shares of the startup company sponsoring the research study.
- •An Investigator whose travel was sponsored by the company manufacturing the IP being utilized in the research study.



What is a Significant Financial Interest?

A SFI is one or more of the following financial interests held by an Investigator or Key Personnel, their spouse, or dependent children:t

- Compensation or honoraria > \$5,000 from an entity*
- Ownership interests valued > \$5,000 in a publicly traded entity
- Ownership interests in a privately held entity (e.g., start-up companies, LLCs)
- Any intellectual property ownership, fees, and/or royalties
- Management positions in a non-Emory entity (e.g., director, officer, trustee, management employee)*
- Sponsored travel over \$5,000 within a 12-month period (except from Emory, U.S. government, U.S. higher ed, U.S. academic medical centers)

Compensation, management positions, and sponsored travel within a 12-month period of the last disclosure

What is NOT a Significant Financial Interest?

- Salary or other compensation for services from Emory
- Compensation or honoraria from the United States' government, institute of higher education, academic teaching hospital and/or medical center, etc.
- Ownership interests from investment vehicles such as mutual funds and retirement accounts not controlled by the owner(s)
- Sponsored travel from Emory
- Gifts to Emory where the Investigator or Key Personnel has no signing authority for the home institution account

WHAT IS A FINANCIAL CONFLICT OF INTEREST?

A FCOI is the institutional determination that an Investigator or Key Personnel's Significant Financial Interest (SFI) could significantly alter the design, conduct, or reporting of research



EMORY Official University Policy

Policy 7.7

Policy for Investigators Holding a Financial Interest in Research

VP for Research Administration

Responsible Official: Administering Division/Department: Research Compliance Effective Date:

August 24, 2012 March 20, 2017

Last Revision Date: Policy Sections:

I.	Overview
н.	Applicability
Ш.	Policy Details
IV.	Definitions
V.	Related Links
VI.	Contact Information

Revision History

Financial Conflict of Commitment Management Strategies

- Disclosure to the research team
- · Disclosure on all presentations, publications, and press releases
- Disclosure on all appropriate informed consent forms
- Disclosure on FDA forms
- Assignment of and reporting to an independent reviewer
- · Change of role within the research study
- Restrictions that include but are not limited to:
 - obtaining and analyzing data
 - obtaining informed consent
 - Analyzing and reporting adverse events
 - Participation until the role identified as the conflict is eliminated

WHAT IS A CONFLICT OF COMMITMENT?

A COC is the institutional determination that an individual's intellectual energy, time, or effort to external activities interferes with Emory responsibilities



13.3 Conflict of Commitment

Guiding Principle: Emory faculty owe their primary professional allegiance to the university; their primary commitment of time and intellectual energies is to the education, research, and other programs supporting the university's mission. The specific responsibilities and professional activities that constitute an appropriate and primary commitment will differ across schools, but they should be based on a general understanding between the faculty member, department chair (if applicable), and dean.

13.3.A POLICY REGARDING TEACHING, RESEARCH, AND OTHER SERVICE OUTSIDE THE FACULTY MEMBER'S SCHOOL AT EMORY OR OTHER INSTITUTIONS (FULL POLICY)

What is NOT a Conflict of Committment?

- Seminars, one-off or invited lectures, service on an advisory committee, or review panel when these activities are undertaken on behalf of a U.S. federal, state, or local government, domestic institution of higher education, or a U.S. academic teaching hospital, medical center or research institute affiliated with a domestic institution of higher education.
- Fellowships or awards managed through Office of Sponsored Projects.
- Postdoctoral fellow or trainee or staff member service to their academic or professional discipline (e.g., serving on a committee for a national scientific organization).
- Activities that are not related to specific expertise as long as commitments to Emory are not impacted.

Conflict of Interest & Commitment at Emory



Research Compliance and Regulatory Affairs Research Administration

CHALLENGES

- Utilization of an outdated system with inability to enhance
 - Did not allow for updates
 - Did not allow for integration of eIRB/eIACUC
- Lack of COI and COC
 awareness



SOLUTIONS

- Implemented new disclosure system
 - Allows for streamlining of disclosures from employees, researchers, and affiliates
 - Allows for the utilization of the research portfolio feature instead of by project
- Education and outreach
- · Created and disseminated guidance documents
- Regularly met with senior leadership to ensure processes are in alignment with regulation and institutional responsibilities
- Assigned school Liaisons to enhance faculty
 engagement



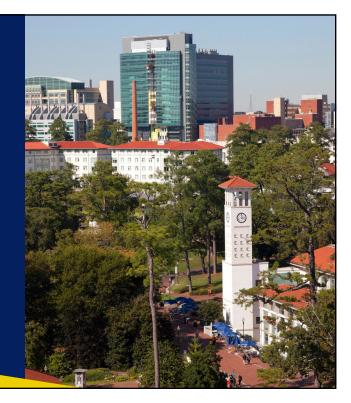
External Assessment: Scope

- External consultant performed an independent assessment from February 1, 2022 to May 1, 2022.
- The assessment included a review of research policies and procedures and a series of knowledge sharing meetings with representatives of EU's and EH's Clinical Research Program (CRP) and facilitated discussions related to best operational and compliance practices in conflict of interest/commitment disclosure and oversight as well as certain critical areas including:
 - Governance, structure and resources of the COI and Conflicts of Commitment (COC) Program, and
 - Policies and procedures supporting COI and COC disclosure, mitigation, and elimination, etc.

EXTERNAL ASSESSMENT: STAKEHOLDERS

ORA Offices

- Research Administrative Services (RAS)
- Office of Sponsored Programs (OSP)
- Office of Technology Transfer (OTT)
- Institutional Review Board (IRB)
- Institutional Animal Care and Use Committee (IACUC)
- University Compliance
- Legal Affairs
- School Liaisons
- Emory Healthcare



External Assessment: Process

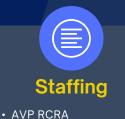
- The external consultant team accomplished the assessment by reviewing applicable organizational charts, job descriptions, staffing metrics, operational metrics, compliance metrics, policies and procedures, technology and other applicable data.
- During the facilitated meetings and interviews with key University and Health Care leaders, the consultant team shared benchmarking results from similar COI programs, best industry practices, common COI/COC program structures and governance, as well as oversight processes to maintain ongoing compliance with financial conflict of interest regulations.

External Assessment: Key Observations

- Need for <u>enhanced awareness</u> among the faculty and administration on the policies and procedures currently in place for the COI/ COC program.
- There is a need to <u>further educate</u> EU and EH faculty, staff, and administrators about the COI regulatory and enforcement environment as well as the mandates for COI and COC disclosure as outlined in EU policy and procedures.
- There is a <u>decentralized system</u> of policies and procedures around the University, various schools and the health system leading to inconsistent procedures for COI/COC.







- AVP RCR
 Director
- Asst. Director
- ASSI. DIFECIO
- Sr. COI Specialist (2)
- COI Specialist



- Provide oversight for Committee meetings
- Conduct Committee education, awareness, and training on policies and processes
- Prepare cases for Committee review and assign Committee reviewers
- Committee meeting facilitation & coordination
- Draft and send management plans
 Ensure management plan acceptance

Reviews

- Administrative
- Expedited
- Full Committee

Conflict of Interest Committee

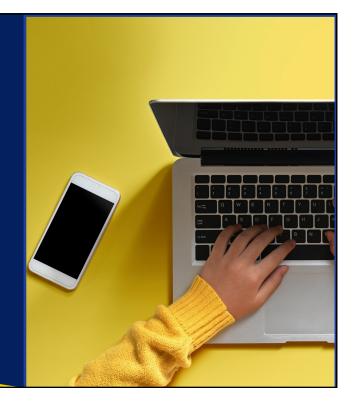
The Conflict of Interest and Conflict of Commitment (COI/COC) Committee ensures objectivity in research by managing or eliminating real or perceived financial conflicts of interest (FCOI) in research and conflicts of commitment (COC) in compliance with U.S. federal regulations, U.S. funding agency policies, and Emory policies.

- Committee Composition:
- Committee Chairs
- Committee Members
- COI Liaisons
- Ex Officio
- COI Office
- Monthly Reviews
- Charter
- Membership
- Appointment
- Attendance

COC/COI PLATFORM

eDisclose

- External Activities
- Disclosures
- COC
- Travel
- Foreign Affiliations
- Reporting



WHEN IS COI DISCLOSURE REQUIRED?

- Annually
- New Hire

Within 30 days of discovering or acquiring (through purchase, marriage, or inheritance) a new SFI
The institution revises its FCOI policy or procedures in any manner that affects the requirements of Investigators

•The Institution finds an Investigator not in compliance with the institution's FCOI policy or management plan

COI Disclosure Checks:

- At proposal submission
- At award set-up

WHO MUST DISCLOSE?

Applies to Investigators, Key Personnel, and covered individuals who, in the course of their association with the University:

- Apply for or receive funding for research at Emory by grant, subgrant, contract, subcontract, cooperative agreement
- Are involved in design, conduct or reporting of research



Who Must Disclose?

Emory Policy 13.3, Conflict of Commitment for Faculty, Postdoctoral Fellows or Trainees, and Research Staff applies to faculty, postdoctoral fellows or trainees, or research staff who engage in professional activities external to Emory due to their expertise and:

- Contribute intellectually to research; or
- Design studies, collect data, conduct experiments, conduct analyses, complete reporting or dissemination activities; or
- Will receive authorship or formal attribution on resulting publication(s) or scholarly products; or
- Support the research infrastructure in a way that could influence the outcome of the research

When is Disclosure Required?

• Before the start of an external activity

Participation in the external activity can only begin AFTER the department chair and dean has approved

WHAT HAPPENS AFTER AN SFI DISCLOSURE?

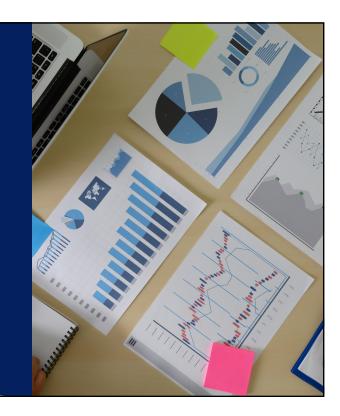
Financial Interest Disclosure	The COI/COC office reviews the financial interest disclosure to determine if the SFI is related to the investigator's research at Emory.
FCOI Determination	If related, the COI/COC Committee reviews the SFI to determine if it is an FCOI or not
Management Determination	If the Committee determines there is an FCOI, management stragies will be implemented via a mangaement plan.
Disclosure to Federal Sponsors	If the management plan issued is for a federally sponsored study, disclosure to the sponsor must be made.

WHAT HAPPENS AFTER AN EXTERNAL ACTIVITY REQUEST?			
Pre-Approval Request	The designated school official reviews the external activity to determine if the activity is related to the Investigator's expertise.		
Approval/Disapproval Determination	If approved, the school official may implement stipulations and/or durations of the approved external activity		
Research Portfolio	The approved external activity now becomes part of the Investigator's research portfolio.		
Financial Interest Disclosure	The COI/COC office reviews the financial interest disclosure to determine if the SFI is related to the investigator's research at Emory.		

WHEN IS DISCLOSURE REQUIRED?

Disclosure is required before the start of an external activity.

Participation in the external activity can only begin AFTER the department chair and dean has approved



COI Operational Improvements

Implementation of new disclosure system

- Allows for stramlining of disclosures from employees, researchers, and affiliates
- Allows for the utilization of the research portfolio feature instead of by project
- Increasing compliance awareness
 - Educating faculty on COI
 - Creating and disseminating guidance documents
 - Meeting with senior Leadership regularly to ensure processes are in alignment with regulation and institutional abilitites
 - Assigning school liaisons to enhance faculty engagement



EMORY

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Research Compliance and Regulatory Affairs Research Administration

Audience Poll: Research ICOI

1

How much do you know about Institutional Conflicts of Interest?

- A lot. I work on Conflicts of Interest as part of my role at my Institution. I implement the policy/process.
- Somewhat. I am familiar with the concept, but I do not engage with the topic as part of my role.
- Not at all. I am new to the topic.



Does your institution have an ICOI policy and/or process?

- Yes
- No
- I am not sure

How would you rate your institution's ICOI policy and/or process?

- Excellent! Call us for best practices.
- Good. We have made progress, but there is room for improvement.
- Fair. We have a policy, but we are still figureing out how to implement it.
- We don't have one, but we need one.

Institutional Conflicts of Interest (ICOI) Overview

When an Institution's own financial interests or those of Institutional Leaders pose risks of undue influence on decisions involving the Institution's primary interests (teaching, research, outreach, business transactions)

- Institutional Leader: Individual who has the capacity to affect, or could reasonably appear to affect, Institutional processes and decisions
 - examples: Vice Presidents, Associate/Assistant Vice Presidents, Deans, Executive Associate and Associate Deans of Research, Department Chairs, Center Directors, and Directors of Research Administration Units.



SCOPE: Research Institutional Conflicts of Interest

An Institution's financial interests could significantly and directly affect or reasonably appear to affect the institutional processes for the design, conduct, reporting, review, or oversight of research

- Includes financial interests of Institutional Leaders who have the capacity to affect institutional processes for the design, conduct, reporting, review, or oversight of research due to their position with the Institution
 - examples: Institutional Leader supervises PI of a research project and holds equity in the company that is sponsoring the research project; in this role, the Institutional Leader could influence the way PI conducts the research to benefit company and herself

SUMMARY OF ICOI POLICY AT EMORY

• Purpose:

- Defines the standards and procedures that Emory University follows to identify and manage or eliminate Research Institutional Conflicts of Interest.
- Outlines roles and responsibilities of:
 - Research ICOI Official
 - Research ICOI Committee
 - Research Compliance COI/COC Office
- Describes process for:
 - identifying and reviewing Institutional SFIs
 - identifying and reviewing Research ICOIs
 evaluating and managing Research ICOIs



FOUNDED 1836

INSTITUTIONAL LEADERS

- Individual who has the capacity to affect, or could reasonably appear to affect, University processes for the design, conduct, reporting, review, or oversight of research due to their position with the University.
- Some examples of titles for these officials can include but are not limited to
 - Vice Presidents
 - Associates Vice President
 - Deans and Associate Deans
 - Associate Deans of Research
 - Department Chairs
 - Center Directors
 - Directors of Research Administration Units



a financial interest held by Emory or an Institutional Leader that meets the following thresholds:

Emory

- Equity Interest or entitlement to equity worth more than \$100,000 in a publicly traded company that is the sponsor or financial supporter of Research at Emory;
- Equity Interest or entitlement to equity of any amount in a non-publicly traded company that is the sponsor or financial supporter of Research at Emory;
- Royalties or licensing fees that exceed \$100,000 annually for technologies being tested or evaluated in Research at Emory;
- Gifts that exceed \$500,000 annually from an entity to Emory, where the donor sponsors or financially supports Research at Emory.

ROLES AND RESPONSIBILITIES Conflict of Interest and Commitment Office identify Institutional SFI Related to **Research ICOI Official** Research • report to Research evaluate Institutional **ICOI** Official SFI Related to **Research** ICOI Committee • assist Research ICOI Research; determine Committee if it creates a confirm Institutional SFI monitor compliance **Research ICOI** Related to Research with management • call upon Research creates Research ICOI plans **ICOI** Committee to evaluate Research ICOI • decide how to resolve review potential **Research ICOI Research ICOI** • manage Research ICOI review and approve management plan

RESEARCH ICOI COMMITTEE

• Purpose:

- Safeguard the objectivity and integrity in research by ensuring that the financial interests of Emory or its Institutional Leaders do not affect the design, conduct, reporting, review, or oversight of research
- Responsibilities
 - Review Institutional Significant Financial Interests Related to Research • Evaluate Research Institutional Conflicts of Interest,
 - per criteria below
 - Manage Research Institutional Conflicts of Interest by reducing or mitigating the Research Institutional Conflict of Interest, per guidelines
 Advise on difficult conflict of interest issues



RESOLVING RESEARCH ICOI

- Permit the research to proceed at Emory, subject to elimination of the Research ICOI (e.g. divestment of the Institutional SFI)
- Permit the research to proceed at Emory, subject to a plan for managing the Research ICOI
 - Human Subject Research
 - Non-Human Subjects Research
- Prohibit the research from proceeding at Emory if the Research ICOI cannot be managed or eliminated



Examples of Criteria to Evaluate Research ICOIs

- Magnitude of potential risks to human subjects inherent in the research and how those risks could be
 affected because of the Research ICOI
- Degree to which the Institutional Significant Financial Interest could be directly and substantially affected
 by the research
- Whether the research involves **Emory Intellectual Property** that is used as a platform technology or a generic method used broadly
- Likelihood that a societally important development project will be substantially impeded if the research is not performed at Emory
- Whether Emory's resources are fundamentally important to the progress of the science or Emory's investigator is truly uniquely qualified or integral to administer the study
- Whether a plan for separation of oversight by the Institutional Leader with the conflict of the faculty/staff
 conducting the research can be implemented that is both practical and effective while the Institutional
 Leader remains in the assigned leadership position

Research ICOI Management Tools

Reduce or Eliminate Conflict • Divesting the institution of an equity interest in an outside entity performing research at the institution; • Placing the conflict-causing economic interests in an independent management relationship that contractually removes control of the interests from the covered individual

Disclosure

 Disclosure of the Research ICOI in public presentations and publications, and to all individuals, including (but not limited to) graduate students and other trainees, engaged in the design, conduct, or reporting of the research;
 Disclosure of the Research ICOI to sponsors of research as required by the sponsor or any applicable regulations and laws:

• External, Independent Oversight • Use of an external IRB

- Use of an external Data Safety Monitoring Board ("DSMB") or similar review board to evaluate the design, analytical protocols, and primary and secondary end-point assessments, and to provide ongoing evaluation of the study for safety, performance issues and the reporting of results;

Internal Controls

- Designation of a "safe haven," e.g., a non-conflicted senior individual, with whom the investigator can address ICOIrelated concerns
- Where the Research ICOI involves an Institutional Leader, formal recusal of the conflicted individual from the chain of authority over the project and possibly also from authority over salary, promotion, and space allocation decisions affecting the investigator, as well as communication of the recusal arrangements to the Institutional Leader's superior and colleagues;



CONFLICT OF INTEREST OPERATIONAL IMPROVEMENTS

Implementing new disclosure system Allows for streamlining of disclosures from

- employees, researchers, and affiliates
- Allows for the utilization of the research portfolio feature instead of by project

Increasing compliance awareness

- Educating faculty on COI
 Creating and disseminating guidance documents
- Meeting with Senior Leadership regularly to ensure processes are in alignment with regulation and institutional abilities
- Assigning school Liaisons to enhance faculty engagement

ENSURING COMPLIANCE THROUGH ANNUAL DISCLOSURE

- Annual Certification Cycle
- 60 day duration
- Disclosures streamlined to
 - New hires
 - New SFIs in 30 days
 - Annual Cert Cycle
- Disclosure monitoring & tracking
- COI Liaisons & COI Office



MONITORING & AWARENESS

- Quarterly email reminders to workforce members in the Research Category – covered individuals involved in design, conduct and reporting of research.
- Monitoring of external activity requests based on activity start date and assessment of SFI by COI team, COI Committee, and respective School COI liaisons.
- Research security reviews for checks to match disclosures on file in edisclose with publications, documents (e.g. Biosketch & Other Support) submitted to funding agencies.
- Robust internal controls as <u>stop gap measures</u> in place for current disclosures to be logged in for research personnel prior to proposal submission and at the time of award set up.
- On a rolling basis the COI office also receives notifications from <u>Management Plan holders</u> for presentations, disclosures to lab/staff members to monitor information in edisclose is up to date with disclosures made.

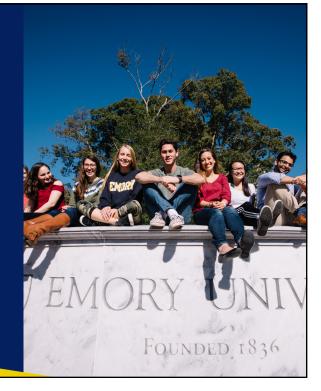


LONG TERM GOALS

- Continued benchmarking with other institutions and Academic Medical Centers (AMCs) across the country for COI operational excellence and to implement best practices for Emory's research community.
- Develop and implement a comprehensive ELMS training module for in depth COI research requirements for institutional and federal policy compliance.
- Continued engagement and guidance for EHC and University Compliance teams for a robust enterprise wide compliant COI program and management for research, healthcare, and university disclosures.

CI/PI OPPORTUNITIES

- Monitoring Enhancements
- SFI disclosures within 30 days
- Equity vs Payments
- Decentralized COI/COC
- Start Ups & ICOI



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EDUCATION & OUTREACH

- Schools
- Affiliates
- Disclosers
- Research Administration
- COI/COC staff



STRUCTURED STAKEHOLDER INVOLVEMENT

