

eDisclose and COI Process Updates

Conflict of Interest and Conflict of Commitment Office
Research Compliance and Regulatory Affairs

October 13, 2022



Objectives

- Review timelines for eDisclose
- Cover requirements for making disclosures
- Steps involved with IRB and COI review
- IRB specific steps to facilitate implementation

eDisclose Overview

WHAT IS IT: New Emory COI/COC e-disclosure system
(will replace eCOI)

WHEN IS THE LAUNCH DATE: November 17, 2022

WHO WILL USE IT: Faculty and staff who are required to disclose financial interests and request approval for external activities

HOW WILL I GET ACCESS: Automatic enrollment

WHY NOW: Modernize Emory's disclosure software, provide expanded disclosure capabilities, streamline disclosure processes amid a changing regulatory environment.

Disclosure Requirements



Financial Interests

Who: Investigators, covered individuals

What: Significant Financial Interests (see Policy 7.7)

When: Within 30 days of hire, within 30 days of receiving new SFIs, Annually

Why: Identify and manage financial conflicts of interest in research



External Activities

Who: Faculty, research staff, post docs, trainees

What: Certain external activities (see 13.3.A Faculty Handbook, Policy 7.38)

When: Prior to start of activity

Why: Identify and manage conflicts of commitment



eDisclose & COI Operations

Conflict of Commitment

- Updated Faculty Policy, New Staff Policy
- COC Policies @ Schools

COI/COC Committee

- Questionnaire
- Expanded FY 23 Committee

Annual Disclosure Cycle

- Nov 17- Jan 18

Reduction in Administrative Burden

- Repeat disclosures at proposal, amendment, renewal not required

COI Monitoring

- Disclosures current for 12 months

Coming Up Next

eDisclose Trainings

- October 17 onwards
- Multiple live sessions each week for disclosers, reviewers, OSP/RAS
- Recorded training available on ELMS
- User guides for disclosers, reviewers, OSP/RAS

eDisclose Labs

- 1:1 training available upon request
- Virtual office hours for live support

Annual Certification Period

- Begins November 17
- Disclosure Profile during 60-day period from November 17, 2022 - January 18, 2023
- eDisclose support and training available during this period

School & Department Outreach

- Similar sessions to Dept Head Trainings



IRB Review of Management Plans

Emory's IRB CoRe Subcommittee must review and approve COI management plans for human subjects' research when Emory is the IRB of record **or** when Emory IRB is responsible for COI management plan review per the terms of a reliance agreement.

The COI and IRB Review Process

COI/COC Office identifies proposed management strategies for cases with human subjects' research.

Following review by the COI/COC Committee, the COI/COC Office sends management plan to Covered Individual and the IRB.

The IRB CoRe Team votes on the proposed management plan and notifies the COI/COC Office of the determination.



How COI Impacts IRB Review

For studies or modifications that require Full Board review, the item can be assigned to an agenda. The COI will remain a **pending issue** until there is confirmation of COI/COC Committee review **or** finding of no conflict; and until a management plan (if applicable) is accepted by the investigator.

For studies or modifications that can undergo expedited review, the IRB **will not review** until COI review is complete, and if applicable, a management plan is accepted by the investigator.

In all cases, the IRB will review the management plan against the eIRB record to ensure that the study team has made the required changes if any (e.g. revising the protocol, Smartform (e.g. recruitment or consent sections, and including updating the COI section, if necessary), consent form(s), etc)

The study team has **10 business days** to implement the proposed management plan

CONTACT US

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