## eDisclose and COI Process Updates

## Conflict of Interest and Conflict of Commitment Office Research Compliance and Regulatory Affairs <sub>October 13, 2022</sub>



## Objectives

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

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

## 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

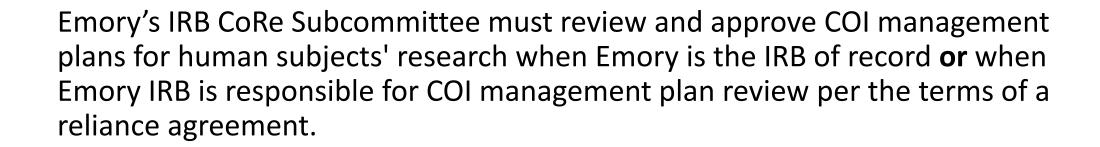
- Begins November 17
- Disclosure Profile during 60-day period from November 17, 2022 -January 18, 2023
- eDisclose support and training available during this period

#### School & Department Outreach

• Similar sessions to Dept Head Trainings



## IRB Review of Management Plans



## **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.



Institutional Review Board

## 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

Visit: https://emory.sharepoint.com/sites/eDisclose

**Email:** <u>edisclose@emory.edu</u>

