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
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

<table>
<thead>
<tr>
<th>eDisclose Trainings</th>
<th>eDisclose Labs</th>
<th>Annual Certification Period</th>
<th>School &amp; Department Outreach</th>
</tr>
</thead>
<tbody>
<tr>
<td>October 17 onwards</td>
<td>1:1 training available upon request</td>
<td>Begins November 17</td>
<td>Similar sessions to Dept Head Trainings</td>
</tr>
<tr>
<td>Multiple live sessions each week for disclosers, reviewers, OSP/RAS</td>
<td>Virtual office hours for live support</td>
<td>Disclosure Profile during 60-day period from November 17, 2022 - January 18, 2023</td>
<td></td>
</tr>
<tr>
<td>Recorded training available on ELMS</td>
<td></td>
<td>eDisclose support and training available during this period</td>
<td></td>
</tr>
<tr>
<td>User guides for disclosers, reviewers, OSP/RAS</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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

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

Following review by the COI/COC Committee, the COI/COC Office sends management plan to Covered Individual and the IRB.
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.
Visit: https://emory.sharepoint.com/sites/eDisclose
Email: edisclose@emory.edu