eCOI:
User Guide
Introduction

Emory's eCOI software program is a University and Healthcare system-wide tool that helps administrators implement Emory's policies and procedures regarding Investigators’ financial interests and external activities related to their Institutional Responsibilities. This program and reporting process is used by Emory University and Emory Healthcare only. If faculty or staff have a government agency appointment or affiliation, they must check with that agency about any additional reporting requirements.
Accessing eCOI

Firefox is recommended as your Internet web browser for this program.

Other web browsers might have compatibility issues and the content of this system might look altered and/or may not function properly. The program does not work well on smart phones or tablet computers.

Instructions:

Open your internet web browser and type or copy/paste www.ecoi.emory.edu into the address bar.

or

Link to the web site by clicking “Enter eCOI” on Emory’s Conflict of Interest home page, located at www.coi.emory.edu.
An Emory Network ID and Password are required to log into the eCOI system.

Log in to the system by using your Emory credentials (this is the same username and password that you use for PeopleSoft, Outlook, Virtual Desktop, etc.).
Once you have logged in, you will see the eCOI Welcome Page.

If this is your first time using the application, it is highly recommended that you take the time to read this section.

**Section Highlights:**
- Application usage
- Who has access to this application
- What you will need to get started
- Who has access to your information
- How do I know when my report is complete
- Whom do I contact with questions

**Instructions:**
Once you finish reading this page, you may click on “eCOI Home” in the upper right corner of the page.

**or**
You can scroll to the bottom of the page and click on “continue” to your homepage.
Your eCOI home page

- System notifications and reminders
- A list by company/entity of all of reported external consulting agreements
- A list by title of research projects and proposals that identify you as a member of the research team
- A list of any of research projects that are under a management plan
- A reminder about when your next Annual Certification is due and when the last one was completed
- A reminder about when your training certification is due and when the last one was completed

The navigation menu on the right side of the page provides an overview and instructional information about each type of report; this also includes links to view and manage reports.
Four Distinct Sections

1. **COI Training**, where faculty and staff certify that they have received information about Emory’s policies and the federal regulations on Objectivity in Research.

2. **Annual Certification**, used by faculty during the annual certification period to review and update their current external activities and financial interests in research and certify that they are up to date.

3. **Faculty External Activities**, used by faculty members to report their external activities, such as consulting agreements, related to their Institutional Responsibilities and receive permission for these activities from their department chairs and deans.

4. **Financial Interests in Research Reports**
   a. Proposal Financial Interest in Research Report, used by research administrators and PIs to initiate the process of collecting Investigator’s Financial Interest in Research Reports for their proposals.
   b. Investigator’s Financial Interest in Research Report, used by an Investigator to report whether s/he has any significant financial interests associated with a specific research proposal.
Completing Training

- Federal regulations require that Institutions receiving funding from the US Public Health Service provide training to their Investigators about the federal regulations, the Institution’s policy, and Investigators’ responsibilities under the policy and regulations. The training is required to be documented and provided at least every four years.

- To use eCOI for the first time, the training **must** be completed **before** any other forms can be initiated.

- eCOI has a one page training that provides access to regulations and policy. Users must certify that they have read the policy, regulations, and understand their responsibilities by initialing where indicated on the form.

Once training is completed and submit button is clicked, a user will be taken back to the personalized eCOI home page.
eCOI

ANNUAL CERTIFICATION
Completing an Annual Certification

Section Highlights:

- All faculty involved in research must complete an Annual Certification.

- Faculty must self-identify whether or not they are involved in research projects funded by the US Public Health Service (e.g. NIH, CDC, FDA, AHRQ, SAMHSA, HRSA, etc.); this will direct them to the correct form that must be completed.

- Those who are not involved in any sponsored research should select “Non-PHS.”
Key terms

- **Investigator:** the Project Directors, Principal Investigators, members of the research team identified as senior/key personnel on the grant or contract application, progress report, or any other report. In addition, individuals identified by the Principal Investigator or Project Director who are responsible for and have substantial independent decision making in respect to the design, conduct or reporting of the research, which might include Collaborators or Consultants named on the grant.

- **Institutional Responsibilities:** activities related to an Investigator’s Research, Teaching, Administrative, or Clinical Duties at Emory

- **Significant Financial Interest:** interests held individually by the Investigator, his/her spouse or same-sex domestic partner, and dependent children, including ownership interests (i.e., stock/options, dividends, equity) that are valued at more than $5,000; remuneration or honoraria valued at more than $5,000; Intellectual Property fees and/or royalties; any ownership interests (i.e., stock/options, equity) in privately held entities (i.e., start-up companies, LLC’s); any fiduciary position (e.g., director, officer, trustee, management employee) in a non-Emory entity.

Definitions of these terms may also be found in Emory Policy 7.7 Policy for Investigators Holding a Financial Interest in Research.
Instructions:

From the eCOI Home page, the Annual Certification form can be completed by clicking on any one of three links to the form on the eCOI home page.
Selection of forms

After reviewing the initial page of information regarding the Annual Certification, you must determine whether or not you are involved in US Public Health Service funded research and click the appropriate button in order to be directed to the correct reporting form.

Annual Certification: PHS Funded/Sponsored vs. Non-PHS Funded/Sponsored Research

Beginning summer 2012, U.S. Public Health Service (PHS) requires institutions to collect additional information regarding investigator’s Significant Financial Interests. In order to best collect this information, we ask you to identify whether you engage in PHS funded research or anticipate engaging in PHS funded research in the next 12 months. Your response will direct you to the appropriate Annual Certification to complete.

If you serve as an investigator (i.e., PD/PI, senior/key personnel, and/or individuals identified by PD/PI as having independent decision making in respect to the design, conduct, or reporting of the research) on a PHS funded project either through a direct award to Emory or as a subaward from another organization (i.e., CFAR, any cancer oncology groups such as RT30, ASSCO, NIH flow-through to subcontract institution), then you must select PHS below. A list of PHS agencies can be found below.

It is imperative that you identify whether you participate in PHS funded research so that Emory University can collect the necessary information required by the federal government.

<table>
<thead>
<tr>
<th>PHS Agencies:</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Administration for Children and Families (ACF);</td>
</tr>
<tr>
<td>- Administration on Aging (AoA);</td>
</tr>
<tr>
<td>- Agency for Healthcare Research and Quality (AHRQ);</td>
</tr>
<tr>
<td>- Agency for Toxic Substances and Disease Registry (ATSDR);</td>
</tr>
<tr>
<td>- Centers for Disease Control and Prevention (CDC);</td>
</tr>
<tr>
<td>- Centers for Medicare &amp; Medicaid Services (CMS);</td>
</tr>
<tr>
<td>- Federal Occupational Health (FOH);</td>
</tr>
<tr>
<td>- Food and Drug Administration (FDA);</td>
</tr>
<tr>
<td>- Health Resources and Services Administration (HRSA);</td>
</tr>
<tr>
<td>- Indian Health Service (IHS);</td>
</tr>
<tr>
<td>- National Institutes of Health (NIH);</td>
</tr>
<tr>
<td>- Substance Abuse and Mental Health Services Administration (SAMHSA)</td>
</tr>
</tbody>
</table>

Non-PHS Agencies: The funding agency/sponsor would be an entity NOT listed above. Some examples include:

- private corporation;
- foundations/non-profits;
- internally/departmentally funded

Please click the PHS box to indicate whether you currently have or plan to participate in PHS funded/sponsored research (primary or flow down under a subaward/subcontract). ONLY click the Non-PHS box if you are not participating or plan to participate in PHS funded/sponsored during the next 12 months.

☐ PHS  ☐ Non-PHS
To complete the **Annual Certification**, you are required to review each section, to update as necessary, and to answer every question within the school/unit pages.

When completed, you will see a summary of your answers.

When prompted, type in your name to certify the report is accurate and complete.

---

By submitting this form, I [enter name here] , certify (please check each box to confirm your affirmative response to each statement):

- [ ] The above information is submitted by me, not a proxy or surrogate, and my electronic signature above certifies that.
- [ ] The above information is true to the best of my knowledge.
- [ ] I understand that I have an obligation to inform my Chair and Dean in writing if my answers to any of the above questions change during the academic calendar year.
- [ ] I agree to comply with the policies and procedures of Emory University and/or Emory Healthcare as applicable, related to Conflict of Interest and annual certification requirements.
Reporting External Activities

Section Highlights:

- Faculty are required to obtain prior approval for external activities from their Department Chair and Dean.
- Adding a new External Activity

Instructions:

An External Activities Report can be entered by clicking “add new” after “My Current External Activities” on the main section of the home page, or in the “External Activities” section in the column at right.
To complete an **External Activity Report**, answer every question and, when prompted, certify the report is accurate and complete.
Completing a Proposal Financial Interest in Research Report

Section Highlights:

- The purpose of this form is to identify project with the various ID numbers of different approval units, the funding source for the project, and the Investigators who will participate in the project in order to initiate the request for each to complete an Investigator Financial Interest in Research Report.

- The research proposal's Research Administrator/Coordinator or Business Administrator, and Lead Principal Investigator are the only individuals authorized to submit a Proposal Financial Interest in Research Report.

- A new form must be completed for each year of a project, continuing award or contract.
Key terms

- **Investigator:** the Project Directors, Principal Investigators, members of the research team identified as senior/key personnel on the grant or contract application, progress report, or any other report. In addition, individuals identified by the Principal Investigator or Project Director who are responsible for and have substantial independent decision making in respect to the design, conduct or reporting of the research, which might include Collaborators or Consultants named on the grant.

- **Institutional Responsibilities:** activities related to an Investigator’s Research, Teaching, Administrative, or Clinical Duties at Emory

- **Significant Financial Interest:** interests held individually by the Investigator, his/her spouse or same-sex domestic partner, and dependent children, including ownership interests (i.e., stock/options, dividends, equity) that are valued at more than $5,000; remuneration or honoraria valued at more than $5,000; Intellectual Property fees and/or royalties; any ownership interests (i.e., stock/options, equity) in privately held entities(i.e., start-up companies, LLC’s); any fiduciary position (e.g., director, officer, trustee, management employee) in a non-Emory entity.

Definitions of these terms may also be found in Emory Policy 7.7 *Policy for Investigators Holding a Financial Interest in Research.*
Instructions

From the eCOI home page, click on “add a new proposal” in the column on the right side of the screen.

The next page will be a general overview regarding Proposal Financial Interest in Research Reports. Clicking “continue” at the bottom of the page will take you to the second page, where you must determine whether the proposed project will be funded by an agency of the Public Health Service.
Choosing The Correct Form

Investigators on projects funded by the PHS are required to complete a different Investigator Financial Interest in Research Report in order provide additional information required by federal regulations. Correctly identifying whether or not the project is funded by the PHS will ensure that the Investigators will be directed to the correct disclosure form.

Choose PHS when primary funding source is a US Public Health Service Agency. Choose non-PHS when primary funding source is industry, foundation, or internal funds.
Proposal Form

Ensure the Principal Investigator and title are the same as the information listed on the grant or contract proposal.

Include the project year for the proposal.

Include the relevant tracking numbers for other review units.

Identify Investigators on Research Team – members who are listed as Senior or Key Personnel on the grant or contract and those identified by the PI/PD who are responsible for and have substantial independent decision making in respect to the design, conduct or reporting of the research.

Identify the deadline for completing Investigator Forms and for the Grant/Contract Submission Date. Indicate if receipt of e-mail notifications is desired.
Completing an Investigator Financial Interest in Research Report

Section Highlights:

- The purpose of this form is to identify which Significant Financial Interests might be related to a specific research project.

- All Investigators must complete this form before a project can begin. A summary report of all Investigators forms must be submitted with a grant or contract to the Office of Sponsored Programs.

- Significant Financial Interests held by the Investigator, as well as those held by his/her spouse/same-sex domestic partner or those held by dependent children must be reported if they are related to the Investigator’s Institutional Responsibilities.

- A new form must be completed for each year of a project, continuing award or contract.

- The form that must be completed for projects funded by the US Public Health Service (PHS) is different than the Investigator Financial Interest in Research Form Investigators complete for projects that do not receive PHS funds.
Key terms

- **Investigator:** the Project Directors, Principal Investigators, members of the research team identified as senior/key personnel on the grant or contract application, progress report, or any other report. In addition, individuals identified by the Principal Investigator or Project Director who are responsible for and have substantial independent decision making in respect to the design, conduct or reporting of the research, which might include Collaborators or Consultants named on the grant.

- **Institutional Responsibilities:** activities related to an Investigator’s Research, Teaching, Administrative, or Clinical Duties at Emory

- **Significant Financial Interest:** interests held individually by the Investigator, his/her spouse or same-sex domestic partner, and dependent children, including ownership interests (i.e., stock/options, dividends, equity) that are valued at more than $5,000; remuneration or honoraria valued at more than $5,000; Intellectual Property fees and/or royalties; any ownership interests (i.e., stock/options, equity) in privately held entities (i.e., start-up companies, LLC’s); any fiduciary position (e.g., director, officer, trustee, management employee) in a non-Emory entity.

Definitions of these terms may also be found in Emory Policy 7.7 Policy for Investigators Holding a Financial Interest in Research.
Instructions:

Your eCOI home page offers two links to access and complete an Investigator Financial Interest in Research Report.
At the top of the non-PHS Investigator Financial Interest in Research Report, you will see all of the external activities that you have reported. If you have no external activities, none will be listed. Using the “Amend” button, you must update the information as necessary.
The PHS **Investigator Financial Interest in Research Report** has all of the different categories of financial interests that must be reported under the regulations. You should update and amend this information as needed. Any new Significant Financial Interests must be reported within 30 days.

<table>
<thead>
<tr>
<th>Fiduciary Role</th>
<th>Please list all current fiduciary positions (i.e., director, officer, partner, trustee, or employee) you hold with a for-profit company/entity related to your teaching, research, administrative, or clinical duties at Emory. Please exclude positions held in Emory-affiliated entities.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Company/Entity</strong></td>
<td><strong>Position Held</strong></td>
</tr>
<tr>
<td>Odyssey Family Counseling</td>
<td>Secretary of Board of Trustees</td>
</tr>
</tbody>
</table>

**Add Another**

2. Of the above activities, do any entities/companies:
   - produce products (equipment, software, compounds, drugs, devices, etc.) or services that are used in this research project; and/or
   - developing a product (equipment, software, compounds drugs, devices, etc.) or service that this research project is intended to evaluate or further develop?

- Yes
- No
- N/A

**Other Honoraria** - Please list all honoraria received from entities, including compensation from non-profits, if valued at more than $5,000 that are related to your teaching, research, administrative, or clinical duties at Emory.

<table>
<thead>
<tr>
<th><strong>Company/Entity</strong></th>
<th><strong>Compensation</strong></th>
<th><strong>Date Received</strong></th>
<th><strong>Action</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>No Honoraria</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Add Another**

3. Of the above activities, do any entities/companies:
   - produce products (equipment, software, compounds, drugs, devices, etc.) or services that are used in this research project; and/or
   - developing a product (equipment, software, compounds drugs, devices, etc.) or service that this research project is intended to evaluate or further develop?
To complete the **Investigator Financial Interest in Research Report** you must answer every question and, when prompted, type in your name to certify the report is accurate and complete. Information previously reported should be updated to ensure that the information is accurate.

If you answer “Yes” to any of the questions, the form will ask you a few additional questions to better understand the relationship. You will be asked to identify whether you are the person with the financial relationship or to identify the family member who does and then to provide a short description of the relationship.

You must complete any External Activity Reports that are added to your Investigator Financial Interest in Research Report. You will be sent an e-mail reminder and a new notification will appear on your eCOI homepage.
Need Additional Help?

Contact Emory’s Office of Research Administration for University Policy information:
1599 Clifton Road
6th Floor East
Atlanta, GA 30322
Phone: (404)712-0046
Fax: (404)712-0069
Email: COI-OFFICE@LISTSERV.CC.EMORY.EDU
Website: http://www.coi.emory.edu
Emory Mailstop: 1599 -001-1BU

Financial interests and clinical activities:
Please contact the Office of Compliance Programs at (404) 778-2757

External activities and school-based policies, please contact your Dean’s Office:

School of Medicine
Helen C McLaughlin MBA
mclaugh@emory.edu
(404) 727-3413

Arts & Sciences/Emory College
Patricia Bauer, PhD
(404) 712-8460
pjbauser@emory.edu
Michael Elliott, PhD
melliot2@emory.edu
404-727-6059

Rollins School of Public Health
Dean Surbey, MBA
(psurbey@emory.edu
404) 727-3023

School of Nursing
Sandra B Dunbar RN/DSN/FAAN
sdunba@emory.edu
(404)727-6939

Goizueta Business School
Maryam Alavi, PhD
maryam.alavi@emory.edu
(404)727-7867

School of Law
Timothy Holbrook, JD
tihbrook@emory.edu
(404)712-0353