Research Financial Conflict of Interest
Training Module
Learning Objectives

This training module will cover:

• The federal conflict of interest (COI) requirements that guide Rockefeller’s research COI policy and procedures;

• Who is subject to research COI requirements;

• The term “Significant Financial Interest” (SFI);
  – Where and when SFIs must be disclosed;
  – How SFIs are reviewed at Rockefeller University;

• The term “Financial Conflict of Interest” (FCOI);
  – How FCOIs are managed;
  – How FCOIs may be reported to sponsors and to the public; and

• Implications for noncompliance with research COI requirements.
Financial Conflict of Interest in Research Training

A Financial Conflict of Interest exists when an Investigator’s Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of the Investigator’s research.
Why Do We Care about Conflicts of Interest in Research?

Identification of conflicts of interest is important to avoid the risk that an Investigator’s external financial interests may bias or compromise – or have the appearance of biasing or compromising – an Investigator’s judgment, objectivity, or decision making with respect to the design, conduct, or reporting of research.

- Innovation
- Entrepreneurship
- $$$

- Objectivity
- Data Integrity
- Safety & Welfare

The relation – even potential or perceived relation – of external interests to research integrity needs to be assessed.
What Must Rockefeller University Do To Comply?

As a condition of federal funding, the University must have a policy and procedure to identify and manage FCOIs of an Investigator, so that the design, conduct, and reporting of the research will be free from bias.

*Federal regulations require that the University:

1. Maintain a current, written, and enforced COI policy;
2. Educate Investigators about the University’s COI policies and procedures;
3. Facilitate and ensure Investigator compliance with initial and ongoing COI disclosure requirements;
4. Identify and manage FCOIs;
5. Apply sponsor COI requirements to subrecipients/collaborators;
6. Meet sponsor and other COI reporting requirements.

*We use the general term “COI” and “FCOI” across the board to avoid confusion about various sponsors’ differing COI terminology.*
Key Aspects of Rockefeller University’s COI Requirements

- **Investigators** must disclose **all SFIs** related to their Institutional Responsibilities on an ongoing basis.

- **The University** must determine whether an SFI could be a COI for each body of research activity in which an Investigator is involved.

- **The University** must eliminate, reduce, or manage COIs, and meet sponsor and other COI reporting requirements.
The Rockefeller University’s Research Policies on Conflict of Interest

- **The University’s Policy on Financial Conflict of Interest in Research** is based on the federal Public Health Service’s regulations, which are designed to foster public confidence in the objectivity of research. [https://www.rockefeller.edu/conflict-of-interest/](https://www.rockefeller.edu/conflict-of-interest/)

- **The University’s Policy on Financial Conflict of Interest in Human Participant Research** supports integrity and transparency with respect to the financial relationships of Investigators who are engaged in human participant research. [https://www.rockefeller.edu/conflict-of-interest/](https://www.rockefeller.edu/conflict-of-interest/)

Please familiarize yourself with the University’s research COI policies.
Research That Is Subject to Rockefeller University’s Conflict of Interest Policy

• Proposals submitted to/research funded by:
  – Federal sponsors;
  – Other sponsors that have specific COI terms and conditions;

• All research involving human participants regardless of funding source.
  – The Policy on Financial Conflict of Interest in Human Participant Research applies in addition to the requirements of the general Financial Conflict of Interest in Research policy.
Who Is Subject to the Research Conflict of Interest Requirements?

Investigators are subject to the research COI requirements. An Investigator is any person, regardless of title or position (e.g., collaborators, consultants), who is responsible for the design, conduct, or reporting of research.

• The following always are Investigators:
  ➢ Project Director/ Principal Investigator (PI);
  ➢ Key Person (by virtue of the definition of Key Personnel*);
  ➢ PI or Co-Investigator of an IRB protocol.

• The following also may be Investigators:
  ➢ Outside collaborators (e.g., subrecipient Investigators, consultants) who are responsible for the design, conduct, or reporting of the research;
  ➢ Any other faculty, staff, post-doctoral and clinical fellows, graduate students, or technicians who are independently responsible for the design, conduct, or reporting of the research.

For example: Sally, the technician, is probably not an Investigator if she:
- Follows protocols to make solutions,
- Feeds the mice and performs husbandry, or
- Maintains equipment though routine maintenance.

Sally may be considered an Investigator if she:
- Independently optimizes a solution for improved antibody staining,
- Pioneers/develops a new strain of mice with a new reporter gene, or
- Alters/improves equipment to have better detection limits.

*Key Personnel is an individual who contributes in a substantial and measurable way to a project. Therefore, someone listed as Key Personnel would most certainly be an Investigator (someone responsible for the design, conduct, or reporting of research).
Where Do Investigators Disclose?

- Investigators disclose by logging into RAS: https://RAS.rockefeller.edu
What Must Be Disclosed?

*Significant Financial Interests* related to an Investigator’s *Institutional Responsibilities* must be disclosed.

*Significant Financial Interest* (definition on next slide) include those held by an Investigator and/or his/her Immediate Family Members.

*Immediate Family Members* are an Investigator’s spouse and dependent children.

*Institutional Responsibilities* are an Investigator’s professional responsibilities performed on behalf of Rockefeller University, including:

- Research;
- Research consultation;
- Teaching and advising;
- Institutional committee memberships and other service;
- Service on institutional panels.
## What Must Be Disclosed?

<table>
<thead>
<tr>
<th>Nature of Significant Financial Interest</th>
<th>Threshold/Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Payments and/or remuneration (e.g., salary, consulting fees, honoraria, paid authorship, prizes, board service payments)</td>
<td>SFI in/from any single external organization must be disclosed if the total aggregated value of:</td>
</tr>
<tr>
<td></td>
<td>• Payments and/or other remuneration in the 12 months prior to disclosure, plus;</td>
</tr>
<tr>
<td></td>
<td>• Equity interests (in a publicly-traded organization) at the time of disclosure exceeds $5,000;</td>
</tr>
<tr>
<td></td>
<td>OR</td>
</tr>
<tr>
<td></td>
<td>• Payments from intellectual property rights and interests received in the 12 months prior to disclosure exceeds $5,000;</td>
</tr>
<tr>
<td></td>
<td>OR</td>
</tr>
<tr>
<td></td>
<td>• Sponsored or reimbursed travel in the 12 months prior to disclosure exceeds $5,000.</td>
</tr>
<tr>
<td>Equity interests (e.g., publicly traded stock, stock options, or other ownership interest) in publicly-traded organization</td>
<td></td>
</tr>
<tr>
<td>Equity interests (e.g., non-publicly traded stock, stock options, or other ownership interest) in a non-publicly traded organization (e.g., startup company)</td>
<td></td>
</tr>
<tr>
<td>Payments from intellectual property rights and interests (e.g., patents, copyrights)</td>
<td></td>
</tr>
<tr>
<td>Sponsored or reimbursed travel</td>
<td>Equity Interest in a non-publicly traded organization must be disclosed regardless of the amount.</td>
</tr>
</tbody>
</table>
Examples of Significant Financial Interests That Need To Be Disclosed

- Investigator receives payment (e.g., stipend or honoraria) over $5,000 from University College of London for a speaking engagement.
  - Disclose because (i) payment is over $5,000 and (ii) is from a foreign organization.
- Investigator receives airfare and hotel accommodations (some of which is paid directly to the airline and the rest to the Investigator) from Tokyo University for a conference at which Investigator makes a presentation.
  - Disclose because (i) total travel payment reasonably may have exceeded $5,000; and (ii) is from a foreign organization.
- Investigator receives prize from Max Planck for $7,000.
  - Disclose because (i) the amount is over $5,000; and (ii) is from a foreign organization.
- Investigator consults with a Swiss pharmaceutical company and receives quarterly payments of $1,000. Investigator also holds $2,000 in the publicly traded stock of this Swiss pharmaceutical company.
  - Disclose because (i) consulting payments over the past 12 months plus the value of the stock exceed $5,000; and (ii) are from a foreign organization.
- Note: these are illustrative examples; they are not meant to be an exhaustive or exclusive summary of the types of Significant Financial Interests that must be reported.
### What Does NOT Need to be Disclosed?

<table>
<thead>
<tr>
<th>Nature of Interest</th>
<th>Excluded from Disclosure: DO NOT DISCLOSE</th>
</tr>
</thead>
<tbody>
<tr>
<td>General</td>
<td>Payments and interests that do not meet the disclosure threshold.</td>
</tr>
<tr>
<td>Payments and/or remuneration</td>
<td>• Income received for lectures, seminars, or service on advisory committees or review panels relating to U.S. federal, state, or local government agencies, a U.S. institution of higher education, a U.S. academic teaching hospital, medical center, or a research institute that is affiliated with a U.S. institution of higher education;</td>
</tr>
<tr>
<td></td>
<td>• Salary, royalties, or other remuneration from Rockefeller University or HHMI.</td>
</tr>
<tr>
<td>Certain mutual funds/retirement accounts</td>
<td>Ownership in or income from in mutual funds or retirement accounts so long as the Investigator does not directly control the investment decisions of these vehicles.</td>
</tr>
<tr>
<td>Intellectual property payments</td>
<td>Royalties received from Rockefeller University, unless you are involved in clinical research.</td>
</tr>
<tr>
<td>Sponsored or reimbursed travel</td>
<td>Travel administered through Rockefeller University, and/or travel reimbursed or sponsored by a U.S. federal, state, or local government agency, a U.S. institution of higher education, a U.S. academic teaching hospital, medical center or a research institute that is affiliated with a U.S. institution of higher education.</td>
</tr>
</tbody>
</table>
Foreign Source Payments

• **Any** Significant Financial Interest associated with:

  (i) a **foreign** government, which includes local, provincial, or equivalent governments of another country (i.e., not within the United States)
  (ii) **foreign** institutions of higher education

  must be disclosed.

• **PLEASE NOTE:** Consider if you must disclose, for conflict of interest purposes, payments that meet the SFI thresholds from any foreign affiliations (e.g., appointments or employment) listed on your biosketch.
In addition to the four general categories of SFI, Key Study Personnel engaged in clinical research also must disclose:

1. **Inventorship of any drug, device, or method** that is to be used in research involving human participants and on which the Investigator is **Key Study Personnel**; and

2. Intellectual property payments exceeding $5,000 **from The Rockefeller University**, received in the 12 months prior to disclosure.
When Do Investigators Need To Disclose Their SFI?

• **Before engaging in research proposed to or funded by Federal sponsors or before submitting an IRB protocol**
  - A disclosure must be on file in RAS for (i) each Investigator on a proposal before the proposal can be submitted to a federal sponsor by Rockefeller University or (ii) each Investigator on an IRB protocol before the proposal can be submitted to Rockefeller University’s Institutional Review Board.

• **Within 30 days of acquiring a new SFI**
  - SFIs must be disclosed in RAS within 30 days of acquiring a new SFI, including reportable travel, etc.
  - Do NOT wait until annual disclosure time to update your disclosure with new SFIs.

• **At least annually**
  - If you have no new SFIs to disclose between annual COI disclosure cycles, the annual COI disclosure is sufficient. You must complete an annual COI disclosure, even if acknowledging no change.
When to Disclose?
Annual and Interim SFI Disclosure Obligations

An Investigator must have completed (1) an Annual Certification, or (2) a research certification to update their SFI disclosures in connection with a new research project, within the preceding 12 months:

- before a grant application on which the Investigator is named can be submitted to a PHS awarding agency (e.g., NIH); and
- before a protocol on which the Investigator is Key Study Personnel can be submitted to the IRB for review.
Faculty Conflict of Interest Committee

• The Faculty Conflict of Interest Committee (“Committee”), comprised of members of Rockefeller University faculty, oversees and manages implementation of the University’s FCOI policies.

• The Committee has authority to determine whether an Investigator’s SFI creates an FCOI.

• If an FCOI is identified, the Committee works with the Investigator to eliminate, reduce, or manage the conflict by implementing a management plan.
Identifying a Conflict

Each SFI disclosure is reviewed by the Committee to determine (a) whether the reported SFI reasonably appears to be related to the Investigator’s research and/or other Institutional Responsibilities; and (b) if related, whether the SFI could directly and significantly affect the design, conduct, or reporting of the research.

If the answer to both (a) and (b) is “Yes”, a FCOI may be found to exist.
Responding to a Conflict

The Committee will work with an Investigator who has an FCOI conflict to create a Management Plan to eliminate, reduce, or manage the conflict.

Management Plan elements may include:
- Disclosing the potential FCOI to laboratory or study team members working on the research, to research participants, and/or to publishing journals;
- Establishing independent review of research data; and/or
- The Investigator’s relinquishing the SFI.

No awarded PHS funds under a grant can be spent, and no research under an IRB-approved protocol can be undertaken, until all FCOI related to the grant or protocol have been eliminated, reduced, or managed.
Reporting Financial Conflicts of Interest

Findings will be reported to various interested parties:

1. **PHS Awarding Agency**: Prior to spending awarded PHS funds, Rockefeller University must report to the PHS awarding agency the existence of any FCOI. Annual reports addressing the status of that FCOI must be submitted for the duration of the research project (or until the FCOI no longer exists).

2. **To Other Institutions**: Rockefeller Investigators may be named as Key Study Personnel on protocols at other institutions or receive sub-awards through other institutions that have agreed to accept and rely on reports generated through Rockefeller University’s conflict of interest process. In such instances, the Committee’s findings will be reported to the other institution(s) for conflict of interest and/or for IRB purposes.
Federal Law Requires the Following Actions

If a financial conflict of interest of an Investigator engaged in PHS-funded research is not timely identified or managed due to (i) the Investigator’s failure to timely disclose SFI, (ii) the University’s failure to review SFI disclosures or manage conflict, or (iii) the Investigator’s failure to comply with a Management Plan, the University must undertake a documented audit of the Investigator’s research activities to identify whether there has been any bias in the design, conduct, or reporting of the Investigator’s research.

The University must notify the awarding agency of any bias found and submit a mitigation report. Additional corrective measures may be required.

Investigator delay in disclosing SFI will result in significant compliance burdens on the Investigator, other KSP, and the University and must be avoided so as not to interfere with ongoing research.
Requests from the Public

Federal law requires that within 5 business days of the University receiving a written request from the public for information about PHS-funded research involving an Investigator with a financial conflict of interest, the University must respond in writing, giving the Investigator’s name, the external organization in which the Investigator holds a Significant Financial Interest, and the nature and approximate dollar value of the Significant Financial Interest, in specified dollar ranges, if known.
Every Investigator must be trained on the federal regulations and the University’s research conflict of interest policies prior to engaging in any PHS-funded research, at least every four years, and immediately if:

- The Investigator is new to the University;
- The University revises its research conflict of interest policies in a way that affects an Investigator’s responsibilities; or
- If an Investigator is not in compliance with the University’s research conflict of interest policies or with a Management Plan.
Certification

When prompted in RAS-COI, please take the comprehension quiz to demonstrate your understanding of The Rockefeller University Financial Conflict of Interest policies.

You will then be permitted to certify that you have completed this training.

Additional Information:
University COI Website:  https://www.rockefeller.edu/conflict-of-interest/