**RF** Corporate-wide COI Policies

# Conflict of Interest Policy (Corporate Policy)

Conflicts of Interest in Public Health Service Sponsored Programs Policy (FCOI Policy) Who do they apply to?

What must you disclose?

When must you disclose?

How do you disclose?

### **RF** Corporate-wide COI Policies

We have created the following comparison guide outlining the general requirements of each corporate-wide policy, including who it applies to, what must be disclosed, and when and how to submit a disclosure.

This comparison is a high level overview of these policies. Campuses have local policies and procedures that vary, particularly regarding when and how disclosures relating to sponsored projects are completed and submitted.

### **RF** Corporate-wide COI Policies

Please contact your local sponsored programs or research compliance office with any questions about submitting FCOI disclosures and please contact your local SUNY campus ethics officers or counsel for guidance on compliance with your state obligations as SUNY employees.

## Who do they apply to?

#### Corporate Policy

- <u>Everyone</u>
- RF Board Members, Officers, Employees, and Representatives
- Includes SUNY employees performing work for the RF
- Includes Principal Investigators

- Principal Investigators, Project Directors
- Anyone responsible for the design, conduct or reporting of an award from a sponsor with FCOI requirements
  - This may include <u>private</u> sponsors who have adopted the Public Health Service ("PHS") FCOI regulations

## Who does it apply to?

**Corporate Policy** 

- RF Representatives are not RF employees but they have authority to carry out RF responsibilities
  - e.g. a SUNY employee delegated authority to approve RF procurement transactions
- Principal Investigators are subject to the policy when managing RF employees or others funded through the award, and spending RF funds

## Who does it apply to?

### FCOI Policy

- Federal Sponsors include PHS (which includes NIH, FDA, CDC, HRSA, SAMHSA), NSF, DOE, etc.
- Some private sponsors have also adopted the PHS FCOI regulations, for example:
  - Patient-Centered Outcomes Research Institute (PCORI)
  - Susan G. Komen for the Cure
  - American Cancer Society (ACS)
  - American Heart Association (AHA)
  - American Lung Association (ALA)

You should independently verify the inclusion of PHS regulations in the proposal and award terms from all sponsors

## Who does it apply to?

- Students, post-doctoral fellows, collaborators, or consultants may be subject to the policy if their work affects the design, conduct or reporting of a federally-funded award
- Current policy applies to PHS funded projects, but please note other federal sponsors have FCOI requirements that must also be followed
- Applies to SBIR/STTR Phase II applicants/awardees, but Phase I SBIR/STTRs are exempt

### Why must you disclose potential conflicts?

#### **Corporate Policy**

- It is required under New York State Public Officers Law Section 74
- It is RF Policy, and one of the 10 Pillars of Conduct in the <u>Code of Conduct</u>
- To maintain independence and objectivity, so personal relationships or activities do not influence or interfere with official RF decisions or activities

- It is a requirement of the sponsor
- It is University and RF Policy
- Transparency to maintain societal trust in sponsored research
- To ensure adherence to ethical standards in higher education and research

#### Corporate Policy

 All interests and activities that you or a family member or business partner may have that could compromise or appear to compromise your performance as an employee or representative of the RF

- Any Significant Financial Conflict of Interest ("SFI") that:
  - could affect the design, conduct, or reporting of an award; or
  - reasonably appears to be related to the investigator's Institutional Responsibilities.

#### Corporate Policy

- Potential conflicts may or may not involve financial benefit. Any of the following scenarios would present a potential conflict:
  - Having access to confidential material that could benefit an external organization or individual you or a family member or business partner are connected to
  - Using RF property, equipment, money or other resources to benefit an external organization or individual
  - Being in any position that could create the impression that your professional judgement may be compromised

**Corporate Policy** 

- Examples:
  - The spouse of an individual who approves RF procurements works for a company that is a prospective vendor.
  - A PI is creating a startup company that will be licensing IP assigned to the RF.
  - An employee at a campus location owns a company that is a vendor for that campus.
  - An RF Operations Manager also serves on the boards of the campus foundation and auxiliary services corporation.

### **FCOI Policy**

• What are Institutional Responsibilities?

(A Significant Financial Conflict of Interest is an interest that appears related to the individual's <u>Institutional Responsibilities</u>)

These include research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.

- What is a Significant Financial Conflicts of Interest ("SFI")?
  - You must refer to the specific definition adopted by your sponsor

### **FCOI Policy**

• What is a Significant Financial Conflicts of Interest ("SFI")?

- Financial Interests (income/remuneration or investment interest)
- Sponsored/reimbursed travel and "Other Support"
- All Foreign Interests

- Financial Interests (PHS/NIH definition):
  - Need to be worth \$5,000 or more per year to be SFIs
    - Income (from consulting, fees, salary, or investment income)
    - Stock/equity value of \$5,000 for publicly traded companies
    - <u>Any stock/equity value in non-public companies must be reported (there is no \$ value threshold for non-public companies)</u>
  - Intellectual property rights and interests (e.g. patents, copyrights)
    - Includes <u>external</u> royalty income, but NOT royalty income from the RF/SUNY (excludes IP owned by SUNY and assigned to the RF)

- Financial Interests (NSF definition):
  - Anything of monetary value, including, but not limited to:
    - Salary or other payments for services (e.g., consulting fees or honoraria)
    - Equity interest (e.g., stocks, stock options or other ownership interests)
    - Intellectual property rights (e.g., patents, copyrights and royalties from such rights)

### **FCOI Policy**

- Sponsored/reimbursed travel and "Other Support":
  - Sponsor-provided Travel related to Institutional Responsibilities
    - Excluding from federal, state, or local government agencies; institutions of higher education as defined at 20 U.S.C. 1001(a); academic teaching hospitals, medical centers, or research institutes affiliated with an institution of higher education
  - "Other Support" means any resources that are available to assist an individual subject to this policy. This includes:
    - Appointments (paid and unpaid)
    - Access to lab space/work space or equipment
    - Access to budgets and/or staff.

• For further details, please visit: <u>https://grants.nih.gov/grants/forms/othersupport.htm</u>

- "All Foreign Interests" includes any of the following from sources outside the U.S.:
  - Money received (any amount) from employment, consulting, and expense reimbursements
  - Trips, airfare, hotels, lab space, and access to intellectual property
  - Unpaid activities, e.g. serving on advisory, scientific and other boards
  - Any resources of any type, or any other source of income
    - Progressive discipline and/or administrative, civil, or criminal penalties may result from failure to report foreign interests

- Examples:
  - A researcher has funding to study the products of a particular company. That researcher has purchased \$7,000 worth of stock in that company for their dependent child.
  - A PI is paid to provide consulting work for a company and that company is also subcontracting part of a research project to that PI's lab.
  - A PI has an informal research collaboration with a foreign university which is providing lab space to that PI.

#### Corporate Policy

- Annual filers must disclose every year at the beginning of August
  - Notifications are sent from the RF's Compliance Management System
  - Disclosures must be updated after learning of a new potential conflict
- All other RF employees and representatives must disclose any time they learn of a new potential conflict

- At the time of application for PHS funds, annually thereafter during the period of the PHS-funded award
- Within 30 days of discovering or acquiring a new SFI
  - e.g., through a purchase, marriage, or inheritance
- For non-PHS funded projects: must follow sponsor and local campus policies

### How do you disclose?

#### Corporate Policy

- Central Office employees & Annual Filers:
  - Must use the RF's <u>Compliance</u> <u>Management System</u>
- All other employees & representatives:
  - Contact <u>rfcompliance@rfsuny.org</u> to be assigned a disclosure in the Compliance System or use the <u>PDF</u> <u>disclosure form</u> or local equivalent and send it to the campus Operations Manager or designee

- The <u>SUNY Pre-Award and Compliance</u> <u>System (PACS) for most locations</u>
  - This is referred to as Click COI at SUNY Buffalo
  - Stony Brook uses the <u>myResearch</u> Conflict of Interest Module
- Campus locations may have different instructions in certain circumstances, e.g. before funding is awarded.

### How do you disclose?

#### Corporate Policy

 Contact the Office of Compliance Services at <u>rfcompliance@rfsuny.org</u> or 518-434-7145. if you are unsure how/where to submit a disclosure relating to this policy.

#### FCOI Policy

 Contact your local sponsored programs or research compliance office if you are unsure how or where to submit a disclosure relating to this policy.

### What Happens Next?

- Your disclosure will be reviewed to determine whether a real or perceived conflict / SFI exists
- A management plan may be developed and executed to eliminate or reduce the conflict / SFI

### Additional Resources

#### Corporate Policy

#### <u>Understanding Conflicts of Interest</u>

- Video: This three-hour training covers what conflicts of interest are, how to recognize conflicts, what to do when they arise, and how conflicts can be managed.
- Procedure for Managing Conflicts of Interest
- Managing Conflicts of Interest Guidelines
  - Outlines the ethical considerations and management plan details for many common scenarios, with particular focus on technology transfer activities

- Contact your local sponsored programs or research compliance office for information on training resources
- <u>Stop, Question, Think What You Need</u> to Know About Ethics at SUNY & RF
  - Video: This two-hour session demystifies conflicts of interest and other ethical scenarios facing SUNY and the RF.