The Public Health Service (PHS) has revised the financial conflict of interest reporting requirements for applicants and awardees for proposals and SBIR/STTR Phase II cooperative agreements. These changes will affect all faculty and non-faculty EPA employees funded by any PHS agency (NIH, CDC, etc.). This brochure provides an overview of the new regulation.

**PHS AGENCIES:**
- National Institutes of Health (NIH)
- Agency for Toxic Substances and Disease Registry (ATSDR)
- Centers for Disease Control and Prevention (CDC)
- Food and Drug Administration (FDA)
- Health Resources and Services Administration (HRSA)
- Indian Health Services (IHS)
- Substance Abuse and Mental Services Administration (SAMHSA)
REGULATION FROM PHS/NIH:
42 CFR Part 50 Subpart F and 45 CFR Part 94

WHAT IS THE GOAL? To ensure that the design, conduct, and reporting of research funded under grants or cooperative agreements will not be biased by any conflict of financial interest of the investigators responsible for the research.

WHOM DOES IT AFFECT? ALL PHS-FUNDED FACULTY AND NON-EPA EMPLOYEES. Specifically, covered employees who are listed on the grant or agreement as:

- Principal investigator
- Co-investigator
- Post-doc
- Graduate student
- Undergraduate student
- Trainee
- Consultant
- Subrecipient

WHAT CAN I DO TO COMPLY? If you already have funding from or you plan to submit a proposal to a PHS agency, you will be required to:

- Disclose financial interest of $5,000 or more (initial/upon application for funding, new significant financial interest (SFI), annual reporting)
- Obtain training (before release of funds, every 4 years, in cases of non-compliance, when there are policy changes, or when first employed by the university)
- Report any costs of sponsored travel
- Comply with a management plan, if required
- Report all new persons on the study for SFI disclosure processing

### Table: Significant Financial Interest (SFI) Disclosure

<table>
<thead>
<tr>
<th>Topic</th>
<th>1995</th>
<th>August 24, 2012</th>
</tr>
</thead>
<tbody>
<tr>
<td>Which SFIs to disclose</td>
<td>Those PI deems related to the research</td>
<td>All SFIs related to the investigator’s institutional responsibilities</td>
</tr>
<tr>
<td>Income from seminars, lectures or teaching, service on advisory committees or review panels</td>
<td>Excluded if done for public or non-profit entities</td>
<td>Included if sponsored by and for service on advisory or review panels for federal, state, or local government agency, and institutions of higher learning as defined at 20 USC 100 (a) an academic teaching hospital, a medical center or research institute that is affiliated with an institution of higher education.</td>
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<tr>
<td>Travel reimbursements and sponsored travel</td>
<td>Not mentioned explicitly but included in the SFI definition</td>
<td>Disclose any occurrence if related to institutional responsibilities. Not required if sponsored by agencies listed in 20 USC 100 (a).</td>
</tr>
<tr>
<td>Training</td>
<td>No requirement</td>
<td>Every 4 years and at other times</td>
</tr>
<tr>
<td>Subrecipient</td>
<td>Institutional oversight to ensure that subrecipients comply with the regulations</td>
<td>Subrecipients are required by written agreement to certify that their institution has an enforced PHS FCOI policy.</td>
</tr>
</tbody>
</table>

**Major Changes for Investigators**

**Significant Financial Interest (SFI):** Interest of the investigator or immediate family members in public and non-publicly traded entities as defined by 42 CFR 50 and appear to be related to the investigator’s institutional responsibilities. The threshold of disclosure is $5,000 for equity interest or remuneration from:

- Stock, stock option
- Ownership interest
- Salary
- Payment for services not described as salary
- Intellectual property rights and interest
- Consulting fees
- Honoraria
- Paid authorship
- Reimbursed or sponsored travel paid on behalf of the investigator

**Financial Conflict of Interest (FCOI):** An SFI that may directly and significantly affect the design, conduct, or reporting of NIH-funded research. The investigator may be required to comply with a management plan.

**External Professional Activities for Pay:** Those supported by private entities and ones which are directly related to an employee’s responsibilities should not interfere with her/his commitment to the university and must be disclosed:

- Initially, one for each new activity, and annually for recurring activities
- To designated university officials (deans, chairs, HR)
- 10 days before initiation