COI Informational Session

Michael Glasgow
Executive Director, Office of Grant and Contract Administration

Jill D. Pagliuca
Director, Conflict of Interest Office
Agenda

• Overview:
  • PHS Requirements
  • NSF Requirements
  • Yale Disclosure Requirements

• Summary of Changes to Yale COI Policy and Disclosure Process

• Resources Available to Business Managers

• Grant Application Considerations
Initial reaction to the new PHS COI Regulations...

“The Scream” Edvard Munch
New PHS COI Regulations

Followed by...

• a thoughtful approach with input from faculty

• branched Policy and branched on-line Disclosure, based on funding circumstances:
  - only those activities that constitute a “Significant Financial Interest” need to be disclosed to Yale (previously, financial interests greater than $0 were disclosed)
Overview PHS Regulations

Applies to research funded by the NIH and other sponsors that mandate compliance with the PHS regulations (effective Aug. 24, 2012)

Public Health Services (PHS) 42 CFR Part 50, Subpart F
Responsibility of Applicants for Promoting Objectivity in Research

Purpose: To ensure that the design, conduct or reporting of the research will not be biased by any conflicting financial interest of the investigator

• Can submit proposals only if a PHS-compliant disclosure form is on file at Yale (hard stop if no current disclosure)

• Before expenditure of any funds, Yale must notify PHS agency of any Financial Conflict of Interest (FCOI) and how it has been managed

• Disclosures must be updated during the period of the award, either annually or as new SFI’s are obtained (within 30 days of acquisition)

• Yale must submit annual FCOI reports (coordinated with progress reports)

Also applies to all subawardee investigators and consultants who are identified by the PI as “responsible” for the research!!!
PHS (NIH) Regulations

Highlights: PHS & Other Sponsors that Mandate Compliance with PHS Regulations (e.g., AHA, ACS, Susan G. Komen)

- General disclosure threshold of >$5K past 12 months only
- Any equity interest in a privately held company
- Third party reimbursed or paid travel in any amount for any travel related to institutional responsibilities (i.e., administrative, teaching, research, or clinical activities) EXCLUDING travel paid by sponsored awards to Yale
- Non-Yale IP income upon receipt of income >$5K
- Update new SFIs (including travel) within 30 days
- Mandated training requirement for investigators (building into PHS branch disclosure form)
- As in the past, FCOIs must be managed, reduced or eliminated before funds are spent

2. Exclusions for:
- a. Income from or travel paid by US government and US higher education (and affiliated organizations)
- b. Income from investment vehicles (e.g., mutual funds, retirements accounts) not directly controlled by the discloser

3. NO Exclusions for:
- a. Foreign academic institutions
- b. Journal editorships/authorship activities for publishing companies
- c. Service to professional societies
- d. Non-profits
Sponsors Applying PHS Requirements

Administration on Aging (AoA)
Administration for Children and Families (ACF)
Agency for Healthcare Research & Quality (AHRQ)
Agency for Toxic Substances & Disease Registry (ATSDR)
Alliance for Lupus (ALR)
American Cancer Society (ACS)
American Heart Association (AHA)
Arthritis Foundation (AF)
California Breast Cancer Research Program (CBCRP)
California HIV/AIDS Research Program (CHRCP)
Centers for Disease Control & Prevention (CDC)
Food and Drug Administration (FDA)
Health Resources & Services Administration (AHRQ)
Indian Health Service (IHS)
Juvenile Diabetes Research Foundation (JDRF)
Lupus Foundation of America (LFA)
National Institutes of Health (NIH)
Substance Abuse & Mental Health Services Administration (SAMHSA)
Susan G. Komen for the Cure
Other Important Information

For PHS-Funded Investigators

• Negative consequences mandated by PHS if an investigator fails to comply with the regulations or with Yale’s COI policy
  – e.g., failure to update disclosures (including travel reimbursed by a 3rd party) in a timely manner or to comply with management plans can result in the need for immediate re-training on Yale’s COI policy and PHS requirements, and could require retrospective reviews of research findings for potential bias

• Public accessibility of FCOIs on PHS-funded research
  – For FCOIs reported to NIH, Yale must make information about the nature of the SFI publicly available
  – Web form for public to submit written requests directly to Yale’s COI Office (Yale must respond within 5 business days)
Other Important Information

For PHS-Funded Investigators

- Mandated training requirement for investigators (built into PHS branch of disclosure form)

- Additional requirements for submitting FCOI Reports to NIH
  - detailed information about the SFI, nature of the FCOI & the management plan
  - annual FCOI updates (submitted in coordination with the PHS 2590 Non-Competing Continuation Progress Report for grants or other progress report for contracts)

- If an Investigator has an FCOI on a PHS award through another institution and transfers that PHS award to Yale, the details of the FCOI need to be disclosed to Yale
Overview NSF Requirements

National Science Foundation (NSF) COI Policy

- Definition of SFI is different than PHS definition, but disclosure must be made to Yale by the time a proposal is submitted (hard stop if no current disclosure on file)

- Before expenditure of any funds, Yale makes a COI determination and manages, reduces or eliminates conflicts

- Yale must only notify NSF when Yale is unable to satisfactorily manage a conflict of interest

- Disclosures must be updated during the period of the award, either annually or as new SFIs are obtained

Also applies to all subawardee investigators and consultants who are identified by the PI as “responsible” for the research!!!
**NSF Requirements**

**SFI Threshold:**

- Income >$10K past 12 months or next 12 months
- Any combination of income + equity in a publicly traded company >$10K past 12 months or next 12 months
- >5% equity (or any equity valued at >$10K) in a publicly traded company
- Any equity interest in a privately held company
- Certain Non-Yale IP rights

**Exclusions for:**

- travel expenses
- royalties paid by Yale
- book royalties
- journal editorships and authorship activities for publishing companies
- speaking/service income from professional societies and public and non-profit entities
- income from investment vehicles (e.g., mutual funds, retirement accounts), as long as the discloser does not directly control the investment decisions
Yale's Disclosure Requirements

Who at Yale must disclose?

• All faculty and non-faculty personnel responsible for the design, conduct or reporting of research

“Responsible” personnel include:
• PIs
• Co-PIs
• Senior Key Personnel
• Any other individuals identified by the PI as having the responsibility for the design, conduct or reporting of the research (may include persons at subrecipient organizations, collaborators, contractors, consultants & consortium participants)

• All faculty with >50% appointments

• All faculty with administrative responsibilities (e.g., deans, department chairs, program directors)

• All members of research compliance committees
Yale Disclosure Requirements

No PHS or NSF Funding:

SFI Threshold:

- Income >$10K past 12 months
- Any combination of income + equity in a publicly traded company >$10K past 12 months
- >5% equity (or any equity valued at >$10K) in a publicly traded company
- Any equity interest in a privately held company
- IP only if income >$10K past 12 months and not through Yale
- Board of Directors or Officer of a non-Yale entity, either paid or unpaid (discloser only, but applies to all disclosure types)

Exclusions for:

- travel expenses
- royalties paid by Yale
- book royalties
- journal editorships and authorship activities for publishing companies
- speaking/service income from professional societies and public and non-profit entities
- income from investment vehicles (e.g., mutual funds retirement accounts), as long as the discloser does not directly control the investment decisions

SFI Threshold:

Exclusions for:
SFI definitions and thresholds for disclosing SFIs differ according to funding circumstances

Branched COI Policy and branched on-line Disclosure, based on funding circumstances

With the exception of intellectual property, only those activities that constitute a SFI need to be disclosed to the University (previously, financial interests of greater than $0 were disclosed)

Mandated training requirement for PHS investigators is built into the PHS branch of the disclosure form
Use this report to see the current status and dates of annual disclosures for your department. *(Coming soon: Disclosure Type will be added to this report)*

<table>
<thead>
<tr>
<th>Name</th>
<th>Net ID</th>
<th>Department</th>
<th>Disclosure Date</th>
<th>Case Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Discloser, Joe 14</td>
<td>dis14</td>
<td>Dept Name</td>
<td>10/12/2011</td>
<td>Inactive</td>
</tr>
<tr>
<td>Discloser, Joe 21</td>
<td>dis21</td>
<td>Dept Name</td>
<td></td>
<td>Required</td>
</tr>
<tr>
<td>Discloser, Joe 23</td>
<td>dis23</td>
<td>Dept Name</td>
<td>10/15/2010</td>
<td>Expired</td>
</tr>
<tr>
<td>Discloser, Joe 2</td>
<td>dis2</td>
<td>Dept Name</td>
<td>06/16/2012</td>
<td>AAN</td>
</tr>
<tr>
<td>Discloser, Joe 17</td>
<td>dis17</td>
<td>Dept Name</td>
<td>06/05/2012</td>
<td>Pending</td>
</tr>
<tr>
<td>Discloser, Joe 18</td>
<td>dis18</td>
<td>Dept Name</td>
<td>05/27/2012</td>
<td>No SFI</td>
</tr>
<tr>
<td>Discloser, Jane 20</td>
<td>dis20</td>
<td>Dept Name</td>
<td>02/15/2012</td>
<td>Transactional Review</td>
</tr>
<tr>
<td>Case Status</td>
<td>Description</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>----------------</td>
<td>-----------------------------------------------------------------------------</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Inactive</td>
<td>Disclosure requirement no longer applicable</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Required</td>
<td>No disclosure on file, but is required</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expired</td>
<td>Disclosure was submitted over a year ago and has expired</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>AAN</td>
<td>“All Answers No”: No external activities or interests were disclosed (i.e., responded “no” to all screening questions)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pending</td>
<td>Disclosure is under COI review</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No SFI</td>
<td>None of the disclosed interests qualify as “significant”</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Transactional</td>
<td>SFIs were disclosed and require further review for potential conflicts with research proposals and University activities</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
This report lists the status of completed and in progress reviews for each required discloser in your department. *(Coming soon: Disclosure Type will be added to this report)*

<table>
<thead>
<tr>
<th>Net ID</th>
<th>Name</th>
<th>Department</th>
<th>Disclosure Date</th>
<th>Review Type</th>
<th>Review Category</th>
<th>Completion Date</th>
<th>Review Status</th>
<th>Award #</th>
<th>Agenda Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>dis14</td>
<td>Discloser, Joe 14</td>
<td>Dept Name</td>
<td>11/3/2011</td>
<td>Activities</td>
<td>Expedited</td>
<td>12/8/2011</td>
<td>SFI: No COI</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>dis21</td>
<td>Discloser, Joe 21</td>
<td>Dept Name</td>
<td>06/10/2012</td>
<td>Transactional</td>
<td>Expedited</td>
<td>6/17/2012</td>
<td>NO SFI</td>
<td>12345</td>
<td></td>
</tr>
<tr>
<td>dis23</td>
<td>Discloser, Joe 23</td>
<td>Dept Name</td>
<td>06/17/2012</td>
<td>Transactional</td>
<td></td>
<td></td>
<td>Pending</td>
<td>6789</td>
<td></td>
</tr>
<tr>
<td>dis2</td>
<td>Discloser, Jane 2</td>
<td>Dept Name</td>
<td>06/28/2012</td>
<td>Activities</td>
<td></td>
<td></td>
<td>SFI: Pending</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>dis17</td>
<td>Discloser, Jane 17</td>
<td>Dept Name</td>
<td>04/08/2012</td>
<td>Activities</td>
<td>Committee</td>
<td>05/20/2012</td>
<td>SFI: COI</td>
<td>N/A</td>
<td>05/20/12</td>
</tr>
<tr>
<td>dis18</td>
<td>Discloser, Jane 18</td>
<td>Dept Name</td>
<td>07/01/2012</td>
<td>Activities</td>
<td>Expedited</td>
<td>07/01/2012</td>
<td>NO SFI</td>
<td>N/A</td>
<td></td>
</tr>
</tbody>
</table>

**Activity review:** This is a review of the disclosure to determine if there are any potential conflicts with University activities.

**Transactional review:** This is a review of a research award against the most recent disclosure for the individuals identified as responsible for the design, conduct, or reporting of the research (“responsible personnel”).
## Review Status Report (continued)

<table>
<thead>
<tr>
<th>Status</th>
<th>Description</th>
<th>Action for Award Set Up</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pending</td>
<td>Review is pending or in progress</td>
<td>On Hold</td>
</tr>
<tr>
<td>No SFI</td>
<td>Review is complete and no SFIs were identified</td>
<td>No Hold</td>
</tr>
<tr>
<td>SFI: Pending</td>
<td>Review indicates a SFI: transactional or activity review is in progress</td>
<td>On Hold</td>
</tr>
<tr>
<td>SFI: No COI</td>
<td>Review is complete: SFIs were identified, but do not present potential conflicts of interest</td>
<td>No Hold</td>
</tr>
<tr>
<td>SFI: COI</td>
<td>Review is complete: SFI presents a potential conflict of interests (a management plan was developed to mitigate the conflict[s])</td>
<td>No Hold</td>
</tr>
</tbody>
</table>
Yale COI Office: Contact Information

Email: conflicts@yale.edu
Fax: (203) 785–4255
Web: www.yale.edu/coi/

COI Office Staff:

Jill D. Pagliuca
Tel: (203) 785–6307
Email: jill.pagliuca@yale.edu

Althea Morgan
Tel: (203) 785–4773
Email: althea.morgan@yale.edu

Laurie Raccuia
Tel: (203) 785–4456
Email: laurie.raccuia@yale.edu

Kenneth Greenquist
Tel: (203) 737-2306
Email: kenneth.greenquist@yale.edu

Sharon Murphy
Tel: (203) 785–4780
Email: sharon.murphy@yale.edu

Pat George
Tel: (203) 785–4774
Email: patricia.george@yale.edu
Grant Application Considerations

PHS and NSF

- Regulations apply to all personnel identified as responsible for the design, conduct or reporting of research
  - Principal Investigators, Co-principal investigators and Key personnel at Yale
  - Subrecipient Principal Investigator
  - Others identified by investigator
    - Collaborators, contractors, consultants and consortium participants

- Applications can be submitted only if responsible personnel have the appropriate disclosure on file (i.e., PHS and/or NSF branch, as applicable)
PIs should carefully consider who they designate as “responsible” personnel
  – take into account the person’s role on the project and the degree of independence with which s/he will work, rather than his/her title
  - Consultants... others....

Independent consultants or others named as responsible personnel must have a PHS or NSF compliant conflict of interest policy
Grant Application Considerations

- Identify key and responsible personnel on the TranSum

NEW:
- Include Non-Yale Personnel
  - Except, do not include names of Subrecipient PI
Grant Application Considerations

Subrecipient Requirements:

- Yale must establish contractually that the subrecipient institution has a PHS or NSF compliant COI policy, **prior to proposal submission**
  - Subrecipient Commitment Form

- If a subrecipient does not have a compliant policy, Yale will provide a generic model policy (and disclosure template) for the subrecipient institution to adopt and implement
  - Subrecipient investigators must submit disclosures to their institution by the time of application
  - For NIH-funded research, must update those disclosures within 30 days of acquiring a new SFI, and update their disclosure at least annually during the period of the award
Subrecipient Requirements (continued)

• Prior to the expenditure of funds under the subaward, the subrecipient institution must report any FCOIs to Yale

• Prior to the expenditure of funds under the subaward, Yale must submit FCOI report to the NIH

• Subrecipient institution must report to Yale new FCOIs (within 30 days) and annual FCOI reports (in conjunction with progress reports) to Yale to enable Yale to comply with its reporting obligations under the PHS regulations
  – This requirement will be part of the term and conditions of the subaward
  – Upon notification, Yale has 30 days to report the FCOI to the NIH
Key points for proposals

- Before sending a proposal to GCA- Administrative Check List
  - Discuss roles and confirm with PI that personnel have been identified appropriately as key personnel or responsible.
  - Confirm disclosures are current for all principal investigators, co-principal investigators, key personnel and anyone else identified as being responsible for the design, conduct or reporting of research.
  - If the proposal includes a subrecipient, confirm that the
    - Subrecipient Commitment Form has been completed
      - An authorized official of the subrecipient has signed the form.
    - The subrecipient has a compliant policy
      - Alert GCA immediately if a subrecipient responds that it does not have a compliant policy.

The proposal cannot be submitted if any of these items are not in place.
Grant Award Considerations

Key points & Reminders for Awards

- All responsible personnel must have a current and appropriate disclosure on file
  - If not, awards will be ‘on-hold’

- Subrecipients must certify that they have a compliant policy before the subcontract is issued or continued

- Before new responsible personnel may be added to a project
  - The individual must have the appropriate disclosure statement on file
  - If the individual has a significant financial interest, the Conflict of Interest Office must complete a transactional review prior to the individual beginning on the project
Fax: (203) 785-4159
(203) 785-5938
Web: www.yale.edu/grants/

Key Contacts:

Michael Glasgow
Tel: (203) 785-3680
Email: michael.glasgow@yale.edu

Tracy Coston - YSM
Tel: (203) 785-6063
Email: tracy.coston@yale.edu

Cheryl Magoveny - Central
Tel: (203) 737-2381
Email: cheryl.magoveny@yale.edu

Cynthia Kane - YSM & Award Setup
Tel: (203) 785-6762
Email: cynthia.kane@yale.edu

Lauren Pite - Subcontracts
Tel: (203) 737-1103
Email: lauren.pite@yale.edu

Donald Deyo - Contracts
Tel: (203) 785-3817
Email: donald.deyo@yale.edu
– GCA letter to all Yale subrecipient institutions under PHS funds

– GCA Alert(s)

– Targeted e-mail announcements to Yale Investigators on PHS-funded projects

– Informational Sessions
  • YSM: June 27, July 13, July 23, August 6
  • Central Campus: June 28, July 10, July 24, August 13