Agenda

- Who is affected by these regulations?
- What needs to be done?
  - EPASS form
  - Annual certification and disclosure
  - Training Module
- What’s next?
Who is Affected?

- The Principal Investigator of a PHS-supported project and
- Everyone else who will share responsibility for the design, conduct or reporting of that project (Investigators)
  - Investigator is defined by the PHS regulations as: “the project director or principal investigator and any other person, regardless of title or position who is responsible for the design, conduct, or reporting of research”
What is PHS?

- PHS agencies include:
  - NIH
  - FDA
  - CDC
  - and others
Policy 926

DRAFT UCLA Policy 926: Public Health Service Regulations on Objectivity in Research
- PHS Agency List
- List of PHS Award Mechanisms

http://rpc.research.ucla.edu/RPC/Pages/COI.aspx
### Additional Forms Required

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>
| ![Box](image1.png) | ![Box](image2.png) | **COI (Disclosure Requirements)**

- **Sponsor/Prime Sponsor is Federal Public Health Service (PHS), American Heart Association or American Cancer Society?**
  - If yes, provide names of other investigators on page 3 (See UCLA Policy 926).

- **Sponsor/Prime Sponsor is Federal (other than PHS), CIRM or special research programs managed by the UC Research Grants Program Office (RGPO)?** If yes, attach COI Form 740 & Supplement to Form 740 (if applicable). See UCLA Procedure 925.3.

- **Non-Government Sponsor/Prime Sponsor?** If yes, attach Form 700-U, 700-U Addendum and 700-U Supplement, as applicable, unless sponsor is exempt. See UCLA Procedure 925.2

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**Public Heath Service (PHS)**
The Principal Investigator must provide RPC with a list of all other Investigators on their research project that must comply with these regulations.

Beginning August 24th, these Investigators will be listed on page 3 of the EPASS.

Prior to August 24th, these Investigators will continue to be listed on Form 740.
Annual Certification

- Must be certified by each Investigator at least annually

- An Investigator’s first disclosure must be completed prior to submitting any PHS proposals on or after August 24, 2012

- Annual certification form used to indicate whether the Investigator has anything to disclose (not specific to a single organization)

- System notifications will be sent to the Investigator when the annual deadline for recertifying is approaching
Annual Certification

Annual Certification for Sally Seattle: What to Disclose

The investigator must disclose anything of monetary value that meets the PHS thresholds for reporting received by the investigator (including the investigator’s spouse or registered domestic partner, and dependent children for the following categories except travel) that reasonably appears to be related to or in the same field of expertise as the investigator’s institutional responsibilities.

Institutional Responsibilities are defined as: teaching/education, research, outreach, clinical service, and University and public service, on behalf of the University of California performed in the course and scope of the investigator’s UC appointment.

The following question relates to any outside organizations (non-UC) with which you have financial interests. Such organizations include companies, service providers, non-government organizations (NGOs), foundations, for-profit and not-for-profit organizations with which you, your spouse or registered domestic partner, or dependent children had a financial relationship in the previous 12 months. Examples include:

Equity (stock, stock options, or other ownership interests) – Any equity in a publicly-traded organization which, when combined with income or other payment for services, exceeds $5,000 OR any equity interest that you hold in a non-publicly traded organization. Mutual funds do not need to be reported.

Income or other payment for services - You are required to disclose any income or other payment for services in a publicly-traded organization which, when combined with equity, exceeds $5,000 OR any income or other payment for services in a non-publicly traded organization which exceeds $5,000. Examples include:

- providing expert testimony or consulting services
- serving on a board of directors, scientific advisory board, committee, panel or commission sponsored by a for-profit or non-profit organization, including professional or scholarly societies
- acting in an editorial capacity for a professional journal
- reviewing journal manuscripts, book manuscripts, or grant or contract proposals for a non-profit or for-profit organization
- salary received outside of the University of California

Income from IP rights and interests - Income you received from an organization, other than the UC, for intellectual property rights and interests during the 12 months prior to disclosure which exceeds $5,000. This could include such things as royalties for books or license fees for software or technology you may have invented before you came to UCLA.

Travel paid directly by or reimbursed by an organization - The investigator must disclose travel payments if the organization is a foreign university or government, a for-profit or a non-profit organization that is not specifically excluded from the reporting requirements. The disclosure requirement does not apply to travel paid directly by or reimbursed by any of the following US institutions:

- a federal, state, or local agency
- an institution of higher education
- an academic teaching hospital
- a medical center
- a research institute that is affiliated with an institution of higher education

* Do you, your spouse or registered domestic partner, or dependent children have any financial interests as defined above?

© Yes © No © Clear
Disclosures should be completed for each organization in which the Investigator has a significant financial interest.

Disclosures should be updated within 30 days of acquiring/discovering a new significant financial interest.

Smart form will ask detailed questions regarding the financial interest, and will determine if the reported interests meet the threshold for review.
Disclosure for Sally Seattle: General Information

General Information concerning the relationship between the external organization and the discloser.

1. * External Organization: Pfizer Inc [Select... Clear]

   or

   If you cannot find the organization in the above list, enter the name as text here:

2. * What type of financial interests do you have in the external organization?:
   - Equity (stock, stock options, or other ownership interests)
   - Income or other payment for services
   - Income from IP rights and interests
   - Travel paid directly by or reimbursed by the organization

3. * Are these financial interests related to:
   - Teaching/Education
   - Research
   - Clinical, University or Public Service on behalf of UC
   - Administration
   - Committee
   - Other
Disclosure for Sally Seattle in Test Company: Disclosure Summary

<table>
<thead>
<tr>
<th>Compensation Type</th>
<th>Dollar Value</th>
</tr>
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<tbody>
<tr>
<td>Equity (stock, stock options, or other ownership interests)</td>
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<tr>
<td>Income or other payment for services</td>
<td></td>
</tr>
<tr>
<td>Income from IP rights and interests</td>
<td>$6,000.00</td>
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<tr>
<td>Travel paid directly by or reimbursed by the organization</td>
<td>$6,000.00</td>
</tr>
<tr>
<td><strong>Total Value</strong></td>
<td><strong>$6,000.00</strong></td>
</tr>
</tbody>
</table>
Training Module

- All Investigators must complete the training module prior to engaging in PHS funded research

- The training module will be embedded into the system so it can be completed with the initial disclosure and will automatically require the Investigator to complete the training module, prior to submitting the annual disclosure form
  - The first time the Investigator logs in
  - Every four years
What’s Next?

- Notifications to PIs and other investigators
- Demo of system
- System Go Live: August 10th
Questions?

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