PHS FCOI – Business Process Redesign
• COI Office Contacts
  – coiprogram@grad.wisc.edu
    • Kelly Ullrick, COI Program Manager: kullrick@grad.wisc.edu

• RSP Contacts
  – preaward@rsp.wisc.edu
    • David Ngo: dvngo@rsp.wisc.edu
Agenda

• What are the new PHS rules?
  • Overview: New federal financial conflict of interest policy

• What do the new PHS rules require us to do?
  • New Requirements in federal policy that intersect with proposal submission and grants management

• How does all of this relate to research administration?
  • Revised Campus/RSP business processes
    • Proposals, Award Setup, Subawards
    • Instructions and case studies
What are the new PHS rules?
New Federal Policy on Financial Conflict of Interest

The Federal policy on financial conflicts of interest has changed. Those changes were implemented across the country on August 24, 2012.

Under current UW-Madison policy,

• All faculty, regardless of appointment and all academic staff with 50% appointment or greater at UW-Madison, as well as all individuals on human subjects protocols or federal grants are required to fill out an Outside Activities Report (OAR) each year and whenever new outside activities are undertaken.

• Review of OARs is handled by the Graduate School and the campus Conflict of Interest Committee. This is the way our campus identifies any financial conflicts of interest for faculty, staff, and other researchers.

The new federal policy requires important changes to our reporting and management of financial conflicts of interest.
A working group has developed a process for our campus to meet new federal policy requirements.

The Graduate School has the primary responsibility for research policy on our campus. Dean Bill Mellon appointed a working group composed of faculty, staff, administrators, and compliance experts to help recommend a process for meeting the new requirements.

The working group has shared its recommendations with Dean Mellon, who has worked with school and college representatives and campus leaders to implement the process.
While much of our practice in managing financial conflicts of interest has not changed, there are several new provisions in the federal policy that require your attention.
Further information regarding the PHS regulations may be found at:

- New federal regulations:

- UW-Madison COI Program Web Page:
  [http://www.grad.wisc.edu/research/policyrp/coi/coiregchanges.html](http://www.grad.wisc.edu/research/policyrp/coi/coiregchanges.html)
  - Page includes information from powerpoint presentation and several important resources
    - Key terms (.pdf)
    - Summary of regulatory changes (table comparing past regulatory requirements with new requirements) (.pdf)
    - Deans Summary (.pdf)
    - Guidance document (.pdf)
What do the new PHS rules require us to do?
Disclosure

• **Who must disclose**
  - Under UW-Madison COI Policy, All UW-Madison faculty, regardless of appointment level
  - All UW-Madison academic staff and limited appointees with total appointments of 50% or greater
  - All principal *investigators*, co-investigators, and *senior/key personnel* on current federal grants and/or on human subjects research protocols

• **When to disclose**
  - Annually
  - Within 30 days of acquiring a new or experiencing a changed outside financial interest
  - At proposal submission for Public Health Service agency funding requests
  - At award set-up for Public Health Service agency funding awards
Travel

• **What does an investigator have to do?**
  – Disclose any reimbursed or sponsored travel related to their institutional responsibilities within 30 days of the start of the travel event.

• **When the disclosure requirement does NOT apply**
  – Travel reimbursed or sponsored by:
    • Federal, state, or local government agency,
    • U.S. institution of higher education,
    • U.S. academic teaching hospital,
    • U.S. medical center, or
    • U.S. research institute that is affiliated with a U.S. institution of higher ed.
  – Travel reported through e-reimbursement (any reimbursed or sponsored travel that goes through the UW-Madison)
Travel

• **What does "reimbursed" or "sponsored" mean?**
  – “Reimbursed” – payments made by an outside entity to cover expenses paid by a PHS-funded investigator as part of the travel event;
  – “Sponsored” – expenditures made by the entity without transfer of funds to the PHS-funded investigator.

• **What to disclose**
  – Purpose of the trip,
  – Identity of the sponsor/organizer,
  – Destination, and
  – Duration of travel.
The new federal definition of an amount constituting a Significant Financial Interest (SFI) is decreased to $5,000

- This new threshold is reduced from the previous $10,000 threshold.
- An SFI includes the sum of paid compensation, ownership in companies and leadership positions.
Training

• **Who must complete training**
  • All federally funded and human subjects investigators are required to complete the on-line UW-Madison COI Training, available through Learn@UW.

• **When training must be completed**
  • 2013 OAR reporting period
  • Per-PHS award, between August 24, 2012 and the 2013 OAR reporting period

• **How to complete training**
  • Go to [http://www.grad.wisc.edu/research/policyrp/coi/COITraining.html](http://www.grad.wisc.edu/research/policyrp/coi/COITraining.html)
The nature and $ value of any SFI determined to constitute a financial conflict of interest will be posted on a publicly accessible website or provided to requesters within 5 business days.

- The new federal policy requirement is to assure greater accessibility of the data on potential financial conflicts of interest to the public.
- This requirement will apply only to PHS-funded investigators.
Sub-recipients

- Federal policy applies to sub-recipient investigators listed on a PHS-funded project

- **Two groups of sub-recipients:**
  - Sub-recipient entities with a COI policy—must certify they have policy compliant with federal regulations
  - Subrecipient entities without a COI policy—must certify they will follow the UW-Madison COI Policy
How does all of this relate to grants administration?
PHS Agencies

- National Institutes of Health (NIH)
- Food and Drug Administration (FDA)
- Centers for Disease Control (CDC)
- Agency for Healthcare Research and Quality (AHRQ)
- Agency for Toxic Substances and Disease Registry (ATSDR)
- Health Resources and Services Administration (HRSA)
- Indian Health Services (IHS)
- Substance Abuse and Mental Health Services Admin (SAMHSA)
Other Agencies Who Have Adopted PHS FCOI Rules

- American Heart Association
- American Cancer Society
- Arthritis Foundation
- Susan G. Komen Foundation
- Juvenile Diabetes Research Foundation
- Alliance for Lupus Research
- Lupus Foundation of America
How Many People Will This Impact?

• PHS is the largest single funder of UW.
• Many Divisions receive funds from PHS.
  – UW has 691 distinct "primary PIs" on PHS awards.
• UW has 700 different organizations we issue subawards
  – About 40% of the organizations are registered on the FDP clearinghouse. More likely to follow.
Key Persons

- UW’s definition for key persons is found on page 24 of the UW-Madison Guidelines for Effort Reporting (https://www.rsp.wisc.edu/effort/index.html).
- That definition reads:

"Key Person: A person who contributes to the scientific or scholarly development or execution of project in a substantive, measurable way. In the context of establishing commitments and tracking effort, a key person is defined as the principal investigator, all co-investigators, and all individuals explicitly listed as key personnel in the proposal. In situations in which the proposal does not explicitly list key persons, the University defines key personnel as the principal investigator and all co-investigators on a sponsored project.

In the context of obligations related to a significant change in work activity, a key person is defined as all individuals who are named as key personnel in the Notice of Grant Award (NOGA). Often, the principal investigator/project director is the only person specifically named in the NOGA."
### WISPER Projects Tab & Key Persons

#### Fund Code
- 133

**Owning Department**
- CNTR POP HEALTH\*CUPH

**Start Date**
- 07/01/2012

**End Date**
- 06/30/2013

**FA Rate Type**
- Research - On Campus

**FA Base**
- No F&A (Base A)

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**Total Sponsor Budget**
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**Save and Return to Record**

**Cancel and Return to Record**

**Save**
• PHS* proposals submitted after 8/24/12 are subject to new PHS FCOI rules
• Cursory Review at proposal submission
  – COI Tasks Completed for Key Persons?
    • Disclosure
• COI reminder emails
Business Process Impacts at UW: Awards

- PHS* awards issued after 8/24/12 are subject to new PHS FCOI rules
- Cannot expend dollars if any COI tasks are incomplete
- Final Review Prior to each Award Setup
  - COI Tasks Completed for Key Persons?
    - Training, Disclosure, Reporting
    - Includes Advance Accounts, new, renewals, NCE
    - Includes each award issuance (ex: Year 2 award notice on 5 year project)
- COI reminder emails to key personnel
- RSP Error Report
Award Setup Process – In a Nutshell

1. Proposal Submission
   - COI check for OAR completion is cursory.
   - (COI emails sent to Key persons)

2. JIT Stage
   - PHS solidifies Key persons (other support) and any other award items

3. Award Acceptance
   - RSP review, negotiation, setup
   - (COI emails sent to Key persons)

4. WISPER record is needed.
   - RSP will use existing/create new one

5. RSP sends out Setup Projects Approval and COI Request Approval

6. Campus confirms Key Persons & RSP loads record in FAST
   - (COI emails sent to Key persons)

7. COI Office confirms training, reviews OAR, addresses any Management Plan & Investigator follow-up

8. RSP submits any Management Plan & finalizes award setup
### COI Approval – Used in Conjunction with Setup Projects Approval

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**Initiate New Approval Request**

### Requested Approvals

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<td>SCHULZ, CHRISTY R</td>
<td>534700 MED</td>
<td>MICROBIOLOGY*MED MICRO</td>
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**General Info**

**Route to Another Person**

**My Worklist**

**Search Page**

**THE UNIVERSITY OF WISCONSIN MADISON**

Slide 26
Add Approval

**Requested By:** NGO, DAVID V

**Approval Type:** COI Request

**Request Date:** 11/21/12 2:09AM

**Approval Request:**
After confirmation of key personnel on the projects tab, RSP will load this WISPER record to FAST (ECOI Award Setup Tool) to begin the COI review processes.

The COI approval should remain open until all conflict of interest obligations are completed.

**Approver Type:**

**Requested Approver**

**Recipients**

**Sequence:** 3

**Business Unit:** UWMSN

**Add Approval** | **Cancel**
Requesting that you complete conflict of interest obligations (OAR Disclosure, FCOI Training, Management Plan Reporting) for all personnel listed on the projects tab. Guidance is available at:  [http://www.grad.wisc.edu/research/policyrp/coi/index.html](http://www.grad.wisc.edu/research/policyrp/coi/index.html)

Please ensure that all key personnel are correctly entered in the projects tab prior to COI review. You can notify RSP that the key personnel are ready for COI review by:

a) Approving the setup projects approval; Or 

b) Submitting comments only to this approval indicating that the personnel section on the projects tab is set

After confirmation of key personnel on the projects tab, RSP will load this WISPER record to FAST (FCOI Award Setup Tool) to begin the COI review processes.

The COI approval should remain open until all conflict of interest obligations are completed.
### WISPER Projects Tab & Key Persons

#### Fund Code
- 133

#### Owning Department
- 531600, CNTR POP HEALTH*CUPH

#### Start Date
- 07/01/2012

#### End Date
- 06/30/2013

#### F & A Rate Type
- Research - On Campus

#### Program Code
- Program Code: 4, Description: Research

#### Budget Details
- **Budget Item**: Research, **Description**: Research, **Budget Amount**: 17,229.00

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#### Action Buttons
- Save and Return to Record
- Cancel and Return to Record
- Save
## Resources: UW Electronic Tools
### FAST (FCOI Award Setup Tool)

### COI Clearances for PHS Awards

#### PHS Award Setup Worklist: Setups requiring COI Clearances

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#### RSP: Award setup completed

No items.

Questions? [Contact the Conflict of Interest Office](#)  
[COI Regulatory Changes Home Page](#)

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Details of WISPER Document MSN155610

Added to the Award Setup Worklist on 11/27/12

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### COI Clearances Required

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Back to the Award Setup Worklist  
RSP COI Dashboard for PHS Awards  
RSP Intranet Tools Menu  
COI Regulatory Changes Home Page  
© Board of Regents of the University of Wisconsin System
**COI Clearances for PHS Awards**

**Details of WISPER Document MSN149767**

*Added to the Award Setup Worklist on 9/11/12*

- **Award PI:** JOHNSON, ERIC A
- **Award Period:** 01-Jun-12 to 31-May-14
- **Award Description:** Therapeutic Delivery Platforms against Botulism
- **Sponsor:** MEDICAL COLLEGE OF WISCONSIN  (Primary Sponsor: DHHS, PHS, NATIONAL INSTITUTES OF HEALTH)
- **Award Reference #:** 072800 -
- **Current Budget:** $15,050.00
- **Award Contract Type:** Grant

**COI Clearances Required**

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*Back to the Award Setup Worklist*
*RSP COI Dashboard for PHS Awards*
*RSP Intranet Tools Menu*
*COI Regulatory Changes Home Page*

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## COI Clearances for PHS Awards

### Details of WISPER Document MSN153639

*Added to the Award Setup Worklist on 10/10/12*

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*Reportable FCOIs:
- Reports Submitted:*

**Back to the Award Setup Worklist**
**RSP COI Dashboard for PHS Awards**
**RSP Intranet Tools Menu**
**COI Regulatory Changes Home Page**
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## Resources: UW Electronic Tools
### COI Clearances Example 4

#### COI Clearances for PHS Awards

**Details of WISPER Document MSN160415**

*Added to the Award Setup Worklist on 11/29/12*

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[Contact the COI Office at coiprogram@grad.wisc.edu or 608-890-1613](mailto:coiprogram@grad.wisc.edu)

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[COI Regulatory Changes Home Page](#)

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## COI Clearances for PHS Awards

### Info to be Submitted to the Sponsor in an FCOI Report

| Case ID: | 564 (OAR Year: 2012) |
| Completed by the COI Office on: | 8/05/2012 |

### The Person
- Investigator: HARMS, JEROME S

### The Award
- MSN Number: MSN150256
- Agency Award Number: 2R01AI073558-05A1
- Sponsor: DHHS, PHS, NATIONAL INSTITUTES OF HEALTH
- Primary Sponsor: 
- Investigator’s Role on this Project: Key Person
- PI Name: Splitter, Gary A

### The Entity and the Relationship
- Entity Name: Westview Technology
- Currently Managed: Yes
- Nature/Value of the Interest:
  - Compensation: $600,000
  - Ownership: $80,000-$99,999
- How the interest relates to the PHS-funded research: Nexus for Harms Westview
- Basis for determination of conflict: Justification for Harms Westview
- Conditions of the plan:
- How the plan safeguards objectivity:
- How the plan will be monitored to ensure compliance:

### printable Version of the Management Plan

- RSP COI Dashboard for PHS Awards
- RSP Intranet Tools Menu
- COI Regulatory Changes Home Page

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Details of WISPER Document MSN156510

Added to the Award Setup Worklist on 10/18/12

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Back to the Award Setup Worklist
RSP COI Dashboard for PHS Awards
RSP Intranet Tools Menu
COI Regulatory Changes Home Page
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### COI Training Completion Status

To search, enter any combination of the following:

**Single UDDS Code:** A07

**UDDS Range:**
- **From:**
- **Through:**

**Names:** Use either a full name (e.g., Chamberlain or William) or a partial name (e.g., Cham or Wi).

**Dates:** Use any of the usual formats (e.g., 11/20/07).

The search screen will convert them to a standard format automatically.

**Show me:**
- People with UW-Madison appointments
- People without UW-Madison appointments (UDDS codes will be ignored)

**Search**  **Reset All Fields**

### Search Results

Search Criteria: UDDS Code starts with "A07"
Your query returned 159 records

- People with multiple appointments appear more than once.
- Current as of 8/17/12, 2:00 a.m.

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<td>A07</td>
<td>AG &amp; SO &amp; APPLIED ECONOMY &amp; APP ECO</td>
</tr>
</tbody>
</table>

**Comments or Questions? Contact Us**

**COI Regulatory Changes Home Page**
The Graduate School
University of Wisconsin - Madison
Closer Look at Amendments

**Old State**
1. Review Award
2. Locate any existing WISPER record (created by campus)
3. Begin setup review
4. If possible to setup, complete the award
5. If not possible to setup, create a WISPER record
6. Send an approval

**New FCOI State**
1. Review Award
2. Locate any existing WISPER record (created by campus)
3. Begin setup review
4. If no WISPER record exists, create one (or ask campus to do so)
   a) Copy previous record
   b) Enter all key persons (name/role) in projects tab
5. If possible to setup, complete the Award
6. If not possible to setup, send approvals
Example: Total Process duration = 2 days

Details of WISPER Document MSN160917

Added to the Award Setup Worklist on 12/04/12

<table>
<thead>
<tr>
<th>Role</th>
<th>Name</th>
<th>Questions?</th>
<th>Contact the COI Office</th>
<th>Questions?</th>
<th>Contact RSP</th>
</tr>
</thead>
<tbody>
<tr>
<td>PI</td>
<td>YOON, TEHSHIK</td>
<td>Training</td>
<td>OK</td>
<td>OAR Submitted</td>
<td>OK</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>COI Office Action</td>
<td>OK</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Investigator Responded</td>
<td>N/A</td>
</tr>
<tr>
<td></td>
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<td></td>
<td></td>
<td>Reportable FCOIs</td>
<td>Reports Submitted</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Check when Submitted</td>
<td></td>
</tr>
</tbody>
</table>

- Award mod received by RSP on 12/4/12
- WISPER record created by RSP on 12/4/12
- FAST record created by RSP on 12/4/12
- COI Tasks completed on 12/5/12
- Award Accepted and SFS setup completed on 12/6/12
Whenever an Institution identifies an SFI that was not disclosed, identified, reviewed or managed in a timely manner, the designated official(s) shall within 60 days: review and make the determination of an FCOI and report the FCOI, if it exists, to the PHS/NIH.

If an FCOI exists, complete and document a retrospective review within 120 days of the Institution’s determination of noncompliance. Implement, on at least an interim basis, a management plan that shall specify the actions that have been, and will be, taken to manage the FCOI going forward.

If applicable, update existing FCOI report to specify the actions that have been, and will be, taken to manage the FCOI going forward or update previously submitted report.

If bias is found, notify NIH promptly. Submit mitigation report through FCOI Module.

Submit annual FCOI report thereafter through FCOI Module.
<table>
<thead>
<tr>
<th>Report</th>
<th>Content</th>
<th>Required when?</th>
</tr>
</thead>
</table>
| New FCOI Report (Initial submission)        | Grant Number, PI, Name of Entity with FCOI, Nature of FCOI, Value of financial interest (in increments), Description of how FI relates to research, Key Elements of Management Plan. | (1) Prior to expenditure of funds  
(2) Within 60 days of any subsequently identified FCOI                                           |
| Annual FCOI Report                          | Status of FCOI (i.e., whether FCOI is still being managed or no longer exists) and Changes to Management Plan, if applicable | Annual report due at the same time as when the Institution is required to submit annual progress report, multi-year progress report, or at time of extension. |
| Revised FCOI Report                         | If applicable, update a previously submitted FCOI report to describe actions that will be taken to manage FCOI going forward or make changes to originally submitted FCOI report. | Following the completion of a retrospective review when there is noncompliance with the regulation, if needed. |
| Mitigation Report                           | Project Number, Project Title, Contact PI/PD, Name of Investigator with FCOI, Name of Entity with FCOI, Reason for review, | When bias is found as a result of a retrospective review.                                           |
Proposal Submission to a PHS Agency with Subaward

Start a WISPER record. At bottom of general tab indicate “Yes” for Outgoing Sub-agreement question.

Go to FDP Clearinghouse to verify subrecipient is listed.

If listed, in the Comments Tab of the WISPER record, note subrecipient name and indicate they are in the FDP Clearinghouse.

If not listed, subrecipient must complete and return the “Subrecipient FCOI Documentation Form.” In Comments Tab, note subrecipient name and indicate the FCOI Documentation Form is attached. Attach FCOI Documentation Form to WISPER record.

If subrecipient indicates on the FCOI Documentation Form (Sect. B.1) that they are following their own policy, nothing else is required.

If subrecipient indicates on the FCOI Documentation Form (Sect. B.2) that they will follow the UW Policy, they must also complete and return the “Subrecipient Disclosure of Financial Conflict of Interest Form” for each investigator.

Nothing else is required. Route WISPER record.

Route WISPER record.

Attach Subrecipient Disclosure of Financial Conflict of Interest Form(s) to WISPER record. Route WISPER record.
Information from PHS & NIH


Some Resources include:
- A tutorial, webinar, PowerPoint presentations
- FAQs are periodically updated and will be updated soon.
• UW COI Office: http://www.grad.wisc.edu/research/policyrp/coi/index.html

• UW FCOI Regulatory Changes: http://www.grad.wisc.edu/research/policyrp/coi/coiregchanges.html

• UW RSP: https://www.rsp.wisc.edu/policies/
Resources: UW Forms

• RSP Forms:
  https://www.rsp.wisc.edu/subfcoi/
  – FCOI Documentation Request Letter
  – Subrecipient FCOI Documentation Form
  – Subrecipient Disclosure of FCOI Form
Resources: UW Electronic Tools

- RSP/Campus Tools: https://www.rsp.wisc.edu/subfcoi/
  - FAST (FCOI Award Setup Tool)
    - COI Clearances
  - COI Training Completion Status
Contacts

• COI Office Contacts
  – coiprogram@grad.wisc.edu
  • Kelly Ullrick: kullrick@grad.wisc.edu

• RSP Contacts
  – preaward@rsp.wisc.edu
  • David Ngo: dvngo@rsp.wisc.edu