

UW FCOI Process Redesign



NCURA Region IV Spring Meeting 2013

1) New PHS rules & key decision points

- Overview: New federal financial conflict of interest policy
- What do the new PHS rules require us to do?
- Intersection of federal policy with grants management

2) UW's Grants Administration

- Least intrusive, streamlined approach
- Revised business processes: Proposals, Award Setups, Subawards

3) Case Study on UW Operations

What are the new PHS rules?

New Federal Policy on Financial Conflict of Interest

The Federal policy on financial conflict of interest has changed. Those changes were implemented nationwide on August 24, 2012.

Under current UW-Madison policy:

- All faculty, regardless of appointment, 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.
- The 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.



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UW-Madison Working Group:

How UW-Madison has met the new federal policy

The UW-Madison Working Group has developed a process for our campus to meet new federal policy requirements.

The Graduate School is primarily responsible for research policy on our campus. The Associate Dean for Research Policy has appointed a working group composed of faculty, staff, administrators, and compliance experts to recommend a process for meeting the new requirements.

The working group has shared its recommendations with the Dean, who in turn has worked with school and college representatives and campus leaders to implement the process.



New Regulatory Requirements that Require Your Attention

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 the attention of our faculty, staff, and researchers.

FCOI Policy

UW-Madison COI Program Web Page:

<http://www.grad.wisc.edu/research/policyrp/coi/coiregchanges.html>

- 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)
 - Dean's Summary (.pdf)
 - Guidance document (.pdf)
- Users frequently visited this page throughout the summer of 2012:
 - April, 2012 = 51
 - May, 2012 = 100
 - June, 2012 = 600
 - July, 2012 = 578
 - August, 2012 = 574

What do the new PHS rules require us to do?

Disclosure

- **Who must disclose**

- 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 outside financial interest
- Within 30 days of a modification to an existing outside financial interest
- At time of proposal submission for Public Health Service agency funding requests
- At time of award set-up for Public Health Service agency funding awards



- **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 agencies
 - U.S. institutions of higher education,
 - U.S. academic teaching hospitals,
 - U.S. medical centers, or
 - U.S. research institutes that are affiliated with a U.S. institution of higher education
 - Travel reported through e-reimbursement (any reimbursed or sponsored travel that goes through 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.
- Appearance of travel questions on disclosure form depends on federal funding status



Threshold for Significant Financial Interest (SFI)

- **The new federal definition of an amount constituting a Significant Financial Interest (SFI) has 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.
 - The definition of an SFI continues to differentiate financial relationships with public companies from financial relationships with private companies



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**
 - During 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>



Public Disclosure

- **The nature and monetary 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 serves to assure greater accessibility to 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



Before We Get Too Far Ahead of Ourselves with Our Own Thinking....



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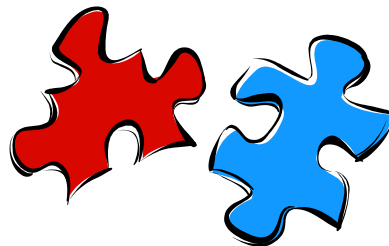
What's the Plan?

Dinner for 20

- Get everybody lined up
- Decide what to cook
- Make a shopping list
- Go shopping
- Do the cooking
- Set the table
- Serve!

FCOI Implementation

- Get Inst. Commitment
- Gather requirements
- Develop RFP
- Select Provider
- Implement Solutions
- Plan “Go Live”
- Roll out!



How Many People Will This Impact?

- PHS is the largest single sponsor of UW.
- Many Divisions receive funds from PHS.
 - UW has 691 distinct "primary PIs" on PHS awards.
- UW has 700 different organizations to which we issue subawards
 - About 40% of the organizations are registered on the FDP clearinghouse. More are 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."



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 Administration (SAMHSA)



Other Agencies Who Have Adopted PHS FCOI Rules

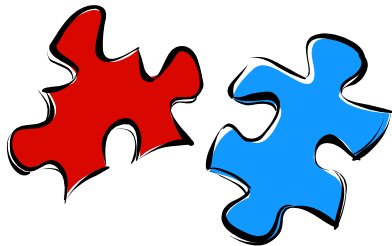
- American Heart Association
- American Cancer Society
- Arthritis Foundation
- Susan G. Komen Foundation
- Juvenile Diabetes Research Foundation
- Alliance for Lupus Research
- Lupus Foundation of America



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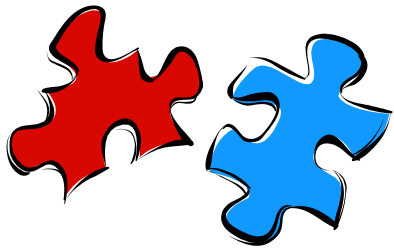
Key Considerations

- Integrated research administration infrastructure
- What might research program look like in 5-10 years?
- Elements of future vision
 - Systems, Functionality, Integration, Users



Key Considerations

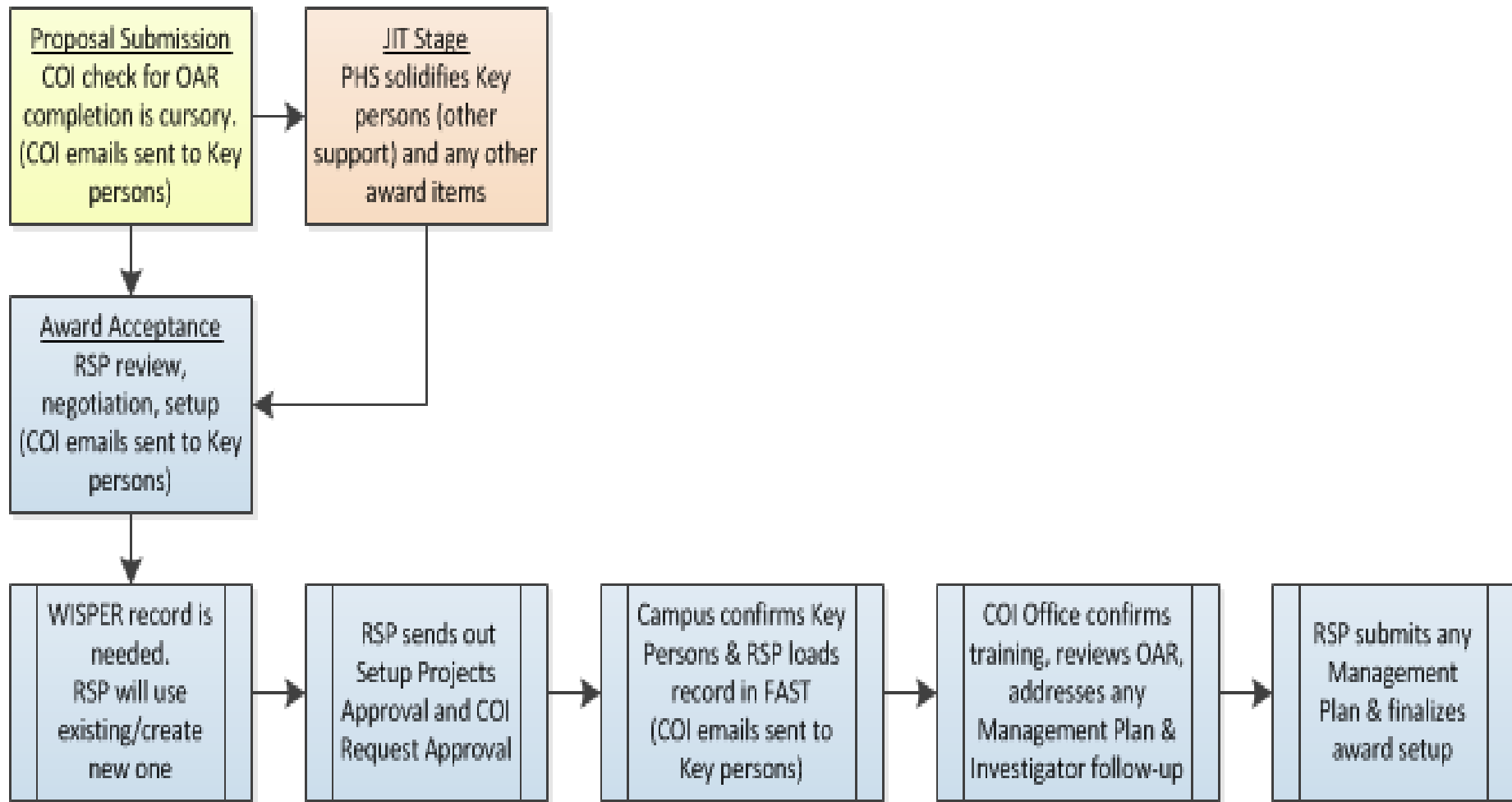
- What currently exists? What needs are likely to emerge? What will the order of priorities be? Timeline, budget, resources?
- Precursors: Dependencies among support processes and policies to achieve an end result
- Quick Wins
- Commitment and Ownership



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How does all of this relate to grants administration?

FCOI Process – In a Nutshell



Business Process Impacts at UW: Proposals

- 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



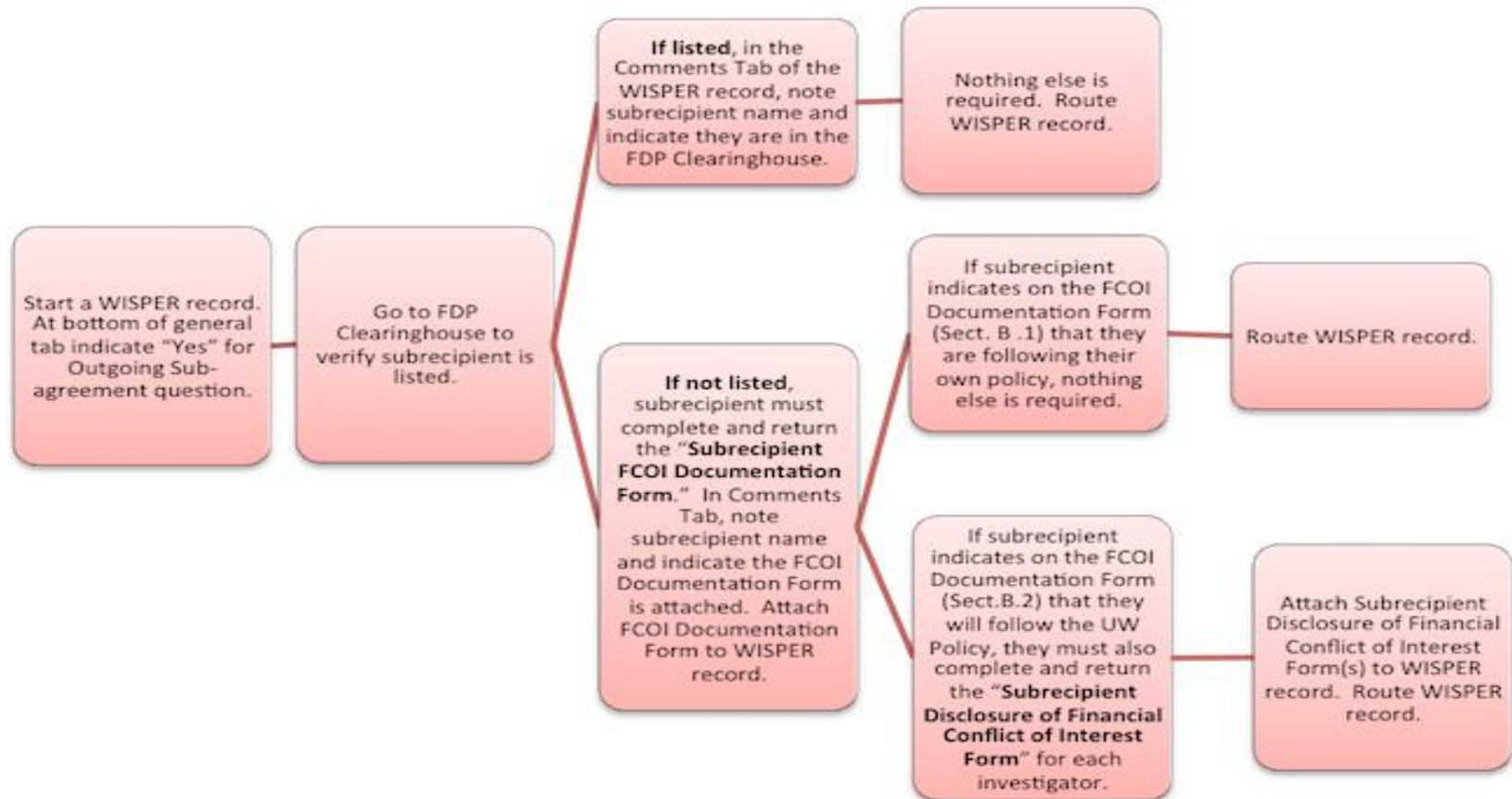
Business Process Impacts at UW: Awards

- 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



Subawards at UW Proposal Stage

Proposal Submission to a PHS Agency with Subaward



Stats



RSP averages 650 award acceptances per month



Prior to 8/24/12: award set-up in average of 19 days



After 8/24/12: award set-up in average of 12 days



Average time for PI to complete COI obligations* is 10 days

Case Study

COI Approval – COI Request

Home

Worklist

Add to Favorites

Add Approval

Requested By NGO,DAVID V

Request Date 11/21/12 2:09AM

Sequence 3

Approval Type

Approval Request After confirmation of key personnel on the projects tab, RSP will load this WISPER record to FAST (ECQI 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

Business Unit UWMSN

Add Approval

Cancel

Requested Approver

Recipients



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COI Approval – Used in Conjunction with Setup Projects Approval

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[General](#) | [Comments](#) | [Projects](#) | **Approvals** | [Attachments](#) | [Division Action](#) | [Terms](#) | [SPO Action](#) | [History](#)

Record ID MSN160498 **Document Type** NoCostExt [Wisper Help](#)
Contact PI DILLARD,JOSEPH P **Sponsor Name** DHHS, PHS, NATIONAL INSTITUTES OF HEALTH
Short Title Dillard R01AI047958 NCE **Status** 4.5-SPO Negotiation

[Initiate New Approval Request](#)

Requested Approvals

Type	Requested	Requested By	Requested Approver	Actual Approver	Action	Details
Chair Approval	11/15/12 10:56AM	LAWLER,JOHN	LAWLER,JOHN	LAWLER,JOHN	Approved	Review/Approve
COI Request	11/20/12 8:33AM	SCHULZ,CHRISTY R	534700 MED MICROBIOLOGY*MED MICRO			Review/Approve

[General Info](#)

[Route to Another Person](#)

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 Save

COI Request – Text/Instructions

Requests 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>

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 Change Department on Project
Start Date 07/01/2012 **End Date** 06/30/2013
F & A Rate Type Research - On Campus **FA Base** No F&A (Base A) **FA Rate %**

Combo Edit Departments and Nodes		Program Code	
Department	Description	Program Code	Description
531600	CNTR POP HEALTH*CUPH	4	Research
<input type="button" value="Add Combo Edit Department"/> <input type="button" value="Add Combo Edit Dept Node"/>		<input type="button" value="Add Program Code"/>	
Department Node	Description		

Budget Item	Description	Budget Amount
		17,229.00
Total Sponsor Budget		17,229.00

Name	Effort Reqs Mt	Project Role	Start Date	End Date	Sponsor %	Cost Shared %	Total %
RICE, JESSICA P	Y	OTHER	07/01/2012	08/23/2012	5		5
LEMKE, MELISSA A	Y	OTHER	07/01/2012	06/30/2013	21		21
FRAZER, DAVID A	Y	PI	07/01/2012	06/30/2013	2		2

Name	Start Date	End Date	From Project ID	From Fund Code	From Department	Cost Shared %	Cost Share Type
	07/01/2012	06/30/2013					

Resources: UW Electronic Tools FAST (FCOI Award Setup Tool)

COI Clearances for PHS Awards

PHS Award Setup Worklist: Setups requiring COI Clearances

Under review by COI Office

MSN Number	PI Name	Sponsor	Primary Sponsor	Date Added to List	Award Start Date
MSN139496	BRANDT, CURTIS R	DHHS, PHS, NATIONAL INSTITUTES OF HEALTH		7/24/12	7/01/11
MSN149980	DILLARD, JOSEPH P	DHHS, PHS, NATIONAL INSTITUTES OF HEALTH		7/24/12	5/01/12
MSN149713	GUSTAFSON, DAVID H	DHHS, PHS, NATIONAL INSTITUTES OF HEALTH		7/24/12	7/01/12
MSN145608	KLEIN, RONALD	DHHS, PHS, NATIONAL INSTITUTES OF HEALTH		7/24/12	5/01/12
MSN147332	SIEGER, THOMAS L	DHHS, PHS, CENTERS FOR DISEASE CONTROL &		8/10/12	9/30/11
MSN138275	VEMUGANTI, RAGHU	DHHS, PHS, NATIONAL INSTITUTES OF HEALTH		7/27/12	6/01/11
MSN146829	WILTON, GEORGIANA	DHHS, PHS, CENTERS FOR DISEASE CONTROL &		8/17/12	9/30/11

RSP: Submit reports to sponsor

MSN Number	PI Name	Sponsor	Primary Sponsor	Date Added to List	Award Start Date
MSN143047	DURKIN, MAUREEN S	DHHS, PHS, NATIONAL INSTITUTES OF HEALTH		7/24/12	4/01/11
MSN150256	SPLITTER, GARY A	DHHS, PHS, NATIONAL INSTITUTES OF HEALTH		7/24/12	5/01/12

RSP: Ready for award setup

MSN Number	PI Name	Sponsor	Primary Sponsor	Date Added to List	Award Start Date
MSN153226	ROBINSON, JAMES M	WISCONSIN DEPT OF HEALTH SERVICES	DHHS, PHS, NATIONAL INSTITUTES OF HEALTH	7/27/12	3/01/12

RSP: Award setup completed

No items.

Questions? [Contact the Conflict of Interest Office](#)

[COI Regulatory Changes Home Page](#)

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Resources: UW Electronic Tools

COI Clearances Example 1

COI Clearances for PHS Awards

Details of WISPER Document MSN155610

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

Award PI: **KAMP, TIMOTHY J**
Award Period: **01-Aug-12 to 31-Jul-13**
Award Description: **The Virtual Physiological Rat Center for The Study of Complex Diseases**
Sponsor: **MEDICAL COLLEGE OF WISCONSIN (Primary Sponsor: DHHS, PHS, NATIONAL INSTITUTES OF HEALTH)**
Award Reference #:
Award Department: **534225 -**
Current Budget: **\$.00**
Award Contract Type: **Grant**

COI Clearances Required

Role	Name	Questions? Contact the COI Office				Questions? Contact RSP		
		Training	OAR Submitted	COI Office Action	Investigator Responded	Reportable FCOIs	Reports Submitted	Check when Submitted
PI	KAMP, TIMOTHY J	OK	OK	In Progress				

[Back to the Award Setup Worklist](#)

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[RSP Intranet Tools Menu](#)

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Resources: UW Electronic Tools

COI Clearances Example 2

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 #:
Award Department: **072800 -**
Current Budget: **\$15,050.00**
Award Contract Type: **Grant**

COI Clearances Required

Role	Name	Questions? Contact the COI Office				Questions? Contact RSP		
		Training	OAR Submitted	COI Office Action	Investigator Responded	Reportable FCOIs	Reports Submitted	Check when Submitted
PI	JOHNSON, ERIC A	OK	OK	OK	Pending			

[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 3

COI Clearances for PHS Awards

Details of WISPER Document MSN153639

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

Award PI: **BUSHMAN, WADE A**
 Award Period: **29-Sep-12 to 31-Aug-14**
 Award Description: **Urinary Biomarkers of Lower Urinary Tract Symptoms (LUTS) in Men**
 Sponsor: **DHHS, PHS, NATIONAL INSTITUTES OF HEALTH**
 Award Reference #: **1 P20 DK097826-01**
 Award Department: **539740 -**
 Current Budget: **\$296,960.00**
 Award Contract Type: **Grant**

COI Clearances Required

Role	Name	Questions? Contact the COI Office				Questions? Contact RSP		
		Training	OAR Submitted	COI Office Action	Investigator Responded	Reportable FCOIs	Reports Submitted	Check when Submitted
PI	BUSHMAN, WADE A	OK	OK	OK	N/A			
CO-INVESTIGATOR	BJORLING, DALE E	OK	OK	OK	N/A			
CO-INVESTIGATOR	BRUSKEWITZ, REGINALD C	Pending	OK	OK	N/A			
CO-INVESTIGATOR	LI, LINGJUN	OK	OK	OK	N/A			
CO-INVESTIGATOR	MARKER, PAUL C	OK	OK	OK	N/A			
CO-INVESTIGATOR	PAGE, CHARLES DAVID	OK	OK	OK	OK	MEDSEEK	10/31/2012	
CO-INVESTIGATOR	RICKE, WILLIAM	OK	OK	OK	N/A			
CO-INVESTIGATOR	SKINNER, HALCYON G	OK	OK	OK	N/A	Kevin Kennedy Associates	Pending	<input type="checkbox"/>
CO-INVESTIGATOR	VEZINA, CHAD M	OK	OK	OK	N/A			
KEY	PENNISTON, KRISTINA L	OK	OK	OK	N/A			

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[Back to the Award Setup Worklist](#)

[RSP COI Dashboard for PHS Awards](#)

[RSP Intranet Tools Menu](#)

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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

Award PI: **DANIS, RONALD P**
 Award Period: **01-Apr-12 to 31-Mar-13**
 Award Description: **Randomized Trial of Lutein, Zexanthin and Omega 3 LCPFAs in Age Related Macular Degeneration (AREDS2)**
 Sponsor: **DHHS, PHS, NATIONAL INSTITUTES OF HEALTH**
 Award Reference #: **HHS-N-260-2006-00003-C MOD #6**
 Award Department: **536000 -**
 Current Budget: **\$789,095.00**
 Award Contract Type: **Cost-Reimbu**

Contact the COI Office at coiprogram@grad.wisc.edu or 608-890-1613

COI Clearances Required

						Questions? Contact RSP		
Role	Name	Training	OAR Submitted	COI Office Action	Investigator Responded	Reportable FCOIs	Reports Submitted	Check when Submitted
PI	DANIS, RONALD P	OK	OK	OK	OK	Topcon Medical Systems Inc Oraya Inc. EyeKor LLC	Pending Pending Pending	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
KEY	BLODI, BARBARA A	Pending	OK	OK	N/A			
KEY	HUBBARD, LARRY DEAN	Pending	Pending	Pending				
KEY	KLEIN, RONALD	OK	OK	OK	N/A			
KEY	NEIDER, MICHAEL W	Pending	OK	OK	Pending			

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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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Resources: UW Electronic Tools Management Plan - Submitted to Sponsor

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:	Paragraph 1 for Harms Westview
How the plan safeguards objectivity:	Paragraph 2 for Harms Westview
How the plan will be monitored to ensure compliance:	Paragraph 3 for Harms Westview

[Printable Version of the Management Plan](#)

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[RSP Intranet Tools Menu](#)

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Resources: UW Electronic Tools

COI Clearances Example 5

COI Clearances for PHS Awards

Details of WISPER Document MSN156510

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

Award PI: **WILDING, GEORGE**
Award Period: **14-Sep-12 to 31-Mar-13**
Award Description: **UW Comprehensive Cancer Center Support - CTRP Supplement**
Sponsor: **DHHS, PHS, NATIONAL INSTITUTES OF HEALTH**
Award Reference #: **3 P30 CA014520-38S4**
Award Department: **533400 -**
Current Budget: **\$74,854.00**
Award Contract Type: **Grant**

COI Clearances Required

Role	Name	Questions? Contact the COI Office				Questions? Contact RSP		
		Training	OAR Submitted	COI Office Action	Investigator Responded	Reportable FCOIs	Reports Submitted	Check when Submitted
PI	WILDING, GEORGE	OK	OK	OK	OK	Colby	11/07/2012	

[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 Training Completion Status

COI Training Completion Status

COI Training Completion Status

To search, enter any combination of the following:

Single UDSS Code: **Hints:**

UDSS Range: From:
 Through:

Last Name:

First Name:

Date Completed: Between and

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

Hints:
 UDSS Codes: Use a full UDSS code (e.g. A340235) or a partial UDSS code to widen the search (e.g. A48 for all of L&S).
 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. 11/2/07). The search screen will convert them to a standard format automatically.

Comments or Questions? [Contact Us](#)
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COI Training Completion Status

Search Results

Search Criteria: UDSS 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.

Name	Email Address	Date	UDSS	Department
1 BLOMBERG, TRAVIS	tblomberg@wisc.edu	04/07/2011	A072000	AG&LSC/AG&APPLIED ECONS/AG&APP ECO
2 CALDEIRA, YURI	ycaldeira@wisc.edu	06/15/2012	A072000	AG&LSC/AG&APPLIED ECONS/AG&APP ECO
3 JACKSON, ABIGAIL	aajackson@wisc.edu	04/24/2011	A072000	AG&LSC/AG&APPLIED ECONS/AG&APP ECO
4 JOLITZ, JASMINE	jolitz@wisc.edu	05/29/2011	A072000	AG&LSC/AG&APPLIED ECONS/AG&APP ECO
5 MARZELLA, JILLIAN	jmarzella@wisc.edu	04/05/2012	A072000	AG&LSC/AG&APPLIED ECONS/AG&APP ECO
6 PADRON, IAN	padron@wisc.edu	03/24/2012	A072000	AG&LSC/AG&APPLIED ECONS/AG&APP ECO
7 ZIPP, KATHERINE	kzippp@wisc.edu	02/21/2012	A072000	AG&LSC/AG&APPLIED ECONS/AG&APP ECO
8 ALBRIGHT, PAULA	pjalbrig@gmail.com	08/04/2012	A072600	AG&LSC/AGRONOMY/AGRONOMY
9 BEISSINGER, TIMOTHY	beissinger@wisc.edu	01/05/2011	A072600	AG&LSC/AGRONOMY/AGRONOMY
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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

COI Clearances for PHS Awards

Details of WISPER Document MSN160917

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

Award PI: **YOON, TEHSHIK**
Award Period: **01-Dec-12 to 30-Nov-13**
Award Description: **Visible Light Photocatalysis**
Sponsor: **DHHS, PHS, NATIONAL INSTITUTES OF HEALTH**
Award Reference #: **5 R01 GM095666-03**
Award Department: **481500 -**
Current Budget: **\$254,565.00**
Award Contract Type: **Grant**

COI Clearances Required

Role	Name	Questions? Contact the COI Office				Questions? Contact RSP		
		Training	OAR Submitted	COI Office Action	Investigator Responded	Reportable FCOIs	Reports Submitted	Check when Submitted
PI	YOON, TEHSHIK	OK	OK	OK	N/A			

[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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- 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



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Summary of FCOI Noncompliance and FCOI Reporting

FCOI REPORT (within 60 days)

- 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.

RETROSPECTIVE REVIEW (to determine bias)

- 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.

UPDATE/REVISE FCOI REPORT (following retrospective review)

- 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.

MITIGATION REPORT (promptly after retrospective review)

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

ANNUAL FCOI REPORT

- Submit annual FCOI report thereafter through FCOI Module



REQUIRED FCOI REPORTS TO BE PROVIDED TO NIH THROUGH eRA COMMONS FCOI MODULE

Report	Content	Required when?
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	When bias is found as a result of a retrospective review.

Information from PHS & NIH

- PHS regulations:
<http://www.gpo.gov/fdsys/pkg/FR-2011-08-25/pdf/2011-21633.pdf>
- NIH Office of Extramural Research FCOI Web Site: <http://grants.nih.gov/grants/policy/coi/>
Some Resources include:
 - Tutorial, webinar, PowerPoint presentations
 - FAQs are periodically updated and will be updated soon.
 - <http://grants.nih.gov/grants/policy/coifaq.htm>



Information on UW Policy & UW Procedures

- 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/>



- 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

Lessons Learned

- Gaining strong institutional sponsor support is critical
- Communication with sponsors and constituents is key to success
- Creating a forum for sponsors to interact with counterparts at other universities doing similar operations affirms values and builds confidence.
- Understanding business needs and requirements reduces project risk
 - Identify areas to prioritize – business processes, conversion, testing, and change management
- Validate implementation methodology with other universities to reduce project risk



Lessons Learned

- Upfront planning is critical for
 - A well-defined scope of the project
 - Creating strong drivers for change
 - Realistic budgets
- Strong project managers are essential to success
- The burden on staff is impossible to overestimate – argue for backfill
- Dedicate your strongest staff to the implementation



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Questions?

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- David Ngo <dvngo@rsp.wisc.edu>
- Matt Richter <msrichter@rsp.wisc.edu>