Conflict of Interest (COI)

Proposal Management Changes

July 2012
Agenda

- Review: PHS Conflict of Interest Regulation
  - Why we’re updating eRPM
  - M-Inform disclosure status

- eRPM Changes
  - PAF
    - Personnel
    - Budget/Subcontracts
  - New (automated!) subcontract process
  - PHS “JIT” notification

- Unit actions
- Resources
- Questions

eRPM Go Live = 08/11/12
To ensure **objectivity in research**, new PHS **Financial Conflict of Interest** regulations will be implemented on **08/24/12**.

**PHS Requirements:**

- Investigators must disclose **ALL** financial interests.
- Disclosures completed annually and within 30 days of a change.
- Significant financial interests reviewed in relation to **ALL** U-M responsibilities (not just research).
- U-M determines relatedness to proposed research.
- U-M manages significant financial interests **before** PHS funding awarded.
- U-M makes financial conflicts of interest (FCOI) and management plans available to the public.

Objectivity in research = the design, conduct, and reporting of the research is not biased by conflicting financial interests.
Who needs to disclose? All **Investigators** including:

Principal Investigators, Project Directors, Senior/Key personnel, and **other investigators** identified as responsible for the design, conduct, or reporting of the research (i.e., not simply working on, or engaged in, the project).

E.g., Those who design the study protocol or methodology; analyze and interpret data or results.

“Other investigators” is a new requirement per the PHS regulation.
New PHS requirements for Sub-recipients:

- Sub-recipient organization must confirm adherence with FCOI regulation or agree to follow for work on specific project.
- Subcontract personnel must disclose outside interests.
- Any financial conflicts of interest (FCOI) must be reviewed and managed prior to subcontract award.
Agencies Following PHS Regulations

**PHS Agencies:**
- NIH – National Institute of Health
- CDC – Centers for Disease Control
- HRSA – Health Resources & Services Administration
- FDA – Food & Drug Administration
- SAMHSA – Substance Abuse & Mental Health Services
- IHS – Indian Health Services
- ATSDR – Agency for Toxic Substances & Disease Registry
- AHRQ - Agency for Health Care Research and Quality
- Office of the Secretary

**Organizations following PHS regulation:**
- American Heart Association
- American Cancer Society
- Arthritis Foundation
- Susan G. Komen Foundation
- Alliance for Lupus Research
Three (3) systems will work together to record, report, and manage COI.

- **Disclose in M-Inform**: M-Inform sends disclosure status to eResearch Proposal Management (eRPM).
- **Capture data on PAF in eRPM**: PAF captures project personnel who need to disclose/have disclosed.
  - Includes subcontract personnel
  - Requires PAF changes that impact all users
  - Provides opportunity to automate subcontract process
- **Manage in Conflict Admin**: M-Inform & eRPM send disclosure & project data to the new Conflict Administration system.

COI committees & staff facilitate the management and reporting of Financial Conflicts of Interest (FCOI):
- By individual
- By project
- By outside entity
U-M disclosure period began 07/01/12.

In the first two (2) weeks using M-Inform:

- 3232 out of 9343 disclosers (35%) signed into M-Inform
- 4215 disclosures entered
- 2726 out of 4215 had “Nothing to disclose” (i.e., answered “No” to 1st three questions)
- 704 unit approvals completed
eRPM Changes

- UM Key Personnel
- Non-UM Personnel
- Subcontracts
- JIT Notification
Updated: UM Key Personnel renamed UM Investigators

- For PHS PAFs - all “investigators” must be listed and must disclose
- New Role: “Other Non-faculty Investigator”
  - Identifies UM study team member who has disclosure responsibility per PHS regulation, but is not necessarily Senior/Key
  - Doesn’t route PAF for unit approval, does route PAF for COI review
- Must indicate “yes” or “no” if person is Senior/Key
New **Project Personnel** questions:

- **2.2**: Subcontract question
  - “Yes” requires Budget Subcontracts section
  - External only! Doesn’t include internal sub-accounts
- **2.22**: “Non-UM affiliated personnel” excludes subcontract personnel
  - “Yes” opens Non-UM Investigators section (question 2.5)

These PAF changes were made to support the new subcontract process.
Updated: Non-UM Investigators

- Four (4) roles associated with subcontractor organization removed
- You will now enter those roles and subcontract personnel details in the Budget section of the PAF
New business process: Subcontracts in eRPM!

- Replaces the “11-question” paper-based procedure to request a subcontract or hybrid PO
  - Doesn’t replace the current criteria for a subcontract!

- **New per PHS**, subcontract personnel must disclose outside interests. Any financial conflicts of interest (FCOI) must be reviewed and managed prior to subcontract award.

- **OCA**: use eRPM to view subcontract & PAF data

- **Project Team**: PAF activity to update subcontract data

Guidelines and models for disclosing & managing FCOI on sub-awards are changing. Expect updates!
### Previous Budget Components

3. Budget

Budget Components

<table>
<thead>
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<th>Description</th>
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<tr>
<td>UM Cost Sharing</td>
<td>The project includes UM cost sharing that is listed in detail in the proposal. (Conventionally referred to as Mandatory Cost Sharing) It is when the University promises a specific, quantified resource to the sponsor without asking for recovery. Effort, supplies with the price listed, etc.)</td>
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<tr>
<td>Subcontracts</td>
<td>The project budget includes Subcontracts, Subawards, Subgrants, Consortium Agreements and Other Subagreements to other institutions or agencies. (Click here for subcontract criteria)</td>
</tr>
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<td>Indirect Cost Waiver</td>
<td>The budget includes a request for an indirect cost waiver, if your unit allows. (A request to use a rate less than the University-recognized recovery for the sponsor and activity types)</td>
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### New Budget Components

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<td>Subproject/Grant Distribution</td>
<td>The unit would like to list projected details of intended subproject/grants with other campus units. (These estimated distribution details are subject to change based on the actual award and subsequent negotiations and are not considered final.)</td>
</tr>
</tbody>
</table>

Subcontracts checkbox removed. Replaced with view-only reminder of answer to question 2.2

- Need to change the subcontract answer? Return to the Personnel section to update question 2.2
Instructions:

1. Click **Add New Subcontract**.
2. Begin typing the organization’s name.
3. Select the organization from the pop-up list.
4. Click OK.
Instructions:

5. The **Subcontract Title** defaults from the PAF. TBD: update?

6. Enter **Total Subcontract Costs**.

7. Add the SubK Investigators & Contact.

Either attach a document or include notes below. For sponsors that follow PHS Conflict of interest guidelines, a COI Compliance Policy attachment is required. INCLUDE LINK TO ORSP FORM? *
Investigator roles for subcontractors that used to be on the Non-UM Investigator page are now found here.
Instructions:

8. Attach appropriate documentation or enter notes (same as today).

Letter of Commitment updated for PHS regulation. Subcontractor certifies disclosure & management of significant financial interests using one of the following:

- Subcontractor’s COI policy
- Federal Demonstration Partnership COI model & Financial Interests Report (thefdp.org/)
- U-M COI policy & Financial Interests Report (requires COI committee action)
After you enter the subcontract information, a SUBK ID number displays on the Subcontracts page in the PAF.

- Click the **ID link** to edit the subcontract details
- Click **Remove** to delete the subcontract from the PAF
New! The **Subcontracts** tab in the PAF lists the related subcontracts.

<table>
<thead>
<tr>
<th>ID</th>
<th>Subcontract State</th>
<th>Organization</th>
<th>PI</th>
<th>My Activities</th>
<th>CAR ID</th>
<th>COI State</th>
</tr>
</thead>
<tbody>
<tr>
<td>SUBK0000123</td>
<td>Pre-submission</td>
<td>Michigan State University</td>
<td>Smith</td>
<td>🍃</td>
<td></td>
<td></td>
</tr>
<tr>
<td>SUBK0000678</td>
<td>Pre-submission</td>
<td>Wayne State University</td>
<td>Taylor</td>
<td>🍃</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
After the PAF is Submitted to Sponsor

- Review Subcontractor disclosure status
- Check for just-in-time notification
A COI Administrative record (CAR) is created when a subcontractor discloses an outside interest.

- **COI State** column displays status/level of disclosure review:
  - Open
  - Under Review
  - No Review Required
  - No Conflict Found
  - Review Complete (Mgt Plan & FCOI Report)
  - Closed

- CAR ID links to Conflict Management system (ORSP only)

Use the new **Subcontracts** tab to check the subcontractor’s disclosure status.
New ORSP Activity: Request JIT
- JIT = Just-in-Time
- Used by PHS sponsors to indicate award is likely
- Puts an alert in the PAF workspace
- Activity displayed in Recent Activity list

This alert indicates that disclosure and compliance review activities should take priority
After the PAF is Awarded

- Set up the Subcontract
- Update UM Investigators
Use the new **Subcontracts** tab to enter the subcontract details.

Click the SUBK ID link to enter subcontract details:
- Period of Performance
- Budget
- Statement of Work
- Sole source justification
- P/G number
- Cost/Price Analysis

**PHS regulation:** U-M cannot award to sub-recipient until any FCOIs are managed and reported to the sponsor!
Subcontract Process: Enter Details

Previous process

Procedure to Obtain a Subcontract or Hybrid PO

When the circumstances meet all of the criteria listed above, the Office of Contract Administration will assist you in the preparation and negotiation of your Subcontracts and Hybrid PO’s issued under Sponsored Projects. It is not necessary for you to determine if it should be a Subcontract or Hybrid PO, only that it meets all 5 of the criteria above. To initiate the process, please forward your request to:

Office of Contract Administration
3044 Wolverine Tower #1273
763-1953

Be sure to include the following information in your request:

1. Name, campus address and phone number for the University of Michigan Principal Investigator and administrative contact person in the department.
2. Official contact for the Subcontractor/Vendor: type of organization (for-profit, non-profit, foreign, etc.), size (small or large business, etc.), and the address of their Contracts and Grants office.
3. Specific statement of work describing the services and deliverables to be provided by the Subcontractor/Vendor.
4. Detailed budget that has been approved by the Subcontractor’s/Vendor’s business office. The budget must have been prepared and reviewed with the Subcontractor/Vendor’s executive management.
5. Period of performance for the Subcontract/Hybrid PO. This will be the period for which funding will be legally committed, rather than the potential total period of the Subcontract/Hybrid PO.
6. Subcontractor’s/Vendor’s key personnel (at a minimum this would include the Principal Investigator for the Subcontractor/Vendor).
7. Copy of the Prime contract/grant received from the Sponsor which approves the Subcontract/Hybrid PO arrangement and a copy of the FWA from HRSA.
8. Explanation of how and why the proposed Subcontractor/Vendor was selected as a sole-source.
9. A statement regarding potential conflict of interest (e.g. P.I., employed or has a financial interest in the Subcontractor/Vendor; Subcontractor/Vendor key personnel employed/apointed at UM, with or without compensation).
10. The following certification is to be signed by the Principal Investigator indicating that he/she has reviewed the budget from the Subcontractor/Vendor and considers the costs to be reasonable.

COST/PRICE REASONABILITY CERTIFICATION

I have reviewed the cost and price data provided by the Subcontractor/Vendor and have determined that the costs proposed are necessary and reasonable for the work to be performed by the Subcontractor/Vendor.

UM PI Name & Signature
Date

The next question may or may not apply. Please read carefully.

11. If the project is funded under a Federal Contract, then the additional Cost/Price Analysis information outlined below also needs to be provided. This does not need to be completed for projects funded under Federal Grants, Cooperative Agreements, or non-Federal projects.

New Process

• Paper-based
• Manually supply PAF data for the subcontract

• Automated!
• Upload budget, statement of work, cost/price analysis in eRPM
• Enter/select P/G number
- PI accesses the subcontract to sign it via **My Activities** drop-down on the **Subcontracts** tab
  - Verifies COI Compliance Policy completed
  - Verifies Cost/Price Certification completed
- PI must sign for subcontract to be routed to OCA/ORSP
The PHS regulation provided U-M an opportunity to automate the subcontract process.

Special thanks to the **SubK Working Group**:

- Carrie Disney – Social Work
- Scott Stanfill – Social Work
- Christine McAllen – SNRE
- Carole Bach - ISR
- Darleen Poisson – ISR
- Emily Hamilton – Medical School
- Heather Offhaus – Medical School
- Patrice Somerville – Public Health
- Linda Chadwick – Engineering
- Linda Forsyth – Engineering
- Cherolyn Brooks – LS&A
- Peggy Westrick – LS&A

- Pete Gerard: Grants/Contracts
- Thom Madden: Sponsored Programs
- Bryan Van Sickle: Sponsored Programs
- Carolyn Pappas: eResearch
- Peter Tracey: eResearch
Impact: U-M must track project personnel post-award.

Process: ORSP to expand “PI change” process to include UM Investigators
- Activate/inactivate UM Investigators on PAF when notified of change

Procedure: Project team to notify ORSP of change by using “Project Team Request DRDA Action” activity
PHS regulation applies to projects awarded on 08/25/12 and beyond.

How can units ensure compliance for PHS proposals that may be awarded soon?

- Review your pending proposals
  - Submitted to Sponsor
  - Just-in-Time Notification
- Identify the UM Investigators on those proposals
- Encourage UM Investigators to complete their disclosure in M-Inform
Communications

- Disclosure reminder emails
  - Next 2 NIH deadlines
- UM Record article
- Tip & Trick emails

Web sites

- UM COI policy
  - [http://orsp.umich.edu/policies/um/COI/policies.html](http://orsp.umich.edu/policies/um/COI/policies.html)
- Subcontract business process
  - [http://orsp.umich.edu/projects/grants_contracts/subagreements.html](http://orsp.umich.edu/projects/grants_contracts/subagreements.html)

Job aids

- New eRPM subcontract step-by-step
- Updated eRPM training & quick references
  - [http://www.umich.edu/~eresinfo/erpm/training.html](http://www.umich.edu/~eresinfo/erpm/training.html)

Training

- Updated PEERRS training
  - [http://my.research.umich.edu/peerrs/](http://my.research.umich.edu/peerrs/)

Business processes & system still being developed. Look for more info on the changes!
Current COI Resources

For more information, visit the web site:

- **Unit Resources**
  - Basic information about the PHS regulation
- **M-Inform quick references**
  - Disclosers
  - Administrators & Reviewers
- **Agencies/organizations following PHS regulation**
  - List updated as known

http://research.umich.edu/conflict-of-interest/outside-interest-disclosure/
Questions?