Improving COI Information Management

Special Projects COI Committee
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New Health and Human Services (HHS) regulations for COI reporting are expected within the year.

These regulations exceed the requirements of the University’s current policy.

- **Responsibility shift from PI to Institution**
  - Broader definition of who needs to report conflicts
    - Includes anyone involved in the design, conduct and reporting of HHS-funded research.

- Additional reporting requirements:
  - Relate COI to all university activities
  - New, more comprehensive definition of “significant financial interest”
  - More detailed reporting requirements to PHS
  - Public disclosure required

Current COI processes do not provide all the information needed to meet the regulations.

Without changes, UM will be at risk of non-compliance.
Current Situation/Analysis

- Currently there are multiple committees reviewing and managing conflicts related to research, with no central repository for identifying, capturing and sharing information.

- As a result:
  - There are different reporting practices and policies across schools, colleges and units within the University and the University Health System.
    - Disclosure requirements are inconsistent
    - No clear definitions for various terms (e.g. study team vs key personnel)
  - Existing information management systems are not comprehensive and do not “talk to” one another.
  - There is potential for situations that need to be managed to remain unidentified.
  - There is no uniform mechanism to generate reports or audit compliance across the University.
Recommendations/Strategies

- In accordance with the existing SPG, clarify and develop improved processes to ensure compliance with the PHS policy.

  **Phase 1:**
  
  - Draft enhanced guidelines for schools/colleges/units to comply with the new PHS policy.
    
    - Sponsored Projects COI group will identify what needs to be added to the college/school/unit COI policies to be in compliance with PHS policy.
  
  - Create a central authority for implementation and oversight of the new process.
  
  - Identify the business owner(s).
    
    - Recommend a co-team incorporating a lead person from OVPR and a lead person from the Provost's Office.
Recommendations/Strategies (Continued)

- **Phase 2:**
  - Design a central information management system to collect, store, manage, and report on data.
    - Integrate with existing systems as much as possible.
    - The system must allow colleges/schools/units flexibility to collect additional data.
    - Include plan for data migration of current electronic processes and integration of paper processes.
  - Conduct a cost analysis of the implementation needs (software, staff time, etc).
  - Dedicate resources for designing, building, implementing and managing this system.
Recommendations/Strategies (Continued)

Phase 3:

- Build the information management system to support the new processes.
- Align current COI committee operations with this new process.
  - OVPR COI Committee
  - Clinical and Educational COI Committee
  - UMHS COI Committee
  - Institutional COI Committee
- Integrate with other compliance areas, including UMHS, OTT, Procurement, UCUCA, IRBs, IBC, PM, and post-award contract administration.
- Develop education and training materials for faculty and staff.
Proposed Next Steps

Define scope for an information management system

- Determine who needs to disclose
  - Includes anyone involved in the design, conduct or reporting of research proposed to or awarded by PHS
    - Utilize existing data to identify all personnel paid off of a PHS grant (salary or tuition)
- Determine how individuals will disclose
  - Conduct fit/gap analysis of existing systems (e.g., M-Inform, paper, etc.)
    - Compile disclosure information into a central system, when available
  - Reevaluate screening and disclosure questions
  - Determine timing and frequency of disclosure
- Formalize processes for relating disclosed interests to ongoing and new institutional activities (i.e., OTT, SRA, Teaching, Purchasing, Contracts, Clinical, Service)
  - Each activity will require additional questions to determine level of management needed
Follow-up

- Develop reporting tools for internal and external requirements, including PHS notification and posting to a public website.

- Audit the process by running a report for everyone who is funded through a PHS grant (salary or tuition).
  - Check that they’ve disclosed.
  - Check that they’ve disclosed in a timely way.
  - Cross-check with other compliance units.
  - Check against outside reporting (i.e. pharmaceutical sites)
  - Check that appropriate reports are made by the institution.
How Can You Help?

- Help identify appropriate individuals for our committee to contact to gather unit-based information.
- Share any unit concerns.

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