Re: Revisions to the Research Conflicts of Interest Policy

Dear colleagues,

In 2008, a WUSTL Conflict of Interest (COI) Task Force recommended changes to WUSTL COI Policy, the implementation of which was delayed pending “imminent” changes to NIH COI Policy. In August 2011, the US Department of Health and Human Services published its revised regulations governing COI in research funded by the Public Health Service (PHS). The changes are summarized on the National Institutes of Health COI webpage.

To implement the Task Force’s recommendations, and the newly established PHS requirements, I convened a University-wide faculty COI Policy Development Committee. Their charge was to review key changes to the PHS COI regulations against our current policies and processes to identify modifications needed to comply with the regulations, and improve overall our COI program and processes. The Committee was thoughtful, insightful, and effective in designing a policy and guidelines/processes that provide greater clarity, consistency, and transparency to the WUSTL research COI program. Specifically, the new Policy will:

- Promote quality and consistency in the identification and management of research related financial conflicts of interest
- Provide greater transparency to investigators regarding the research COI program
- Ensure compliance with the federal regulations

Highlighted major improvements to the new Policy include:

- A clear statement of purpose and the importance of appropriate management of conflicts of interest to maintaining research integrity, while enabling interactions which promote research and knowledge dissemination
- Consolidation of the three current WUSTL research COI policies into one cohesive Policy, paired with a new document which describes processes and implementation
- A COI process that clearly articulates key principles of disclosure, review, assessment, management, and monitoring
- Revision and clarification of language regarding human studies research that has been viewed as problematic
- Streamlined presentation and consolidated documents with improved format, all web-available, to enhance readability and communication
- Strong affirmative endorsement of requiring appropriate education in the responsible conduct of research and COI policy, a clear commitment to prompt, full, and accurate provision of relevant information, and full compliance with COI management programs

By federal law, the new COI Policy will be implemented on August 24, 2012. The revised policy and process changes are currently available for preview using your WUSTL Key at http://coi.wustl.edu. A quick reference guide has also been developed to highlight the details of the changes.
Key changes to the Research COI policy and processes include:

- An expanded population of individuals that will be required to disclose financial interests
- Requirement that individuals disclose all personal financial relationships related to their institutional responsibilities (formerly required to disclose only research-related activities)
- Renaming the Disclosure Review Committee to the Conflicts of Interest Review Committee (CIRC)
- Revised standards/guidelines for managing financial COIs, and inclusion of additional information about what is considered when identifying and managing financial COIs
- Required web-based COI education within the next 12 months, and then every four years, for all individuals who complete a disclosure statement
- Implementing some aspects of the COI program specific to the source of research funding (PHS/NIH or other) to minimize the impact of the NIH/PHS-specific regulations on our investigators, such as
  - Disclosure of travel paid for or reimbursement by an outside entity will be required only for PHS/NIH funded individuals
  - The threshold for review of financial interests and management of any financial COIs will be specific to the source of research funding
  - Required public disclosure of COI information will be applied only to PHS/NIH funded individuals

Please note: You will not need to resubmit a Financial Disclosure Statement due to the changes in the policy and processes until your current disclosure is due for renewal or your personal financial interests have changed.

I thank the faculty COI Policy Committee and staff for their excellent work, and believe the new Policy is a significant enhancement to our program for maintaining research ethics, and the public trust in research and their investment therein.

If you have any questions, concerns, or would like to provide feedback regarding these changes please contact the Conflict of Interest Review Committee/Research Ethics and Compliance office at 362-2709 or drc@msnotes.wustl.edu.

Sincerely,

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Vice Chancellor for Research