

August 28, 2012

## **MEMORANDUM**

TO:	Principal Investigators
FROM:	Patrick G. O'Shea Add Other Vice President and Chief Research Officer

**SUBJECT:** Public Health Service Financial Conflict of Interest

New regulations pertaining to financial conflicts of interest in research sponsored by the U.S. Public Health Service (PHS) went into effect on August 24, 2012. These regulations, Responsibility of Applicants for Promoting Objectivity in Research for Which Public Health Service Funding is Sought, found at <u>http://grants.nih.gov/grants/policy/coi/</u>, differ significantly from the regulations they are replacing in the following ways:

- 1. Previous regulations required investigators to disclose to the University only those financial conflicts of interest relating to their research. The new regulations require investigators to disclose any potential financial conflicts of interest that could relate to their University responsibilities and the University is then responsible for determining whether or not the financial interest is related to PHS-funded research and poses a significant financial conflict of interest.
- 2. Previous regulations specified a threshold (\$10,000) at or under which disclosure of a financial interest was not required. The new regulations lower the threshold to \$5,000, and additionally, they require institutions to apply stricter specifications, if stricter specifications are in effect at the institution. Because of the State of Maryland requirements, there will be no minimum dollar threshold. Therefore, any potential conflict of interest, regardless of its actual or potential financial value, must be disclosed.
- 3. Previous regulations had no requirements for the reporting of travel reimbursements. The new policy requires investigators to report all travel reimbursements other than those reimbursed by the University, a sponsored program, a federal, state or local government agency, or other institutions or research institutes affiliated with US institutions of higher education. Travel reimbursements received for any non-US entity must be reported.
- 4. Failure by the University to report financial conflicts of interest to the PHS in a timely manner will necessitate a retrospective review of research to determine whether or not the design, conduct or reporting of the research was biased by a conflict.

5. The new regulations require all investigators to receive training in the PHS regulations and the University conflict of interest policy and procedures.

Training online modules are available at <u>www.citiprogram.org</u>.

A University Policy and Procedures on Financial Conflicts of Interest in Public Health Service Funded Research has been approved and is at: <u>http://president.umd.edu/policies/ii310c.html</u>.

The new policy does not replace the existing University Conflict of Interest policy <u>http://www.president.umd.edu/policies/docs/II-310A.pdf</u> and University procedures implementing that policy <u>http://www.president.umd.edu/policies/docs/II-310B.pdf</u>. Rather, the new policy supplements existing policy by providing additional requirements for conflicts of interest in PHS-funded research at the University.

This coming year will be a time for adjustment as we learn lessons from the implementation and the practical consequences of these new regulations, and we appreciate your patience during this time. We will continue to seek your input on how to improve our internal processes, and welcome constructive suggestions on improving the disclosure process. You can submit your comments to jsmith54@umd.edu.

Please do not hesitate to contact Joe Smith (jsmith54@umd.edu) in the Research Compliance Office or Toni Lawson (tlawson@umd.edu) in the Office of Research Administration with questions, concerns and suggestions.