

Board Meeting
July 19, 2012

APPROVE REVISIONS TO *THE UNIVERSITY OF ILLINOIS POLICY ON
CONFLICTS OF COMMITMENT AND INTEREST*

Action: Approve Revisions to Policy on Conflicts of Commitment and Interest

Funding: No New Funding Required

The *University of Illinois Policy on Conflicts of Commitment and Interest* was implemented in 1996 to provide a framework for measuring and monitoring the propriety and advisability of non-University activities of academic staff members. The policy was amended in January 2011 in response to the increasing complexity of conflict management as the University's research and technology transfer portfolios expand, and to ensure the policy was compliant with Federal regulations.

The proposed revisions to the current policy are in response to the amended Department of Health and Human Services (HHS) regulations related to conflict of interest in federally funded research. All institutions receiving Public Health Service (PHS) funding from a grant cooperative agreement, or contract must be in full compliance with all of the HHS regulatory requirements by August 24, 2012. The following are the principal proposed changes to be made:

1. Persons Covered

Current Provision: Current policy does not cover Civil Service Staff.

Recommendation: Revise policy language to provide flexibility in employee disclosure requirements:

“Although civil service staff, students, and medical residents are not covered by this Policy, they are not exempted from making *disclosures as required by federal or state laws and regulations or from making situation-specific disclosures* as described in Section III.D.3.”

Rationale: Due to recent changes in federal regulations, all employees and staff involved in the design, conduct, or reporting of research must report potential conflicts of interest, regardless of their employment classification.

2. Definition of “Significant Financial Interests”

Current Provision: The definition of “significant financial interest” may vary. The definition to be used is based on either the federal or State definition and depends on whether the PHS regulation or the State Procurement Code is most clearly invoked in the situation prompting the disclosure. In the absence of other applicable regulations, the PHS definition will be used.

Recommendation: Include statement defining the level of financial interest that will be considered significant if the PHS regulation or the State Procurement Code are not applicable.

“In the absence of other applicable regulations, financial interests greater than \$5,000 will be considered significant.”

Rationale: One of the most significant changes in the federal regulations involves the scope of interests that now qualify as “significant financial interests” that must be disclosed by the investigator to the institution through a disclosure process. The dollar threshold for significant financial interests was lowered from \$10,000 to \$5,000 for remuneration or equity interest in publicly traded entities. Setting a de minimis reporting threshold of \$5,000 simplifies the process and eliminates the need for individuals to look up PHS regulations to determine if disclosure is required.

3. Subrecipient Compliance

Current Provision: Current policy does not provide guidance on subrecipients of grants.

Recommendation: Require agreements with subrecipients or subcontractors to establish applicable conflicts policy.

“If the university carries out federally funded research under an agreement with a third party, the agreement must establish that either the third party’s or the university’s conflicts policy will apply to the conduct of the third party’s investigators and, if the former, that the third party’s policy complies with the relevant federal regulations. The agreement must also prescribe when the third party must report all identified financial conflicts of interest to the university.”

Rationale: The new regulations explicitly require prime awardees that carry out PHS-funded research through subrecipients to “take reasonable steps” to ensure that the subrecipient complies with the new rule.

4. Responsibility for Information and Training

Current Provision: Current policy does not provide guidance on information dissemination and training.

Recommendation: Add section that outlines responsibility for information and training.

“The President will designate to the Vice President for Research the responsibility to identify a campus official that will be responsible for annually informing academic staff of this policy and implementing any associated training required by law. Academic staff members are responsible for complying with this policy and all training requirements. Training requirements may be imposed on other staff as required by federal and state law.”

Rationale: The new rule requires institutions to ensure that, prior to engaging in PHS-funded research and at least every four years, investigators are trained on the regulations, the institution’s financial conflict of interest policies, and the investigator’s responsibilities to disclose significant financial interests.

5. Retrospective Review and Reporting

Current Provision: Current policy does not provide guidance on action required if potential conflict is not disclosed or conflict management plan is not followed.

Recommendation: Add section that addresses non-compliance.

“If a conflict of interest was not disclosed, reviewed or managed in a timely manner, or if an employee failed to comply with a conflict management plan, the university will complete a retrospective review, mitigation report or other procedures required by law.”

Rationale: The new federal regulations introduce specific institutional responsibilities regarding information that may arise in the course of an ongoing PHS-research project. If a significant financial interest is identified that was not disclosed by the investigator or reviewed in a timely manner by the institution, the institution has sixty days to determine if a conflict of interest exists and implement a management plan if needed. In addition, if a conflict of interest is identified and it was not managed due to noncompliance by the investigator or the institution, the institution has 120 days from the date the non-compliance was identified to conduct a retrospective review of the investigator’s activities and the research project itself to determine whether there was any bias in the design, conduct or reporting of the research as a result. Institutions are required to document the retrospective review. Furthermore, if the review finds bias in the research, the institution is required to develop and submit a mitigation report to the PHS funding agency that outlines a plan to mitigate the effect of the bias.

Attached to this Board item is a comparison copy of the proposed revisions to the *University of Illinois Policy on Conflicts of Commitment and Interest* in a format to reflect all of the proposed changes. The University Senates Conference has approved the proposed revisions. The Vice President for Research, the President’s Designee on matters concerning conflicts of commitment or interest, recommends approval of the revised policy.

The Board action recommended in this item complies in all material respects with applicable State and federal laws, University of Illinois *Statutes*, *The General Rules Concerning University Organization and Procedure*, and Board of Trustees policies and directives.

The President of the University concurs.