

## MEMORANDUM

**TO:** Andrew S. Weyrich, Vice President for Research

**FROM:** Jeffrey R. Botkin, Associate Vice President for Research Integrity  
Marc Rinehart, PhD, Director, Conflict of Interest Office

**SUBJECT:** Proposed Replacement of Interim Rule 7-006 with Policy 7:006:  
Institutional Financial Conflicts of Interest for Research Involving Human  
Subjects

**DATE:** July 5, 2017

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### I. Overview

This is a proposal to make various important changes to what was originally adopted as Interim Rule 7-006 and convert it to a permanent University policy titled “Policy 7-006: Institutional Financial Conflicts of Interest for Research Involving Human Subjects.”

### II. Background

During the spring of 2015, the University’s Human Research Protection Program (“HRRP”) was undergoing reaccreditation by the Association for Accreditation of Human Research Protection Programs (“AAHRPP”). Upon completion of its review, AAHRPP’s only major institutional finding for the University was the lack of an institutional conflict of interest (“ICOI”) policy – a policy that AAHRPP did not previously require and that the federal government does not currently require of grantees, although the NIH is actively discussing it. AAHRPP gave the University until May 6, 2015, to put in place an ICOI policy or rule.

To ensure the University’s HRRP did not lose its accreditation, President Pershing directed the Institutional Policy Committee to put into effect Interim Rule 7-006 by May 1, 2015, prior to presentation to the Senate Executive Committee and/or without the prior approval by, or consultation with, the Academic Senate. President Pershing did so based on the extraordinary circumstances at hand and pursuant to the authority granted to him by University Policy 1-001(III)(A)(4)(d). At the time, the office of the Associate Vice President for Research Integrity planned to work with various stakeholders over the following year to refine the University’s ICOI process and promulgate a policy that would encompass, and eventually replace, Interim Rule 7-006.

Since that time, we have worked to develop and test the procedures and to learn through early experience about the strengths and weaknesses of the interim policy. This

has taken an unexpected length of time due to the need to develop an IT infrastructure capable of processing and documenting information gathered from the reporting systems for the several databases relevant to the ICOI system. These databases include the names of campus leadership, studies managed through OSP, studies involving human subjects through the IRB, gifts managed through the Development office, and intellectual property managed through TVC. In addition, prior to the new policy, we could not anticipate the number and nature of the potential conflicts identified. We have learned that the number and types of conflicts requiring some management is modest (less than 10 per month) but they are often complex. Our work to establish reporting mechanisms and gain familiarity with the issues has contributed to our knowledge of the issues on our campus and to the proposed changes outlined below.

With the benefit of that experience and further study, it is now appropriate for Interim Rule 7-006 to be revised and enacted in the form of a University policy.

### **III. Summary of Major Changes (From Interim Rule 7-006 to New Policy 7-006)**

#### Section II – Changes to Definitions

- Definition of “Institutional Conflict of Interest” revised to clarify:
  - that the existence of an “Institutional Conflict of Interest” is a determination by the ICOI Officer; and
  - that an “Institutional Conflict of Interest” can arise from either an institutional interest relevant to human subjects research or a University Official who has an external financial interest relevant to human subjects research.
- Definition of “Significant Institutional Financial Interest” revised to change the definition to technology that is currently licensed or previously licensed from an option to license or is licensed. The intent is to limit the definition – the inclusion of options to license is considered to be too broad.
- Definition of “Significant Gift” revised to increase the threshold to \$100,000 from \$50,000. The intent is to limit the gift amount to what we think might reasonably create a meaningful institutional conflict of interest. There are no data to support any particular threshold, so this is a subjective determination.

#### Section III – Policy, Part (B) – Heading Change and Redundancy Eliminated

- The section heading is changed because this section only includes activities that cannot be approved.
- To eliminate a redundancy with the heading, this sentence is removed: “For this reason, the following activities are not allowed and/or require prior approval.”

#### Section III – Policy, Part (C)(3)(b)(i) – Changes re: Steps for Evaluating/Managing Potential ICOIs for Proposed Research with Human Subjects

- The previous version included, as a threshold step, the ICOI Officer conducting an analysis of whether the research is minimal risk or greater than minimal risk. However, the approach outlined for the ICOI Officer in both circumstances was the same. The new language does not refer to whether the research is minimal risk or not. The risk associated with the research will remain an important factor in determining a management strategy, but there is no reason to include reference to risk levels in the policy itself.

#### Section III – Policy, Part (C)(4)(b)(i) – Changes re: Steps for Evaluating/Managing Potential ICOIs for Proposed Significant Financial Transactions

- Same as above for Section III(C)(3)(b)(i) – this change eliminates the redundant language in the policy regarding the analysis the ICOI Officer must conduct when assessing risk.

#### Section III – Policy, Part (D)(1)(b) – Changes re: Updating Disclosures

- The original language requires updating a disclosure within 30 days of acquiring a new Significant Individual Financial Interest. However, individuals may not be immediately aware of conflicts when they arise from family members. The revised version permits the 30 days to begin upon the individual “*discovering* or acquiring” a Significant Individual Financial Interest.

#### Section III – Policy, Part (D)(2) – Changes to Heading / Subheadings and Language re: Management of Potential Conflicts

- The heading for this subsection is changed from “Management of University Official Conflicts” to “Identification of Potential Conflicts Related to Significant Individual Financial Interests of University Officials” to better reflect the content in this subsection.
- The following subheadings are removed because they are not needed: “Identification of Conflicts,” “Reporting to Individual Conflict of Interest Committee,” and “Management of Potential Conflicts.”
- Several provisions related to the management of potential conflicts are removed to ensure this section is consistent with the new provisions contained in Part (D)(3). The reasons for these changes are detailed below.

#### Section III – Policy, Part(D)(3) – Significant Changes re: Responsibilities of the ICOI Officer Relative to the Individual COI Committee

- The Individual COI Committee established under Policy 1-006 has had responsibilities related to both *individual* and *institutional conflicts that arise from the interests of individual University Officials*. More specifically, the interim rule called for the ICOI Officer to make determinations about institutional COI’s for conflicts arising from institutional investments, gifts, etc., but for the Individual COI Committee to make determinations when institutional COI’s arise from the external financial interests of individual University Officials. The proposed

change retains the ICOI Officer's role with respect to institutional investments, gifts, etc., but also places responsibility with the ICOI Officer for institutional COI management for conflicts arising from interests on individual University Officials. The revised policy makes the COI Committee advisory to the ICOI Officer in the management of institutional COI's arising from interests of individual University Officials.

- This change establishes a consistent role for the ICOI Officer with respect to conflicts arising from both sources and permits routine input from the Individual COI Committee on issues related to University Officials, so that there is appropriate consistency between decisions made about individual COI's and institutional COI's. Further, this change allows the ICOI Officer to benefit from the experience and values of the Individual COI Committee members.
- Many institutional COI's arising from University Officials involve senior officials in our University community. Placing the responsibility of decisions for ICOI management with the ICOI Officer protects Individual COI Committee members who might be reluctant to address or manage issues arising with a senior official. The ICOI policy provides explicit protections for the ICOI Officer against retaliation. (See Section III(A))

#### Section III – Policy, Part (E) – Changes re: IRB Oversight

- This sentence is added: “The Institutional Review Board retains authority over human subjects protection oversight, when relevant.” This is to clarify that the IRB is not subject to determinations of the University central administration regarding COI appeals relevant to particular research protocols (or other protocol-specific determinations). For example, if the IRB determines that an institutional COI should be disclosed to prospective research participants in the informed consent process, the University central administration cannot overrule this determination.

#### Section III – Policy, Part (G)(1) – Changes re: Reporting Policy Violations

- This provision is changed to provide that after investigating a possible violation of the policy, the ICOI Officer will report findings to the cognizant vice president, rather than the president. This change ensures the policy is consistent with other University policies, including Policy 1-006: Individual Financial Conflicts of Interest Policy.

### **IV. Proposal Development Process – Consultation**

The proposal was developed by a revision team consisting of:

Jeffrey R. Botkin, Associate Vice President for Research Integrity  
Marc Rinehart, Conflict of Interest Officer

Jahn Barlow, Ex Officio Member of the Conflict of Interest Committee and former  
Conflict of Interest Officer  
Past and present members of the Individual COI Committee  
Robert Payne, Office of General Counsel  
Hailey Bandy, Office of General Counsel

The proposal was presented to the Individual Conflict of Interest Committee on January 21, 2016. The policy draft was also discussed with Dr. Vivian Lee, Dr. Ruth Watkins, Dr. Thomas Parks, and Mr. John Morris. The policy revisions were reviewed by the Institutional Policy Committee on April 14, 2017.

## **V. Proposal Contents**

The proposal materials consist of (A) this Memorandum, (B) a “clean” version of the new Policy 7-006, and (C) a redlined version of the new Policy 7-006, showing the specific changes being proposed to convert Interim Rule 7-006 to a permanent University policy.

If you approve of this proposal, it should next be presented to the Senate Executive Committee, Academic Senate, and subsequently the Board of Trustees.