

THE UNIVERSITY OF IOWA



October 23, 2002

To: Faculty Council and Senate

From: Lee Anna Clark, Associate Provost
David Wynes, Assistant VP for Research

Re: Conflict of Interest Policy revision

In the fall of 2001, Provost Whitmore and Vice President Skorton formed and charged a committee to review and revise the University of Iowa Policy on Conflicts of Commitment and Interest. In addition to the two of us, the committee included:

Carolyn Colvin, Professor of Curriculum and Instruction, and then-President/Past-President of the Faculty Senate
Patricia Donohoue, Professor of Pediatrics, then-Chair of the Conflict of Interest in Research Review Committee
Michael Todd, Professor of Anesthesia
Grainne Martin, General Counsel, VP-Research
Charlotte Talman, Program Associate, Human Subjects Office
Kathryn Wynes, Program Associate, Office of the Provost

This document (appended) has been reviewed by—and extensively revised based on feedback from—the collegiate Deans' offices, the Staff Council, Professor Shelley Kurtz, a primary author of the existing policy, and the Faculty Senate Officers.

We are now presenting the document to you for your feedback. We would like an opportunity to meet with you to review the revisions and answer any questions you may have. For your convenience, in addition to the revision, a copy of the current policy is appended.

The appearance of the existing and revised policies is quite different. For that reason, we are not providing a line-edited version of the existing policy showing the changes made. We wish to emphasize, however, that **we made very few changes to the basic standards in the policy, as these generally are dictated by state law and federal regulation.** We provide here a summary of notable changes in the policy and the rationale for these changes:

1. The Policy is substantially shorter. This was a primary goal of the revision process, because the existing policy is complex and difficult to understand. The simplification is, to a large extent, the result of removing redundant UI policies and referencing their location in the Operations Manual at the end of the Conflicts of Commitment and Interest Policy rather than incorporating them into the policy itself as in the currently existing version.
2. The Policy more clearly delineates the three major types of conflict of interest it addresses: conflict of commitment, conflict of interest in the workplace, and conflict of interest in research.

3. Potential conflicts of commitment and conflicts of interest in the workplace now require a written disclosure and management plan prior to engaging the activity that is potentially conflictual. The existing policy mandates prior disclosure but only recommends, not requires, that the disclosure be written. Thus, it often was impossible to determine whether or not disclosure had occurred. Therefore, this change was recommended by the University's internal auditor to ensure documentation of disclosures of conflicts as well as the approval, management, or disapproval of the situation. Web-based forms for disclosure are being developed by the Office of the Provost.
- ~~5.4.~~ Conflict of interest in research has been expanded from sponsored research to all research, irrespective of funding. This is to provide a consistent process and recognize that financial conflicts of interest can occur (and should be managed) whether or not there is an outside sponsor of the activity.
- ~~6.5.~~ Using technology in research when the researcher is named as an inventor on the technology's patent is now identified as a conflict requiring disclosure and management. In the past, this was not considered a conflict of interest if the University of Iowa held the patent even though the inventor/investigator stood to gain financially from these inventions under University policy. This change recognizes the potential for financial benefit by the inventor/investigator.
- ~~7.6.~~ The policy contains new restrictions on involvement in human subjects research by investigators with a conflict of interest. This change represents an evolution of concerns specifically related to human subjects research that is reflected in policy statements from the American Association of Medical Colleges, American Association of Universities, and the federal Office of Human Research Protections. Thus, these changes were required to bring the UI policy in line with current national norms.

An additional note. The Board of Regents requires annual reporting of outside paid professional activities by full-time faculty. In the past, faculty have been required to disclose only the number of "consulting" days per year, if the number of days exceeded the (relatively low) threshold set by the Board of Regents. However, both the Board of Regents and the UI internal auditor have requested additional information about faculty's involvement in outside paid professional activities. Therefore, because of the close relation between conflicts of interest and outside paid professional activities, the Provost's Office is revising its collection of information about the latter in parallel with the conflict-of-interest policy revision. Neither the existing nor revised policy specifies the data to be provided to the Board of Regents, so there are no revisions to the policy per se addressing these changes. However, it is likely that this change in data collection for the Board of Regents will affect faculty more than the policy revisions themselves. We emphasize this here to clarify the distinction between the policy revisions, about which we are seeking your feedback, and implementation of changes in reporting "consulting activity" mandated by the Board of Regents.