

POLICY ON CONFLICTS OF INTEREST AND DISCLOSURE

(Revised April, 2009)

I. INTRODUCTION

Conflicts of interest most frequently arise in connection with research activities, but may also arise with educational activities (e.g., speaking engagements) or in providing consultation to industry. Effective interaction between universities conducting research and industry is essential to ensure the rapid application of scientific discoveries to the needs of the Nation and to maintain the international competitiveness of domestic industry. Nonetheless, prudent stewardship of public funds includes protecting sponsored research from being compromised by the conflicting financial and fiduciary interests of any Individuals responsible for the design, conduct, or reporting of sponsored research in accordance with PHS regulation 42 CFR, Part 50, Subpart F (http://grants.nih.gov/grants/compliance/42_CFR_50_Subpart_F.htm). Institutional policy seeks to maintain a reasonable balance between these competing interests, give the School the ability to identify and manage any conflicting interests that may bias the research, and minimize reporting and other burdens on the Individuals. In summary, the purpose of this policy is to comply with federal PHS regulation 42 CFR, Part 50, Subpart F and state regulations and to protect the credibility and integrity of the School's faculty and staff so that public trust and confidence in the School's activities are ensured.

II. HUMAN SUBJECT RESEARCH

Since clinical research commonly involves potential risks to human subjects that other types of research do not, conflicts of interest in research involving human subjects, e.g., clinical trials, necessitate closer scrutiny. The Institutional Review Board (IRB) will address the rights and welfare of human study participants (e.g., recruiting, patient contact, and consent). Whereas, the Conflict of Interest Review Committee (CIRC) generally will address issues of scientific integrity, financial management, use of university resources and the protection of students and other trainees involved in the conduct of the proposed study. The CIRC is advisory to the IRB and may recommend restrictions in the conduct of human subjects research; however, the IRB may choose to strengthen, but may not independently weaken, recommendations of CIRC. Effective and efficient management of relationships involving conflicts of interests in human subject research demands excellent interaction and communication between the IRB and the CIRC.

III. POLICY

The School has the responsibility to *identify, manage, reduce, or eliminate any conflicts of interest* that may be created by a conflict of interest of an Individual. Thus, the School requires that Individuals disclose any significant conflicts of interest annually through the online

disclosure process and transactionally through submission of grants, contracts, regulatory protocols and purchases at the time of each new application. The School will hold final approval of any grant or contract applications, regulatory protocol applications, or purchase orders until all key personnel listed have completed or updated the mandatory online significant financial interest and conflict of commitment disclosure.

- ◆ Upon identifying a potential conflict of interest, the CIRC has the responsibility to review the relationship creating the conflict of interest to determine if it can be managed or eliminated.
- ◆ If human subjects are involved and a potential conflict of interest is found, the IRB and CIRC will conduct their respective reviews in parallel, and the IRB will hold final approval pending the completion of the CIRC review, resolution of the issues and recommendations for management are made.