



## RESEARCH WEBNOTES ONLINE

August 2012

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### New Policy on Conflict of Interest in Research

New policies on conflict of interest in research as well as disclosure and professional commitment will be in effect as of **August 24, 2012**. Changes in federal regulation required that the University and School of Medicine revise these policies. Key provisions of the new policies are summarized below.

#### Disclosure Requirements

Investigators must disclose outside activities and/or personal financial interests that relate to any of their institutional responsibilities including, but not limited to, research, teaching, clinical care and administrative and committee roles. Under the new regulation, this includes services to any organization, whether for-profit or not-for-profit, remuneration for the services, or other financial interests related to one's institutional responsibilities. This includes, for example:

- Service as a consultant, scientific advisor or speaker
- Board of directors service, founder, officer or manager role
- Publishing, editing and/or authoring if remuneration is anticipated
- Service on an advisory committee, advisory board or review panel. (*Exceptions: advisory committee and review panel services to U.S. state, federal or local government agencies, teaching hospitals, medical centers, and institutions of higher education or related research institutes.*)
- Teaching and lecturing. (*Exceptions: teaching and lecturing for U.S. state, federal, or local government agencies, teaching hospitals, medical centers, and institutions of higher education or related research institutes.*)
- Royalty or entitlement to royalty related to intellectual property
- Stock, stock options, or other forms of equity, whether acquired through professional services or independently. (*Exceptions: interests in mutual funds and retirement accounts as long as the investigator does not control investment decisions in the accounts.*)

#### Disclosure of Sponsored or Reimbursed Travel

Investigators who participate in projects supported by Public Health Service (PHS) agencies (e.g., NIH, CDC, FDA) must disclose instances of travel that are sponsored or reimbursed to the researcher personally by any organization, whether for-profit or non-profit. Exceptions include travel that is sponsored or reimbursed by U.S. federal, state and local government agencies, U.S. institutions of higher education, teaching hospitals, and affiliated research institutes.

#### Sub-awards

Investigators on sub-awards must comply with their institutions' policies on research conflict of interest or, if the institution does not have a policy that complies with the regulation, comply with the JHU SOM policies as they relate to the sub-award project.

#### When and Where to Disclose

Disclosures of new financial interests must be made within 30 days of acquiring the interests or learning about them. Investigators need to disclose changes in financial interests as they occur. Investigators who

participate in projects supported by PHS agencies should disclose the occurrence of sponsored or reimbursed travel as soon as possible upon returning to Johns Hopkins. Disclosures must be made using eDisclose, the University's online system for reporting outside interests and activities. eDisclose is a modified version of eOPC, the system used by the School of Medicine since 2007, and it will replace eOPC in mid-August.

### **Reporting and Public Disclosure of Financial Conflicts of Interest**

As in the past, the Office of Policy Coordination will review disclosures for financial conflicts of interest with research. When a financial conflict of interest with a PHS-supported project is identified, in compliance with federal regulation, the School will report details of the arrangements to the PHS awarding agency and will make certain information available to members of the public upon inquiry.

### **Full-time and Salaried Part-time Faculty**

All full-time and salaried part-time School of Medicine faculty members, whether or not they engage in research, must disclose outside activities under the revised policy on disclosure and professional commitment and must annually certify that their disclosures are accurate and up-to-date.

### **Implementation**

Office of Policy Coordination staff members have made numerous presentations to departmental and administrative groups in recent months. If your department or division would like to arrange for a presentation, please contact Christina Doty, director of outside interests, at [cdoty2@jhmi.edu](mailto:cdoty2@jhmi.edu). Guidance and FAQs about the new policies will be made available in the coming weeks at <http://www.hopkinsmedicine.org/Research/OPC/index.html>. For immediate information, please email [policy@jhmi.edu](mailto:policy@jhmi.edu). New online training modules will be rolled out in late August in order to meet the formal training requirements.

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