



Financial Conflicts of Interest and Research

Bob Buhrman

Senior Vice Provost for Research

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Research Compliance

090513-
11150S

- A substantial and **required** administrative burden on Cornell researchers and on the institution.
- Broad and growing spectrum of regulatory areas
 - 40+ sets of regulations and compliance areas of major concern to sponsored research (3 new in 2008: sub-award reporting (700), Homeland Security e-Verify, and “training and oversight in the responsible and ethical conduct of research”)
- Areas of current concern and greatest impact on researchers
 - Effort reporting and certification
 - Research Integrity and Assurance (ORIA)
 - Export Control (*144 cases in 2008, none in 2005*)
 - Animal Care and Use (*776 active protocols, 150% increase since 2005*)
 - 114 facilities, AAALAC re-accreditation process on track, 2009
 - Biosafety (*288 active protocols, 58% increase since 2005*)
 - Human Participants (*1497 active protocols, 200% increase since 2005*)
 - **Financial Conflicts of Interest** (FCOI) (*all lead investigators*)

Financial Conflicts of Interest

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- Identification, management, and appropriate disclosure of FCOIs is essential for ensuring the public trust of research institutions and for continued access to federal funding.
 - Real conflicts, and situations where a neutral observer might reasonably conclude a conflict exists (apparent conflict)
 - *Must properly **report and manage** all real and apparent conflicts*
- Research-related FCOI the subject of significant, and growing, federal scrutiny and public attention.
 - Senator Grassley's inquiries to NIH and NY Times articles on same
 - AAMC/AAU report on FCOI and research (clinical and non-clinical)
 - Many leading universities updating FCOI policies - e.g. Columbia
http://evpr.columbia.edu/files_sponsoredprojectprocedures/imce_shared/COI_Policy_4_3_09_new.pdf
 - NIH mail reviews of universities' FCOI policies
 - NIH soliciting comments regarding a planned revision of its FCOI regulations - May 8, 2009

Financial Conflicts of Interest - Cornell

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- Research-related FCOI covered by overall Cornell Conflicts Policy
www.policy.cornell.edu/Conflicts_Policy.cfm
Adopted May 31, 1986. Amended January 29, 1987;
October 29, 1992 (established University Conflicts Committee);
October 28, 2000 (annual electronic disclosure process established)
- The University encourages academic personnel, consistent with university policy, to engage in sponsored research, to participate in professional practice as appropriate and necessary to sustaining intellectual output, to consult widely, and to engage in entrepreneurial and other activities that may benefit not only the participants but also the university and the larger public. The academic community at Cornell strives toward these objectives in a context of freedom with responsibility. Cornell's conflicts policy recognizes and affirms the settled tradition and expectation that members will conduct their relationships with each other and the University with candor and integrity. ...Cornell does not require individuals to avoid all situations where there may be a seeming or potential conflict of interest. On the contrary, some types of conflicts are unavoidable and completely acceptable. ...The obligation to disclose external financial interests and time commitments stems from the public trust vested in a University, is required by the Cornell University Conflicts Policy, and fulfills legal reporting requirements to funding agencies. (preamble to Part I disclosure)
- Recent NSF and NIH audit findings indicate that Cornell is not in full compliance with federal FCOI regulations.

Financial Conflicts of Interest - Cornell

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- Cornell is currently reviewing and updating Cornell policy and procedures for **research-related FCOI**.
 - Internal Ithaca process
 - OVPR; **University Conflicts Committee**, Dean Bill Fry (co-Chair);
Counsel's Office; Audit Office
 - President's Task Force on FCOI: Charge: "Recommend working principles and best practices"
 - Bill Fry, Trustees, Ithaca and Weill administrators, David Hajjar (Weill co-chair) and Bob Buhrman (co-chair)
- Expected result: A research-related FCOI policy and procedures for Faculty and Administration review, and subsequent Board of Trustees review and approval in the coming year.
 - **Cornell Policy on Financial Conflicts of Interest and Research**
 - Supplement to overall Conflicts Policy

Impact on Cornell Faculty

- If have no research-related financial interests or external relationships
 - ***no impact***
- If have research-related financial interests and commitments
 - Improved reporting process
 - annually and at time of proposal submittal (modified Form 10)
 - objective is to assist and better guide faculty in proper FCOI reporting
 - Central, confidential, oversight of development and implementation of FCOI management plans
 - goal is not to eliminate relationships but to manage them appropriately
 - Meet requirements of federal regulations
 - Assure public trust in the integrity of Cornell research