Financial Conflicts of Interest Related to Research Policy

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Principles Regarding Financial Conflicts of Interest

- Reporting, management, and appropriate disclosure of FCOIs is essential for:
  - ensuring research objectivity is not compromised by possibility of individual financial gain
  - assuring the public trust in research institutions
  - continued access to federal funding

- Must consider both real conflicts and apparent conflicts, i.e., situations where a neutral observer might reasonably conclude a conflict exists

- Federal regulations and Cornell policy require that all real and apparent conflicts of interest are properly reported and managed
Financial Conflicts of Interest

Research-related FCOI is the subject of significant federal scrutiny and public attention

- AAMC/AAU report (2008) on FCOI and research (clinical, pre-clinical and non-clinical)

- OIG finds NIH in non-compliance; NIH reviewed university FCOI policies, including Cornell’s (2008)

- NIH solicited comments regarding a planned revision of its FCOI regulations (5/8/2009); AAMC/AAU supports most proposed steps
Proposed NIH Regulations (generally AAMC/AAU recommended best practices)

• Disclose all directly and indirectly related financial interests related to institutional activities, regardless of amount; report all interests greater than $5K to funding agency
• Require management or elimination of certain types of financial interests
• Require an independent committee review of financial disclosures and mandatory development of FCOI management plans for cases where FCOI elimination is not required
• Prohibit investigators leading clinical trials from having a significant financial interest in a related or potentially impacted commercial entity
• Enhance FCOI sanctions
• Require an institutional conflict of interest policy for all major NIH funding recipients
Financial Conflicts of Interest - Cornell

- Cornell Conflicts Policy covers Conflicts of Commitment and Conflicts of Interest
  
  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 disclosure process established, partially electronic)

- Recent NSF and NIH audit findings stated that Cornell is not in full compliance with federal FCOI regulations. Deficiencies in:
  - procedure and policy regarding reporting, managing, and disclosing all research related FCOIs
  - identification of sanctions
  - timely agency notification

- Internal Cornell Audit (2008-2009) found “major audit concerns”
“Disclosure, review and conflict management procedures for conflicts of interest and commitment are not adequate:

- Reviewers are not consistently engaging in conversations with filers to obtain critical information necessary to assess the adequacy of disclosure;
- Disclosure forms do not provide adequate information for reviewers;
- Upon identification of a conflict, management plans are not consistently completed;
- Reviewers do not have sufficient training or guidance in the development and execution of management plans;
- Lack of timely follow-up with non-compliant filers;
- Insufficient follow-up for disclosures under review.”
Steps In-Process to Address FCOI Issues

• Review and update Cornell policy and procedures for research-related FCOI.
  – Internal process
    OVPR; **University Conflicts Committee**, Dean Bill Fry and Bob Buhrman (co-Chairs); coordination with Weill counterparts, Counsel’s Office, Audit Office
    **Benched-marked policy against regulations, peers, and AAMC/AAU recommendations**
  – 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)
    **Final report in draft form: “fully comply with all applicable regulations, and with AAMC/AAU recommendations wherever feasible.”**

• Cornell Policy on Financial Conflicts of Interest Related to Research
  • Complements Conflicts Policy
FCOI Related to Research Policy

• Covers all research, even if not federally sponsored

• Improves annual reporting (disclosure) process - electronic and updateable on line
  – Report all research-related financial interests - *regardless of amount*

• Implements **event-based reporting of external interests**
  – at time of proposal submission (*required by NSF and NIH regulations*)
  – at time of submittal of IRB protocols (*required by federal regulation*)

• Units handle conflicts of commitment and non-research-related FCOI
Implementation of FCOI Related to Research Policy

• FCOI Committee, faculty members appointed by SVPR, meets monthly; ex-officio, non-voting membership by Counsel’s office, OSP, IRB, CCTEC

• ORIA FCOI staff supports FCOI Committee in review and management plan process, similar to support provided IRB

• FCOI Committee actions:
  - reviews the financial reports of faculty and all others who have the responsibility for the design, conduct, and reporting of research
  - determines when real or potential FCOI exists
  - develops and approves management plans, or requires elimination of conflict
  - management plans developed in discussion with researchers, and, as appropriate, with the involvement of the college leadership

• Annual reports and proposal-specific reports of external interests maintained in secure database in ORIA
Impact on Cornell Faculty

• If have no research-related financial interests or external relationships
  – *no impact, apart from completing, online, annual report and event driven reports*

• If have research-related financial interests and external commitments
  – Improved, and more effective, fact-based reporting process: Objective is to assist and better guide researchers in proper FCOI reporting
  – Central, confidential development and implementation of FCOI management plans: Goal is not to eliminate most intersecting relationships but to manage them appropriately

• Outcome
  – Meet requirements of current and pending federal regulations
  – Ensure that Cornell’s research integrity is not compromised and that the reputation of our researchers cannot be impugned
  – Assure public trust in Cornell research