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APPENDIX 4

Financial Conflicts of Interest Related to Research Policy

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Cornell Faculty Senate Meeting
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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”

Internal 2009 Audit Report - Conflicts^{091014-11270S}

“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