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Approaches to Developing an Institutional Conflict of Interest Policy - Introduction

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INTRODUCTION (What is this web page about?)

As a companion to COGR's **Recognizing and Managing Personal Financial Conflicts of Interest** (Winter 2002), this site is designed to consider financial conflicts of interest at an institutional level.

The management of the financial conflicts of interests of **individual** scientists or investigators is governed, in part, by the Objectivity in Research policy at the National Institutes of Health and financial conflicts of interest policy off the National Science Foundation. State law and institutional policies govern investigator financial conflicts as well. The processes for disclosing, managing, reducing, or eliminating these conflicts are relatively well established at research universities.

The path for identifying and managing **institutional** conflicts of interest that may affect the research enterprise on our campuses is less well defined but is increasingly an area of heightened concern for most universities and for the federal funding agencies. A number of organizations and agencies have proposed approaches for addressing these institutional conflicts. In 2008, the Association of American Medical Colleges (AAMC) and Association of American Universities (AAU) followed up on their 2201/2002 reports on financial conflicts of interest in *Protecting Patients, Preserving Integrity, Advancing Health: Accelerating the Implementation of COI Policies in Human Subjects Research* (February 2008). This report looks at conflicts in biomedical research and refines the Associations' earlier recommendations. The report includes a sample institutional conflict of interest policy designed to address human subject research issues.¹ The area of conflicts in relation to the broader institutional operation and human subject research has been addressed by the American Council on Education, the Institutes of Medicine and the US Department of Health and Human Services, offering additional guidance for managing institutional financial conflicts of interest.² These organizations agree that universities should develop mechanisms for the thoughtful and thorough consideration of the university's financial relationships if those relationships hold the potential for or present actual conflicts of interest that affect the conduct and reporting of research.

¹ Association of American Universities (AAU), *Report on Individual and Institutional Financial Conflict of Interest* (October 2001) offers an overview on the question of institutional conflicts of interest as it affects the entire campus. See also Association of American Medical Colleges (AAMC), *Protecting Subjects, Preserving Trust, Promoting Progress II: Principles and Recommendations for Oversight of an Institution's Financial Interests in Human Subjects Research* (October 2002).

² See, for example, the American Council on Education (ACE), *Working Paper on Conflict of Interest*, Institute of Medicine (IOM), *Responsible Research: A Systems Approach to Protecting Research Participants* (2003); and HHS/PHS Office of Human Research Protections (OHRP), *Draft Guidance: Financial Relationships and Interests in Research Involving Human Subjects: Guidance for Human Subject Protection* (March 2003)

Consistent with these recommendations, universities have begun the process of developing policies and related procedures that describe in varying levels of detail how potential conflicts will be disclosed and to whom; the criteria for determining whether a conflict exists and how those determinations are reported, and to whom; and the individual or group of individuals who will make a final decision on how to proceed.

As more universities consider the development of new policies and procedures a general framework is beginning to emerge. Based in part on the recommendations of AAU, AAMC, and others, as well as on unique institutional policy development strategies, these experiences may be useful to others embarking down this path. This web-based discussion is intended to assist universities in the policy development process. In a series of short documents or sections that will be updated as needed – briefing papers; checklists; bibliographies – COGR hopes to assist its members in building an effective approach for identifying and managing institutional conflicts of interest.

Of interest to administrators and senior officers, as well as members of committees charged with creating these institutional conflict of interest policies, each section will be supplemented by links to other documents. We encourage you to help build this site by making contributions of references or information that will help build a consensus on guiding principles and best practices for addressing our shared goal – preserving the integrity and objectivity of the research enterprise at our universities.