AAMC, AAU Issue New Guidelines on Managing Conflicts of Interest

Goal Is to Make Academic Policies Stronger and More Consistent

Washington, D.C., February 28, 2008—A new report, issued today by the AAMC (Association of American Medical Colleges) and the Association American of Universities (AAU), calls on all medical schools and major research universities to develop and implement institutional financial conflicts of interest (COI) policies within the next two years, and to refine standards for addressing individual financial COI. “Protecting Patients, Preserving Integrity, Advancing Health: Accelerating the Implementation of COI Policies in Human Subjects Research,” provides a detailed roadmap for academic institutions to identify, evaluate, and manage financial conflicts of interest in research that involves human research subjects.

The report is the product of two years’ work by an AAMC/AAU joint advisory committee, created in 2006, to refine and amplify both associations’ previously issued COI policy recommendations, and provide medical schools and major research universities with precise guidance on how to handle conflict of interest cases that arise in human subjects research. The 21-member committee, made up of senior officials from the nation’s medical schools and major research universities, was co-chaired by Robert R. Rich, M.D., senior vice president for medicine and dean of the University of Alabama at Birmingham School of Medicine, and Mark S. Wrighton, Ph.D., chancellor of Washington University in St. Louis. The panel’s key recommendations are intended to accelerate implementation by medical schools, teaching hospitals, and major research universities of effective policies that address both individual and institutional financial conflicts of interest and make the policies more consistent, while allowing for each institution’s culture and history.

---more---
“The effective management of financial conflicts of interest is essential to protect patients and preserve research integrity,” said AAMC President and CEO Darrell G. Kirch, M.D. “To achieve the promise of biomedical research, there must be ongoing collaboration among research universities, medical schools, teaching hospitals, and industry. This report provides excellent practical advice on how institutions can enhance their oversight and management of these vital relationships and sustain the trust the public places in us.”

“Financial or personal gain must not be allowed to compromise patient safety or the validity of human subjects research, and AAU and AAMC have led the research community in addressing these challenging and extraordinarily complex issues,” said AAU President Robert M. Berdahl, Ph.D. “Our institutional leaders and faculty, making use of the associations’ previous reports, have put substantial time, energy, and resources into improving their oversight and management of conflicts of interest. These new guidelines build upon our earlier efforts, and we look forward to working with our member institutions as they continue to strengthen their policies and procedures for managing these conflicts.”

Ensuring the trustworthiness and accountability of the academic research enterprise has long been a top priority of the AAMC and the AAU. In 2001 and 2002, the two associations issued strong recommendations addressing individual and institutional financial conflicts of interest in human subjects research (www.aamc.org/research/coi/start.htm). Two years ago, in the wake of the conflicts of interest scandal at the National Institutes of Health, the AAMC and the AAU charged the new joint advisory committee with developing an updated report on COI policies in human subjects research that would build on the associations’ earlier guidance.

According to the report, institutional conflicts of interest are becoming a growing concern as academic institutions assume more complex roles and expand their relationships with industry. Conflicts of interest policies are critical to assure that these essential interactions remain principled and are conducted within a rigorous, transparent, and credible framework. As a result, the report recommends that all medical schools, teaching hospitals, and AAU institutions:

- Accelerate the development of COI policies that cover the financial interests of faculty, institutions and their officials, including deans, department chairs, and division chiefs
- Implement a reporting, evaluation and management process for both individual and institutional financial COI, that includes a review system that involves a standing internal committee or an external review entity
- Complete the development and implementation of institutional COI policies in the next two years.

The report underscores the urgent necessity for all academic medical centers and major research universities to address conflicts of interest consistently throughout their organizations, ensuring that all faculty, officials and institutions are subjected to a thorough reporting, disclosure, and management process for their financial interests.

--more--
Implementing comprehensive programs of oversight and management of institutional financial conflicts of interest has been a challenge for the academic community. A recent study, undertaken by the AAMC and the Health Policy Institute of Massachusetts General Hospital, revealed that as of 2006, 38 percent of the medical schools surveyed had policies addressing institutional conflicts of interest. The study cited a variety of reasons for the delay in developing these policies, including the need for highly integrated trans-institutional databases and management systems to track institutional financial holdings, and the perception that such policies may inhibit efforts to quickly bring research discoveries to the health care market.

To help academic institutions overcome this challenge, the AAMC/AAU report offers a model template for analyzing and managing conflict of interest cases. As further guidance, the report provides 10 detailed case studies, based on real situations that have arisen in research universities and medical schools. This compilation of cases will be built upon and updated in order to provide the academic community with contemporary materials for educating faculty, students, staff, and institutional officials.

For a copy of “Protecting Patients, Preserving Integrity, Advancing Health: Accelerating the Implementation of COI Policies in Human Subjects Research,” go to:

www.aamc.org/jointcoireport

The Association of American Medical Colleges is a not-for-profit association representing all 129 accredited U.S. and 17 accredited Canadian medical schools; nearly 400 major teaching hospitals and health systems, including 68 Department of Veterans Affairs medical centers; and 94 academic and scientific societies. Through these institutions and organizations, the AAMC represents 109,000 faculty members, 67,000 medical students, and 104,000 resident physicians. Additional information about the AAMC and U.S. medical schools and teaching hospitals is available at www.aamc.org/newsroom.

The Association of American Universities (www.aau.edu) is an association of 62 leading public and private research universities in the United States and Canada organized to develop and implement effective national and institutional policies supporting research and scholarship, graduate, professional, and undergraduate education, and public service in research universities. AAU universities award more than one-half of all U.S. doctoral degrees and 55 percent of those in the sciences and engineering.