DEPARTMENT OF HEALTH & HUMAN SERVICES

National Institutes of Health
Bethesda, Maryland 20892

APR 17 2009

The Honorable Joe Barton
House of Representatives
Washington, DC 20515

Dear Mr. Barton:

This is in response to your March 19 letter in which you express concern about effective oversight of potential conflicts of interest in grants awarded with funds appropriated to the National Institutes of Health (NIH) under the American Recovery and Reinvestment Act of 2009 (ARRA). The NIH is grateful to the President and Congress for recognizing the role of research in stimulating the economy, and in particular, for providing $8.2 billion in extramural funding that will facilitate the NIH's efforts to advance biological science and create public health benefits. The NIH is currently developing its plan for spending these funds and is committed to obligating these funds quickly, as directed by Congress. ARRA funds will be spent consistent with current legal and regulatory requirements governing NIH funding, including existing financial conflict of interest (FCOI) rules.

As you know, however, the NIH has been reviewing current requirements governing FCOI in extramural research and is developing ways of enhancing its oversight of such conflicts. I share your view that it is vital to maintain objectivity in research. We believe rigorous oversight must apply to all NIH-funded research, whether related to ARRA or other sources of support. The introduction of bias in the conduct of NIH-supported research will not be tolerated. In fact, the NIH has suspended one grant at an institution because it did not comply with the regulatory requirements of 42 CFR Part 50 Subpart F, Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought (Financial Conflict of Interest regulation) and imposed institution-wide special reporting requirements to address weaknesses in the institution's administrative process to identify and manage, reduce or eliminate conflicting interests at the institution. The NIH does not take such actions lightly and will not hesitate to take similar enforcement actions when warranted. The NIH is confident that its enhanced oversight initiatives together with the pending ANPRM, as discussed in the enclosure, will provide the framework for a vigorous system of compliance oversight.

I hope this information is helpful to you. If you need any additional information, please contact Marc Smolonsky, NIH Associate Director for Legislative Policy and Analysis, at (301) 496-3471. I am also sending this response to Representative Walden.

Sincerely yours,

Raynard S. Kington, M.D., Ph.D.
Acting Director

Enclosure

Enclosure to NIH Response to March 19, 2009,
Letter from Representatives Barton and Walden

The Federal Conflict of Interest (FCOI) regulation promotes objectivity in research by establishing standards to protect research funded by Public Health Service (PHS) grants or cooperative agreements against bias by conflicting financial interests of the involved Investigators. The FCOI regulation applies to each Institution that applies for PHS grants or cooperative agreements for research and to each Investigator participating in such research (Small Business Innovation Research Program Phase I applications are exempt). Therefore, the FCOI regulation is applicable to grants and cooperative agreements awarded by the NIH with funds received under the American Recovery Reinvestment Act.

Over the last year, the NIH has conducted a comprehensive review of its system of oversight of grantee institution compliance to ensure that it is both vigorous and effective. The NIH also carefully considered the recommendations contained in a January 2008 Office of Inspector General, Department of Health and Human Services, report titled, "National Institutes of Health: Conflict of Interest in Extramural Research." As a result of this intensive effort, the NIH identified several areas requiring enhancement and has implemented a number of actions. The following is a list of the NIH's most recent activities with respect to compliance oversight:

- Developed an electronic FCOI Reporting Module as for grantee institutions to manage and report FCOIs to the NIH. This Module interfaces with the Web-based reporting tool already in use by NIH staff and will provide a full spectrum of tracking and oversight capabilities. The full implementation of this system will result in a more accurate and efficient means to manage institutional FCOI reports. As a result of a successful pilot phase, the NIH plans to require its grantees to use the Module for FCOI reporting effective July 1, 2009.
- Developed an FCOI review protocol for use by NIH staff in evaluating institutional FCOI reports and conducted mandatory NIH-wide training for extramural program and grants management staff on the use of the protocol and other FCOI issues (2008).
- Updated and expanded online Frequently Asked Questions on FCOI as a resource for extramural recipients (2008).
- Developed an FCOI on-line tutorial for grantee institutions and investigators that emphasizes regulatory requirements and institutional and investigator responsibilities (2008).
- Conducted an in-depth review of more than 20 cases of alleged FCOI involving extramural grantees during the last year and as new allegations arise (ongoing).
- Continue to evaluate and analyze grantee institutions' FCOI policies and practices—over 50 such evaluations have been completed (ongoing initiative) .
- Formed an FCOI Liaison group consisting of representatives from each of the NIH Institutes and/or Centers (IC) to discuss FCOI issues and guide FCOI

activities in their respective ICs, with assistance from the NIH Office of Extramural Research (OER) (2008).

- Developed and included new language for the NIH's "Notice of Award" template that highlights FCOI requirements (2008).
- Developed a Web-based reporting and tracking tool for NIH staff (2007).
- Developed and conducted a number of initiatives and site visits to evaluate institutional FCOI policies for compliance with the Federal regulation. These initiatives include:
    - NIH Pilot Compliance Program on FCOI (2007)
    - NIH Targeted Site Reviews (2006).
- Following evaluation of the institutional FCOI policies, the NIH publicized on-line "Lessons Learned" summaries to encourage enhanced compliance in the grantee community.
- Issued a number of communications to remind extramural grant recipients of their FCOI compliance responsibilities. These communications include:
    - Articles (Nexus) (2008 and 2006)
    - NIH Guide Notices (2007, 2004, 2003).
- Continue to respond to grantee questions directed to the OER FCOI mailbox concerning compliance with the Federal regulation (ongoing since 2004).
- Continue to issue Web postings and resource documents (ongoing since 2002).
- Provide education and outreach activities aimed at raising awareness of the issues surrounding FCOI at the institutional and investigator levels, e.g., NIH Regional Seminars and presentations at professional organizations and meetings (ongoing since 2001).

The NIH has developed an Advanced Notice of Proposed Rulemaking (ANPRM) to gain public input on potential changes to the FCOI regulation. It is anticipated that the ANPRM will be published soon for public comment. The complex and controversial issues surrounding FCOI warrant a carefully considered, open dialogue with all affected parties in order to facilitate regulatory compliance and effective oversight. The ANPRM is organized into the following six areas:

1. Expanding the scope of the regulation and disclosure of interests (including questions addressing a new requirement for grantees to provide details regarding the nature of financial conflicts of interest and how they are managed, reduced, or eliminated).
2. Definition of "significant financial interest."
3. Identification and Management of Conflicts by Institutions.
4. Assuring Institutional Compliance.
5. Requiring Institutions to provide additional information to the PHS.
6. Institutional Conflict of Interest (institutional conflict of interest is an area of increasing concern that currently is not addressed by the Federal regulations).