



JUN 20 2008

The Honorable Charles E. Grassley  
United States Senate  
Washington, D.C. 20510

Dear Senator Grassley:

This is an interim response to your June 4, 2008, letter concerning the National Institutes of Health (NIH) oversight of extramural institutions' compliance with Federal financial conflict of interest rules.

Let me first concur with your stated concerns about the management of conflict of interest in NIH-supported institutions. From recent examples, it is clear that we need to increase transparency and enhance the NIH's system of oversight. The NIH believes that it is vital to maintain objectivity in research and that all research must be conducted in accordance with the highest scientific and ethical standards and in a manner that assures the integrity of the scientific record. I assure you that the NIH takes its responsibilities in this area very seriously and that I am committed to taking all necessary action within my power to ensure that the research that the NIH supports continues to be conducted objectively and with integrity. It is essential that we preserve the public trust.

The regulation at 42 CFR Part 50, Subpart F, places the responsibility for the identification and management of investigators' financial conflicts of interest (FCOI) with the grantee institution which oversees the investigator's activities. The NIH, as the grantor agency, has primary responsibility for overseeing institutional compliance with these requirements. The two keystones of this process are (1) prompt and full disclosure by investigators of financial interests that may be impacted by their NIH-supported research and (2) sound institutional management of any conflicting interests. Ensuring objectivity in research requires the full commitment of investigators, institutions, and the NIH.

The NIH has been undergoing a comprehensive review of our oversight of extramural institutions' financial conflicts of interest. As a result of this intensive effort, the NIH has identified and is reviewing several areas for oversight enhancement. We will more fully inform you of the results of this review in our forthcoming response. The NIH also is considering gathering public comment on whether to modify the regulations at 42 CFR Part 50, Subpart F.

The NIH has completed its initial evaluation of the case examples included in your letter, and we are working with Massachusetts General Hospital and Harvard University to

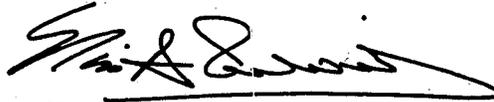
Page 2 – The Honorable Charles E. Grassley

provide the information you have requested. We will provide detailed answers to your specific questions by July 31.

With the support of you and other Members of Congress, the research community, and the public—all of whom are interested in ensuring objectivity in research—I am hopeful that we can significantly enhance the identification and management of FCOIs to ensure that undisclosed, and therefore unmanaged, conflicts do not bias the design, conduct, or reporting of NIH-supported research.

You have my assurance that the NIH is working diligently on providing responses to each of the examples you cited. I will keep you informed as we proceed.

Sincerely,

A handwritten signature in black ink, appearing to read 'Elias A. Zerhouni', with a long horizontal flourish extending to the right.

Elias A. Zerhouni, M.D.  
Director