

NIH Freezes \$9.3 Million Emory Grant Due to Failure to Report Researcher Payments

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In an unprecedented action, the National Institutes of Health (NIH) has suspended a five-year, \$9.3 million grant to Emory University amid allegations of failure to report pharmaceutical company consulting payments and conflict of interest in the medical school's psychiatry department. Under NIH regulations, researchers with NIH grants must disclose to their institutions any outside income, including private research funding, that is at least \$10,000 within a calendar year or any 5% ownership in a single entity. NIH grantee institutions are required to apply appropriate conflicts of interest management policies and procedures to such disclosures.

Until now, NIH has deferred to grantee institutions regarding primary compliance oversight responsibilities related to disclosure requirements. NIH has now taken direct action at Emory University based on allegations of noncompliance uncovered in an investigation into pharma consulting payments and potential conflicts of interest at NIH grantee institutions led by Senator Charles Grassley (R-Iowa), Ranking Member of the Senate Finance Committee. Any academic institution receiving NIH biomedical research grant funds should be aware of this major new noncompliance risk exposure, and should take immediate action to assure compliance.

The Regulation of Conflicts of Interest in Biomedical Research

The foundation of sound biomedical research, including clinical trials testing promising new drugs and medical devices on human research volunteers, depends on unbiased research, researchers and results reporting. Significant financial conflicts of interest involving researchers and/or their institutions raise fundamental concerns about the reliability of the research and its conclusions. As noted by Senator Grassley and others, federal regulations are intended to ensure objectivity in publicly funded research.

In 1995, NIH promulgated a regulation addressing potential conflicts of interest by requiring all NIH grantee researchers to disclose to their grantee institutions any "significant financial interest," which is defined as

income from a private entity totaling \$10,000 or more in a calendar year or 5% ownership in a single entity.¹ Once the financial interests are disclosed, the institution is required to manage actual or potential conflicts of interest, including investigator recusal or replacement, if necessary.

Conflicts of interest issues affecting the Food and Drug Administration (FDA) are also attracting Congressional attention. On October 9, 2008, the Government Accountability Office released a report that the FDA must expand its outreach efforts to retired experts and academics to mitigate any conflicts of interest among the various FDA advisory committees.²

Senate Finance Committee Investigation and Its Implications

To foster greater transparency, Senator Grassley wrote letters to over 20 academic institutions inquiring about the physician private payments disclosures in recent years. During his investigation, Senator Grassley uncovered large apparent discrepancies between the disclosure the physicians provided to their institutions and the consulting payment information provided by pharmaceutical companies.

Senator Grassley called upon the NIH to use its power to enforce the disclosure requirement by suspending any grant where there has been noncompliance. Although previously reluctant to do so, NIH this week took Senator Grassley's recommended course of action by freezing a five-year, \$9.3 million grant to Emory University after it was discovered that Dr. Charles B. Nemeroff, Chair of the Emory University medical school's psychiatry department, allegedly failed to report at least \$1.2 million of private income to the university.

The potential impacts of this NIH grant suspension at Emory are far-reaching. The suspension clearly indicates that oversight of conflicts of interest compliance at NIH grantee institutions is in the spotlight. Any noncompliant researcher and institutions receiving NIH funding will be exposed to potential cancellation of current NIH grants. Additional risk exposures to affected researchers and institutions include loss of competitiveness, suspension or debarment from future research funding, departure of research faculty and support personnel, adverse publicity, damage to reputations, and possible civil and criminal penalties and liability. Additional possible exposure includes claims of biased or compromised research by research sponsors, research volunteers, and other stakeholders.

Senator Grassley and Senator Herbert Kohl (D-Wisconsin) have introduced S.2029, the Physician Payments Sunshine Act, to require pharmaceutical and medical device companies to report publicly any payments that they make to physicians, within certain parameters. Given today's challenging environment for biopharmaceutical companies, documented compliance with all federal and institutional requirements is imperative.

Recommendations

Academic medical centers and parent academic institutions receiving NIH biomedical research grants should immediately undertake a coordinated series of actions to address the potential risks, including:

- Conducting a complete review of research policies and procedures, compliance infrastructure, and documentation for compliance with all applicable federal, institution, and other requirements at every medical school and campus in the institution;
- Addressing instances of potential or actual noncompliance with federal and institutional requirements and recognized best practices;

- Providing enhanced education and training of institution faculty and personnel to assure rigorous adherence to all applicable federal, institutional and other research requirements;
- Assuring that appropriate modifications to institution policies and procedures based on the above review are expeditiously implemented;
- Obtaining credible outside validation of the grantee institution's compliance program.

Live Links

NIH Suspends Emory Grant Amid Questions Over Pharma Payments; Jacob Goldstein; The Wall Street Journal Health Blog; October 14, 2008

Top Psychiatrist Failed to Report Drug Income; Gardiner Harris; The New York Times; October 3, 2008

Pressured, Schools Review Ties to Drug Firms; Alicia Mundy; The Wall Street Journal Health, September 11, 2008

NIH Grants: Trust But Don't Verify, Daniel S. Greenberg; Association for Psychological Science; September 2008, Volume 21, Number 8

Grassley Vows To Pressure NIH Over Grants; Ed Silverman; Pharmalot Pharma Blog; July 25, 2008

Researchers Go Unchecked, Report Says; Gardiner Harris; The New York Times; January 19, 2008

NIH Partnership with the Extramural Community—Reporting Conflict of Interest; NIH Extramural Nexus; July 2006 (PDF, 12 pages)

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¹ Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding is Sought, 42 C.F.R. 50 (1995).

² United States Government Accountability Office, GAO-08-640 (September 2008), FDA Advisory Committees: Process for Recruiting Members and Evaluating Potential Conflicts of Interest.

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