



AMERICAN ACADEMY OF
ORTHOPAEDIC SURGEONS

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July 6, 2009

Mr. Jerry Moore
NIH Regulations Officer
National Institutes of Health
Office of Management Assessment
6011 Executive Boulevard
Suite 601, MSC 7669
Rockville, MD 20852

RE: Responsibility of Applicants for Promoting Objectivity in Research for Which
Public Health Service Funding is Sought and Responsible Prospective Contractors;
Request for Comments
RIN 0925-AA53; Docket Number NIH-2008-0002

Dear Mr. Moore:

The American Academy of Orthopaedic Surgeons (AAOS), representing over 17,000 board-certified orthopaedic surgeons and researchers, welcomes the opportunity to respond to the Department of Health and Human Services (HHS) and the Public Health Service (PHS), through the National Institutes of Health (NIH), for the Request for Comments: Responsibility of Applicants for Promoting Objectivity in Research for Which Public Health Service Funding is Sought and Responsible Prospective Contractors, Docket No. NIH-2008-002 RIN 0925-AA53, FR Doc. E9-10666.

The AAOS is pleased to comment on the following areas:

Expanding the Scope of the Regulation and Disclosure Interests:

The regulations should be expanded from current regulation to include Phase I Small Business Innovation Research (SBIR) and Small Business Technology Transfer Research (STTR) research. In order to maintain transparency regarding conflict of interest, all entities applying for PHS funding should be required to follow similar regulations. This is particularly important as the environment for research becomes more complex and involves parties across the academic and private sectors.

We agree that investigators should be required to disclose to their institution all Significant Financial Interests (SFI). This open disclosure will provide further protection for the institutions as well as assure the public that FCOI (financial conflicts of interest) are recognized and managed appropriately. However, institutions must

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also be able to ensure the protection of researcher information – carefully balancing privacy with transparency.

The Definition of “Significant Financial Interest (SFI)”:

The SFI exemptions should be maintained with the exception of the exemption for SBIR/STTR programs. These programs should have the same obligations to the PHS as other programs applying for PHS funding.

The exemption of financial interests of less than \$10,000 annually is reasonable. However, language that includes disclosure of SFI for income from seminars, lectures, teaching engagements, advisory committees or review panels sponsored by for-profit companies that may have an interest in the research should be included in the regulations.

The AAOS recommends that all SFI should be considered as potential FCOI, and therefore should be disclosed.

Identification and Management of Conflicts by Institutions:

Eliminating FCOI may not be possible in today’s society; however, maintaining a management plan is possible. Management plans should be applicable to all forms of research, and these plans should be part of the funding application process. However, it is imperative not to limit funding based on FCOI as this may create a disincentive for performing critical PHS research.

The regulations should seek balance in determining whether investigators involved in the selection, informed consent, and management of a trial should be prohibited from having SFI. In many cases, the level of financial investment, with proper disclosure, will not present a conflict of interest, and we would caution against a complete prohibition of SFI. While there will be certain levels of investment that accompany human subject research that will require a heightened level of scrutiny, an outright prohibition could potentially eliminate the most informed and motivated individuals from performing trials.

A prescription for management of FCOI should not be required; however, examples of appropriate management plans should be made available and would facilitate appropriate management plans for FCOI.

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Regulations should apply universally to all participants in the PHS funded research. This type of open disclosure will engender public trust and assure appropriate FCOI management.

Disclosure and management of CFOI should be required to ensure a transparent process. However, limitations on amounts received should not be required as this type of regulation will create a disincentive for critical research by those most suited to investigate.

Assuring Institutional Compliance:

The current options allow for a Stop Work until the FCOI issue is resolved which should be sufficient. The PHS funding component should not enhance further enforcement options.

Many, if not most, institutions already require FCOI training; however, the PHS should provide an online system for training that would ensure an appropriate and thorough FCOI training. A system created by PHS would confirm that all funded investigators and affiliated institutions receive adequate FCOI training.

Independent confirmation of institutional compliance should not be required. The additional expense of such a system could decrease the available research funding, and again, create a disincentive for legitimate investigators.

Requiring Institutions to Provide Additional Information to the PHS:

Institutions and investigators for all PHS-funded research should be required to submit detailed financial information for all SFI's above the stated dollar threshold. This open disclosure policy will create a transparent environment that engenders public trust. In response to the posed question, the AAOS believes that full disclosure with appropriate management plans will allow institutions and investigators to proceed with research, but with appropriate controls.

Broadening the Regulations to Address Institutional Conflicts of Interest:

Institutional conflict of interest should be addressed in a manner similar to that for individual investigators with a FCOI. SFI for the institution could include copyrights and royalties, income from joint ventures with industry, employment contracts with



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industry, income from seminars, review boards or advisory boards and trustee positions held by members of the institution should be openly disclosed with appropriate management plans in order to reduce any potential or perceived research bias.

The AAOS is appreciative for the opportunity to provide feedback. We look forward to our continued dialogue and partnerships with the NIH in the future. If you have any questions about our comments, please feel free to contact us or Robert Jasak, Office of Government Relations, at 202-546-4430 or jasak@aaos.org.

With Kind Regards,

Denis Clohisey, MD
Chair, AAOS Research Development Committee

Kristy Weber, MD
Chair, AAOS Council on Research, Quality Assessment, and Technology