



June 23, 2009

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RE: NIH Advance Notice of Proposed Rule Making (ANPRM) on Objectivity in Research for Which Public Health Funding is Sought and Responsible Prospective Contractors; Request for Comments, May 8, 2009

Dear Mr. Moore:

The Case Western Reserve University (Case) community extends appreciation to the NIH for allowing this opportunity to comment upon the May 8, 2009 ANPRM pertaining to Objectivity in Research and Responsible Public Contractors.

The University recognizes that, since the publishing in 1995 of 42 CFR Part 50 Subpart F and 45 CFR Part 94, the "increased potential of investigators to hold financial interests in multiple sources," has resulted in the need for "a more vigorous approach" to identifying and managing conflicts of interest related to research, as stated in the ANPRM.

Under the leadership of President Barbara Snyder, Case Western Reserve University in 2009 revised its conflict of interest policies, and these policies proactively address some of the issues raised in the ANPRM. The 2009 Case Policies on Individual Conflicts of Interest and Institutional Conflicts of Interest, for example, require Investigators to report to the University all financial interests directly related to research, regardless of amount.

The Outside Interests Committee of Case Western Reserve University endorses the recommendations made by the AAU/AAMC in the joint letter to you of June 10, 2009.

Regarding Section III.C of the NIH ANPRM: we support the AAU/AAMC comments. We would add, however, that if NIH has particular views on any of the questions suggested in the AAU/AAMC response to III-C (questions #1-5) or which questions should be weighted more heavily, we would appreciate that guidance.

Regarding Section IV-B of the NIH ANPRM: while we agree with the AAU/AAMC view that institutional conflict of interest policies do not lend themselves to federal regulation, we would welcome any additional guidance from the NIH on treatment of institutional conflicts of interest.

Once again, thank you for this opportunity to comment on proposed changes in rule-making. The Outside Interests Committee of Case Western Reserve University is pleased to participate in this important dialogue.

Sincerely,

Michael T. Edwards

Associate Vice President for Research

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