

July 20, 2010

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

Re: RIN 0925-AA53 (NIH-2010-001)

Dear Mr. Moore,

On behalf of the American Society of Nephrology (ASN), thank you for the opportunity to provide comment to the National Institutes of Health (NIH) regarding RIN 0925-AA53 Responsibility of Applicants for Promoting Objectivity in Research for Which Public Health Service Funding is Sought and Responsible Prospective Contractors. ASN is a not-for-profit organization of 11,000 scientists and physicians dedicated to cutting-edge medical research and delivering the highest quality therapies to patients. Foremost among ASN's concerns is the continued support of basic, translational, and clinical nephrology research.

ASN recognizes the vital importance of transparency and objectivity in medical research. The society applauds NIH's current efforts to strengthen and clarify policies regarding potential conflicts of interest. The preservation of public trust in our research institutions is essential for the future scientific breakthroughs. The society is supportive of the principles of increased and uniform transparency standards, and offers the following comments regarding NIH's Proposed Rule.

Historically there has been significant variance between conflict of interest standards and enforcement at academic institutions nationwide. In the Proposed Rule, NIH places considerable responsibility on individual academic institutions to develop and execute new policies that safeguard objectivity. While ASN is in agreement with the principle behind the Proposed Rule, ASN is concerned that in practice the reliance on individual academic institutions to safeguard COI could result in disparate standards across research facilities, potentially to the detriment of researchers at institutions that enforce more stringent policies. The society recommends that NIH develop clear guidelines for enforcement and administration of conflict of interest management efforts to create a uniform and level playing field across all institutions nationwide. Such guidelines would alleviate the potential for wide variances in enforcement of conflicts of interest rules across institutions.

ASN encourages NIH to bear in mind administrative burdens associated with reporting COI, as excessive detail could become laborious and impede the research agenda and translational activities. The administrative burden would fall equally on researchers as well as academic institutions, potentially inadvertently becoming an impediment to valuable research.

On the subsections where NIH specifically requests comment, ASN offers the following remarks:

Regarding all aspects of the proposed “significant financial interest” definition (Page 28692, Column 3), ASN supports lowering the threshold for “equity interests and payment for services which include salary but not royalties” to \$5,000. This is a reasonable threshold that takes into consideration a balance between capturing conflicts of interest and the potential for administrative burden. We suggest however that NIH offer further clarification of definition of exclusion to investments, including mutual funds.

The society supports NIH’s proposal to include income from non-profit entities other than institutions of higher education (or sponsored by a federal, state or local government agency) in the SFI definition. We believe that income from non-profit entities other than these institutions should be subject to disclosure. We do not believe this would place an unreasonable burden on researchers, and it may in some cases provide valuable information on an individual’s other associations.

ASN supports the public disclosure of SFI and related information online (page 28698, Column 2). However, the society requests that NIH clarify that it will collate the information into one central repository web site, rather than requiring each institution develop its own separate web site. We believe this would most effectively present the information to the public as well as streamline submission of SFI information.

NIH requests public comment on the elements it proposes including in the FCOI report, including a description of how the financial interest relates to the PHS-funded research and the basis for the institution’s determination that the financial interest conflicts with such research. ASN concurs that the information listed by NIH in this section is of interest, the society again urges the Institute to weigh the administrative burden of collecting this amount of information. In particular, ASN suggests that NIH prepare a standard form for each institution to use, thereby ensuring uniform response and minimizing the administrative burden on the institutions. The society would also like to verify that these disclosures would apply to only investigators with \$5,000 or more in significant financial interest, not the \$4,999 listed within the proposed rule.

NIH solicits comment on whether the regulations 42CFR50.607 should be deleted. ASN agrees with NIH that this section may not provide additional clarity or value, and is not necessary to include in the Final Rule. The society supports its deletion.

NIH asks for input on whether the regulations should be further revised to require institutions, at a minimum, to adopt some type of policy on institutional conflict of interest, even if the scope and elements of the policy remain undefined in the federal regulations. ASN supports NIH’s proposal to require institutions, at a minimum, to adopt some type of policy on institutional conflict of interest related to the patents the institution holds. However, the society believes NIH should offer a template or guidance on the minimum standards the Institute would like to see adopted. Again, this will promote a uniform and level playing field across institutions.

On behalf of the ASN, thank you for your willingness to consider our comments on RIN 0925-AA53. Our members are committed to cutting edge research and dedicated to objectivity and transparency in all these efforts. We believe that our recommendations in this letter will prove helpful in establishing uniform standards and processes with which to promote transparency and public trust in our nation's research institutes. However, the society urges NIH to be mindful that a final rule balance vigilance in assessing potential conflicts of interest with the danger of stifling future innovation by adopting a policy under which researchers with ties to industry are viewed with undue suspicion. The relationship between the research and industry communities is vital to the development and distribution of future effective new therapies. This important role should be reflected in any final rule.

The society would be pleased to discuss these comments and recommendations with NIH. If it would be helpful, please contact ASN Director of Policy and Public Affairs, Paul C. Smedberg, at (202) 416-0640 or at psmedberg@asn-online.org.

Sincerely,

A handwritten signature in black ink, appearing to read "Sharon Anderson". The signature is fluid and cursive, with a large, sweeping flourish at the end.

Sharon Anderson, MD, FASN
President