



AMERICAN SOCIETY OF HEMATOLOGY

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RE: Department of Health and Human Services RIN 0925-AA53, Docket
Number NIH-2010-001

Dear Mr. Moore:

The American Society of Hematology (ASH) appreciates this opportunity to respond to the Department of Health and Human Services proposed revisions to the regulations on "Responsibility of Applicants for Promoting Objectivity in Research for Which Public Health Service Funding Is Sought and Responsible Prospective Contractors" (RIN 0925-AA53, Docket Number NIH-2010-001). The Society fully supports efforts at federal research agencies to craft and enforce regulations that manage significant financial conflicts of interest and that require the National Institutes of Health's (NIH's) efforts to promote objectivity and transparency in federally funded research and the Society supports the general principles contained in the proposed revisions to the current regulation.

ASH represents over 16,000 clinicians and scientists committed to the study and treatment of blood and blood-related diseases. These areas include anemia (including sickle cell and thalassemia), thrombosis (including venous thrombosis, heart attack and stroke), bleeding disorders, transfusion medicine, and gene therapy, as well as the malignant hematologic leukemia, lymphoma, and myeloma. In addition, hematologists have been pioneers in the fields of bone marrow transplantation and stem cell research. Hematology research has been a pathway for new avenues of inquiry and has actually spawned entire new disciplines. ASH members are active participants in NIH programs, recipients of NIH grants from multiple institutes, and contributors to NIH's research accomplishments.

The Society strongly believes that the integrity of the scientific research conducted through NIH and the other Public Health Service (PHS) agencies depends on the avoidance of bias arising from conflicts of interest (COI), or from the appearance of such conflicts, by the individuals involved with those activities. Personal financial considerations must never be allowed to cloud scientists' decisions on proper conduct of biomedical research.

ASH is dedicated to advancing the specialty of hematology. To accomplish this mission, the Society provides support for a variety of activities in the areas of research, education, training, and advocacy. The integrity of ASH and the activities it undertakes depends on the avoidance of conflicts of interest, or even the appearance of conflicts, by the individuals involved with those activities. Consequently, the Society has implemented strong policies to identify, disclose, and manage COI.

The most important aspect of any COI policy is, of course, the identification and disclosure of conflicts. Within the Society's own COI policy, ASH believes that a conflict of interest exists when an individual has material interests, regardless of value or dollar amount, outside of ASH that could influence or could be perceived as influencing his/her decisions, actions, or presentations. These interests, which include employment, consultancy, equity, research funding, honoraria, patents and royalties, speakers bureau involvement, advisory committee or board of directors membership, expert testimony, and financial support for the costs of travel to the ASH annual meeting, are relevant if they occurred in the past 24 months for the volunteer, partner, or spouse. Conflicts of commercial interest may involve either an agent or device as the subject in question or an agent or device that might be in competition with the subject in question. Although NIH's proposed revisions are not as expansive as the requirements of ASH's COI policy, the Society supports NIH's efforts to broaden the significant financial interests that must be disclosed by investigators by lowering the threshold for interests that must be disclosed from \$10,000 to \$5,000.

Additionally, ASH believes that any policy concerning conflicts of interest must also strive to manage the real and potential conflicts of interest. A core principle of ASH's COI disclosure policy is the creation of an atmosphere where people are comfortable asking questions relating to conflict of interest without feeling awkward or accusatorial and where recusing one's self from participation in discussions that might be perceived as constituting a conflict is the norm rather than the exception. The Society also believes that the mere existence of a conflict should not necessarily preclude participation in an activity and the Society supports the proposed provision requiring institutions to manage investigators' conflicts. Requiring institutions to develop and implement plans that specify the actions that shall be taken to manage COI will mean that investigators are not automatically disqualified from participating in an activity based solely on an identified COI. This will help to ensure that the best and most appropriate people are able to participate in research activities.

However, there are certain aspects of the proposed rule that concern the Society. First, the proposal to make all significant financial interests available on publicly accessible websites could result in a breach of privacy for the individual and also an undue burden on the university system. As a specific example, posting the investigator's particular financial interests, such as contracts with industry or consultancy agreements, where anybody can view and potentially use this information could disrupt these relationships and cause unneeded and undue harm to the investigator. In addition, given the absence of any direct evidence that making the information publicly available will be more effective at "solving" the COI "problem," ASH is also concerned about the potential for increased administrative burdens and added costs. Finally, the proposed rule appears to have no tolerance for any real or perceived conflicts. The Society believes it is

important to recognize that success in translating basic discoveries into clinical practice, in fact, requires effective collaborations between NIH-funded investigators and industry. Therefore, while strongly supporting disclosure, ASH urges the NIH to reconsider this proposal and require that financial information be made only available to the NIH and not posted to a public website.

ASH strongly believes that any COI policy must incorporate the transparent disclosure and management of relationships, include restrictions on financial interests for those in decision-making positions, and institute clear and fair protective measures to ensure the integrity of science and research as well as public trust. Such a policy must seek to balance increased transparency in the research process while not placing any undue burdens on investigators that may impede scientific discovery. By proposing to broaden the applicability of the current regulations, expanding and clarifying the definition of a significant financial interest, increasing disclosure and reporting requirements, and making this information publicly available, the Society believes NIH is seeking to achieve these goals in a manner consistent with ASH's COI policy.

Again, ASH appreciates the opportunity to provide feedback on the proposed revisions and share the Society's support of and concerns with several initiatives contained in the proposed revisions. Please contact ASH Research Advocacy Manager Tracy Roades at 202-776-0544 or troades@hematology.org if you have any questions or require any additional information.

Sincerely,

A handwritten signature in black ink that reads "Hal E. Broxmeyer". The signature is written in a cursive, flowing style.

Hal E. Broxmeyer, PhD
President