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September 15, 2005

BY ELECTRONIC MAIL: ephillip@omb.eop.gov

Beth Phillips
Office of Federal Financial Management
Office of Management and Budget
Executive Office of the President
725 17th Street, NW
Washington, DC 20503

Re: Request for Information Relating to Research Awards, 70 FR 41220-22

Dear Ms. Phillips:

I appreciate this opportunity to respond on behalf of the Association of American Medical Colleges (AAMC) to the request by the Office of Science and Technology Policy and the Office of Management and Budget for information relating to federal research awards with multiple principal investigators (PIs). The AAMC represents the nation's 126 accredited medical schools, over 400 affiliated teaching hospitals, and 94 academic medical societies comprising nearly 109,000 faculty members. Our member institutions perform more than half of the extramural research sponsored by NIH, and more than 70 percent of NIH research sponsored at academic institutions.

In general, as indicated by our responses below to the specific questions requested in the July 18 *Federal Register* notice, the AAMC strongly supports the recognition of multiple PIs on federal research awards, as directed to research agency heads by OSTP Director Dr. John Marburger on January 4, 2005. However, AAMC conditions its endorsement on the government's clear definition of "principal investigator" such that the well settled meaning of that term is not in any way degraded. We have expressed the identical conditional support in our comments to the National Institutes of Health.

Questions from the *Federal Register*:

Q1: Are there any difficulties associated by listing more than one individual as a PI?

We support the definition of *principal investigator* implicit in the statement of the notice and urge that it be made explicit:

The expectation is that a proposing institution will name as PIs in its proposal those individuals who share the major authority and responsibility for leading and directing the project, *intellectually and logistically*. This concept is similar to the widely accepted practice of recognizing the contributions and responsibilities of business partners [emphasis added].

In supporting this proposal, which we believe is necessary to foster continued growth in important multidisciplinary research, particularly in the life and biomedical sciences, the AAMC is concerned to see that the implementation of this policy does not diminish the value and irreplaceable role of project leadership.

The AAMC expects that institutions will, of course, need to adapt some record keeping and management operations to accommodate multiple PIs. Prior to receipt of an award, institutions will need to work with faculty on crafting agreements concerning the appropriate allocation formulae for resources on the project, and a detailed leadership plan to determine future allocations. However, such efforts are already undertaken in the development of many large, complex research projects, and should not hinder the efficient operation of the research team. The AAMC believes that the benefits of recognizing multiple PIs outweigh the initial administrative burdens that will be encountered.

Q2: Are there any difficulties that would be created by the designation of one PI as the Contact PI? Are there issues that would affect institutions?

We would support the designation of a Project Director as a necessary measure to ensure accountability, both scientific and administrative, for the entire project, as well as to effect efficient and responsive communication between the research team and a funding agency. This measure would be somewhat analogous to the designation of a corresponding author on research publications.

The designation of a Project Director is essential to ensure compliance and assurance, for example, on issues involving the protection of human and animal subjects. We believe that institutions are capable of making such designations and appropriately assuring accountability, and should be permitted to do so without excessive prescription from the funding agency. As necessary, requirements should be interpreted or re-evaluated by the federal agencies that enforce regulations and support research to provide necessary flexibility in the assignment of key compliance obligations among multiple PI's.

We expect that many institutions and researchers will favor a designation of a Project Director or other individual to take responsibility for management and regulatory compliance, similar to the

role currently played by lead investigators on large NIH “research program projects” (such as “P01” awards, in NIH parlance).

Q3: What issues should the agencies consider in developing their instructions for applications naming more than one PI?

As noted above, the AAMC expects institutions will work with research teams to identify the Project Director and approve comprehensive management plans and formulae for allocation of resources and assignment of responsibilities, but we do not believe that the funding agencies themselves need to be excessively specific in requirements for such plans. Rather, we believe that the funding agencies should be flexible in their requirements and instructions. We do not support the designation “Contact PI,” since that connotes a set of administrative and clerical responsibilities and fails to recognize the essentiality of a designated Project Director.

Because roles and contributions change in both anticipated and unanticipated ways during the course of a multi-year award, AAMC feels that apportionment of funds should be specified on the notice of grant award and revised with each subsequent yearly award. AAMC recommends that these budget apportionments be added to agency databases that track research awards (currently, this is not provided by the NIH’s central database, Computer Retrieval of Information on Scientific Projects (CRISP), but are publicly available by PI name in the State and Foreign Site Award database.

Q4: Recognizing that agencies differ in the structure of their business arrangements with institutions, are there ways for the agencies to recognize PIs for a team effort involving multiple departments or institutions? What issues should the agencies consider in deciding on the most appropriate award structure?

The AAMC believes that offering linked awards in the case of multiple PIs located across multiple institutions is at least as important, and arguably more important, than the apportioning of the budget among PIs in a single institutional award. Linked awards would result not only in fairer crediting for the PIs, but for their institutions as well. Instead of receiving the award as a subcontract from another institution, the award would be received from the NIH or other federal agency, and the institution would receive credit in the awards database. Again, AAMC expects that allocation and leadership plans will be forged prior to the receipt of award and will not hinder effective project management. Lastly, AAMC would like to recognize that there are many instances where a consortium or sub-contract arrangement will continue to be appropriate for certain projects, namely those cases where the secondary institution does not house a Principal Investigator and makes a more limited scientific contribution.

Q5: What are the benefits of granting access to award and review information to all named PIs, not just the Contact PI? What are the difficulties, if any, in granting such access?

Granting access to award and review information to all named PIs will better support the coordination and leadership of multidisciplinary research teams, which is one of the objectives of the policy.

Q6a: What are the benefits, if any, from listing more than one PI in agency databases? What are the difficulties, if any with such listings?

Recognition of all named PIs in agency databases will strengthen recognition of all individuals who meet the stringent definition noted earlier. It is hoped that such recognition will create further incentives for the team research demanded by complex science

Q 6b: Would use of agency data systems with PI information, warrant an investment in alterations of such systems?

Absolutely

Q7. Overall, how will the changes proposed for official recognition of multiple PIs benefit multi-disciplinary and inter-disciplinary research? Would the proposed changes help or harm the process of cooperation among researchers on a collaborative project?

Modern biomedical research, with which we are most familiar, is rarely an independent activity. Multidisciplinary studies and complex science necessitate the intellectual leadership and contributions of research team members. This is particularly true for clinical research, which requires a broad variety of specialists with many highly specialized skills. We believe the proposed changes would increase opportunities for recognition of team leadership, and increase the incidence of collaboration.

Q8: What other suggestions do you have for facilitating the recognition of multiple PIs?

In its comments to NIH on recognition of multiple PIs, the AAMC strongly endorsed the proposal that agencies' databases track apportionment of research project budgets and resources to the leaders of the project team (in the instance of NIH, this would include the Agency's "CRISP" project awards and financial databases).

In closing, the AAMC would like to emphasize again, as I did in a letter several years ago,¹ our appreciation for the Research Business Models subcommittee, the National Science and Technology Council, and the Administration in pursuing such useful and welcome reforms. The policies and systems established for the Federal Government's support of university-based, independent scientific research are among the most significant and successful achievements of

¹ Letter to Dr. Michael Holland, OSTP from Jordan Cohen, responding to a request for information for the Research Business Models Subcommittee of the NSTC, October 2, 2003.

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American public policy in the 20th Century, and it is incumbent on government and universities alike to help strengthen and adapt these policies to the continuing advancement of science.

Sincerely,

A handwritten signature in black ink, appearing to read "Jordan J. Cohen". The signature is written in a cursive style with a large initial "J" and "C".

Jordan J. Cohen, M.D.
President