



Association of
American Medical Colleges
2450 N Street, N.W., Washington, D.C. 20037-1127
T 202 828 0460 F 202 862 6161
www.aamc.org

Darrell G. Kirch, M.D.
President

August 15, 2007

Jerry Moore
NIH Regulations Officer
Office of Management Assessment
National Institutes of Health
6011 Executive Blvd, Suite 601 MSC 7669
Rockville, MD 20892

By email:
Ref. RIN 0925-AA42

Re: Notice of Proposed Rulemaking, Grants for Research Projects, 72 FR 34655-7

Dear Mr. Moore:

The Association of American Medical Colleges (AAMC) is grateful for this opportunity to comment on the notice of proposed rulemaking (NPRM) published in the Federal Register on June 25 relating to the definition of *principal investigator* on research project grants and a provision to permit multiple awards from a single application. The AAMC represents all 125 U.S. allopathic medical schools, nearly 400 teaching hospitals, and 89 academic societies comprising about 109,000 faculty. Our members have a clear interest in the proposed rulemaking.

The NPRM would revise the definition of *principal investigator* in 42 CFR Section 52, governing research project grants within the Public Health Service. The current definition (Section 52.2) provides that:

Principal investigator means a single individual designated by the grantee in the grant application and approved by the Secretary, who is responsible for the scientific and technical direction of the project.¹

The revised definition proposed in the NPRM reflects new federal policies promulgated in 2005 by the Office of Science and Technology Policy (OSTP), the National Institutes of Health, and other science agencies to recognize multiple principal investigators on PHS and other federal research grants. The new definition would provide that:

Principal investigator means the individual(s) judged by the applicant organization to have the appropriate level of authority and responsibility to direct the project or program

¹ http://www.access.gpo.gov/nara/cfr/waisidx_06/42cfr52_06.html, accessed Aug. 6, 2007.

supported by the grant and who is or are responsible for the scientific and technical direction of the project.

The AAMC supports the proposed revision. In comments to the NIH and jointly to the OSTP and the Office of Management and Budget in 2005,² the Association endorsed recognition of multiple-PIs on NIH and other PHS research grants, substantially agreeing with the rationale that many new, promising areas for medical advancement depend on multi- or interdisciplinary research, or otherwise depend on large research teams with complex structures and organization.³ Recognition of multiple-PIs would facilitate such research.

However, our comments also stressed AAMC's concerns that new policies not lead to a diminution of the role and responsibilities of the principal investigators. This apprehension was later amplified at a meeting in October 2005 with the AAMC's external Advisory Panel on Research (APR), a panel consisting of eminently accomplished scientists and academic leaders from across the nation. While the APR agreed with arguments supporting the designation of multiple-PIs for many types of research projects, the panel also argued that there needs to be countervailing emphasis from academic institutions, NIH, and the scientific community on the unique importance of the principal investigator in ensuring leadership and accountability, in respect to both the science and the administration of research projects, distinct from the many other vital roles played by other members of a research team. In the absence of such emphasis, "principal" investigators could proliferate in ways that actually would be counterproductive and even injurious to the goals of strengthening collaborative research.

The NPRM's new definition recognizing multiple PIs stipulates that such individuals must have an appropriate level of authority and responsibility, and that the organization submitting the grant proposal is ultimately accountable for determining such qualifications. The language in the proposed definition is necessarily terse, but we think sufficient. The preamble to the NPRM reinforces this interpretation:

While this rule would permit the applicant organization to designate multiple individuals as Principal Investigators who share the authority and responsibility for leading and directing the projects, intellectually and logistically, each Principal Investigator is responsible and accountable to the applicant organization (or, as appropriate, to the collaborating organization), for the proper conduct of the project or program...In other words, the presence of more than one identified Principal Investigator on an application or award *diminishes neither the responsibility nor the accountability* of any individual Principal Investigator (emphasis added).

² See: <http://www.aamc.org/advocacy/library/research/corres/2005/091505.pdf>, accessed Aug. 6, 2007.

³ NB: Many important, promising new areas of research also fall within the boundaries of established disciplines, and are pursued by research teams of more traditional size and structure. We believe that NIH and the research community must be careful never to give a contrary impression.

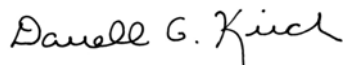
In supporting this proposed change in definition, the AAMC again urges NIH to expand its CRISP database (and other information systems as appropriate) to report the names of *co-investigators* for all research projects. Their inclusion would help faculty and other investigators document their record of contribution to sponsored research projects and programs, and thereby assist institutions in their evaluation of recommendations for promotion and career advancement. Such listing in NIH records may help to mitigate undesirable pressure from some research team members and, particularly, collaborators to be included as principal investigators on grant applications. Far more importantly, such modification of CRISP would assist the career advancement of many junior investigators and, we believe, physician scientists working in large team-research projects. For this reason, listing of co-investigators in CRISP was a specific recommendation of the AAMC's Task Force II on Clinical Research.⁴

A second provision in the NPRM would revise 42 CFR Sec. 52.6 to grant the Secretary authority to "evaluate, approve, or make" multiple awards pursuant to a single application. The preamble states that, "In some cases...it may be desirable to disaggregate a single application to make more than one award," and provides hypothetical examples of projects that might be more effectively managed if divided among multiple awards.

Unfortunately, the preamble does not convey a compelling argument for this change. Presumably, the organizations submitting the project application fully appreciate the management implications, at least locally or among the collaborating institutions. Disaggregation of a single proposed application into several awards might disrupt careful planning or negotiations by the submitting organization(s). The AAMC in its earlier comments on multiple PIs supported, for example, the use of linked awards to facilitate NIH management of large projects, but linked awards are not discussed as an option in the NPRM. The Association therefore respectfully requests that more information and a further opportunity to comment on this provision of the NPRM be provided before it is finalized.

For further information or clarification of these comments, please contact Howard Dickler, M.D., Director for Clinical Research at hdickler@aamc.org or 202-828-0567.

Sincerely,


Darrell G. Kirch, M.D.

⁴AAMC, Task Force II on Clinical Research. *Promoting Translational and Clinical Science*. AAMC: Washington, D.C., 2006. www.aamc.org/promotingclinicalscience.