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Establishment of Multiple Principal Investigator Awards

Author: Anthony P. DeCrappeo

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1200 New York Avenue, N.W., Suite 320, Washington, D.C. 20005
(202) 289-6655/(202) 289-6698 (FAX)

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April 17, 2006

Walter T. Schaffer
Senior Scientific Advisor for Extramural Research
Office of Extramural Research
National Institutes of Health
Shannon Building
1 Center Drive, Room 250
MSC 154
Bethesda MD 20892-0154

Subject: Establishment of Multiple Principal Investigator Awards

Dear Dr. Schaffer:

The recently announced National Institutes of Health's implementation of multiple principal investigator (PI) option to support team science is an appropriately measured and thoughtful approach to an important subject. The Council on Governmental Relations (COGR) and its 170 member research universities, affiliated hospitals and research institutes in the United States welcome key features of the NIH's policy as critical tools to aid research institutions in the support of team science. The posted Frequently Asked Questions (FAQ) identified areas that remain under discussion and consideration and invited consultation with the research community. We intend by this letter to continue those discussions.

At the outset, we want to congratulate NIH on the expansion of access and information available in eRA Commons and Computer Retrieval of Information of Scientific Projects (CRISP). As we pointed out in our comment on NIH's proposal, it is the single most important step NIH can take to ensure that appropriate recognition and credit is given to all investigators. The eCommons access will assist the members of the scientific team to access the information they need to assume the shared responsibility for the project. The additional information on CRISP will aid the institutions in documenting and assigning scientific credit to all investigators.

We acknowledge NIH's call for institutional responsibility to accurately assess PIs contributions to scientific knowledge irrespective of levels of external funding. In order to meet this challenge, we urge NIH to include the names of "key personnel" on single-investigator awards in CRISP as well. Key personnel, by NIH's definition, "contribute to the scientific development or execution of a project in a substantive, measurable way."

Thus, these key scientific team members should appear in CRISP to assist institutions in crediting their intellectual contributions.

Policy Overview and FAQ

It would help investigators if the Overview on the Multiple Principal Investigator web site included a definition of “principal investigator” that organizes in one place the shared roles and responsibilities of named PIs. Investigators must understand that as a named PI each shares equally the responsibility for and is accountable to NIH for the scientific and technical direction of the project as a whole including responsibility for the proper conduct of the research including submitting reports no matter the level of effort committed to the project. The emphasis on shared responsibility for the entire project is scattered throughout the Frequently Asked Questions (FAQ) making it difficult to get an overall understanding of the implications of choosing the Multiple PI model.

In general, we recommend additions to the Overview to alleviate this reliance on the FAQ for details of the policy. As a consequence, we want to outline our understanding of selected elements.

- The multiple PI model supplements the traditional single PI model.
- If available as an option for a particular program, the selection of the model to be used is a local decision based on scientific need and the nature of the research proposed.
- There can be as few as two and no maximum limit on the number of PIs participating in a project.
- The use of this model (beyond the pilot in May/June/October 2006) will depend on the development of Grants.gov.
- All multiple PI applications will require a Leadership Plan no matter the number of PIs involved.
- A contact PI must be designated and that designation can change during the life of a project.
- The allocation of funds to individuals within a single institution is NOT required but permitted and the exercise of the option to allocate funds is a JOINT decision by the PIs and institution.

We recommend NIH clarify the FAQ if we have misunderstood any of these elements.

Allocation and Reallocation of Funds

We understand the question of the allocation of funds remains under discussion. The use of a “soft” allocation at the institution’s request during the pilot is a reasonable approach in the case of a single institutional applicant. If NIH contemplates a more formal allocation process, any such formal allocation must be only at the request of the grantee institution. In either case, we are concerned how auditors and agency investigators will assess the allocation approach if funds are reallocated during the project. It will be critical that NIH make it clear to the audit community that institutions have the freedom and authority to reallocate.

In addressing reallocation of funds among linked awards, we are concerned with the reallocation process. We understand the statement in Question H.6. to mean that if linked institutions wish to reallocate funds among themselves, a modification would occur during the annual progress reporting process. The reallocation would be reflected in the Notices of Grant Award to all the linked institutions for that budget period. H.6. goes on to note that any variance in F&A rates resulting from the reallocation will be absorbed by the total project costs identified in the original Notices of Award. If this is an accurate understanding, we fear this approach will serve to discourage reasonable reallocations for

scientific purposes. If each linked award is a separate award and direct costs are reallocated among the participating institutions, we believe NIH should provide the F&A costs reflected in the NGA at the negotiated rate for the particular institution. This approach would be consistent with NIH's current practice.

Question G.2. notes that reallocations of funds and changes in the Leadership Plan are joint decisions of the PIs. We would recommend a modification of the response to Question G.2 to note such reallocations and changes are a joint decision of the PIs and the institution.

Leadership Plan

As we argued in our original comment, a leadership plan for a two-member team seems to beg the question. We agree that mapping out the leadership questions – intellectual contribution; allocation of funds, etc. – for a team of ≥ 3 members at the outset will ensure a smoother operation. However, we suspect a Leadership Plan for groups of ≤ 3 is not as useful an exercise.

We strongly urge NIH to reconsider the designation of a “contact PI.” At a minimum, NIH should evaluate the approach during its pilot period. The responsibilities serve as a disincentive for anyone considering the role. The responsibilities for constructing and submitting the annual progress reports might naturally fall to the contact. The proposed approaches – a single overall and, in the case of linked awards, appended individual institutional reports – will be a burdensome task. Permitting the designation of contact PI to rotate among the investigators clearly undermines NIH’s goal for streamlined communications. We appreciate NIH’s need for clear communications but we fear this isn’t the solution.

Peer Review Process

The role of the peer review panels in assessing the merit of a proposal for support will have a significant impact on the success of NIH’s multiple PI initiative. Because of the critical role of the peer review panels, we believe NIUH should use the pilot period as an opportunity to monitor and evaluate the impact of peer review on the success of multiple PI projects. Two areas of review are of particular concern: the leadership plan and the selection of a model.

Leadership Plan Review

Some areas are particularly vulnerable to individual and collective judgments. We understand the quality of the leadership plan will be reviewed and evaluated during the peer review process. A broad the range of issues will be covered in a Leadership Plan for the project management – roles & responsibilities; decision-making process; allocation of resources; publications; intellectual property issues, etc.. The approach chosen will likely reflect, in part, the unique decision-making structures within the institution. It is possible that members of a review panel may take issue with a particular element that reflects the unique institutional environment, e.g., appeal of a conflict to a dean. Will this type of questions lower the proposal’s score? Will the elements of the Leadership Plan be part of the negotiation of an award or is the project rejected?

Selection of Model

We support the decision to offer, as opposed to require, a multiple PI model in selected programs. We agree that the nature of the scientific questions to be addressed should help the investigators determine which model they choose to implement. Is it possible that the peer review panel would endorse the project but reject the use of the multiple PI approach? If the multiple PI model is offered, some investigators may see that as a signal from the Institute/Center and feel compelled to adopt the approach. Thus, electing to use a multiple PI approach that is not clearly and convincingly argued puts an otherwise scientifically worthy project at risk. Can review panels lower the score of a proposal for using a single PI with

consultants, collaborators and service providers because the panel believes it should have been a multiple PI model application?

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A evaluation or assessment of how the decision to use or not use a multiple PI model affects the review of the proposal and, if necessary, steps NIH is taking to ensure fair and equitable review will give applicants greater confidence to pursue a team approach.

We recognize that Question E.5. offers the assurance that applications will be considered on their merit and panelists are not to advise on or redesign projects. We hope this includes aspects of the leadership plan and the selection of a model

Progress Reports

In addressing progress reporting, NIH is considering a single overall progress report from a single institution and a overall report with individual reports from each institution for linked multiple PI award. If a single award has been made, a single report is the most appropriate requirement. Linked award are separate awards to each institution pursuing a single project. In this case, a separate report from each participating institution is appropriate.

Departmental Ranking Tables

We continue to believe the Departmental Ranking Tables are out-of-date and fail to provide an accurate portrait of activity in a particular sub-discipline or institution. We urge time and resources to be spent developing the search and reporting capacity of CRISP to allow individuals and departments to organize data on awards in the manner that best meets their needs.

We appreciate NIH's commitment to continuing to discuss the development and implementation of its Multiple Principal Investigator Award policy.

Sincerely

Anthony P. DeCrappeo
President

Cc: Norka Ruiz Bravo