



## OFFICE OF SPONSORED PROGRAMS

Charles R. Drew University of Medicine and Science

### Guidance on Establishment of Multiple Principal Investigator Awards for the Support of Team Science Projects

#### **Description:**

NIH has announced the Establishment of Multiple Principal Investigators (PI) Awards for the Support of Team Science Project. The announcement is posted to the NIH Multiple PI website at: [http://grants.nih.gov/grants/multi\\_pi/index.htm](http://grants.nih.gov/grants/multi_pi/index.htm) . The Multiple PI policy allows investigators to choose either a single or multiple PI approach for virtually all NIH programs. Key features and aspects of the policy include: multiple PIs share responsibility and authority for the project; all PIs will be listed in the summary statement, Notice of Award, and listed in CRISP. All PIs have access to status information through eRA Commons. The first PI listed must be affiliated with the applicant institution and will serve as the contact for NIH.

#### **Implementation of the Multiple Principal Investigator Policy:**

Beginning with applications submitted in February 2007, the Multiple PI option will be extended to most research grant applications submitted electronically through Grants.gov when they transition to an electronic format. Some paper applications submitted on PHS 398 application forms also will allow inclusion of more than one PI, but only when the multiple PI option is clearly specified in the soliciting Request for Applications or Program Announcement. Grant applications that will accommodate more than one PI beginning in February will include the R01, R03, and R21. Grant mechanisms that **will not** accommodate more than a single PI include individual career K awards, individual fellowships (Fs), Director's Pioneer Awards (DP1), Construction Grants, and Shared Instrumentation Grants.

#### **Decision to Use the Multiple PI Option:**

The decision to apply for a single PI/PD or multiple PI/PD grant is the responsibility of the investigators and the applicant organization and should be determined by the scientific goals of the project. It is important to note that NIH expects the availability of the Multiple PI option to encourage interdisciplinary and other team science approaches to biomedical research. When considering multiple PI/PDs, please be aware that the organizational structure and governance of the PI/PD leadership team as well as the knowledge, skills and experience of the individual PI/PDs will be factored into the assessment of the overall scientific merit of the application.

#### **Multiple PI/PD Leadership Plan:**

Multiple PI/PDs on a project share the authority and responsibility for leading and directing the project, intellectually and logistically. For applications designating multiple PI/PDs, a new section of the research plan, entitled "Multiple PI/PD Leadership Plan" must be included. A rationale for choosing a multiple PD/PI approach should be described. The governance and organizational structure of the leadership team and the research project should be described, including

communication plans, process for making decisions on scientific direction, and procedures for resolving conflicts. The roles and administrative, technical, and scientific responsibilities for the project or program should be delineated for the PI/PDs and other collaborators. If budget allocation is planned, the distribution of resources to specific components of the project or the individual PI/PDs must be delineated in the Leadership Plan. In the event of an award, the requested allocation may be reflected in a footnote on the Notice of Grant Award.

**Findings from the NIH Multiple PI Pilot** *(caution should be exercised in the option to use multiple PIs):*

NIH and the reviewers emphasize that the choice of the model should be driven by the nature of the science. The Leadership Plan should include a rationale for the choice of the multiple PI approach in addition to a description of the governance and organization of the team of scientists. Investigators should be included because the nature of the scientific question makes it necessary to bring the team together and the Plan should describe how each member functions on the project to achieve the scientific goals. Because the foundation for the multiple PI option is a shared responsibility and accountability for the project, the assumption underlining the approach is a collaboration of equals. This assumption is reinforced by the relationship between this policy and the New Investigator policy. The New Investigator provisions will apply to multiple PI awards only when all PIs involved in the project can be classified as "new."

During the Pilot, peer reviewers expressed the following reservations about applications that included teams of scientists:

- In some cases, applications described projects that included PIs that did not have an identified function within the leadership team based on their expertise and the nature of the project.
- In some cases applications identified PIs who seemed too junior to function in a leadership role and in other cases it appeared that senior PIs were included in what might be a considered a "courtesy role".
- In other cases, it appeared that the leadership team had been expanded only to justify additional salary support for involved personnel.

According to NIH, "Inclusion of a "weak" or inappropriate PI will reflect negatively on both the 'Approach' and the Investigators' review criteria".

**Criteria for using the Multiple PI/PD Option:**

The multiple PD/PI option will be exercised for applications in which an interdisciplinary "team science" approach will best achieve the aims of the research. Each PD/PI is scientifically considered equal for merit in achieving the project outcome. For all Charles Drew University applications that propose the Multiple PD/PI option, the following criteria must be met prior to submission:

- All proposed PIs must have PI status as defined in the Charles Drew University's Policy and Procedures or from their home institution.
- Each identified PD/PI must complete and sign a separate Request for Proposal Approval and Submission (RPAS) form.

- The Multiple PI/PD Leadership Plan must be included in the proposal sent to Office of Sponsored Programs. The grants management staff will review the plan to determine whether the planned multiple PD/PI submission is consistent with agency and University requirements.
- If separate budget allocations are desired for each PI/PD, discrete internal budgets for each PD/PI will be required with the application materials. These budgets will not be sent to NIH, but the amounts should be reflected in the portion of the Multiple PI/PD Leadership Plan addressing resource allocation. If awarded, the funds will be allocated into separate accounts for each PI.

The first PI/PD named in the proposal (typically on the application face page) will be the designated Contact PI/PD. Review of the proposal and signature approval by the appropriate department head(s) for each PI must be secured prior to submission. Each multiple PI/PD has equal responsibility for leading and directing the project; each is equally accountable for the proper conduct of the program including fiscal oversight and submission of all required reports. It is important that each department head is aware of the commitments of his/her PIs.

#### Awards Involving More Than One Institution

Awards involving PIs at different institutions will be managed using subawards until options involving linked awards have been developed.

#### New Investigator Policies

- NIH policies related to New Investigators will be applied to applications only when all PIs involved are classified as New Investigators.
- The New Investigator Box on the application may be checked only when all PIs involved are classified as New Investigators.
- For the purpose of classification as a New Investigator, serving as a PI on a multiple PI grant will be equivalent to serving as a PI on a single PI grant.

### **Examples of Project Leadership Plans for Multiple PI Grant Applications**

For Multiple PI applications, a new section for Leadership Plans (PHS 398, Section I) must be included, unless the RFA/PA announcement requests the information be provided in another section. There are no page limitations for Section I. Leadership Plans should address the following administrative processes and PI/PD responsibilities:

- Roles/areas of responsibility of the PIs
- Fiscal and management coordination
- Process for making decisions on scientific direction and allocation of resources
- Data sharing and communication among investigators
- Publication and intellectual property (if needed) policies
- Procedures for resolving conflicts

## Examples of Single Project Leadership Plans

Examples of Leadership Plans for single project applications are provided below. (Applicants should follow any special instructions in the specific RFA/PA to ensure the requested information and format is included.)

### **Example 1 (Same Institution)**

PI#1 and PI#2 will provide oversight of the entire Program and development and implementation of all policies, procedures and processes. In these roles, PI#1 and PI#2 will be responsible for the implementation of the Scientific Agenda, the Leadership Plan and the specific aims and ensure that systems are in place to guarantee institutional compliance with US laws, DHHS and NIH policies including biosafety, human and animal research, data and facilities. Specifically, PI#1 will oversee aim 1 and be responsible for all animal research approvals. PI#2 is responsible for aims 2, 3, and 4 including the implementation of all human subjects' research and approvals. PI#1 will serve as contact PI and will assume fiscal and administrative management including maintaining communication among PI s and key personnel through monthly meetings. He will be responsible for communication with NIH and submission of annual reports. The responsibilities of the contact PI will be rotated to PI #2 in even years of the grant award. Publication authorship will be based on the relative scientific contributions of the PIs and key personnel.

#### *Conflict Resolution*

If a potential conflict develops, the PIs shall meet and attempt to resolve the dispute. If they fail to resolve the dispute, the disagreement shall be referred to an arbitration committee consisting of impartial senior faculty officials. No members of the arbitration committee will be directly involved in the research grant or disagreement.

#### *Change in PI Location*

If a PI moves to a new institution, attempts will be made to transfer the relevant portion of the grant to the new institution. In the event that a PI cannot carry out his/her duties, a new PI will be recruited as a replacement at one of the participating institutions.

### **Example 2 (Different Institutions)**

PI#1 at Institution A will be responsible for the oversight and coordination of project management for aim 1 involving the molecular design and production of vectors expressing tumor specific antigens. PI#2 at Institution B will be responsible for aims 2 and 3 including the in vivo and in vitro testing of vaccines. Each PI will be responsible for his own fiscal and research administration. The PIs will communicate weekly, either by phone, e-mail, or in person, to discuss experimental design, data analysis, and all administrative responsibilities. All PIs will share their respective research results with other PIs, key personnel, and consultants. They will work together to discuss any changes in the direction of the research projects and the reprogramming of funds, if necessary. A publication policy will be established based on the relative scientific contributions of the PIs and key personnel. PI#1 will serve as contact PI and be responsible for submission of progress reports to NIH and all communication.

#### *Intellectual Property*

The Technology Transfer Offices at Institutions A and B will be responsible for preparing and negotiating an agreement for the conduct of the research, including any intellectual property. An

Intellectual Property Committee composed of representatives from each institution that is part of the grant award, will be formed to work together to ensure the intellectual property developed by the PIs is protected according to the policies established in the agreement.

#### *Change in PI Location*

If a PI moves to a new institution, attempts will be made to transfer the relevant portion of the grant to the new institution. In the event that a PI cannot carry out his/her duties, a new PI will be recruited as a replacement at one of the participating institutions.

#### **Example 3 (>2 PI's)**

PI#1, PI#2, and PI#3 will serve as PIs for the project. PI#1 will be responsible for the gene expression studies. He will supervise Technician #1 for all microarrays. PI#2 will be responsible for the endothelial cell studies and flow cytometry studies proposed in the grant. She will supervise the Technician #2 at 50% effort for the flow cytometry studies and the post Doc for the endothelial cell studies. PI#3 will oversee all bioinformatics work in the gene expression and flow cytometry studies and will work with PI#1 and PI#2 on all data analysis. The PIs will form a Steering Committee (membership may include PIs, key personnel, consultants, etc) that will manage the oversight and coordination of project management, research administration, publications and data sharing, and integration of all resources needed for the project. The Institution will subdivide the award funds and each PI will be responsible for his own budget. The Steering Committee will oversee decisions on minor changes in research direction and have the authority to reallocate funds and resources between PIs. PI#1 will serve as Chair of the Steering Committee and be responsible for communication among PIs, including meeting schedules and agendas. The position of Chair will rotate among the PIs on a yearly basis. PI#2 will be designated the contact PI and be responsible for submitting all necessary documents to NIH, including IRB approvals, and annual progress reports.

#### *Intellectual Property*

The PIs will grant necessary access rights to the pre-existing patents and or the patents potentially generated within the frame of this project for the purpose of this research project to all the other PIs and key personnel on a non-exclusive royalty-free basis. Each PI shall take appropriate measures to ensure that he/she can grant these access rights. Right in any pre-existing intellectual property will remain the property of the party that created and/or controls it.

#### *Conflict Resolution*

If a potential conflict develops, the PIs shall meet and attempt to resolve the dispute. If they fail to resolve the dispute, the disagreement shall be referred to an arbitration committee consisting of one impartial senior executive from each PI's institution and a third impartial senior executive mutually agreed upon by both PIs. No members of the arbitration committee will be directly involved in the research grant or disagreement.

#### *Change in PI Location*

If one of the PIs moves to a new institution, attempts will be made to transfer the relevant portion of the grant to the new institution. In the event that a PI cannot carry out his/her duties, a new PI will be recruited as a replacement, subject to the approval of the Steering Committee and the Institution.

## NIH Guidance: Tips for Writing a Strong Multiple PI Leadership Plan

When preparing a multiple PI application, give time and attention to the required Leadership Plan. The following pointers may help you create a sound one.

### General Advice

Here are some general tips to keep in mind as you approach and write your plan.

**Ask questions.** Approach the Leadership Plan as you would the Research Plan. That is, ask yourself and the other PIs some basic questions, such as: Why are we going to the trouble of making this a multi-PI application? How will we organize and execute the overall project? What will we do if we run into problems? What provisions can we make ahead of time against potential pitfalls?

**Do more than what's required.** While good plans address several points required by NIH, e.g., rationale for using the multi-PI approach, governance, conflict resolution, the best plans go a step further. They cover additional ground by discussing potentially sensitive issues, such as data sharing between PIs, collaborative publication policies, contingency plans in case one PI changes institutions, and procedures for allocating resources.

**Get organized.** Just like exemplary Research Plans, the best Leadership Plans are typically organized into succinct sections or paragraphs with informative headings, for example, Rationale, Organizational Structure, and Procedures for Resolving Conflicts.

Dividing into sections and clearly labeling them not only makes for easy reading (which is important for reviewers who have many applications to evaluate), but also lets reviewers follow the applicants' thought processes and find answers to questions they may have.

Since the Leadership Plan has no page limit and does not count toward the Research Strategy page limit, use the lack of space constraints to include what you need and present the information in an easy-to-find way. Do not use this section as a way to circumvent the page limit for the Research Strategy section.

**Avoid pitfalls.** Weaker Leadership Plans tend to suffer pitfalls: poor organization, lack of specifics on roles and responsibilities, omitting critical information like plans for deciding scientific direction or resolving conflicts, and projecting an attitude of “trust us, we've been working together for years.”

Another major pitfall is stating that all PIs will take joint responsibility for everything—finances, project direction, and necessary scientific expertise. Reviewers know that even the closest collaborations can run into problems and that there will be times when PIs do not agree. Therefore, reviewers will appreciate a sensible division of responsibilities much more than a frequently implemented conflict resolution procedure.

Plans with faults like these may sometimes pass scrutiny by reviewers, but you don't want to take a chance on undermining their confidence in your application by simply recycling a plan from another application.

### Know What Reviewers Want, Like, and Expect

As noted in [Multiple PI Facts](#), you must cover several required bases in your Leadership Plan.

We focus on a few of those here and provide advice on how you might address them based on what reviewers expect to see.

### **Why Multiple PIs?**

Reviewers like to see a solid, scientifically based answer to this question. Since the multiple PI option is for collaborative, usually multidisciplinary, research, they must understand why your proposed research requires bringing in and working with other PIs with distinct and complementary expertise.

In the absence of a clear scientific rationale, reviewers will likely question why you wouldn't be able to complete the research without the other PIs.

**What to do.** Provide a strong rationale and justification for choosing the multiple PI approach. For instance, describe why the Specific Aims of the project could not be accomplished without the combined leadership and expertise of all the PIs.

### **Who Will Do What?**

Reviewers expect to see Leadership Plans that clearly and specifically delineate the PIs' respective roles and responsibilities. Those that do may receive more favorable evaluations than those that don't.

**What to do.** We touched on this above, but it's worth repeating. Rather than stating that the PIs will share all responsibilities equally, which reviewers usually view as unrealistic, describe specific "assignments": PI #1 will be responsible for Specific Aim #1 and be responsible for doing X, PI #2 will work on Specific Aim #2 and be in charge of Y, and so on.

Also, be sure to say who will serve as contact PI, the person who will coordinate 1) communication among all PIs and NIH and 2) the progress report.

### **Organizational Structure**

Reviewers look for a sound organizational and governance plan. In the absence of one, they'll be concerned that the level of coordination and communication among the PIs might be insufficient to fully realize the collaborative aspects of the project.

In instances where a multiple PI application includes an established researcher and a more junior investigator, reviewers will look for and carefully evaluate the time commitment and plans for decision making and resource allocation to determine whether they are appropriate and equitable. Keep in mind that while the level of effort of each PI on a multi-PI application does not have to be the same (whether established or junior), it does need to be appropriate and justified for the work proposed.

**What to do.** In your governance plan, describe the process for deciding scientific direction and communication procedures, for example, regularly scheduled meetings of the PIs, periodic evaluation of research progress and finances, and publication policies.

### **Conflict Resolution**

Reviewers like to see a carefully considered conflict resolution plan, which preferably includes the involvement of well-respected people outside of the project to mediate disputes if the PIs are unable to resolve the issues by themselves.

**What to do.** Disputes are likely to arise, so you'll need to describe how you'll handle them. If you can't come to an agreement, will you bring in an arbitration committee? If so, who and how many will be on it? Will you give a timeframe in which the conflict must be resolved?

## Related Links

- [Strategy for NIH Funding](#)
  - [Should You Consider a Multiple PI Application?](#)
  - [Team Science](#)
  - [Note for Multiple PI Applications](#)