

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 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 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 (i.e., R01, R21, etc) 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

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.

Example 2

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 intellectually property developed by the PIs is protected according to the policies established in the agreement.

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 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

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 appropriate Departmental administrators representing the PIs shall meet and attempt in good faith to settle any dispute, claim or controversy arising out of or relating to the interpretation, performance or breach of this disagreement. However, if the Departmental administrators fail to resolve the disagreement within thirty business days, then such disagreement shall be referred for resolution to a designated senior executive of the parties who has the authority to settle the disagreement but who is not directly involved in the 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.