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Multiple PI Guidance on NIH and AHRQ Applications

Effective February 5, 2007, the National Institutes of Health (NIH) began to allow grant applications with multiple PIs on grant mechanisms utilizing the SF 424 submission packet. NIH's web-page devoted to this policy may be accessed <u>here</u>. The Agency for Healthcare Research and Quality (AHRQ) accepted this policy effective with new applications submitted on or after October 1, 2016 (<u>NOT-HS-16-018</u>).

Program Highlights

- Multiple PIs are all primary PIs NIH/AHRQ has never formally recognized a Co-Prinicipal Investigator designation, and this policy will continue. Never use the term Co-Prinicipal Investigator on a NIH/AHRQ grant.
- 2. A substantial level of effort in itself does not qualify an investigator for PI status.
- 3. The PIs must share responsibility for the scientific and technical direction of the project as a whole and will remain accountable to the grantee organization and to the NIH/AHRQ for the proper conduct of the project or activity.
- 4. Inclusion of a "weak" or inappropriate PI will reflect negatively on both the "Approach" and "Investigators" review criteria and make the grant less competitive/less likely to be funded.
- 5. NIH/AHRQ is <u>not</u> requesting separate budgets for each MPI at this time.
- 6. You must designate a contact PI at the institution receiving the award. In other words, if the grant will be awarded to Mount Sinai, the contact PI must be from Mount Sinai. The contact PI is the person who will be allowed to speak to individuals at NIH/AHRQ regarding the grant. No other privileges are conferred.
- 7. A leadership plan is required of all grants proposing mutliple PIs. This plan will be scored. **ISMMS has developed guidance and standard required language to include in the leadership plan of your application.** Please see below.
- 8. NIH/AHRQ and Institutional prior approvals will require all PIs' signatures.

InfoEd Requirements

- 1. Only the Contact PI completes the "Finalize" tab of the InfoEd application. The other PIs do not.
- 2. If there are other PIs at Mount Sinai, they will be prompted to sign off on additional required PI certification language before the InfoEd application is routed to the department(s).

Common Errors

NIH piloted the program over the Fall of 2007 on a limited number of RFAs. The most common errors that they found were:

- 1. 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.
- 2. 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".
- 3. In other cases, it appeared that the leadership team had been expanded only to justify additional salary support for involved personnel.

Please use the multiple PI option judiciously and contact the GCO if you have additional questions or concerns.

Guidance and Standard Required Language for MPI Project Leadership Plan

Roles/Areas of Responsibility of the Principal Investigators (PIs)

PIs' discretion with the following exceptions:

- where human subject or vertebrate animal research are involved , one PI will be the responsible PI of record for the compliance committees; and
- One PI will be the Contact PI for NIH.

Fiscal and Management Coordination

Pls' discretion

<u>Process for Making Decisions on Scientific Direction and Allocation of Resources</u> PIs' discretion

Data Sharing and Communication among Investigators PIs' discretion

Publication and Intellectual Property (if needed) Policies

"Publication authorship will be based upon the relative scientific contributions of the PIs and key personnel, as is currently handled in any collaboration."

Additional IP language should not be necessary unless PIs are at multiple institutions since patent ownership is determined by federal law. If there are multiple institutions involved and absent any special circumstances, please use the following language: "Ownership of intellectual property will follow inventorship, and intellectual property will be managed by the institutions' respective Intellectual Property policies. If joint intellectual property arises, the technology management offices of the respective institutions will agree to a management plan for that jointly owned technology."

Please contact Mount Sinai Innovation Partners at <u>MSIPinfo@mssm.edu</u> for additional guidance if the standard language above is insufficient or there are special circumstances that require different management.

Procedures for Resolving Conflicts

Required Language for Single Institution Applications:

"If a potential conflict develops, the PIs shall meet and attempt to resolve the dispute. If they fail to resolve the dispute, the disagreement will be referred to a multiple PI arbitration committee composed of faculty of ISMMS. Any Chairs, Institute Directors or Division Chiefs on the committee must recuse themselves if any of the PIs have appointments in their department, institute, or division, respectively. The committee will be co- chaired by the Dean for Research Operations and Infrastructure and the Dean for Translational Biomedical Research. All PIs agree that any decisions made will be final and binding."

Alternate **Required** Language for Applications with a PI at a Sub-Awardee Institution:

"If a potential conflict develops, the PIs shall meet and attempt to resolve the dispute. If they fail to resolve the dispute, the disagreement will be referred to a multiple PI arbitration committee composed of faculty of ISMMS. In addition, [Insert Name of Sub-Awardee Institution] may elect to send a faculty member to serve on this committee. Any Chairs, Institute Directors or Division Chiefs on the committee must recuse themselves if any of the PIs have appointments in their department, institute, or division, respectively. The committee will be co-chaired by the Dean for Research Operations and Infrastructure and the Dean for Translational Biomedical Research. All PIs agree that any decisions made will be final and binding."

Alternate Required Language for Applications with PIs at multiple Sub-Awardee Institutions: "If a potential conflict develops, the PIs shall meet and attempt to resolve the dispute. If they fail to resolve the dispute, the disagreement will be referred to a multiple PI arbitration committee composed of faculty of ISMMS. In addition, [Insert Name of first Sub-Awardee Institution] and [Insert Name of second Sub-Awardee Institution] may each elect to send a faculty member to serve on this committee. Any Chairs, Institute Directors or Division Chiefs on the committee must recuse themselves if any of the PIs have appointments in their department, institute, or division, respectively. The committee will be co- chaired by the Dean for Research Operations and Infrastructure and the Dean for Translational Biomedical Research. All PIs agree that any decisions made will be final and binding."

PD/PIs Change of Institution

Suggested language

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 or other restructuring will occur necessary to maintain the scope of work and with NIH's prior approval.