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Final ASIP response to NIGMS regarding the Maximizing Investigators' Research Award (MIRA)

1. The merits of this funding program for established and early-stage investigators.

The American Society for Investigative Pathology (ASIP) is pleased to provide comments on the potential new NIGMS program for research funding entitled Maximizing Investigators' Research Award (MIRA). ASIP is a nonprofit educational 501(c)(3) organization primarily representing the academic pathology research community. We are a society of biomedical scientists who investigate disease, linking the presentation of disease in the whole organism to its fundamental cellular and molecular mechanisms. Our members seek to ultimately apply research findings to the diagnosis and treatment of patients. ASIP advocates for the practice of investigative pathology and fosters the professional career development and education of its members. Many of our members receive funding from NIGMS.

As a member of the Federation of American Societies for Experimental Biology (FASEB), ASIP has been involved in and supports the comments provided by FASEB on the MIRA program. The pilot MIRA program has merit with both established and early-stage investigators accessing significant funding supportive of ambitious scientific projects, interdisciplinary collaboration, and the pursuit of more "high risk" research.

2. The likelihood that established and early-stage investigators would apply for NIGMS MIRAs.

The American Society for Investigative Pathology (ASIP) encourages NIGMS to further explore the challenges faced by midcareer investigators, as well as those of new or early-stage investigators. It is fairly straightforward to understand how early-stage investigators will likely be at a competitive disadvantage for MIRAs. We also believe there may be unique challenges faced by mid-stage investigators, especially as they transition from their early grants to a more established series of ongoing grants. We share the concerns of The Federation of American Societies for Experimental Biology (FASEB) and support the FASEB proposal to specify a minimum percentage of MIRA funding dedicated to early-stage investigator support. We would also encourage NIGMS to consider specifying a minimum percentage for mid-stage investigators as well.

3. Concerns about the NIGMS MIRA proposal.



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The American Society for Investigative Pathology (ASIP) believes there is a unique concern related to physician scientists. Clinical duties, administrative functions and teaching responsibilities are ongoing obligations of many physician scientists practicing in the academic setting. Including the time spent on clinical care, administration, and teaching in the calculation of minimum effort will make it challenging, if not impossible, for some outstanding physician scientists to achieve the required 50% minimum effort. The National Cancer Institute was aware of this concern as they developed their Outstanding Investigator Award (Funding Opportunity Announcement Number PAR-14-267). As such, in calculating an investigator's commitment to research activities, NCI stated "... effort expended towards teaching, administrative, or clinical duties should not be included in this calculation" (PAR-14-267, 3. Additional Information on Eligibility, Additional Eligibility Requirements, third bullet). We encourage NIGMS to include such a provision. ASIP believes that this will allow physician researchers to successfully apply for MIRAs, demonstrating the required high level of commitment to the MIRA research effort while meeting any required obligations towards clinical care, administration, and teaching.

We are concerned that the MIRA program will result in concentrating research in larger laboratories with high profile researchers. In essence, as the program seeks to fund "people" versus "projects," it may inadvertently fund "already high profile people" over those investigators with worthy, innovative and creative approaches. This is a specific concern for physician scientists. Without the modification described above removing clinical, teaching, and administrative duties from the denominator, only those that are established, high profile physician researchers could hope to achieve the 50% minimum effort requirement.

ASIP is concerned that funding for physician scientists conducting important research continues to be available. During this time of limited research funding, the advent of the MIRA program has the potential to compromise the funding available for individual research projects. ASIP encourages NIGMS to establish a limitation on the total funds allocated under the MIRA program.

ASIP also encourages NIGMS to evaluate the variety of concerns raised by FASEB in its commentary. In particular, NIGMS should address how the receipt of a MIRA grant would affect researchers that were listed as a principal investigator on a grant containing multiple investigators, as increasingly physician scientists are working collaboratively with other investigators on multi-site and multi-researcher studies. ASIP also supports the FASEB recommendation that a minimum percentage of MIRA grant dollars be designated for early-stage investigators.

As NIGMS has proposed this program as a pilot, ASIP suggests that NIGMS develop and provide more specific program details, including a description of the size of the pilot (total awards and total dollars) and additional specificity on the criteria to be used in the peer review process. Developing in advance the criteria for evaluating MIRA's success, and sharing them publically, will ensure a balanced evaluation of MIRA's success. Furthermore, a robust and



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public evaluation of the pilot should be conducted allowing for a balanced assessment of the pilot's strengths and weaknesses.

4. Suggestions for changes to improve the NIGMS MIRA proposal or associated processes.

The American Society for Investigative Pathology (ASIP) has raised a number of concerns outlined above. To address these, we are suggesting that NIGMS do the following.

- Specify that time spent on clinical duties, administration, and teaching responsibilities will be excluded from the denominator when calculating whether a physician scientist is devoting the minimum of 50% of his or her time towards the MIRA research proposal.
- Design and institute safeguards to ensure that MIRA research dollars are not used to concentrate research funding with already high profile researchers but are evenly distributed among researchers with worthy, innovative and creative research ideas.
- Clarify and release for public comment the criteria that will be used to evaluate the success of the MIRA pilot program, ensuring that a thorough evaluation of the program can be conducted.
- Establish a minimum percentage of MIRA funding to be used to support early-stage and mid-stage investigators.
- Specify the total funding to be provided to the MIRA pilot program.
- Specify the criteria to be considered by reviewers when evaluating a MIRA proposal.
- Further clarify how MIRA grants will interact with grants from other Institutes or Centers, as well as research projects where the MIRA grant applicant is listed as a principal investigator on a multi-investigator NIGMS grant.

5. Additional comments.

The American Society for Investigative Pathology appreciates the opportunity to provide comments and are available to provide additional information should it be helpful. Please contact Mark Sobel, M.D., Ph.D. at (301) 634-7130 or mesobel@asip.org.