



Science Policy News November 2014

American Society for Investigative Pathology's Response to Request for Information: Physician-scientists Specific Grant Program to Facilitate the Transition from Training to Independence (to be submitted electronically only using categories as presented below)

Consideration 1 Physician-scientists (MD, DO, DDS/DMD, DVM/VMD, or nurses with research doctoral degrees) may face barriers to research independence different from individuals with research doctoral degrees. For example, following clinical or fellowship training periods, clinicians often obtain a clinical faculty position that denotes independence in clinical responsibilities but not in research. Your feedback may address factors NIH may consider in encouraging the transition to research independence:

Comment 1a Modifying the existing Mentored Clinical Scientist Research Career Development Award ([PA-14-046](#)) and Mentored Patient-Oriented Research Career Development Award ([PA-14-049](#)) to better meet the needs of physician-scientists.

No comment.

Comment 1b Developing institutional training or institutional career development programs to meet the particular needs of physician-scientists.

The American Society for Investigative Pathology (ASIP) maintains that the needs of a diverse cadre of future physician-scientists will be best met by Career Development Offices responsible for overseeing the physician-scientist training programs. Recent reviews conducted under the Clinical and Translational Science Award programs have highlighted the need for multidisciplinary training. A Career Development Office can assess the needs of individual physician-scientists during their training and offer (or arrange for) training in disciplines such as quantitative sciences; clinical trial design and implementation; research ethics/bioethics training; team science approaches; grant writing and administration; oral and written presentations; academic medical center finances; and administrative skills such as leadership, negotiation, and conflict resolution. Programs can be highly individualized meeting both the needs of those outside of a dual degree program and those within such programs.

ASIP suggests that NIH propose a pilot program to explore alternative methods for providing integrated, customize career development support to physician-scientists. Key attributes of successful programs can then be determined. Metrics for evaluating program success should be determined in advance.



Science Policy News

November 2014

Comment 1c Mentoring needs or requirements specific to physician-scientists.

The American Society for Investigative Pathology (ASIP) believes that oversight of physician-scientists in training is frequently the responsibility of residency/fellowship directors and/or the research lab mentor. However, the clinical care and research components are rarely synchronized. Neither of these types of mentors can meet the diverse mentorship needs of a developing physician-scientist. Physician-scientists need several types of mentors, including career mentors, scholarly mentors, and peer mentors. Mentorship needs may also vary depending on whether the physician-scientist is in a dual degree program or training as a physician with a strong interest in research.

ASIP maintains that to be a successful physician-scientist, training is needed in more than just research techniques. Institutions should be encouraged to have Physician-Scientist Career Development Offices (similar to Offices of Postdoctoral Education) that are specifically tasked to oversee institutional career development programs for physician-scientists (see 1b response). When available, these offices can expand upon or build relationships with NIH-funded Clinical and Translational Science Award programs. Unique skills needed by physician-scientists can be fostered through such a career development office and include training in quantitative sciences; clinical trial design and implementation; research ethics/bioethics training; team science approaches; grant writing and administration; oral and written presentations; academic medical center finances; and administrative skills such as leadership, negotiation, and conflict resolution. Trainees should be able to choose from these topics to develop highly individualized training and career-development plans. Individuals outside of a dual degree program may have different needs than those in a dual degree program (MD-PhD or DVM-PhD). Career Development offices should be able to customize the services as needed.

We propose a pilot program to explore alternative methods for mentoring physician-scientists. ASIP suggests that NIH consider supporting or piloting innovative, integrated mentoring programs, evaluating different structures in hopes of determining key attributes of success. Metrics for evaluating program success should be determined in advance, with an extended window for evaluation to ensure that creative approaches allow physician-scientists to successfully obtain more than one RO1 grant over time. One such alternative is to use teams to develop something akin to an Individualized Development Plan for the physician-scientist trainee, through regularly scheduled meetings. This plan would then be reviewed with the developing physician-scientist on at least a semiannual basis. Mentorship teams should be in place both for (1) individuals pursuing a medical degree with an interest in research and (2) individuals that are in a combined degree program.



Science Policy News

November 2014

It is also important that mentors have protected time to mentor incoming physician-scientists. Lessons learned under the CTSA program may offer additional information related to the importance of a multidisciplinary mentoring approach. As NIH seeks to address mentorship concerns, it is vital to address both the needs of the mentor and the needs of the mentee, ensuring that both parties have protected time to invest in this relationship.

Comment 1d Any unique needs of dual-degree holders, e.g. MD/PhD, DDS/PhD, DVM/PhD, in successfully transitioning to research independence.

For those pursuing an MD-PhD, The American Society for Investigative Pathology (ASIP) believes that, by far, the most attractive path from a cost and time perspective is to obtain necessary physician-scientist credentials through an integrated MD-PhD program such as, but not limited to, those offered by the almost 50 Medical Science Training Programs (MSTP) in the United States. Combined programs have two major advantages. First, such programs mitigate the financial challenges that may lead physicians to pursue more lucrative clinical careers. In addition, such programs increase the likelihood that physician-scientists-in-training will have substantial exposure to role models and mentors.

Currently, NIH promotes the development of dual-degree physician-scientists via the MSTP model. Once trainees achieve their PhD's, they typically return to medical school for two years, followed by at least another three years of residency. Many find themselves out-of-touch and out-of-date when they strive to return to research either as a post-doctoral fellow or as junior faculty, with 5 to 7 years elapsed from when they last conducted full-time research. Conversely, entering a full time post-doctoral fellowship after clinical training interrupts the momentum gained in their area of clinical expertise. While the NIH Director's Early Independent Awards (RM-14-004), may help with the exceptional person that does not need post-doctoral training, it does not address the potential 5 to 7 year gap in research efforts that most individuals may experience. This is important because of the ever-accelerating rates by which research fields are continually evolving.

ASIP is aware of at least one such program that has made strides to combat the above described problem when training physician-scientists in pathology. The University of Pittsburgh created a PI-Training Track (PIRRT) within their Residency/Fellowship program, designed to facilitate an efficient integration of abbreviated post-doctoral research experience into the middle of clinical residency training while offering longitudinal mentor support. Information about this program is available at <http://path.upmc.edu/pirrt/index.htm>. The University of Pittsburgh program reduces the research gap time from over five years to no more than three years in either direction. University of Pittsburgh initial graduates have transitioned directly to



Science Policy News

November 2014

dual career faculty positions with start-up support, receiving major funding within the first two years.

Encouragement of innovative arrangements is important as it incorporates research throughout the educational continuum. Since 2006, pathology residents wishing to pursue research have faced major challenges due to the compression of their clinical training into a shorter period. The traditional five-year residency training program in anatomic and clinical pathology was shorted in 2006 to four years, with a maximum of six months of elective research time eligible for meeting certification requirements by the American Board of Pathology. This change made it increasingly challenging for pathology residents to step out of clinical training and take advantage of the elective research time. Pathology residents interested in pursuing more research opportunities were faced with another major obstacle when the maximum number of duty hours was decreased by the Accreditation Council of Graduate Medical Education, thus compressing the time that might be used for research.

Once completing a pathology residency, individuals interested in an additional year of research experience have faced funding challenges. Since 2006, there has been a decline in physician-scientists enrolling in pathology residency programs. In the summer of 2014, as a response to the crisis in declining talent, the American Board of Pathology approved an innovative Physician-Scientist track that endorses a fifth year of training (thereby allowing a maximum of 18 months of research in a five-year program). There continue to be ongoing concerns around funding a fifth year of research training.

ASIP suggests that NIH consider supporting the new Pathology Physician-Scientist track of integrated residency-research programs. The pathology community offers to help develop metrics for evaluating program success, with an extended window for evaluation to ensure that creative approaches allow physician-scientists to successfully obtain more than one RO1 grant over time.

Consideration 2

The career trajectory of physician-scientists (MD, DO, DDS/DMD, DVM/VMD, or nurses with research doctoral degrees) is often different from others with research doctoral degrees. The K99/R00 award ([PA-14-042](#)), one NIH career transition award, provides a phased program of mentored training and independent NIH research support. The K99/R00 program is open to all eligible applicants with a clinical or research doctorate (including PhD, MD, DO, DC, ND, DDS, DMD, DVM, ScD, DNS, PharmD or equivalent doctoral degrees); however, relatively few physician-scientists apply. In developing a career transition award suited to physician-scientists, NIH may consider several provisions of the current K99/R00 program, including the



Science Policy News

November 2014

following:

Comment 2a

The K99/R00 is intended to facilitate a timely transition of outstanding individuals from mentored, postdoctoral research positions to independent, tenure-track or equivalent faculty positions, and to provide independent NIH research support during the transition that will help these individuals launch competitive, independent research careers.

The American Society for Investigative Pathology (ASIP) perceives that one clear implication of such a long and rigorous training period is that the new physician-scientist needs a faster transition to independence that provides sufficient funds to do meaningful research. Without more immediate, positive and sustained support, the newly trained physician-scientist will turn away from a career in research towards only clinical care.

The current K99/R00 program was intended to address some of these issues for physician-scientists as well as PhD scientists, but in practice many physician-scientists believe they are not eligible for this grant mechanism. This occurs when there is confusion over whether clinical fellows doing research are eligible; in particular, there is confusion over whether a physician-scientist is eligible when he or she spends some amount under 75% of time on research (even if only 5% below this threshold) and the rest on clinical care. Many pathology clinical fellows do not apply to the K99/R00 program, believing they cannot meet the strict 75% standard.

ASIP strongly supports the development of a physician-specific K99/R00 award program. Such an award program will need to be crafted to specifically address the unique challenges faced by physician-scientists as they progress to research independence. These include:

- the need to have time to maintain clinical skills during research training, including meeting recertification requirements;
- access to and use of grant funding to counter the increased emphasis by clinical departments on salary support based on Relative Value Units (RVUs); and
- structured career development and mentorship programs to enable trainees to achieve career goals (for further information see ASIP's answer to 1b, c & d).

Comment 2b Applicants must have no more than 4 years of postdoctoral research experience at the time of the initial or the subsequent resubmission application.

Referring back to earlier comments (1d), an extensive gap can exist for the physician-scientist-in-training between their postdoctoral research experience and their time of initial application



Science Policy News

November 2014

for a K99/R00 grant. The American Society for Investigative Pathology (ASIP) believes that this challenge could be ameliorated should NIH develop a physician-specific K99/R00 granting mechanism that could accommodate such potential time away from research. Equally, or perhaps more effective, would be to foster creative approaches to ensure that the research experience is fully integrated throughout a physician-scientist's training (as described in 1d).

Comment 2c The award is intended for individuals who require at least 12, but no more than 24, months of mentored research training and career development before transitioning to the independent award phase of the program.

Mentoring needs of the physician-scientist may vary depending upon a variety of issues including whether the physician-scientist has received a dual degree or, alternately, been trained as a physician and expressed a strong interest in a research career. Individuals trained through medical schools but outside of dual degree programs may have more needs for mentored research training and career development to ensure their success as a physician-scientist. Should NIH adopt a physician-specific K99/R00 granting mechanism (as proposed by The American Society for Investigative Pathology under 2a), offering 36 to 48 months of mentored research training and career development may best ensure that the physician-scientist can meet both clinical and research training obligations and receive the career development support needed to succeed. This is all the more important as multidisciplinary fields such as bioengineering have more extended learning curves.

Comment 2d The K99/R00 provides up to 5 years of support in two phases. The initial phase provides support for up to 2 years of mentored postdoctoral research training and career development. The second phase provides up to 3 years of independent research support, which is contingent on satisfactory progress during the mentored phase and an approved, independent, tenure-track (or equivalent) faculty position.

As a component of the physician-specific K99/R00 award, the American Society for Investigative Pathology (ASIP) suggests that the National Institutes of Health consider the development of a physician-specific K99/R00 award program that extends beyond the traditional 2+3 years of support. An extended time would not only allow the physician-scientists to have additional years of mentored postdoctoral research training and career development (see Comment 2c), but also allow an extended second phase of additional years of independent research support.

Comment 3 Please provide any other comments on this general issue that do not fit into the categories listed above.



Science Policy News

November 2014

The American Society for Investigative Pathology (ASIP) is pleased to comment on the Request for Information: Physician-scientists Specific Grant Program to Facilitate the Transition from Training to Independence (deadline November 3, 2014). 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, three-quarters of whom hold dual degrees (primarily MD/PhD and DVM/PhD), use a variety of structural, functional, and genetic techniques, seeking 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. As an association fostering academic pathology research, ASIP is uniquely positioned to provide commentary on ways to support the transition from training to independence of physician-scientists.

ASIP believes that among the many factors that significantly impact the ability for physician-scientist to successfully launch a research career, four stand out as most relevant to this RFI:

- meaningful support for training programs that are feasible from both a financial perspective as well as of a reasonable duration, whether they be Medical Scientist Training Programs (MSTP) or other options;
- support for innovative programs such as the new Physician-Scientist track endorsed by the American Board of Pathology in 2014;
- sustained and physician-specific funding for research through development of K99/R00 funding program unique to physicians; and
- availability of role models and mentors to support and guide early career investigators.

The American Society for Investigative Pathology appreciates this opportunity to respond to NIH's RFI. Should you have questions or concerns, please feel free to contact Mark E Sobel, MD, PhD at (301) 634-7130 or mesobel@asip.org.

Thank you for your consideration.

Sincerely,

Mark E. Sobel, MD, PhD
Executive Officer