

Response to <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-26-095.html>

Clinical Trial Training and Career Development (500 words)

NIH seeks input on considerations for supporting the development of independent clinical trial investigators under these funding models. Responses may address training, mentorship, transition to research independence, or other factors relevant to preparing investigators to lead clinical trials.

Federal grants for research, public health, and workforce programs are essential to advancing the United States' leadership in clinical research, lifesaving treatments, and innovative therapies, which have been identified as key goals of the [Department of Health and Human Services](#). To advance these national priorities, the United States needs to cultivate and retain the most skilled clinician-investigators who can design and lead high-quality clinical trials. However, the nation faces a growing shortage of clinician-scientists at a time when the need for medical innovation has never been greater. At the same time, the pool of experienced investigators available to mentor and train the next generation is shrinking. Strategic action is needed to sustain this critical workforce.

The American Urogynecologic Society (AUGS), representing clinicians that benefit from national, multicenter trial research in care of their patients, recognizes the need for development of clinical trialists to advance the care provided for our patients. The next generation of investigators do not currently have adequate funding mechanisms, training programs, knowledge, or time to perform paradigm-shifting clinical trials. There are far too few clinician-scientists in training and a waning pool of appropriate mentors. Change is needed to sustain our workforce. Currently, most healthcare systems cannot support clinical research at the expense of provider availability for clinical care. Asking mentors to provide substantial training without dedicated support—and to use their limited research funding to support junior investigators—is not a sustainable workforce strategy. It risks concentrating clinical research training within the largest and best-resourced academic medical centers, while further limiting opportunities at rural, community-based, and resource-constrained institutions.

A sustainable strategy should be developed to protect funding for the time and experiences early-career clinician-investigators require to achieve independence and support mentors directly, particularly those providing clinical trial expertise. A proposed solution could be creating a well-funded grant mechanism solely for mentors to apply for with mentees that would provide adequate funding for a robust clinical trial. This may encourage mentors to take on mentees, and result in more impactful research than that which can be conducted with the current level of funding provided to trainees through the K mechanism. The goal should be to create a sustainable pathway from trainee to independent investigator. Without an alternative mechanism to support the trials, mentorship, and infrastructure required for this transition,

restrictions in funding will narrow the clinical research workforce to those with access to the most elite institutions.

Proposed Funding Approaches (500 words)

NIH seeks input on the design of the two proposed funding models. Responses may address the suitability of each model for its intended investigator population, eligibility criteria, timing of support, peer review considerations, transition between phases, budgetary or administrative features, and other recommendations to improve the proposed models. NIH also welcomes suggestions for alternative funding models.

Clinician-scientists typically begin their careers overstretched clinically and have limited time and funding to access the mentorship and training required to cultivate sufficient expertise to obtain funding for, conduct, and disseminate clinical trials. If all clinical trialist development is removed from the NIH K-award funding model, a replacement mechanism would be needed; one built specifically for clinical trialist development. One option could be a mechanism through which a junior investigator leads the trial under a mentor, with the same rigor of mentorship and structured development plan that K-awards require. Another option could be a well-funded grant mechanism solely for mentors to apply for with mentees that would provide adequate funding for a robust clinical trial. Lastly, to ensure a pipeline of mentors and mentees in clinical trials, there needs to be assurance of continued funding to multicenter clinical trial networks, such as the NICHD Pelvic Floor Disorders Network and the Maternal-Fetal Medicine Units (MFMU) Network. These networks are essential to women's health research. They train and mentor junior investigators in clinical trial design at their network centers, which often serve as the only places where mentors qualified to train clinical trialists in our field can be found.

Other Suggestions for Optimizing the Development of Clinical Trialists (500 words)

NIH seeks any other relevant input related to how best to support the development of researchers who will lead or participate in running well-designed, efficient clinical trials that produce important information for improving clinical practice and human health.

This notice advocates that “K awardees who wish to lead a clinical trial as PI must secure separate funding (e.g., institutional, philanthropic, or other grant awards) to support those activities.” However, a partner funding opportunity must be created by the NIH. The limited funding opportunities that exist for training and mentoring clinical trial investigators, such as the Robert A. Winn Career Development Award or the Career Development Award through the American Society of Clinical Oncology, have limited focus on oncologic disorders, are extremely competitive, and have very tight timelines (12-16 months) and funding. Furthermore, outcomes for these grants may not be known at the time of K submission due to varied timelines.

Philanthropic fund availability is often biased towards certain diseases, many of which are already disproportionately funded by the NIH relative to their population impact. For example,

pelvic floor disorders impact over one quarter of the United States population, but account for less than 2% of NIH funding. Non-NIH sources of funding are not currently set up to bear the burden of training all the investigators we need to perform clinical trials in this country. This has already been demonstrated through the insufficient pipeline of clinician-investigators- if the resources were available, they would have been accessed. Therefore, they must be created.

If the NIH is no longer available to support junior investigators in areas that have limited foundation or private funding, these fields without support outside the NIH will rapidly falter. AUGS is deeply concerned about the future of pelvic floor health and health of the aging female population, two areas that already have a significant deficit of clinical trialists and are of low priority in philanthropic funding. To protect a strong, stable federal research enterprise and ensure that taxpayer investments translate into meaningful benefits to the health of all Americans, we urge you to reconsider the restriction of clinical trial support within Career Development Awards. If the goal is to ensure trial funding is directed at more impactful trials, a separate mechanism must be created that sustainably advances meaningful research while still providing clinical trials training.