

ASN Response to NIH's Request for Information: Input on Potential NIH Funding Approaches to Support the Development of Future Clinical Trial Investigators

<https://rfi.grants.nih.gov/?s=6a57b31c69fc50193d0eb712>

1) Clinical Trial Training and Career Development

The American Society of Nephrology (ASN) appreciates the National Institutes of Health's (NIH's) commitment to strengthening the pipeline of independent clinical trial investigators. Sharing this objective, ASN agrees that helping investigators develop the skills to design, conduct, and lead high-quality clinical trials or clinical feasibility studies is essential to advancing human health. However, ASN is concerned that the proposed funding models could inadvertently undermine the primary purpose of mentored career development awards (K awards): providing protected time, mentorship, and structured training to prepare promising investigators for research independence.

Clinical trial leadership requires expertise extending well beyond scientific investigation, including protocol development, biostatistics, regulatory requirements, recruitment and retention, data management, safety monitoring, budgeting, patient engagement, and dissemination of findings. It is essential that early-stage investigators have opportunities to develop these skills, but not supporting an independent clinical trial or clinical feasibility study during the mentored K award period weakens the growth opportunity for investigators who are still developing their research programs. Requiring a K award recipient to obtain alternative funding for an independent clinical trial could add substantial fundraising, administrative, and scientific demands at a critical stage of career development, undermining their ability to focus on the very work the K award funds during the mentored award period. It could also create a funding gap for investigators who are ready to lead a stand-alone trial.

ASN appreciates NIH's broader efforts to simplify and clarify the K award framework and supports efforts that reduce unnecessary complexity for early-career investigators. ASN recommends that NIH provide K award recipients with meaningful clinical trial experience through established trials, networks, and research infrastructure. Investigators could participate in trial design and implementation, lead ancillary or embedded studies, serve in site-level or protocol leadership roles, and receive structured mentorship from experienced clinical trialists. These experiences would prepare investigators for future independent trial leadership without requiring them to establish the infrastructure or obtain separate funding for a stand-alone clinical trial during the mentored award period.

ASN further encourages NIH to ensure that clinical trial training opportunities are accessible across institutions and disease areas, including at institutions without extensive clinical trial infrastructure. Kidney diseases have substantially fewer clinical trials than several other major disease areas, and nephrology has documented clinical research capacity/workforce challenges. For example, a systematic review of ClinicalTrials.gov found 1,054 nephrology trials

versus 2,264 cardiology trials in its study period, with nephrology trials tending to be smaller¹. Strengthening training opportunities within the existing K award framework would preserve the important role of mentored career development awards while creating a stronger and more sustainable pipeline of investigators prepared to lead clinical trials when they are ready for independence.

2) Proposed Funding Approaches

ASN appreciates NIH's consideration of new approaches to facilitate the transition of mentored investigators toward independent clinical trial leadership. However, ASN does not support the proposed limited-competition Research Project Grant (RPG) or phased K-to-RPG transition model as the appropriate approaches for achieving this goal.

ASN is concerned that requiring or incentivizing K award recipients to obtain separate clinical trial funding during the mentored award period introduces administrative complexity, uncertainty, and additional competition at a critical stage of career development. Clinical trials are resource-intensive undertakings requiring substantial infrastructure, personnel, regulatory support, recruitment capacity, and institutional expertise. Asking early-stage investigators to assume responsibility for these activities while simultaneously meeting the expectations of a mentored K award could shift the focus of the award away from career development.

ASN supports additional NIH investment in clinical trial training and in the resources needed to provide emerging investigators with meaningful clinical trial experience. ASN's concern is not with providing supplemental support for clinical research, but with the structure, timing, and expectations associated with requiring emerging investigators to assume independent trial leadership during the mentored career development period.

These concerns are particularly significant for investigators at institutions with limited clinical trial infrastructure and for investigators studying diseases or populations in which recruitment is difficult. NIH should avoid creating a pathway in which access to clinical trial leadership opportunities depends on an investigator's institutional resources rather than scientific potential and quality of mentorship.

ASN recommends that NIH retain the existing K award structure with respect to clinical trials and allow investigators to pursue independent clinical trial funding through established NIH mechanisms when they are prepared to do so. Participation in clinical trials during the K award period should be encouraged as a training opportunity but should not become a prerequisite for demonstrating readiness for research independence.

Any new mechanism should also provide sufficient funding for the full scope of the proposed research and avoid unnecessary administrative requirements. NIH should consider leveraging existing clinical trial networks, coordinating centers, and institutional infrastructure rather than requiring emerging investigators to independently recreate these capabilities.

¹ Inrig JK, Califf RM, Tasneem A, Vegunta RK, Molina C, Stanifer JW, Chiswell K, Patel UD. The landscape of clinical trials in nephrology: a systematic review of Clinicaltrials.gov. *Am J Kidney Dis*. 2014 May;63(5):771-80. doi: 10.1053/j.ajkd.2013.10.043. Epub 2013 Dec 6. PMID: 24315119; PMCID: PMC3988265.

ASN encourages NIH to consider alternative approaches that provide structured clinical trial leadership opportunities within existing programs and networks. Such approaches could provide a more effective bridge to independence while preserving the core purpose and accessibility of mentored career development awards.

3) Other Suggestions for Optimizing the Development of Clinical Trialists

ASN encourages NIH to pursue a comprehensive strategy for developing clinical trialists that emphasizes sustained mentorship, access to infrastructure, and progressive opportunities for leadership rather than relying primarily on new funding mechanisms.

For example, NIH should consider creating formal pathways within NIH-supported clinical trial networks and consortia for early-stage investigators to develop trial leadership skills. These opportunities could include participation on trial committees, leadership of ancillary studies, responsibility for specific trial components, and progressively greater responsibility for protocol development and implementation. Such experiences would allow investigators to develop practical expertise while benefiting from established infrastructure and experienced clinical trialists.

NIH should also invest in training in innovative and efficient trial methodologies, including adaptive, pragmatic, platform, decentralized, and other approaches where scientifically appropriate. Training should address not only study design and statistical methods, but also recruitment and retention, patient and caregiver engagement, regulatory requirements, data quality, safety, dissemination, and implementation.

ASN encourages NIH to increase investment in clinical trial infrastructure to make training the next generation a more efficient process. Emerging investigators should have access to experienced coordinating centers, biostatistical support, data-management systems, recruitment networks, and regulatory expertise. Shared infrastructure can reduce duplication, lower barriers to entry, and allow investigators to focus on developing the scientific and leadership skills needed to conduct successful trials.

Patient and care partner engagement should be incorporated throughout clinical trial training. Investigators who understand the priorities, experiences, and burdens of trial participants will be better positioned to design studies that are feasible, meaningful, and capable of producing results that can improve clinical practice.

These considerations are particularly important for research to improve the lives of more than 37 million Americans living with kidney diseases. Clinical trials in kidney diseases may face challenges related to recruitment, heterogeneous patient populations, long disease trajectories, competing comorbidities, and the need for meaningful clinical endpoints which has led to a documented gap in the number and scale of clinical trials in kidney diseases compared with several other major disease areas, as well as longstanding challenges in developing the kidney clinical research workforce. Developing investigators who can navigate these challenges will require both methodological training and experience working within collaborative clinical research environments.

NIH should evaluate the success of its clinical trial workforce initiatives based not simply on the number of awards or trials initiated, but on whether participants progress to independent research careers, obtain subsequent funding, assume leadership roles, and conduct trials that generate evidence capable of improving patient care.

Finally, ASN strongly encourages NIH in the future to seek community input and formalize replacement programs or initiatives prior to terminating the established programs or policies that they are attempting to replace.

ASN appreciates NIH's commitment to strengthening the clinical trial workforce and welcomes continued collaboration to identify approaches that expand opportunities for emerging investigators while preserving the effectiveness of the existing mentored career development framework.