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September 28, 2026

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Re: NOT-OD-26-098 (Notice of NIH Updates to Career Development (K) Award Programs) and NOT-OD-26-095 (Request for Information on NIH Funding Approaches for Clinical Trial Investigator Development)

Dear Dr. Bhattacharya and Dr. Lorsch:

We write regarding NOT-OD-26-098, which consolidates the career development (K) award portfolio and prohibits the use of K award funds to support the conduct of any clinical trial, including feasibility and ancillary studies, effective for due dates on or after October 12, 2027; we submit this letter in response to the companion request for information as well (NOT-OD-26-095). While we understand the goal of simplifying the K portfolio, we have significant concern about eliminating independent clinical trials from K awards. This pathway has served clinician-scientists well and should not be closed before an alternative has demonstrated comparable outcomes.

For a clinician training to become a clinical trialist, leading a small, mentored trial is essential. Protocol development, recruitment and retention, intervention delivery, regulatory compliance, and trial operations are learned by running an appropriately sized study with protected time under supervision, not through coursework or by watching a mentor's trial. NIH's own Stage Model describes this sequence: early-stage studies establish feasibility and acceptability and prepare an intervention for larger testing. The pilot is also what makes progression possible, because R01 study sections look for evidence that a candidate has led a trial and for the preliminary data generated by a pilot study. An awardee whose only trial experience comes from a mentor's study arrives at R01 review without either, and is far less likely to advance. This creates a significant challenge for trainees: investigators are expected to demonstrate trial leadership when applying for independent funding, but the K award would no longer support the experience needed to develop those skills. The feasibility and ancillary studies the notice prohibits are the small, low-cost vehicles through which trainees have gained that experience.

These changes would affect a workforce that is already under strain. Physician-scientists make up 1.3% of U.S. physicians and early-career attrition has risen from about 15% to over 50% (National Academy of Medicine, 2026).

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Physicians may carry heavy clinical demands, start research training later than their PhD colleagues, and have a competing, well-compensated exit into full-time practice, so each additional funding hurdle has a disproportionate effect. Requiring a second peer-reviewed award before a trainee may lead any trial will accelerate the loss of investigators needed to conduct research in order to move evidence into routine clinical practice.

The available evidence argues against eliminating the trial-permitted K pathway. To assess the impact of this pathway, we analyzed NIH RePORTER data covering 6,588 investigators who received K01, K08, or K23 awards from FY2010 through FY2020. Awardees whose K award included a clinical trial were as likely as their peers to obtain subsequent NIH funding, including R01 funding, and were nearly two and a half times as likely to receive NIH funding to conduct a clinical trial of their own (adjusted risk ratio 2.48; 95% CI, 2.17–2.82). The K-related trials are small by design, with a median enrollment of roughly 60 participants, and in the current portfolio about two-thirds of the trial-designated awards describe pilot or feasibility studies. The pathway is not marginal, either. The clinical trial share of K awards grew from roughly 8% in FY2010 to about 21% in FY2020, and close to a third of the K01, K08, and K23 awards funded in FY2024 and FY2025 were issued under trial-related funding announcements.

The policy also appears inconsistent with NIH's stated priorities. Industry does not fund implementation trials because there is no product, and foundation support is scarce. Small federal grants such as R21s are not a workable substitute either because historical paylines for these awards are lower than those for R01s and they give no consideration to early-stage or new investigator status. Directing awardees to secure separate institutional or philanthropic funding therefore would make access to clinical trial training increasingly dependent on local resources and funding capacity. Well-resourced institutions can bridge the gap, while safety-net systems and smaller medical centers largely cannot. Over time, the opportunities to develop as a trial investigator would become increasingly clustered within a limited set of heavily resourced institutions and the patient populations and care settings represented in NIH-funded trials would narrow, weakening the generalizability of the evidence produced.

Our first recommendation is that NIH preserve a pathway for mentored pilot and feasibility trials within K awards by adopting a tiered framework that distinguishes these studies from definitive efficacy and effectiveness trials. NIH has already recognized that a single framework is not appropriate for all human-subjects research. For example, when basic science studies involving human participants were brought under the clinical trial definition, NIH created a separate category, Basic Experimental Studies Involving Humans (BESH), with its own funding announcements and reporting requirements. Similarly, a small feasibility study, implementation pilot, or ancillary study should not be treated identically to a large, multisite efficacy trial. NIH should establish a category of mentored clinical trials (pilot and feasibility studies, implementation science pilots, and ancillary studies) that K awardees may continue to lead within the award.

Our second recommendation is to keep the current mechanism (the trial-permitted K01, K08, and K23 series) open and funded for at least five more years while NIH works through the challenges of a new model for clinical trial training and until that model has demonstrated comparable outcomes to the current awards. The new model can be introduced alongside the existing series, and the two can run in parallel while evidence accumulates. Simply publishing a new NOFO should not automatically close existing pathways. Final receipt dates for trial-containing K awards are expected in early 2027. Applicants who score favorably in those final cycles but are not

funded would also have no route to resubmit. If a funded and demonstrated replacement is not in place by then, trainees entering the pipeline now will have no pathway, and the resulting gap will drive further attrition from a critically important workforce.

As NIH shapes the approaches described in the RFI, we also offer the following three recommendations regarding their design and implementation:

1. Design any separate trial award so that the trial can be started and completed within the award's protected time.

The RFI describes two models: a mentored K paired with a limited-competition companion research award, and a phased K-to-RPG award. Under either model, several design features will determine whether an awardee can realistically plan, launch, and complete a trial while maintaining the protected research time necessary for career development:

- Sufficient time during the K phase for pre-trial work, including a pilot study when appropriate. Protected time at the K level (75%) should continue through trial completion and be supported by the RPG during the second phase.
- A trial phase that can extend up to five years, long enough for recruitment, delivery of the intervention, follow-up, and reporting. For example, an awardee in a five-year K who applies for the trial phase late in year three may have only two years of K support remaining when the trial begins, which is unlikely to be sufficient to complete the study. The trial award should therefore provide additional years of support beyond the K period rather than rely on the remaining K-award time.
- An administrative review at the transition rather than a second competing review, so that there is no funding gap. Under the phased model, completion of pre-trial milestones (a final protocol, regulatory approvals, a trained study team) should drive the transition decision. The companion RPG application should be streamlined and function more like an administrative supplement than a new competing application. Under the companion model, review and funding decisions should be coordinated so that awardees begin the K with funding for the pilot their training depends on.
- An RPG budget sufficient to complete the trial, with administrative supplements available when a trial needs more time or resources than projected.

2. Review these applications separately and establish clear expectations for applicants and reviewers.

- For Approach 1, NIH should specify what information applicants are expected to provide about a future RPG-supported clinical trial at the time of K-award submission. Because applicants may not yet have fully developed a trial concept, reviewers should have explicit guidance regarding whether a general research direction, a preliminary trial concept, or a fully developed protocol is expected. Without clear expectations, applicants may be penalized either for providing too little detail or for proposing a trial that is not yet sufficiently mature.
- Applications submitted under Approach 1 should be reviewed separately from applications submitted under Approach 2. The two mechanisms are intended for investigators at different stages of development and support different objectives. Under a mixed review process, reviewers may compare the scope and maturity of an Approach 1 application against an Approach 2 application, even though the expected level of trial development, investigator independence, and study complexity should differ across the two mechanisms.

3. Track the outcomes of any new model. NIH should define, before implementation, how it will judge the success of a new funding mechanism. Metrics should include application and award rates among clinician-scientists, time to trial launch, trial completion, and transition to independent clinical trial funding. These outcomes should be benchmarked against the current K-award portfolio. Because the key outcomes of interest, particularly trial completion and transition to independence, may take a decade or more to observe, NIH should commit to long-term evaluation. Maintaining the current K-award mechanisms during this period would provide a benchmark for evaluating the new approach and a safeguard against unintended consequences for trainees.

More broadly, we ask NIH to treat the development of clinical trial investigators as an explicit objective of its training investment. Evaluation of career development programs should be transparent; every outcome examined in that analysis is measurable in public data, and could be reported routinely through a workforce outcomes dashboard. NIH should also ensure that access to clinical trial training remains broad. The current pathway has supported investigators at 340 institutions across all 50 states and Puerto Rico, and NIH should monitor whether a replacement concentrates trial training in a smaller number of research-intensive centers. NIH should also regard the ability to lead clinical trials as a specialized area of scientific workforce development that warrants sustained investment and stewardship, alongside NIH's long-standing attention to physician-scientists and translational scientists.

Physician-scientists who design and lead clinical trials play a critical role in translating scientific advances into better patient care. Their work translates NIH's investment in discovery into improved patient care in the real-world settings where patients receive treatment. Ensuring that these investigators can develop the skills, experience, and independence needed to lead rigorous clinical trials is fully aligned with NIH's long-standing commitment to developing the next generation of biomedical researchers (Unified Funding Strategy). The ASCI stands ready to work with NIH on the design of these mechanisms, and we would welcome the opportunity to discuss these recommendations with you.

Sincerely,



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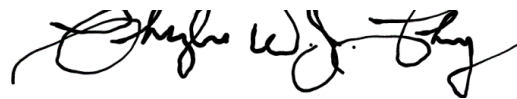
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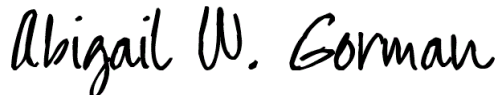
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