

September 29, 2026

Erica Boone, PhD
Division of Biomedical Research Workforce
Office of Extramural Research
National Institutes of Health
6705 Rockledge Drive, 8th Floor
Bethesda, MD 20892-7974

Re: University of Colorado Anschutz Comments on Notice [NOT-OD-26-098](#), Updates to NIH Career Development (K) Award Programs, and Request for Information [NOT-OD-26-095](#), NIH Funding Approaches for Clinical Trial Investigator Development

Dear Dr. Boone,

On behalf of the University of Colorado (CU) Anschutz, please find our comments regarding NOT-OD-26-098 and NOT-OD-26-095, which describe the National Institutes of Health's (NIH) proposed changes to career development (K) award programs for early-stage investigators (ESIs), published on August 12, 2026.

CU Anschutz is the largest academic medical campus in the Rocky Mountain region and the principal site of health sciences research and training for a large, geographically dispersed part of the United States. The campus unites six health professional schools and colleges, two nationally ranked hospital partners ([UCHealth, University of Colorado Hospital](#) and [Children's Hospital Colorado](#)), with close clinical and research affiliations with [Denver Health](#) and the [Rocky Mountain Regional Veterans Affairs Medical Center](#). Annually, our more than 6,000 faculty members secure more than \$760 million in sponsored research funding and lead >3,800 active studies.¹ The Colorado Clinical and Translational Sciences Institute, supported by a \$54 million, seven-year grant from the National Center for Advancing Translational Sciences, supports hundreds of investigators and >500 trial sites across Colorado and the western US.² Patients travel from a seven-state region for care that is often available nowhere else for hundreds of miles, and much of the clinical research serving that region runs through this campus.

As a gold-standard scientific research institution, we support the spirit of these notices: streamlining inefficiencies, promoting feasible research, and bolstering the nation's next generation of competent, innovative academic researchers.

¹ Research Studies at CU Anschutz. (2026). <https://researchstudies.cuanschutz.edu/>

² Science, Discovery, Health and Healing: CCTSI advances research across the state of Colorado. (2025). <https://news.cuanschutz.edu/cctsi/science-discovery-health-and-healing>

However, these same principles lead us to raise concerns about the concrete risks introduced by the proposed changes. As described below, we believe the benefits of these proposed changes do not outweigh their risks, which could destabilize support for the nation's next generation of clinical trialists and clinical researchers. On behalf of our 643 current and prior K awardees, and those who will follow them, we ask NIH to keep the existing K mechanisms active until suitable replacements have been vetted, implemented, and evaluated to ensure they achieve their intended purposes of supporting career development of future clinical trialists. We illustrate these risks with quotes from our faculty, including ESIs and mentors who participated in several opportunities to share their perspectives including a research community listening session, small group meetings, individual conversations, and emails in early September to gather their thoughts and insights related to the proposed changes.

Risk 1: Inadequate training in clinical trials under Approach 1 and Approach 2.

The opportunity to lead a clinical trial is an essential component of a K award for ESIs who wish to receive such training. The faculty who mentor our K awardees were consistent in their feedback on the following point: trial leadership cannot be learned secondhand. A scientist learns to run a trial by writing the protocol, navigating regulatory reviews, enrolling and retaining participants, delivering the intervention, ensuring complete and secure data collection, managing the budget, and leading the study team. In both approaches proposed, the only in-scope clinical trial activity during the mentored period is participating in a trial led by a mentor or co-mentor. That preserves *observation* of trial conduct, not *responsibility* for trial conduct. Our mentors were clear that the two are not interchangeable. As one of our faculty summarized, becoming trial-ready requires "the experience of running the trial itself," including recruitment, randomization, intervention delivery, and longitudinal follow-up, which are aims that have to be learned by doing, not observed secondhand.

Neither proposed replacement approach equips a K awardee with this essential clinical trial leadership experience during the K award period itself. Approach 1 pairs the K with a separate, limited-competition research project grant (RPG) that the awardee would apply for after receiving the K. This RPG would undergo standard NIH peer review as a separately scoped and budgeted trial. But because the same policy that creates this Approach 1 also eliminates the opportunity for feasibility pilot trials as part of the K-funded work (see *Risk 2*), Approach 1 asks a K awardee to compete to lead a trial using evidence the policy prevents them from generating.

Approach 2 avoids that immediate bind only by definition: NOT-OD-26-095 describes Approach 2 as best suited to ESIs who already have substantial prior clinical trial experience and are nearing independence. In our campus' experience, this is a description of what a K is meant to produce, not of the trainee entering a K award period. An awardee who has not yet led a trial has no trial-specific milestones to complete, and the notice offers no detail on how a transition review would be evaluated for a candidate in that position. As one

participant in our research community listening session questioned: “what happens if there is a lag between the mentored and independent phases, and how is that ‘scary gap,’” in her words, “meant to be bridged?”

Risk 2: Plummeting success rates for R-level grants among K awardees.

Under NIH’s clinical trial definition, the early-stage pilot or feasibility studies that comprise the bulk of K-award trials are classified as clinical trials and receive the same level of regulatory and administrative oversight as multi-site, fully powered definitive trials. NIH’s own Stage Model reflects the same logic, with small early-stage studies establishing feasibility before anything larger is attempted.

Thus, mentored pilots serve two critical functions for a K awardee’s future R-level success: (1) experience in clinical trial leadership; and (2) preliminary data.³ Under the new policy, a K awardee would not be supported to acquire either of these elements, effectively hampering their competitiveness for future R-level funding. CUCU Anschutz’s research training programs highlight the need for pilot feasibility trials, as the majority of successfully funded ESIs in our highly selective, competitive structured mentorship programs (CCTSI Clinical Faculty Scholars Program, CCTSI K12 program) propose feasibility clinical trials as part of their K training. As one mentor participant commented, “Most of my mentees do propose pilot trials as a third aim of their career development awards, as most of them are seeking to become trialists.”

The empirical data does not support terminating federal research dollars for K award trials. A national analysis of NIH RePORTER records for 6,588 K01, K08, and K23 recipients funded between FY2010 and FY2020 found that awardees whose K included a clinical trial were substantially more likely to later hold NIH funding for a trial they led (adjusted risk ratio 2.48; 95% CI, 2.17-2.82).⁴ Clinical trials in K awards are generally small in size, with median enrollment near 60 participants, and about two thirds of the trial-designated awards in the current portfolio describe pilot or feasibility trials.⁵ At our institution, among 1,211 K proposals submitted between 2015 and 2025, those with a clinical trial component were awarded at a meaningfully lower rate than those without: 38% (90 of 234) versus 58% (566 of 977). This pathway is already challenging to secure; removing structural support for it compounds an existing disadvantage rather than correcting one. Within our active K01/K08/K23 awardee cohort of 100 individuals, 39 include a clinical trial element. These scientists are conducting critical research that may lack a viable funding pathway under the new paradigm, illustrating the potential impact of these proposed changes at our institution alone.

⁴ Kaiser J. “NIH is ending a key grant for budding clinical researchers.” Science. 14 August 2026. Available from: <https://www.science.org/content/article/ni-h-ending-key-grant-budding-clinical-researchers>.

⁵ Derington CG, Cervantes L, Allen LA, Trinkley KE, Huebschmann AG, Ho PM. Clinical Trial Components of NIH Career Development Awards: Supporting the Nation's Future Trialists. medRxiv. <https://doi.org/10.64898/2026.09.18.26363419>

Risk 3: Workforce attrition and a narrowing funding base.

Within academic and public service institutions, ESIs must balance their research duties and career development against the clinical and educational missions of the organization.

Securing a K award is a signal of success that ESIs rely on to build the foundation for the rest of their careers. Because positions in service-focused organizations often depend upon securing grants, additional barriers to obtaining a K award may prompt promising ESIs to leave positions in which they cannot be successful for ones in which they can. These alternative positions are lucrative and compelling for many ESIs under the current funding paradigm. NIH should monitor whether the proposed changes disincentivize K submissions for clinical trial training or participation in the proposed clinical trial leadership approaches.

The two replacement funding models add more complexity to ESI success, not less, and as a result there is greater risk of compromising the already-small clinical science workforce. Requiring a second competitive award (Approach 1) between the K and the investigator's first independent trial may push some promising scientists out of the academic research workforce. While the academic and private sectors work in tandem for scientific innovation, the proposed changes risk placing greater pressure on institutions, private foundations, and other sectors to fund scientific innovation without any indication that these secondary funding sources can accommodate that added pressure or will be aligned with the U.S. population's health needs.

For our ESIs, there are several problems with directing this burden to non-NIH funding sources. Industry has little interest in implementation trials with no product attached, foundation support in this space is thin and disease-specific, and institutional bridge funds are finite. Even a campus of our size could not underwrite a pilot trial for every K awardee who needs one, and the smaller medical schools and safety-net systems in our region could not underwrite any. The predictable result is that trial training concentrates at a handful of well-resourced institutions, and the populations enrolled in NIH-funded trials come to resemble the patients those institutions serve. For our region, where studies at Denver Health and in rural Colorado communities reach populations that are otherwise missing from the evidence base, that narrowing is a direct scientific loss. One of our faculty mentors summarized that "...the foundations really want cure-oriented clinical trials, not quality-of-life-oriented clinical trials...", concluding with "we have a workforce issue."

Risk 4: Administrative and financial complications that inhibit NIH's own goals.

Folding a mentee's trial work into a mentor's award may create grant administration problems: adding a mentee's clinical trial activities that were not part of the mentor's original peer-reviewed application may constitute a significant change in scope requiring NIH prior approval and raises questions about cost allocability. This arrangement may also undercut a K awardee's ability to demonstrate an independent research trajectory. No administrative guidance exists for these questions, leaving applicants, mentors, and institutions to navigate them on their own.

The uncertainty is not only administrative but also temporal. As one participant in our campus discussion put it, the open question is, "What is the timeline going to look like for getting that pilot trial funding from a different source, and how much does it distract you from accomplishing things on your K to get to the R01?" Every path to separate trial funding, whether Approach 1's limited-competition RPG or even a streamlined administrative supplement, adds a review cycle within an already time-limited, 75%-protected-time award, with no guarantee that the two award timelines will align. Finally, if a K awardee is unsuccessful with the limited-competition RPG submission or supplementary sources to fund their trial, it is not clear how NIH will handle circumstances in which a mentor's funding lapses or is terminated, or in which the K awardee's support must be renegotiated year-by-year through Notices of Award.

Our central recommendation is to keep the trial-permitted K01, K08, and K23 series open and funded for at least the next five years, and until a replacement for researchers seeking training in clinical trials has been designed, funded, and demonstrated to work. Nothing prevents a new model from operating alongside the current series while evidence accumulates, and the publication of a new funding opportunity is not by itself a reason to retire mechanisms with a strong track record. The last receipt dates for K applications that include a trial are expected in early 2027, and applicants who score well in those final cycles but miss the payline will have no way to resubmit. Without an overlap between old and new mechanisms, trainees entering the pipeline today will face a stretch with no pathway available to them at all.

Additional recommendations include:

Designing the new K mechanisms so that an awardee can start and finish a trial within it, without a second competing application in the middle. K awardees need enough time to gain clinical trial experience and gather preliminary data. The trial phase needs to be able to run as long as five years, since recruitment, intervention delivery, follow-up, and reporting rarely fit a shorter window. The transition between phases should be an administrative review tied to concrete milestones (a final protocol, regulatory approvals, a trained study team), so that no awardee faces a funding gap; under the companion model, the two reviews should be coordinated so that pilot funding is in hand when the K begins. Protected time should stay at the K level of 75% research time through trial completion, carried by the RPG in the later phase, and the RPG budget should be sized to finish the trial. This concern was raised directly in our campus discussion: participants noted that if the K's 75% protected time is not preserved through the RPG phase, awardees would need to seek out additional grants concurrently just "to keep our overall salaries afloat."

Adopting a tiered clinical trial definition so that K awardees can continue to lead small pilot, feasibility, implementation, and ancillary studies within the new KC1 or KR1 mechanisms. NIH has already accepted the principle that not every human-subjects study needs the full clinical trial apparatus; its handling of basic experimental studies

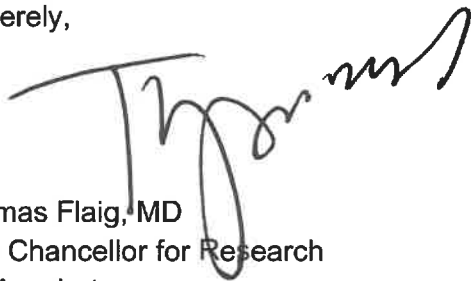
involving humans (BESH) is the precedent. As one participant illustrated concretely: a single-arm pilot, "almost like a BESH study," would teach an awardee "how to deploy the intervention with a single-arm trial," citing randomization as the "lightest lift." The same logic applies here to tailor oversight to size and scope. In the experience of our awardees and mentors, these mentored pilots designed to answer specific feasibility questions and obtain essential preliminary data are where the foundational skills of a trialist are formed.

Reviewing K applications in their own study section, and communicate to applicants in advance how much trial detail is expected at submission. Clinician applicants proposing trials (Approach 1 in the RFI) should not be pooled with other transition awards (Approach 2) if that alternative is adopted. Without that guidance, phased applications will be marked down for deferring power calculations or full analysis plans that the design intentionally leaves to the transition point. As one participant observed, "I think especially Approach 2 does have more emphasis on the research rather than the mentee." Approach 2 may shift away from the candidate-centered review that has historically defined the K mechanism, providing a strong argument for evaluating Approach 1 and Approach 2 applications under separate, clearly defined criteria.

Setting outcomes that will judge the new mechanism before it launches, and benchmark them against the legacy K series. The KC1 and KR1 award outcomes should include clinician application and award rates, time from award to trial launch, completion rates, and progression to independent trial funding. Completion and independence take a decade or more to observe, necessitating long-term evaluation. Interim analyses should identify preliminary success of the new mechanism, and if it falls short, its design should be revised. This is an additional argument for keeping the current series open in the meantime, since the current series provides both the comparison group and the mechanism to maintain the effective clinical trialist training pathway.

CU Anschutz shares NIH's interest in a simpler and more effective career development portfolio, and we would welcome the chance to contribute to the design work ahead, including sharing campus data on the outcomes of our own K awardees. Patients in our region benefit from NIH-funded discovery only when our scientists can test and deliver it in practice, and the pathway that trains those investigators should stay open while better structures are built.

Sincerely,

A handwritten signature in black ink, appearing to read 'Thomas Flaig', with a stylized flourish at the end.

Thomas Flaig, MD
Vice Chancellor for Research
CU Anschutz