



**AMERICAN
PSYCHOLOGICAL
ASSOCIATION**

September 29, 2026

Jon R. Lorsch, Ph.D.
Deputy Director for Extramural Research
National Institutes of Health
6705 Rockledge Drive, 8th Floor
Bethesda, MD 20890

Re: NIH Request for Information: Input on Potential NIH Funding Approaches to Support the Development of Future Clinical Trial Investigators (NOT-OD-26-095)

Submitted electronically via email at oeer@od.nih.gov and through the National Institutes of Health response portal

Dear Dr. Lorsch:

The American Psychological Association (APA) is pleased to submit comments in response to the National Institutes of Health (NIH) Request for Information on potential funding approaches to support the development of future clinical trial investigators ([NOT-OD-26-095](#)). APA is the nation's largest scientific and professional nonprofit organization representing psychology, with 190,000 members and affiliates who are clinicians, researchers, educators, consultants, and students in psychological science.

APA appreciates NIH's effort to strengthen the clinical trial workforce and clarify the relationship between mentored career development and clinical trial research support. Psychologists and behavioral scientists design, test, and implement interventions addressing mental health, substance use, chronic disease management, health behavior, prevention, implementation, and health equity. Their preparation therefore must include opportunities to develop the scientific, ethical, regulatory, and operational skills required to lead rigorous, participant-centered trials.

APA recommends that NIH retain a pathway through which mentored K awardees may lead well-scoped pilot and feasibility trials, while providing separate or transition-stage research support for trials whose scale, cost, risk, or infrastructure needs exceed the purpose of a career development award. NIH should not treat the two approaches described in the RFI as mutually exclusive. Instead, it should adopt a flexible framework that matches the funding mechanism to the investigator's developmental stage and the proposed trial's complexity.

A principal strength of the current independent clinical trial-required K pathway is that it permits an early-career investigator to gain direct experience designing and leading a trial while receiving mentorship, protected research time, and structured career development support. For an appropriately scoped study, both the findings and the experience of managing design, implementation, oversight, and reporting can provide a foundation for a subsequent R-series or other independent award. Removing all

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Advocating for APA members and psychology

750 First Street, NE
Washington, DC 20002-4242

202.336.5800
202.336.6123 TDD

trial leadership from K awards would delay this learning until the point at which structured mentorship may be less available.

Assessment of Approach 1: Separate Trial Support During the Mentored K Period

APA could support Approach 1 only if NIH makes access to trial funding timely, predictable, and administratively manageable. The approach would preserve protected mentored time, permit independent peer review of trial proposals, and allow investigators to seek trial support after receiving a K award. However, requiring a second competitive award could delay a planned trial, interrupt an integrated training trajectory, and divert protected time toward duplicative application requirements.

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These risks may be greatest at institutions with limited bridge funding, regulatory personnel, trial coordinators, data systems, or established clinical trial offices. Investigators serving rural, underserved, or historically underrepresented communities may also depend on sustained partnerships that cannot easily absorb uncertain review timelines. NIH should therefore ensure that a separate-award model does not shift unfunded costs or timing risks to applicants and their institutions.

If NIH adopts Approach 1, it should:

- **Coordinate review and award timing.** Establish synchronized or expedited review so that a trial can begin without avoidable delay after the K award.
- **Publish clear eligibility and scope standards.** Define allowable study types, budgets, durations, effort expectations, mentorship requirements, and Institute and Center responsibilities.
- **Minimize duplicative requirements.** Permit streamlined or just-in-time submission of materials already evaluated through the K application.
- **Support developmentally appropriate studies.** Allow pilot, feasibility, and early-stage behavioral intervention trials that generate evidence needed for later efficacy or effectiveness research.
- **Provide continuity protections.** Clarify portability, bridge support, and options when NIH review timing would otherwise disrupt training or community partnerships.

Assessment of Approach 2: Transition to an Independent Research Award

APA supports a K/R transition model as an option for larger, later-stage, multi-site, or infrastructure-intensive trials, but not as a universal replacement for mentored trial leadership. Deferring all principal-investigator responsibility until the independent phase could postpone essential learning and remove structured guidance at the point when an investigator first confronts recruitment, fidelity, safety, regulatory, staffing, and data-management challenges. Any transition model should preserve meaningful supervised leadership during the K phase, allow appropriate refinement of the proposed study, and use transparent readiness criteria that consider scientific progress, leadership development, mentoring outcomes, and career preparation rather than a single predefined milestone.

Recommended Complementary Funding Framework

NIH should make three pathways available:

- **K-supported trial leadership** for modest, well-defined pilot or feasibility studies that are compatible with protected training time and strong mentor oversight;
- **Separate, limited-duration trial support** for a discrete study that is appropriate during the K period but requires independently reviewed research costs; and

- **A K/R transition pathway** for larger, later-stage, multisite, or infrastructure-intensive trials that should begin or expand during the investigator’s independent phase.

Behavioral and Psychological Science Considerations

Behavioral and psychological trials often require iterative intervention development, stakeholder engagement, recruitment and retention strategies, fidelity monitoring, implementation planning, and multilevel outcome assessment. NIH’s Stage Model likewise recognizes the value of developmentally sequenced behavioral intervention research, from intervention generation and refinement through efficacy, effectiveness, and implementation (National Institute on Aging, 2025). Funding and review criteria should accommodate these features rather than assume a single biomedical trial model.

Pilot and feasibility trials can provide appropriate mentored experience in intervention refinement, recruitment, human-subjects protections, trial registration and reporting, staff training, data collection, and operational leadership. NIH should permit such studies within a K award when peer review determines that the scope, risk, budget, infrastructure, and timeline are compatible with the award’s career development purpose. Larger efficacy, effectiveness, multisite, or resource-intensive trials should receive dedicated research support. Suitability should be determined case by case; behavioral trials should not be presumed to be uniformly small, low-cost, or low-risk (Murray & Simoni, 2025).

Safeguards, Equity, and Implementation

NIH should require that any K-supported trial preserve protected training time, include explicit mentor oversight of scientific, ethical, regulatory, and operational issues, and demonstrate how trial leadership advances the awardee’s career development goals. Peer review should assess feasibility, mentorship expertise, institutional capacity, and alignment between the research and training plans. NIH should also publish implementation criteria across Institutes and Centers and monitor whether application sequencing, matching or bridge-resource expectations, transition requirements, and review standards create differential barriers by institution type, study setting, or investigator career stage.

Investigators at institutions with limited clinical trial infrastructure may have less access to coordinators, programmers, regulatory personnel, data systems, and bridge funding. NIH should make trial-related support available through clear and predictable processes rather than presume that institutions can absorb unfunded costs. It should also preserve continuity of mentorship and community partnerships across award phases and publicly report implementation outcomes sufficient to identify and correct unintended access barriers.

In closing, APA urges NIH to: (1) preserve mentored leadership of appropriately scoped pilot and feasibility trials; (2) provide separate or transition-stage funding when a trial exceeds the K mechanism’s training purpose; and (3) establish transparent, equitable, and administratively coordinated implementation standards. This flexible framework would strengthen preparation for research independence without narrowing the pipeline of future investigators and would ensure that psychologists and behavioral scientists can contribute fully to the next generation of clinical trials. Should you have questions, please contact Angela L. Sharpe, MG, Senior Director, Congressional & Federal Relations, at asharpe@apa.org.

Sincerely,

Adrienne Stith

Adrienne Stith, Ph.D.
Executive Lead Psychologist, Science
American Psychological Association

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