

Comment Form (<https://rfi.grants.nih.gov/?s=6a57b31c69fc50193d0eb712>)

Clinical Trial Training and Career Development

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.

Response: The American Association of Colleges of Pharmacy (AACP) signed onto the response to this RFI submitted by the American Society for Clinical Investigation. We'd like to take this opportunity to reiterate our support for the recommendations in that response. We'd also like to emphasize that the relatively short timeline for implementation of the proposed changes to clinical trial training support for K awardees is a significant challenge to early career clinician scientists, especially at smaller institutions. Timelines for career development planning are often years long, especially when clinical trials are planned, and changes in the NIH funding landscape are difficult for researchers to respond to and prepare for within one year. NIH should maintain support for clinical trial research in mentored K awards until new mechanisms to support this research training are available for early career scientists.

If NIH is unwilling to keep the current clinical trial required funding opportunities open while alternative funding opportunities are developed, NIH should distinguish between interventional clinical trials and feasibility studies, implementation pilots and ancillary studies. These latter study types provide valuable training opportunities for emerging clinician scientists, and NIH should continue to allow support for these studies in K awards while developing approaches for mentored training in interventional and effectiveness trials. This is particularly important as there will be a gap period in which K awards will not support clinical trials, including feasibility and ancillary studies, but no alternative mechanisms for support will be available from NIH.

Proposed Funding Approaches

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.

Response: None – this is covered in detail in the ASCI letter.

Other Suggestions for Optimizing the Development of Clinical Trialists

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.

Response: Given the significant research planning and grants management requirements involved in NIH grant submissions, especially for those that involve clinical studies and trials, rapid changes in NIH policies and funding mechanisms are challenging for researchers to absorb and adapt to. Even when the community recognizes the substantive value of proposed reforms, it takes time and effort to understand changes to grant mechanisms, review criteria and grants management requirements. This generally requires time and training for researchers and support staff to ensure research and career development plans are appropriate for the mechanism and that proposals adequately respond to review criteria. This is particularly burdensome for researchers at smaller institutions that don't have large sponsored research offices with dedicated staff to assist with interpretation of NIH policies, announcements, and requirements and resources for grant writing support. Uncertainty about the responsiveness of proposed research training to a mechanism, as in determining if a study using clinical trial materials will be considered an ancillary clinical trial, can prevent investigators from submitting proposals or prompt them to change their line of research inquiry. Neither are desired outcomes for mechanisms aims at preparing independent researchers.

We appreciate NIH providing this opportunity to provide input on approaches to funding the development of future clinical trial investigators, but we recommend that in the future NIH provide more time and opportunities for input from the community prior to the announcement of significant changes to research and career development mechanisms. Timed or tiered implementation of changes would help researchers adapt to changes without disrupting their research or training plans.

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REQUEST FOR INFORMATION (RFI): INPUT ON POTENTIAL NIH FUNDING APPROACHES TO SUPPORT THE DEVELOPMENT OF FUTURE CLINICAL TRIAL INVESTIGATORS

Purpose

NIH is issuing this Request for Information (RFI) to seek public input on potential funding models that would allow recipients of mentored K awards to serve as principal investigators (PIs) of clinical trials while receiving support for the clinical trial through a funding mechanism separate from the K award.

BACKGROUND

NIH career development ("K") awards provide intensive, supervised research and career development experiences that prepare investigators to transition to research independence. These awards provide protected time, mentorship, and structured research and professional development opportunities that enable investigators to acquire the knowledge, skills, and experience needed for successful independent research careers.

To strengthen the future clinical trial workforce, NIH is revising its mentored career development award policies to better distinguish career development support from support for the conduct of clinical trials. Under the revised policy:

- NIH will no longer support "Independent Clinical Trial Required" K award Notices of Funding Opportunities (NOFOs).
- K award funds may not be used to support or offset the costs of conducting a clinical trial, clinical feasibility study, or a separate ancillary study to an existing clinical trial.
- K award recipients who wish to lead a clinical trial as PI must secure separate funding (e.g., institutional, philanthropic, or other research grant support) to support those activities.

Under this policy, K awards will continue to support activities that prepare investigators for independent clinical trial research careers, including additional coursework, participation in a clinical trial led by a mentor or co-mentor, research that builds skills relevant to clinical trial leadership (e.g., qualitative research, observational studies, or secondary data analyses), and development of a clinical trial protocol.

NIH recognizes that serving as the PI of a clinical trial can be an important step toward research independence for many clinician-scientists by providing experience designing, leading, and managing complex clinical research and generating preliminary data to support future studies. Accordingly, NIH is exploring funding models that would allow mentored K award recipients to lead clinical trials while maintaining the K award's primary focus on career development. Under these models, support for the clinical trial would be provided through a funding mechanism separate from the K award, either during the mentored K award period (Approach 1) or during the subsequent Research Project Grant (RPG) stage of a K/R transition award (Approach 2).

NIH seeks public input on the advantages, challenges, and implementation considerations associated with these potential funding models.

	Approach 1	Approach 2
Best suited for	K award recipients leading their first clinical trial	Investigators with substantial prior experience are nearing independence
Career stage	Overlapping with a mentored K award	Transition from mentored development
Clinical trial application	Submitted after obtaining a K award	Submitted as part of the initial application
Goal	Add separate trial funding while remaining on a K award	Transition to an independent RPG

POTENTIAL NEW FUNDING MODELS

Approach 1 – Mentored K Award + Limited-Competition Clinical Trial Research Project Grant (RPG)

NIH is considering a limited-competition Research Project Grant (RPG) available only to recipients of mentored K awards. Under this approach, eligible investigators could apply for a separate RPG to support the costs of conducting their first clinical trial as PI. The RPG would support clinical trial-related expenses, while the investigator's salary would continue to be supported through the K award.

Applications would undergo NIH peer review and would include standard information required for review of clinical trial applications. The scope and budget of the proposed clinical trial would be expected to be appropriate for an investigator at the mentored career development stage.

This approach is intended for investigators who require separate support to conduct their first clinical trial while continuing to receive the protected time and career development provided through the K award. It would replace the current approach where recipients of "Independent Clinical Trial Required" K award NOFOs may use K award funds, with or without supplemental research support, to conduct clinical trials.

Approach 2 – Phased Transitional Award (Mentored Phase Followed by an Independent Research Project Grant Phase)

NIH is considering a phased transitional award consisting of a mentored K phase followed by an independent Research Project Grant (RPG) phase. Applicants would submit all information required for peer review of the proposed clinical trial as part of the initial application.

During the mentored phase, recipients could participate in a clinical trial led by a mentor or co-mentor, conduct research that prepares them for independent clinical trial leadership (e.g., qualitative research, observational studies, or secondary data analyses), and further refine plans for the proposed clinical trial.

Transition from the mentored phase to the independent RPG phase would be contingent upon successful completion of predefined programmatic milestones and NIH approval. The independent phase would provide funding to support the recipient as PI of the proposed clinical trial, including the resources needed to conduct the trial.

HOW TO SUBMIT A RESPONSE

Responses may be submitted by any interested stakeholder, including investigators, academic institutions, professional societies, patient advocacy organizations, industry, scientific organizations, and members of the public. NIH encourages organizations to submit a single coordinated response when appropriate.

This RFI is for planning purposes only and should not be construed as a funding opportunity announcement or solicitation for proposals. Responses are voluntary and may be submitted anonymously. Please do not include personally identifiable information or any information you do not wish to make public. NIH will not provide individual feedback on submissions; information received may be used for planning purposes and summarized in publicly available materials.

INFORMATION REQUESTED

NIH invites comments from the public on the topics below. Respondents are encouraged to address any or all areas and provide examples, evidence, or other information that may inform NIH's consideration of these potential funding models.

**To ensure consideration, responses must be submitted by : September 30, 2026
11:59:59 PM EST**

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If NIH is unwilling to keep the current clinical trial required funding opportunities open while alternative funding opportunities are developed, NIH should distinguish between interventional clinical trials and feasibility studies, implementation pilots and ancillary studies. These latter study types provide valuable training opportunities for emerging clinician scientists, and NIH should continue to allow support for these studies in K awards while developing approaches for mentored training in interventional and effectiveness trials. This is particularly important as there will be a gap period in which K awards will not support clinical trials including feasibility and ancillary studies, but no alternative mechanisms for support will be available from NIH.

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Response: Given the significant research planning and grants management requirements involved in NIH grant submissions, especially for those that involve clinical studies and

trials, rapid changes in NIH policies and funding mechanisms are challenging for researchers to absorb and adapt to. Even when the community recognizes the substantive value of proposed reforms, it takes time and effort to understand changes to grant mechanisms, review criteria and grants management requirements. This generally requires time and training for researchers and support staff to ensure research and career development plans are appropriate for the mechanism and that proposals adequately respond to review criteria. This is particularly burdensome for researchers at smaller institutions that don't have large sponsored research offices with dedicated staff to assist with interpretation of NIH policies, announcements, and requirements. Uncertainty about the responsiveness of research to a mechanism, as in determining if a study using clinical trial materials will be considered an ancillary clinical trial, can prevent investigators from submitting proposals or discourage them from pursuing avenues of research inquiry.

We appreciate NIH providing this opportunity to provide input on approaches to funding the development of future clinical trial investigators, but we recommend that in the future NIH provide more time and opportunities for input from the community prior to the announcement of significant changes to funding mechanisms.

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