



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

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Gemini 3.6 Flash (Google) and Lumo 2.0 Max (Proton) provided assistance with drafting and editing the comments.

Contributor disclaimer: The views do not necessarily represent the views of contributors' employers or affiliated institutions. Theresa Kim provided scientific and technical input during off-duty hours and without use of government-furnished equipment; her participation does not represent the views of NIH, HHS, or the U.S. Government.

The [American Statistical Association](#) appreciates the opportunity to respond to the RFI, [Input on Potential NIH Funding Approaches to Support the Development of Future Clinical Trial Investigators](#). Of the two approaches to support the path to independent researchers for scientists who aspire to lead clinical trials, we recommend a hybrid strategy, as described below.

Background:

NIH career development (K) awards are designed to provide intensive, mentored research and career development experiences to ensure a smooth transition from trainee to independent researcher. K Awards provide protected time and mentorship and help ensure investigators

have opportunities for structured career and research development experiences, resulting in establishing the skillset necessary for independent research careers. They represent an important investment in the future scientific workforce.

Until October 2027 (see [NOT-OD-26-098](#)), NIH K awards may include “independent clinical trial required” notices of funding opportunities to ensure that awardees received the necessary mentoring and training from established investigators necessary to lead in NIH-funded clinical trials research. Through this mechanism, investigators would also receive funding to implement clinical trials, clinical trials feasibility studies, or ancillary studies to on-going clinical trials. NOT-OD-26-098 has eliminated the option of funding clinical trials as part of a K award, to “improve consistency, reduce administrative burden, and align policies across K award [programs](#)”. K awardees who would like to lead a clinical trial as PI would be required to obtain separate funding (e.g., institutional, philanthropic, or other awards) to support these efforts, although they may still participate in a trial led by a mentor or co-mentor.

NIH Proposal: NOT-OD-26-095

In lieu of allowing funding for clinical trials to K awardees, the NIH proposes two approaches to support the path to independent researchers for scientists who aspire to lead clinical trials.

Approach 1 proposes that NIH provides a limited competition Research Project Grant (RPG) mechanism available only to recipients of mentored K awards, with the timeframe overlapping the K award. This approach would enable eligible investigators to apply for a separate RPG that would cover the costs of conducting the investigator’s first clinical trial; however, salary support would come through the K award.

Approach 2 proposes a phased transitional award, in which the recipient of the K award would apply for an independent RPG that includes all the information required for peer review of the proposed clinical trial. During the mentored phase, the K awardee could participate in a clinical trial led by a mentor or co-mentor, engaging in research that would prepare them to lead a trial independently. Transition to the independent trial phase would be contingent on successful completion of predefined programmatic milestones and NIH approval. The independent phase would provide full funding to support clinical trials costs and salary for the PI.

Recommendations

Recognizing the importance of training future clinical trialists, the American Statistical Association (ASA) recommends a hybrid strategy to training future clinical trialists that combines aspects of Approaches 1 & 2 and includes additional recommendations. The ASA suggests a mentored training phase, followed by an independent research project grant (RPG) phase with some modifications, as described below, as well as additional recommendations also presented below.

1. Require K award applicants to include statisticians with expertise in clinical trials/study design on their mentoring committee during the training phase;
2. Require trainees to fulfill programmatic milestones confirming acceptability, validity, and fidelity of the proposed intervention prior to proceeding to the independent RPG phase;
3. Consider awarding funding for trials other than NIH-defined Phase III clinical trials during the independent phase, such as pilot awards or planning awards (R34s);
4. Promote limited competition planning grants after training completion that can prepare investigators to lead more complex designed clinical trials, such as cluster trials, adaptive trials, or pragmatic trials;
5. Continue to ensure that statisticians play a vital role in the review and assessment of readiness for independent clinical trials RPGs, both through requiring statistical expertise on review panels and through statistical expertise on the NIH staff; and
6. Continue to promote and fund training in clinical trials, such as through the NINDS-supported Clinical Trials Methodology Course, the NIA-supported IMPACT Collaboratory, and other programs to help train future clinical trialists, including possible partnerships with groups such as the American Statistical Association and the Society for Clinical Trials.

As statisticians, we are aware that even simple studies can go awry if they are not well-designed, managed, and analyzed.^{1,2} The inclusion of statisticians on mentoring teams for K awardees can help ensure investigators understand the vital role of team science in research success, as recognized by the International Conference on Harmonization's guidelines for Good Clinical Practice ([ICP E6.5](#)). Further, inclusion of statisticians on mentoring teams can help to provide the trainee the data management and statistical understanding necessary to lead large clinical trials. Including a statistician on the mentoring team will ensure a smooth transition to including a statistician at the earliest stages of study design – another marker for successful RPGs.³

Questions or comments may be directed to ASA Director of Science Policy Steve Pierson: spierson@amstat.org.

¹ Zaki M, O'Sullivan L, Devane D, Segurado R, McAuliffe E. Factors influencing the statistical planning, design, conduct, analysis and reporting of trials in health care: A systematic review. *Contemp Clin Trials Commun*. 2022 Jan 29;26:100897. doi: 10.1016/j.conctc.2022.100897. PMID: 35198793; PMCID: PMC8842005.

² Simon R. The role of statisticians in intervention trials. *Stat Methods Med Res*. 1999 Dec;8(4):281-6. doi: 10.1177/096228029900800402. PMID: 10730334. <https://pubmed.ncbi.nlm.nih.gov/10730334/>

³ Adams-Huet B, Ahn C. Bridging clinical investigators and statisticians: writing the statistical methodology for a research proposal. *J Investig Med*. 2009 Dec;57(8):818-24. doi: 10.2310/JIM.0b013e3181c2996c. PMID: 19875966; PMCID: PMC4415704. <https://pmc.ncbi.nlm.nih.gov/articles/PMC4415704/>