Request for Information (RFI): Input on Potential NIH Funding Approaches to Support the Development of Future Clinical Trial Investigators

Clinical Trial Training and Career Development (500 words)

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.

The Women First Research Coalition (WFRC) appreciates the opportunity to provide input on how to support the development of independent clinical trial investigators. We strongly oppose NIH's decision to eliminate clinical trials, clinical trial feasibility studies, and ancillary studies to existing clinical trials from allowable costs under the K Career Development Awards.

WFRC is a coalition comprised of the nation's leading professional medical and research organizations specializing in women's health. Our coalition was formed to address pressing challenges in women's health research and to raise awareness among federal policymakers, Executive Branch officials, and the public about the need for sustained and strengthened investment in women's health research, the prioritization of research in conditions that are specific to women or those conditions that may present differently in women than men, advance an equitable and appropriate investment in women's health research that improves the health outcomes of women, and ensure an adequate women's health research workforce.

One of WFRC's priorities is assuring a pipeline of researchers in women's health. For this reason, we have concerns regarding the proposed elimination of K award support not only for clinical trials, but also for ancillary and feasibility studies which can be rigorously and effectively conducted within the scope and resources of a K award. For instance, the K23 mechanism has been a key pathway for junior physician-scientists pursuing clinical research. Several WFRC members shared personal examples of how K23 awards supported pilot trials and feasibility testing, generating the preliminary data needed to secure R01 funding for larger clinical trials. These experiences underscore the critical role of K awards in training, advancing early-stage research, and laying the groundwork for larger studies. WFRC is extremely concerned that elimination of this valuable source of funding will close a common career entry point for those who wish to gain independence and experience in leading clinical trials.

At a time when the nation faces a growing shortage of physician-scientists, with 1 in 3 U.S. counties as a maternity care desert, there is a strong need for a robust pool of trainees who

wish to advance women's health research and for experienced investigators available to mentor and train the next generation. We are concerned that eliminating K award funding for clinical trials and related activities will disproportionately impact research areas without alternative private funding or areas that have historically been underfunded, including women's health. We recommend that NIH strengthens all current funding mechanisms available to support the development of clinical trial leaders, not eliminate a critical mechanism that has proven to be effective in training clinical trialists.

Proposed Funding Approaches (500 words)

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.

Rather than replacing the current K funding approach, we encourage NIH to strengthen and improve the K awards in providing support for clinical trials and related activities, as well as explore all approaches that can comprehensively address the unique challenges that physician-scientists face. For most physician-scientists, heavy clinical demands can leave little protected time to obtain mentorship, generate preliminary data, gain hands-on experience designing and leading clinical studies, and compete successfully for independent funding.

Current NIH K awards can help address these barriers by providing protected research time, mentorship, and structured career development during this critical transition. K awards are essential to preparing the next generation of clinical trialists, but the mechanism could be strengthened by providing compensation for mentors' time and effort, which often goes uncompensated despite the substantial commitment required. Supporting both awardees and mentors, while preserving opportunities to gain meaningful clinical trial experience, is critical to developing the next generation of physician-scientists.

To ensure a robust pipeline of mentors and mentees in clinical trials, WFRC recommends that NIH create additional training opportunities specifically within existing multicenter clinical trial networks, such as the Pelvic Floor Disorders Network and the Maternal-Fetal Medicine Units, the Contraceptive Clinical Trials Network, and recommend the reconstitution of the Reproductive Medicine Network. These platforms are essential to women's health research. Additionally, these programs train and mentor junior investigators in clinical trial design at their network centers, which often serve as the only places where mentors qualified to train clinical trialists in women's health can be found.

Other Suggestions for Optimizing the Development of Clinical Trialists (500 words)

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.

Given that the clinical research workforce already faces limited funding, protected time, and mentorship, WFRC is concerned that restricting clinical trial support through K awards could further disadvantage investigators at smaller, less-resourced institutions and in fields with limited philanthropic or private funding, further widening the research gap in women's health.

In conclusion, NIH should preserve K award support for meaningful clinical trial experience while boosting support for protected investigator and mentor time. If clinical trial funding were to be removed from K awards, NIH must establish a dedicated, sustainable mechanism that supports trials, mentorship, and infrastructure and provides a clear pathway from training to independent investigation. By providing stronger incentives and dedicated support for clinicians to pursue clinical trials research, NIH can strengthen the pipeline of investigators uniquely positioned to bridge bench and bedside and translate scientific discoveries into new treatments and cures for patients.