Pre-Application Technical Webinar for

Research Opportunity Announcement (OTA-24-016): *Integrating Clinical Research into Primary Care Settings through Network Research Hubs – A Pilot (OT2)*

May 14, 2024, at 12:00 PM ET
and
May 22, 2024, at 12:00 PM ET

Dr. Felicia Qashu – Program Leader, Common Fund

Dr. Amy Patterson – Scientific and Medical Director, Clinical Research in Primary Care Settings, Division of Program Coordination Planning and Strategic Initiatives

Ms. Kristina Faulk – Senior Advisor for Program Administration & Policy, Common Fund

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Turning Discovery into Health®

Housekeeping

This webinar will be recorded

All participants except speakers will be muted

Please place questions in the Questions and Answers module; they will be answered either in the chat box or during the Q&A session.
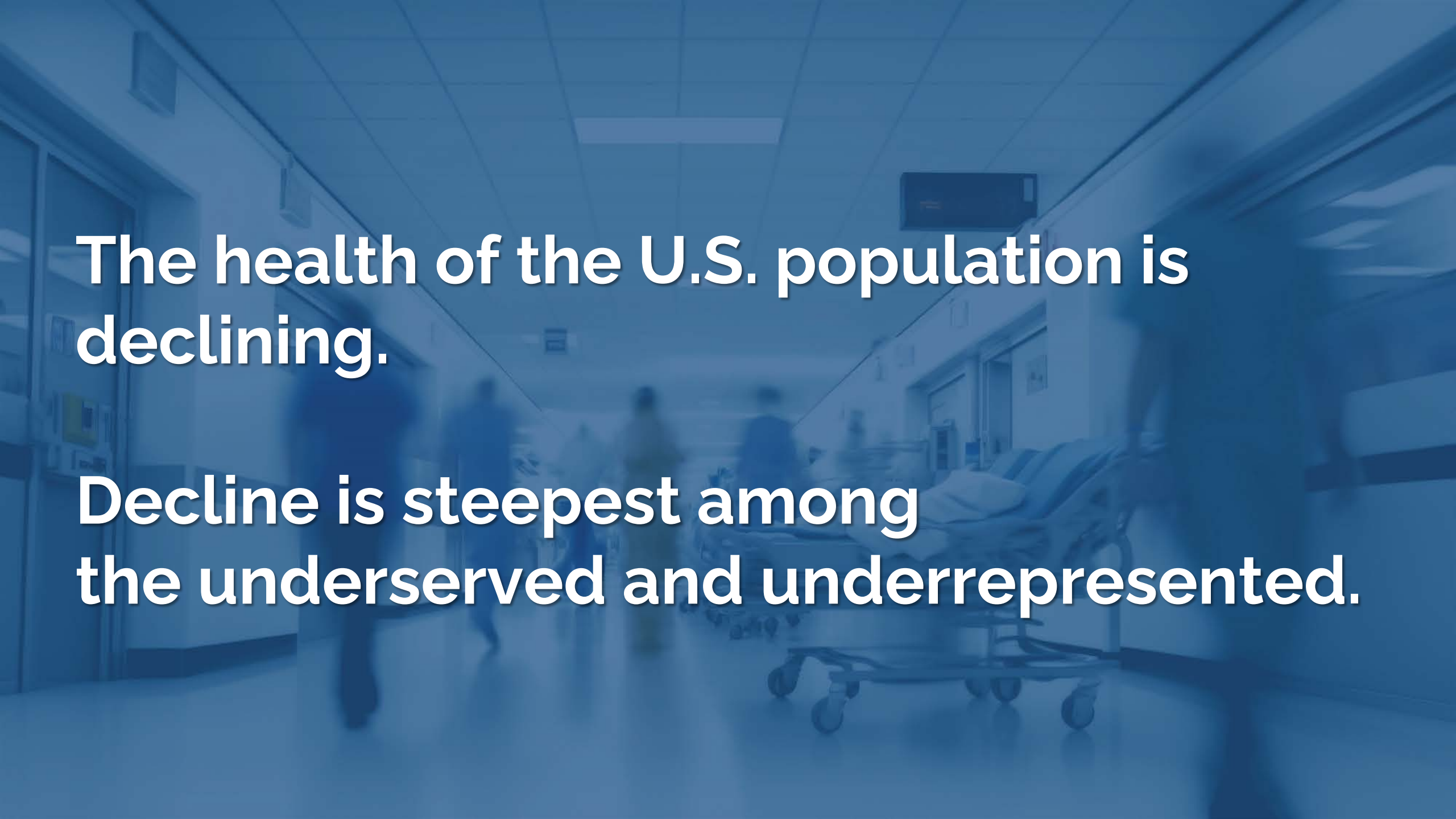
An extended Q&A session at the end will cover questions received during the presentations

The recording from today's webinar will be posted on the Common Fund website

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Agenda

12:00 PM   Welcome & Opening Remarks

12:05 PM   Overview of ROA: *Integrating Clinical Research into Primary Care Settings Through Network Research Hubs – A Pilot (OT2)*

12:35 PM   Questions and Answers

12:55 PM   Closing Remarks

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The health of the U.S. population is declining.

Decline is steepest among the underserved and underrepresented.

Common Fund program establishing an NIH Network for Research in Primary Care Settings

Coordinated infrastructure that integrates innovative research into routine clinical care in primary care settings, that will...

- Support primary care-based clinical research in mission areas **spanning prevention and treatment** and with a **focus on health equity and whole person health**

- Establish a foundation for **sustained engagement with communities underrepresented** in clinical research

- Implement **innovative study designs** that address common health issues

- Utilize a **full range of clinical research designs** as appropriate to inform clinical practice

...thereby facilitating and accelerating research advances for adoption and implementation into everyday clinical care, improving health outcomes, and advancing health equity for all Americans.

Timeline

Spring 2024: Obtain perspectives from external partners to inform planning

- Listening sessions
- **Public workshop (June 7, 2024, 10am-1pm EDT)**

Quick Launch in 2024: Expand existing studies to increase engagement with underrepresented populations and to enhance accrual and collaboration

Expand in 2025 and Beyond: Launch new studies across the network and further establish and solidify the network infrastructure

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Infrastructure to Integrate Research into Primary Care

Infrastructure components anticipated to be piloted and implemented

Clinical Science Center

Operations Center

Independent Review and Monitoring Boards

Network Research Hubs

Community Engagement

Industry Partnerships

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Network Research Hubs: Objectives

Research in Primary Care Settings in collaboration with Clinical Sites on Select Existing NIH-Funded Studies and New Studies

Participant and Community Engagement

Innovations in Clinical Study Design

Participation in Coordinated Infrastructure Supporting Research in Primary Care Settings

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Phased Approach to Launching Studies and Building Infrastructure

This effort is expected to be a **two-year pilot**

Year 1: Selecting and funding Network Research Hubs through this ROA to support participation in select existing NIH-funded studies. These initial studies may be interventional or observational and are expected to be suitable for primary care settings

Year 2: New research in coordination with the other components of the infrastructure following approval by the Scientific and Medical Director, and Operations Director and funding from external sources for all study aspects not covered by the coordinated infrastructure. NIH will conduct an evaluation of the program to assess which approaches and efforts are working. NIH may expand, pivot, and/or sunset awards and/or components based on the results.

Anticipated Awards and Budget

Number of Awards

Between 2 to 5 Awards Issued in FY24

Budget

Approximately $5 Million total in FY24
Approximately $20 Million total in FY25

Contingent on programmatic objectives, performance and availability of funds.

Eligibility Criteria

Eligible Organizations

✓ Lead or funded partner organizations of:
- NIH IDeA-CTRs
- NIH CTSA
- PCORI PCORnet

✓ Organizations with IDeA-CTR and CTSA awards or sub-awards in no-cost-extensions.

✓ Organizations where at least 25% of its census tracts are defined as [rural](#).*

X Foreign Institutions, including non-domestic entities, non-domestic components of domestic organizations, and foreign components are not eligible

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States that meet the eligibility criteria of those with >25% rural census tracts per the Revised 2010 RUCA codes 4-10

• Alabama	• Idaho	• Maine	• Montana	• North Carolina	• South Dakota	• Wisconsin
• Alaska	• Iowa	• Minnesota	• Nebraska	• North Dakota	• Tennessee	• Wyoming
• Arkansas	• Kansas	• Mississippi	• New Hampshire	• Oklahoma	• Vermont	
• Hawaii	• Kentucky	• Missouri	• New Mexico	• Oregon	• West Virginia	

*For the purposes of this ROA, rural areas are defined according to the Office of Management and Budget and Federal Office of Rural Health Policy (FORHP) definitions, where primary Rural-Urban Commuting Area (RUCA) codes between 4 and 10 correspond to rural areas and primary RUCA codes 1-3 correspond to urban areas.

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Application Requirements

Submission Format

- Upload in eRA Commons

- Searchable PDF

- Font: Calibri, Aptos, Arial or Times New Roman; Size 11 or 12

- 1-inch margins on all sides (top, bottom, left, and right).

- Components loaded as separate attachments and titled as specified in each section Guidance for OT application submission can be found on the NIH website.

Sections and Page Limits

Section	Page Limit
Cover	2 pages
Abstract	No more than 250 words
Specific Aims	1 page
Project Plan	16 pages
Technical Approach	6 pages
Primary Care Research Experience	6 pages
Environment and Resources	3 pages
Leadership Plan	1 page
Budget	Unlimited Pages
List of Key Personnel	1 page
Biosketches of Key Personnel	3 pages
Letters of Interest/Support	1 page per institution/organization
Appendix	Unlimited Pages

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Project Plan and Budget

Project Plan

Technical Approach (up to *6 pages*)

- Subsection A: Overview and Organization
- Subsection B: Developing and Implementing Studies and Use of Innovative Designs
- Subsection C: Participant and Community Engagement

Primary Care Research Experience *(up to 6 pages)*

Environment and Resources *(up to 3 pages)*

Leadership Plan *(1 page)*

Budget

Estimated baseline costs of adding a select and limited number of primary care Clinical Sites to existing studies, where the operational aspects are covered by other NIH awards.

Budgets are expected to be negotiated as the initial study is selected before an award is issued.

Include **costs for community partners to be fully engaged** and successfully participate in research prioritization, design and implementation

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Objective Review

- Applications will not be evaluated against each other during the review process but rather on their own individual merit.

- Submission of written critiques by subject matter experts documenting the strengths and weaknesses of responsive applications.

- Applications may be triaged for review based on the proposed catchment area of potential research participants.

- NIH will NOT provide feedback on applications, except as a part of follow-up on an as-needed basis as time permits. NIH will not accept an appeal of the objective review or funding decision outcomes.

- Review Criteria:

  ❑ Potential Contribution to the Coordinated Infrastructure for Supporting Research in Primary Care

  ❑ Capabilities and Experience

  ❑ Resources and Environment

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Objective Review Criteria Considerations

Potential Contribution to the Coordinated Infrastructure for Supporting Research in Primary Care

- ✓ High likelihood of meeting the objectives of a Network Research Hub

- ✓ Adequate plans for collaboration and plans to engage the community they serve

Capabilities and Experience

- ✓ Track record of successfully implementing research in primary care

- ✓ Key personnel have sufficient and relevant expertise

Resources and Environment

- ✓ Currently participating in and affiliated with networks (NIH IDeA-CTRs, NIH CTSA, and/or PCORI PCORnet)

Award Negotiation and Selection Information

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NIH will determine whether an application will be selected for negotiation and/or award.

- **Up to six** viable applications will be chosen to move forward in negotiations for a potential award

- Negotiations involve **identification of the initial study already funded by NIH** to which the Network Research Hub will serve as an additional enrollment site

- Coordination with the NIH team overseeing those studies will be required to understand the needs and existing support for the studies and to **develop a final budget and milestone plan for the Network Research Hub**.

- Final award selection involves assessment of applications with **successful negotiations and review and approval** by NIH leadership and development of objective milestones as agreed upon by NIH and the applicant.

- The **level of funding** for any award(s) made will **depend on the negotiated studies and milestones** and availability of funds.

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OT Agreement Governance

OTA-24-016

Other Transactions (OT) are a special type of legal instrument other than contracts, grants or cooperative agreements that are not subject to the [Federal Acquisition Regulation (FAR)](#), nor to grant regulations unless otherwise noted

- For the awards funded under this ROA, NIH will engage in negotiations, and all agreed upon terms and conditions will be incorporated into the Agreement

- Either a bilateral agreement or a Notice of Award (NoA) will be used as the official Agreement

- Each award will be assigned an

  - OT Agreement Officer who is responsible for legally committing funds on behalf of the government,

  - OT Agreement Specialist who serves as the first line contact with award recipients,

  - OT Program Official for day-to-day programmatic oversight, and

  - Potential subject matter experts to assist the PO in scientific and technical discussions with awardees

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Special Award Terms

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The complete terms and conditions of each OT award issued under this ROA are subject to negotiation and will be contained in the Agreement entered between NIH and award recipient.

Lower Tier Agreements

- Award recipients will be expected to issue sub-awards to entities identified in their applications and approved by NIH under this ROA. Any changes to sub-awards must be in consultation with NIH prior to adding or removing partners.
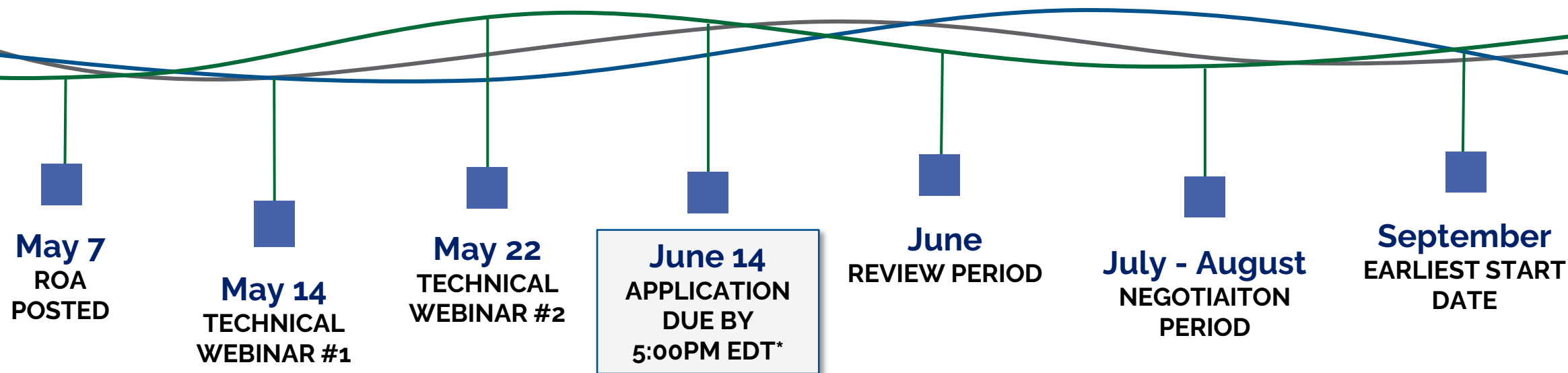
Milestone-Based Workplan

- A milestone-based workplan will be requested and negotiated prior to award for inclusion in the OT Agreement. The workplan should include a description of operational milestones, completion criteria, and expected start and completion dates.

Enhancing Diversity, Equity, Inclusivity, and Accessibility in the Research Community

- Award recipients will be encouraged to diversify their staff populations to facilitate engagement with diverse research partners and to enhance the participation of individuals from groups that are underrepresented in the biomedical, clinical, behavioral and social sciences, such as those defined in Notice of NIH's Interest in Diversity (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-031.html).

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Key 2024 Dates (OTA-24-016)

See below a timeline with key dates for the application, review, and start period for OTA-24-016.

May 7
ROA POSTED

May 14
TECHNICAL WEBINAR #1

May 22
TECHNICAL WEBINAR #2

June 14
APPLICATION DUE BY 5:00PM EDT*

June
REVIEW PERIOD

July - August
NEGOTIAITON PERIOD

September
EARLIEST START DATE

*NO LATE APPLICATIONS WILL BE ACCEPTED.

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Question and Answer

Following this webinar, the recording and slide presentation will be posted on the NIH website.

Thank you for joining.

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