Pragmatic Trials across the Cancer Control Continuum (Clinical Trials Required)

UG3/UH3 PAR-22-256

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Pre-Application Webinar Agenda

- Purpose of funding opportunity announcement
- UG3/UH3 funding mechanism
- Requirements
- Review criteria
- Additional information
- FAQs
- Scientific contacts

Purpose of FOA

Through this funding opportunity announcement (FOA), the National Cancer Institute (NCI) intends to:

- accelerate the development of evidence-based cancer-related interventions that reflect the diversity of people, places, contexts, and settings in the United States.
- support research that tests the impact of cancer-related interventions on cancer-related outcomes across the cancer control continuum using a pragmatic trial study design.
- use the UG3/UH3 phased cooperative agreement mechanism. The UG3 phase will support refining the cancer-related intervention and finalizing study-related activities in preparation for conducting the pragmatic trial during the UH3 phase.

Select Key Terms

- Cancer-related Intervention*:* An action taken to affect one or more cancer-related outcomes. Cancer-related interventions may include (but are not limited to) a cancer-related behavioral intervention, technology-mediated intervention, community-based intervention, healthcare delivery intervention, multilevel intervention, and implementation strategy.

- Cancer-related Outcome*:* Any cancer-related variable that is hypothesized to change in response to exposure to a cancer-related intervention. Examples of cancer-related outcomes include (but are not limited to) clinical health outcomes, health status, health behaviors, quality of care, healthcare utilization, community health, and implementation outcomes.

Select Key Terms (*cont'd*)

- Clinical Trial*:* A clinical trial ("trial") is a research study in which:
  - One or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes. (See NIH clinical trials website for more information.)
  - For the purpose of this FOA, a trial includes at least one intervention condition and at least one control or comparison condition.
  - Trial designs may be randomized or non-randomized but must be pragmatic.

- Pragmatic Trial: A trial that is primarily designed to determine the effects of an intervention under "usual" contexts or circumstances.
  - Primary intent is to generate information that directly informs decision making among key partners and collaborators.

Examples of Cancer-related Interventions

- Cancer-related interventions to:
  - integrate shared decision making into screening for lung, colorectal, and prostate cancer
  - reduce cancer-related risk factor behaviors, including obesity, unhealthy diets, sedentary lifestyles, UV exposure, and alcohol use
  - reduce exposure to environmental carcinogens
  - alleviate economic hardship among cancer survivors
  - provide cancer genetic counseling, testing uptake, and follow-up care
  - integrate geriatric assessment and management into care of older adults undergoing cancer treatment
  - deliver bundled evidence-based interventions into healthcare and public health settings

What is the UG3/UH3 Mechanism?

- U: Cooperative agreement award
  - Investigator-initiated applications
  - Funding agency anticipates federal staff will be involved in activities of the award (Project Scientist[s])

- UG3/UH3: Phased award
  - Two distinct phases: UG3 phase and UH3 phase
  - Successful transition (award/funding) from UG3 to UH3 phase is contingent upon meeting several criteria

What is the UG3/UH3 Mechanism (*cont'd*)?

- Transition from UG3 to UH3 phase criteria and process
  - UG3 milestones met
  - Potential for meeting UH3 milestones
  - Availability of funds
  - NCI priorities
  - NCI administrative review

- NOTE: Award/funding for UG3 phase **does not** guarantee award/funding for UH3 phase

Requirements: UG3 Phase

- UG3 phase of the application **must** describe all preparatory activities necessary for conducting the pragmatic trial during the UH3 phase.

- Activities include those related to:
  1. Piloting and refining the cancer-related intervention *and*
  2. Revising and finalizing plans and processes necessary for conducting the pragmatic trial.

Requirements: Timelines, Milestones

- Milestones: Scheduled event in the project timeline signifying the completion of a major project stage or activity.
- Applications **must** include a section of proposed milestones that are well-defined, quantifiable, and include objective criteria to allow for assessment of progress and success.
- For UG3 milestones, include a:
  - study timeline
  - discussion of the suitability of the milestones for assessing success in the UG3 phase, and
  - discussion of the implications of successful completion of these milestones for the proposed UH3 phase.
- For UH3 milestones: Include annual milestones.

Requirements: UH3 Phase

- UH3 Phase of the application **must** include plans and activities to test the effect of a cancer-related intervention on a cancer-related outcome in a pragmatic trial and to achieve the following goals:
  1. Successfully conduct and complete all aspects of the pragmatic trial.
  2. Identify whether the proposed cancer-related intervention has a statistically significant impact on improving the cancer-related outcome as tested in the pragmatic trial.

Non-Responsive Applications

- Applications that propose to test cancer-related therapies, imaging, diagnostics, biologics, or devices (e.g., first-in-human studies or drug/device safety trials).

- Applications that propose a pragmatic trial that **does not** have at least one intervention condition and at least one control or comparison condition.

- Applications lacking milestones for the UG3 phase and the UH3 phase.

Review Criteria Specific to this FOA: *Significance*

How well does the application:

- provide an explanation and justification for why the proposed cancer-related intervention is needed and how it fills a gap in the evidence base?
- demonstrate that the cancer-related outcome is important to key collaborators and decision makers?
- describe the potential impact of the cancer-related intervention on improving a major cancer-related health issue?

Review Criteria Specific to this FOA: *Investigator(s)*

How well does the application:

- provide evidence that the investigative team has scientific expertise in cancer-related interventions and pragmatic trials?
- describe the involvement and inclusion of key partners and decision makers as collaborators in the proposed research?

Review Criteria Specific to this FOA: *Innovation*

- How well does the application demonstrate that the proposed cancer-related intervention is important yet missing, largely absent, or underrepresented in the current evidence base of effective interventions?

Review Criteria Specific to this FOA: *Approach*

How well does the application:

- describe the process for piloting and refining the cancer-related intervention as well as revising and finalizing plans and processes necessary for conducting the pragmatic trial?
- describe and justify the design elements of the pragmatic trial?

Additional Application Information

- Page Limitations:
  - Research Strategy section is limited to **25 pages**

- Eligibility:
  - Non-domestic (non-U.S.) entities (foreign institutions) **are not** eligible to apply.
  - Non-domestic (non-U.S.) components of U.S. organizations **are not** eligible to apply.
  - Foreign components, as defined by the NIH Grants Policy Statement, **are** allowed.

Due Dates

- First application due date (new application): February 14th, 2023
- Last application due date (new application): October 17th, 2025
- *See full PAR text for additional dates*

Funding Period and Budget

- UG3 Phase:
  - Maximum of 2 years, up to $500,000 in direct costs per year

- UH3 Phase:
  - Maximum of 4 years, up to $750,000 in direct costs per year

Letters of Support

- Applications must include letters of support from key partners and decision makers collaborating on the project.

- Key partners and decision makers may include (but are not limited to) those from or representing patients, community advisory boards, practitioners, healthcare systems, public health departments, professional associations, clinics, hospitals, community-based organizations, community leaders, and others.

Resource Sharing Plan

- The NIH has issued a Data Management and Sharing (DMS) policy, effective for applications received on/after January 25, 2023, to promote the sharing of scientific data
- Under the DMS policy, NIH intramural investigators will:
  - Prospectively plan for the managing and sharing of scientific data
  - Submit a DMS plan
  - Comply with the approved plan
- Data sharing plans will become a term and condition of the award
- These applications will fall under the new NIH Data Sharing Policy
- Policy details and templates are available online

FAQs

- **Is an Awaiting Receipt of Application (ARA) required for budgets that exceed $500k direct costs in any of the award years?**
  - No. The ARA policy does not apply to this FOA.

- **Is there a suggested budget for the UG3 phase and the UH3 phase?**
  - There is no suggested budget for either phase. However, budgets must reflect the actual needs of the proposed project and be within the budget caps for each phase.
    - UG3: $500k direct cost per year
    - UH3: $750k direct cost per year

FAQs

- **Where will applications be reviewed? What standing study section(s) and/or special panel(s)?**
  - Applications will be reviewed at the Center for Scientific Research (CSR).
  - Applications will likely be reviewed within the Division of AIDS, Behavioral and Population Sciences (DABP), including (but not limited to) those within the following branches:
    - Health services and systems review (HSS)
    - Clinical care and health interventions review (CCHI)
    - Social and community influences across the lifecourse review branch (SCIL)

FAQs

- **How will NCI Project Scientists be involved in the studies? Do I need to identify someone before I submit my application?**
  - NCI Project Scientists will have substantial programmatic and scientific involvement that is above and beyond normal stewardship role in awards.
  - If funded, an NCI Project Scientist will be assigned to your project. Do not include information about the NCI project scientist (e.g., role, names) in your application. Do not contact NCI program staff asking them to be the project scientist for your award.

FAQs

- **What are some examples of UG3 and UH3 milestones? How many milestones should I propose in the application?**

- Pilot test the virtual intervention accessibility and timing in 30 subjects.
- Translate and validate study surveys into Spanish.
- Integrate the electronic health record algorithm and test functionality at all study sites.
- Complete staff and community partner intervention training.

Scientific Contacts

- **Susan Czajkowski**, PhD, Behavioral Research Program: susan.czajkowski@nih.gov
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Thank You!

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