PAR-18-577: New Epidemiology Cohort Studies in Heart, Lung, Blood, and Sleep Diseases and Disorders (U01, Clinical Trial Not Allowed)

Applicant Information Webinar

Monday, February 5, 2018
2:30-3:30 pm Eastern

National Heart, Lung, and Blood Institute

WebEx instructions

- All attendees are muted upon entry
- Send questions to “All panelists” using the Q&A feature at any time during the presentation
  - Questions submitted during the webinar may be added to the FAQ page for PAR-18-577
- This event is being recorded
  - Slides and recording will be posted on the FAQ page

Overview of PAR-18-577

FOA purpose

The purpose of this Funding Opportunity Announcement (FOA) is to support new and innovative epidemiology research in heart, lung, blood, and/or sleep (HLBS) diseases, disorders, and/or phenotypes. Through this FOA, the National Heart, Lung, and Blood Institute (NHLBI) aims to establish a new epidemiology cohort of at least 2000 participants to stimulate research on a wide range of HLBS research hypotheses.

FOA background

- FOA designed to address research gaps and support innovative HLBS epidemiology research
- Issued in response to recommendations made by a 2013 working group comprised of members from the NHLBI's Advisory Council and Board of External Experts to implement a competitive peer review-based model for the NHLBI’s portfolio of large epidemiologic and population studies

Cohort eligibility

- 2000+ participants
- Predominantly focus on U.S. populations
- Addresses HLBS research gaps
- Innovative
- Investigates a broad array of putative exposures and risk factors
- Supports the study of research questions across a range of HLBS phenotypes

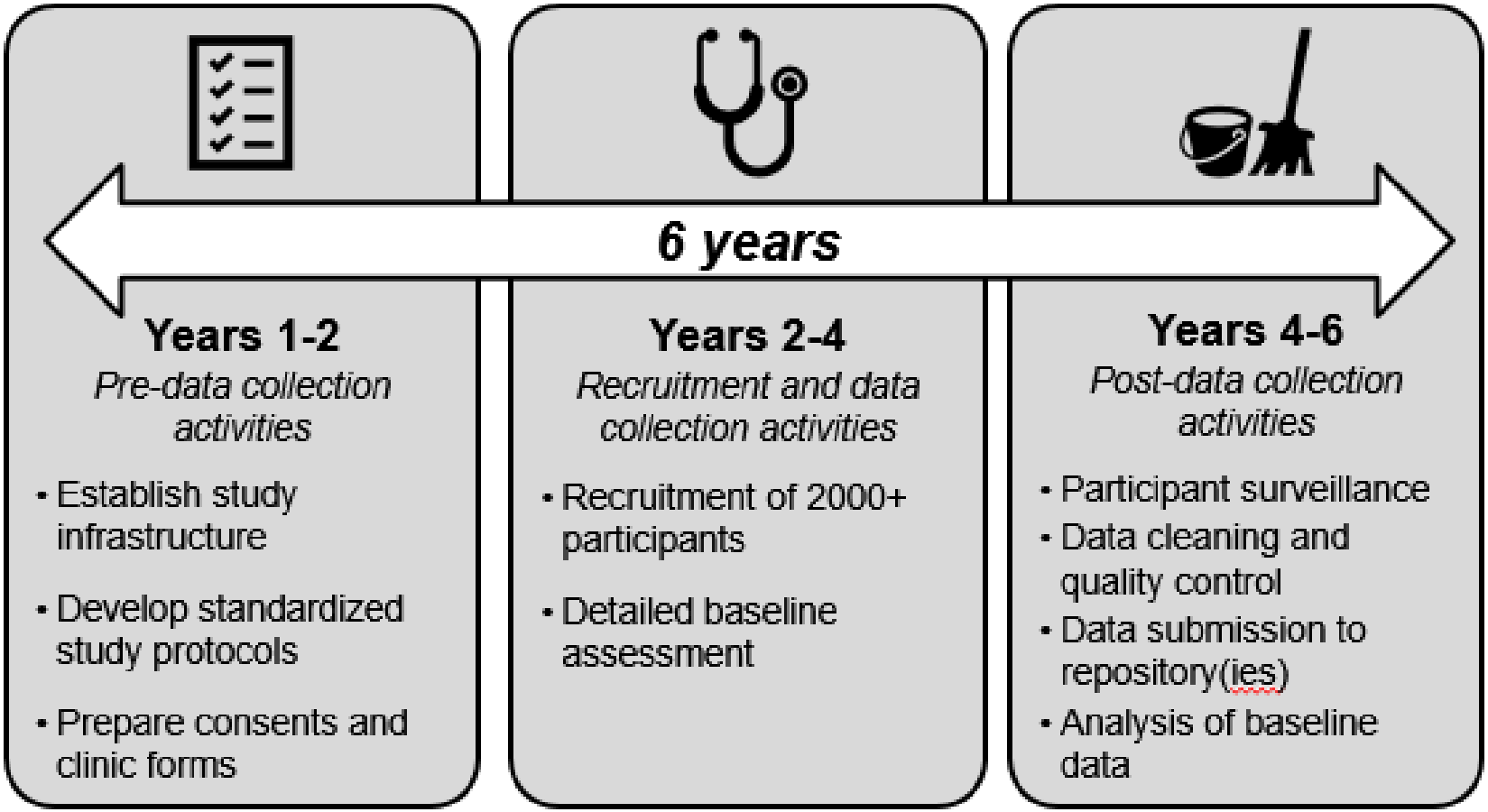
Programmatic interest in applications that…

- Align with NHLBI's Strategic Vision
- Propose to adopt or use data standards, common data elements (CDEs), and/or standard ontologies to facilitate harmonization and sharing/analysis of data across studies
  - See the NIH's CDE Repository and Resource Portal
- Support research capable of addressing multiple scientific hypotheses
- Have short-, medium-, and long-term visions for the cohort study

What is supported under this FOA?

- *Both* the study infrastructure and a detailed baseline assessment of participants
- Sample activities include, but are not limited to, the following:
  - Protocol development and approval
  - Collection, analysis, storage, and maintenance of biological samples
  - Data management, and administrative and communication tasks
  - Participant follow-up
  - *The FOA includes a longer list of sample activities*

Example project period



Budget

- Entire budget for each award (FY 2019, FY 2021) is $33 million (total costs)
  - Contingent upon NIH appropriations
  - Application budget should reflect *actual* needs of the proposed project
    - Year 1: $3M total costs (~$1.948M direct costs)
    - Years 2-6: $6M total costs (~$3.896M direct costs)
- ***ONE** award will be funded per application cycle*
- For FY 2019 award (total costs):

Year	FY2019	FY2020	FY2021	FY2022	FY2023	FY2024
Limit	$3M	$6M	$6M	$6M	$6M	$6M

Other notes

- A similar FOA, PAR-17-338, is available to support the continuation of existing cohort studies
- Applications will be reviewed by a special emphasis panel convened by the NHLBI (see FOA, Section V)
- Interventions done to phenotype participants (e.g., induced phenotypes such as glucose or methacholine challenges) can be supported under this FOA; however, clinical trials are not allowed
  - NHLBI staff can help determine whether a proposed intervention would be considered a clinical trial and thus not appropriate for this FOA

Submission Timeline

PAR-18-577 has two application cycles

Milestone	Cycle 1	Cycle 2
Staff consultation due	March 1, 2018	Feb. 28, 2020
Letter of request due	March 6, 2018	March 8, 2020
Notification of NHLBI's decision	April 17, 2018	April 17, 2020
Receipt date	***June 5, 2018***	***June 5, 2020***
Scientific merit review	October 2018	October 2020
Advisory Council review	January 2019	January 2021
Earliest start date	April 2019	April 2021

Applications with direct costs >$500k

- NHLBI's policy regarding applications requesting >$500k in direct costs in any one year will apply to PAR-18-577
- Applicants ***MUST*** obtain approval from NHLBI stating that we will accept the application for initial peer review
- For applications requesting >$1.515M in direct costs, the process to obtain NHLBI's acceptance of an application for review involves:
  - Staff consultation
  - Letter of request

Staff consultation (*due March 1, 2018*)

- Large anticipated interest in FOA means NHLBI will not be able to hold a typical staff consultation, in which a team of staff discuss a proposed study with investigators in detail
  - *For this FOA only*, an abbreviated staff consult will be used

- Applicants satisfy this FOA's staff consultation requirement by completing *both* of the following:
  - Review the FAQ page
  - View this webinar, either live or via the recording
  - *Indicate the date(s) this requirement was completed in the letter of request*

Letter of request (*due March 6, 2018*)

- Limited to 5 pages, excluding references
- Required content for letter is outlined on NHLBI's $500k policy page
  - Use the provided budget template
- When describing the significance of the proposed research, emphasize:
  - The HLBS research gap(s) the proposed cohort study aims to address
  - How the proposed cohort study is innovative
- When emailing the letter to the appropriate division director, cc the NewEpiCohorts@nhlbi.nih.gov email address

Letter of Request required components

- Title of the proposed project
- Application receipt date (here, June 5, 2018)
- Specific aims of the proposed project, including any subprojects
- Significance of the proposed research
  - The HLBS research gap(s) the proposed cohort study aims to address
  - How the proposed cohort study is innovative
- Key personnel and the (contact) PI's eRA Commons *userid*
- Submitting organization or institution
- Yearly direct costs, subcontract F&A (if any), and total costs
  - Any proposed third-party support, the estimated commitment level, and possible contingency plans in the event that the third-party support is terminated during the research project
- Specific plan for disseminating the results for clinical/public health practice
  - Intended audience, approaches to reach that audience, and a timeline
- Plans for data sharing

Criteria for NHLBI's decision

- Relevance to the NHLBI mission and Strategic Vision
- Complementary nature of the proposed program to other NHLBI programs
- Potential value of knowledge gained
- Reasonableness of the proposed annual costs
- Appropriateness of the proposed plans for data sharing
- Potential for cost sharing with other federal and non-federal entities
- Applicability to public health
- Adequacy of the dissemination plan
- Compliance of the proposed study with:
  - NIH Policy and Guidelines on the Inclusion of Children as Participants in Research Involving Human Subjects
  - NHLBI Policy for Inclusion of Women and Minorities as Subjects in Clinical Research

Approval to submit application for peer review

- Large anticipated interest in FOA means NHLBI anticipates receiving many Letters of Request
- As such, NHLBI anticipates being selective with which applications to accept for peer review
  - Permission to accept an application for peer review will not be granted to all Letters of Request the NHLBI receives
- Include NHLBI's approval letter in your application
- ***Note:*** *If NHLBI grants permission to submit an application for review, this does* ***NOT*** *guarantee the NHLBI will fund the application or that it will fund the application at the requested levels, regardless of the outcome of peer review*

Application Instructions

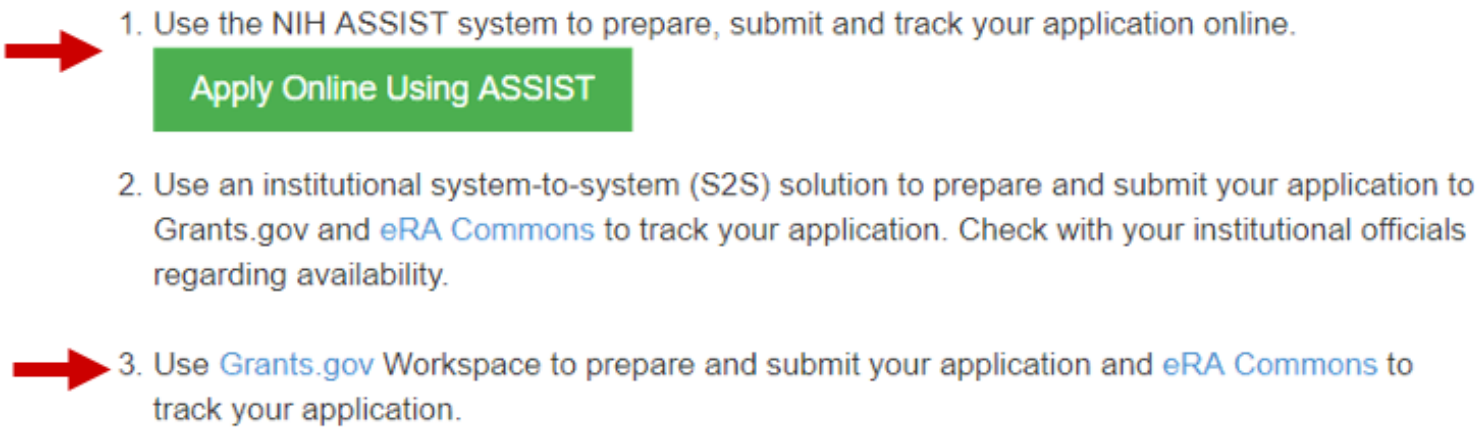
Application: Other Attachments, Budget

- All three Other Attachments must be completed or application will not be reviewed
  - Baseline assessment, 3 pages
  - Cohort management, 5 pages
  - Biospecimen plan (*only if applicable*), 5 pages

- Budget: direct costs requested in the application may be less than, but cannot exceed, the budget outlined in the Letter of Request
  - Application budget cannot exceed the LoR's budget either in total or by year

Application: FORMS-E

- FORMS-E application package: new Human Subjects and Clinical Trial Information form
  - See NOT-OD-17-119 and NOT-OD-17-062 for more information
  - Access the FORMS-E package through ASSIST or grants.gov



Application: FORMS-E

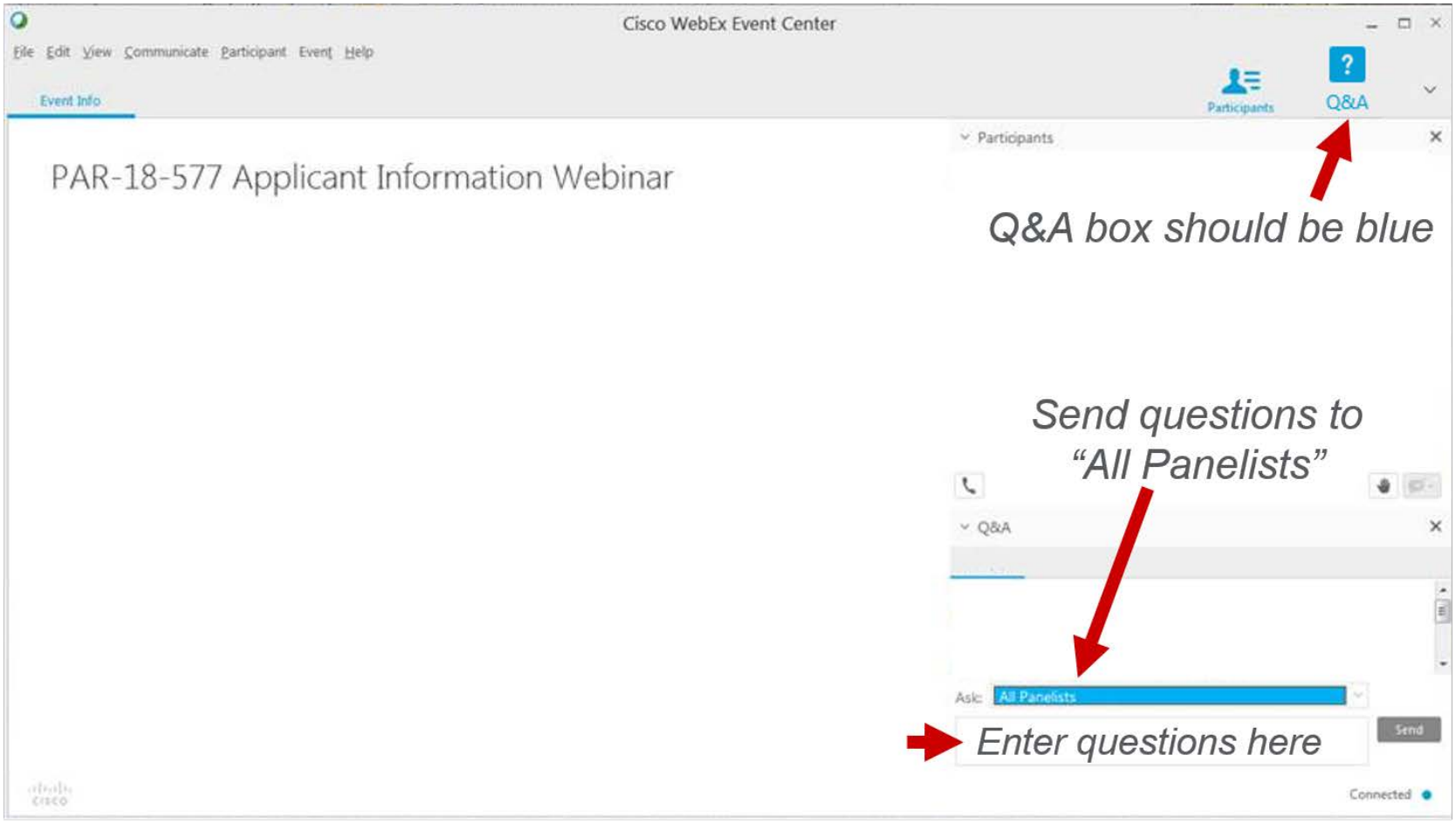
- FOA-specific instructions for sections:
  - 2.4: Inclusion of Women, Minorities, and Children
  - 2.5: Recruitment and Retention Plan
  - 2.7: Study Timeline
  - 3.1: Protection of Human Subjects
  - 3.5: Overall Structure of Study Team
    - *Note: While section 3.5 is typically optional for non-clinical trial applications, it is required for this FOA*
- FORMS-E Sections 4 and 5 *only* apply to clinical trials
  - *Inputting information in this section will result in errors and will prevent your application from being accepted*

Application: Single IRB

- Applications subject to NIH policy on use of a single IRB (sIRB) for multi-site research (NOT-OD-16-094)
  - See NOT-OD-18-004 for policy implementation guidance
- Exceptions will be made where the proposed sIRB would be prohibited by a federal, state, or tribal law, regulation, or policy
  - See NOT-OD-18-003 for more on sIRB exceptions
- Include sIRB costs in your budget (NOT-OD-16-109)
  - See FAQs regarding sIRB costs

Audience Q&A

Audience Q&A



National Heart, Lung, and Blood Institute

Still have questions about PAR-18-577?

- Email NewEpiCohorts@nhlbi.nih.gov
  - Multiple NHLBI program staff are monitoring this inbox to ensure timely responses
  - Questions sent to this email address may be posted on the FAQ page; however, identifying details about the applicant or the proposed study will be removed before posting
- Periodically check the FAQ page for updates
- Pay attention to the FOA-specific application instructions for PAR-18-577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