Pre-Application Webinar: PAR-22-233

Time-Sensitive Opportunities for Health Research

October 6, 2022

Sarika Parasuraman, PhD MPH (OBSSR)

Mark Rubert, PhD (Center for Scientific Review)

Program Officers In Attendance

Gregory Bloss National Institute on Alcohol Abuse and Alcoholism (NIAAA)	**Layla Esposito** *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD)
Karen A. Kehl National Institute of Nursing Research	**Marsha Lopez** National Institute on Drug Abuse (NIDA)
Stephanie M George National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS)	**Arielle Samantha Gillman** National Institute on Minority Health and Health Disparities (NIMHD)
Elizabeth Barr Office of Research on Women's Health (ORWH)	**Bramaramba Kowtha** Office of Disease Prevention (ODP)
Marissa Shams-White National Cancer Institute (NCI)	

Webinar Tips

Participants will be in Listening Mode and will not be able to ask questions verbally or use the ”Chat” function.

Participants must ask questions using the “Q and A” feature. Questions will be answered during the Q&A session at the end of the webinar as time permits.

These slides and a recording of today’s webinar will be available on the OBSSR website: https://obssr.od.nih.gov/news-and-events/news/resources-par-22-233-time-sensitive-opportunities-health-research-r61r33

Agenda

I. PAR Background, Objectives, and Expectations

II. Peer Review Process

III. Timeline for Submission, Review, and Selection of Applications

IV. Participant Questions

Part I:

PAR Background, Objectives, and Expectations

Sarika Parasuraman, Ph.D, MPH
Office of Behavioral and Social Sciences Research (OBSSR)

NIH
National Institutes of Health
Office of Behavioral and Social Sciences Research

Purpose

- Purpose: To establish an accelerated review/award process to support research to understand health outcomes related to an unexpected and/or time-sensitive event (e.g., emergent environmental threat; pandemic; change in local, state, or national policy; natural disaster).

- Applications in response to this FOA must demonstrate that the research proposed is time-sensitive and must be initiated with minimum delay due to a limited window of opportunity to collect baseline data, answer key research questions, and/or prospectively evaluate a new policy or program that will likely impact health-related behavior or health outcomes in a given population.

Key Definitions

- **Event:** A unique and often unanticipated issue that arises in a particular community/population, due to emerging environmental threats, other public health threats, disaster events, or policy changes.
- **Policy:** Includes both formal public policies at local, state, and federal levels of government, and organizational level policies, such as those implemented by large organizations, worksites, or school districts.
- **Program:** A set of activities such as implementation of system-level interventions, tools, or guidelines initiated by governmental or other organizational bodies, within public or private entities in local, state, or federal jurisdictions.
- **Infrastructure changes:** Alterations to the built environment such as housing, roads and other aspects of transportation systems, retail environments, and building of parks or green spaces.

Research Scope

- This FOA is intended to support research and data collection opportunities:
  - For **unanticipated real-world events** (i.e., those that occur outside of a laboratory or other controlled setting for research purposes) that have limited windows of opportunity for planning and conducting rigorous research and data collection.
  - In which empirical **study could only be available through expedited review and funding**, necessitating a substantially shorter process than the typical NIH grant review/award cycle.
- This FOA encourages:
  - **Partnerships and collaboration** between researchers and the impacted community, which *may* include the following types of entities (as appropriate): community-based organizations, local and state governments, private or non-profit organizations, behavioral health or health care systems, individual health care providers, departments of health, community health clinics, juvenile or criminal justice settings, schools, child welfare systems.
  - Research that has the potential to be **generalizable beyond a particular locality** (region, community, or other defined geographic area) **or population.**
  - Proposed studies demonstrate the ability to inform the understanding of the impact of the event, policy, program or infrastructure change in the near-term.

Research Scope (continued)

- The distinguishing features of a **responsive study** are:
  1) The unpredictable and unanticipated nature of the research opportunity.
  2) The clear scientific value and feasibility of the study.
  3) A feasible plan for collection of baseline data and primary data collection (although use of existing data is allowed, a plan for collecting important and new data rapidly should be provided).
  4) A justification for why an expedited review and funding (substantially shorter than the typical NIH grant review/award cycle) are required in order for the scientific question(s) to be addressed and the research design to be implemented.
- Applicants are encouraged to consider or include:
  - Study methodologies such as interrupted time-series, difference-in-difference designs, regression discontinuity, or propensity scoring.
  - Methodological developments and approaches for strengthening causal inference from evaluation of these “natural experiments” or observational study designs.
  - Secondary implementation related outcomes that could inform interpretation of outcomes for future researchers and decision-makers, such as unintended consequences or barriers and facilitators associated with implementation.
- Applicants are also encouraged to review the NIH-led efforts that recommend research strategies for ensuring study rigor and reducing bias, such as including an appropriate comparison group where possible: NIH Pathways to Prevention (P2P) Workshop: Method for Evaluating Natural Experiments in Obesity.

Non-Responsive Criteria

The following types of applications are **not responsive** to this FOA.

- Applications that do not explicitly justify the time sensitivity of the proposed work, the urgent need for data collection, and the need for an expedited review timeline. Include this explanation in the Significance section of the application.
- Applications that propose to use qualitative data exclusively (though mixed method approaches are encouraged).
- Applications that propose to conduct analyses of existing data exclusively (unless allowed in IC-specific interests).
- Applications aimed at addressing unanticipated needs or additional aims for an existing study (i.e., expansion of an existing study).
- Applications proposing to use animals (e.g., pets, laboratory animals, or wildlife) as surrogates for human health or exposure.
- Applications where the PD/PI of the evaluation study application is the Director and/or initiator of the policy, program, or infrastructure change that will be evaluated.
- Applications that independently propose initiation and/or delivery of new policies or programs.

It is strongly recommended that you reach out to the relevant PO prior to submission. Non-responsive applications will not be reviewed.

R61/R33 Structure and Research Expectations

R61/R33: Two-phased, milestone-driven grant mechanism.

- R61 phase will support with developmental, exploratory research activities, Institutional Review Board approval for human subjects protection, further development of study partnerships, and the collection of baseline data for **up to one year**.
- R33 phase is expected to have expanded activities designed to achieve the full research aims, and may include further development, application, follow-up data collection, or implementation as appropriate and relevant to the proposed research questions for **up to four years**.

Application expectations and transition from R61 to R33 phase:

- Applications should articulate clear aims and objectives for each phase of the proposed research, with specific discussion of how results from the R61 phase will inform the R33 phase.
- Applicants must delineate explicit milestones for the R61 and R33 phases. A **milestone** is defined as a scheduled event in the project timeline that indicates completion of a project stage or activity.
- It is expected that **baseline data collection will be conducted within six months of award**, which should be included in the applicant's submission of a project timeline and milestones.
- At the completion of the R61 phase, the Program Director (PD)/Principal Investigator (PI) will submit a report that includes the progress on each of the milestones and a clear description of how research during the R33 phase will be impacted by attainment of the R61 milestones. Determination of continuation to an R33 grant will depend on the Program Officers' review of this report with regard to 1) the preliminary research results and achievement of the milestones and 2) availability of funds and program priorities, irrespective of milestone achievements.

Additional considerations

- **Transition to the R33 phase is neither automatic nor guaranteed.** Funding for the R33 phase is subject to availability of funds and program priorities, independent of milestone achievement.
- Given the possibility for changes in policy or program implementation that are beyond the control of the grantee, grant awards may be terminated early if these changes limit the possibility to collect meaningful outcome data.

- **Outreach to Program Officers:**
  - Applicants are strongly encouraged to contact the relevant scientific contact(s) listed in the FOA to discuss whether their application would likely be responsive based on time-sensitivity four (4) weeks in advance of planned application.

- **Letter of Intent:**
  - Although a letter of intent is not required, is not binding, and does not enter into the review of a subsequent application, the information that it contains allows IC staff to estimate the potential review workload and plan the review. Further information on elements to include in the letter may be found in the FOA.

Specific Areas of Research Interest: National Cancer Institute (NCI)

NCI supports time-sensitive evaluation of programs, policies, and major events that concern aspects of cancer prevention and control including, but not limited to:

Evaluation of the effects of:

- Laws, regulations, or policies that may influence cancer risk factors including use of tobacco, alcohol, and other substances, sun safety and indoor tanning, diet, physical activity, and sleep.
- Changes to the built and natural environment involving factors such as housing, transportation infrastructure, food environment, parks and other green and blue spaces and the potential effect on cancer risk factors, exposure to environmental carcinogens, access to care, or other cancer-related health outcomes.
- Emerging programs and policies related to cancer screening, diagnosis, vaccination (e.g., HPV), treatment, and survivorship.
- New policies, programs, and practices in cancer care delivery related to standards of care, health insurance coverage, access to services, reimbursement, and other factors that influence delivery of cancer care services and its outcomes
- The impact and response to public health emergencies or disasters (natural or man-made) on acute stress, allostatic load or other aspects of accumulated stress, or cancer-related care, including preventative, diagnostic, treatment, and survivorship care.

Proposals evaluating policy and program efforts and responses to major events from diverse sectors, including government, educational, non-profit, and commercial sectors are of interest.

Specific Areas of Research Interest: *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD)

NICHD has particular interest in research on time-sensitive events, policies, programs, or infrastructure changes on vulnerable populations falling within the NICHD scientific mission area, including infants, children, and adolescents and pregnant and post-partum people; individuals with physical and/or intellectual disabilities; and children who are unhoused or in foster care. The NICHD Strategic Plan outlines high priority areas for the Institute.

Examples of research questions include but are not limited to the following:

- Understanding the short- and long-term impact of the time-sensitive event on child development outcomes, as well as family functioning.
- The impact of climate/environmental changes on dietary patterns, food choices, and eating behaviors.
- How changes in access to school lunch programs affect dietary patterns, food choices, and eating behaviors in children and their families.
- The impact of the event and the concomitant public health response on the management of complex medical conditions, critical illness, and severe, life-threatening injuries in children.
- The impact of the event on emergency medical services to children (EMSC) and the availability of these services during and after the event to affected children in low- to moderate- resourced communities.
- Studies identifying and developing data sources, tools and resources needed to strengthen tracking, reporting and communication among systems of care for traumatized, injured and affected children during and after the unexpected event.
- The impact of the event and the concomitant public health response on children and adults with physical and/or intellectual disabilities, and disparities in outcomes experienced by persons with disabilities compared to persons without disabilities.
- Studies that examine how unexpected disruptions in access to therapies and special education services affect developmental, behavioral and functional outcomes in children and adults with disabilities.

Specific Areas of Research Interest: National Institute on Drug Abuse (NIDA)

NIDA welcomes time-sensitive priority research areas in substance use epidemiology, prevention, and health services, including responses to unexpected and time-sensitive:

1) emerging drug issues (e.g., the ability to look into a large acute spike in opioid or synthetic cannabinoid use/overdoses in a particular community; examination of drug markets as they are impacted by immediate circumstances, such as COVID-19 pandemic);
2) emerging cannabis trends and topics related to the shifting policy landscape, related to imminent policy change;
3) prescription drug abuse research opportunities (e.g., new state or local efforts);
4) medical system issues (e.g., opportunities to understand addiction services in the evolving health care system);
5) criminal or juvenile justice opportunities (e.g., new system and/or structural level changes) that relate to drug abuse and access and provision of health care service.

Specific Areas of Research Interest:
National Institute on Minority Health and Health Disparities (NIMHD)

The mission of NIMHD is to lead scientific research to improve minority health and reduce health disparities. NIMHD focuses on all aspects of health and health care for racial and ethnic minority populations in the U.S. and the full continuum of health disparity causes as well as the interrelation of these causes. NIMHD projects must include a focus on one or more of the following populations that NIH-designates as experiencing health disparities in the United States and its territories: African Americans, Latinos/Hispanics, American Indians and Alaska Natives, Asian Americans, Native Hawaiians and other Pacific Islanders, less privileged socioeconomic groups, underserved rural populations, and sexual and gender minorities. Comparison groups/populations may also be included as appropriate for the research questions posed. NIMHD encourages research projects that use approaches encompassing multiple domains of influence (e.g., biological, behavioral, sociocultural, environmental, physical environment, health system) and multiple levels of influence (e.g., individual, interpersonal, family, peer group, community, societal) to understand and address health disparities (see the NIMHD Research Framework, https://www.nimhd.nih.gov/about/overview/research-framework.html, for more information). Studies based outside the U.S. or its territories will not be supported by NIMHD under this FOA. Time-sensitive research that NIMHD is interested in supporting includes:

- The effects of policy changes on health outcomes, and mechanisms of those health outcomes, in populations that experience health disparities, including: immigration policy, health care coverage, gun policy, police use-of-force policy, environmental regulations, prescribing practices, and vaccination requirements
- The immediate and longer-term impact of natural disasters on the health of populations that experience health disparities (particularly through the lens of understanding how climate change is impacting health disparities)
- Effects of changes to the built environment (e.g., greenspace, pedestrian walkways, bike paths) on health and health behaviors for populations that experience health disparities

Specific Areas of Research Interest: National Institute of Nursing Research (NINR)

NINR supports research to solve pressing health challenges and inform practice and policy - optimizing health and advancing health equity into the future. NINR discovers solutions to health challenges through the lenses of health equity, social determinants of health, population and community health, prevention and health promotion, and systems and models of care. Drawing on the strengths of nursing's holistic, contextualized perspective, core values, and broad reach, NINR funds multilevel and cross-sectoral research that examines the factors that impact health across the many settings in which nurses work, including homes, schools, workplaces, clinics, justice settings, and the community. Observational, intervention, and implementation research are of interest to NINR.

Research is encouraged in the following areas:

- Factors involved in a response to a time-sensitive event that affect health equity, including mechanisms involved.
- Effects of social determinants of health on the response to and health effects resulting from a time-sensitive event.
- Prevention and early detection of health effects of a time-sensitive event, including plans for health promotion during and following the event.
- Examining clinical, organizational and/or policy changes to address health related needs during and following a time-sensitive event.

Specific Areas of Research Interest: National Institute on Alcohol Abuse and Alcoholism (NIAAA)

NIAAA will support time-sensitive research in public health priority areas in alcohol and related substance use epidemiology, prevention, and health services, including but not necessarily limited to:

- time-sensitive research opportunities to study the effects of changes in alcohol-related policies, including effects on combined use of alcohol and other substances and evaluation of the implementation or effectiveness of policies, programs, or practices affecting alcohol-related behaviors and outcomes;
- time-sensitive research opportunities to study changes in factors affecting access, delivery, or financing of health care services for alcohol use disorder and alcohol-related conditions;
- time-sensitive research opportunities to study alcohol-related effects associated with sudden and severe events, such as natural disasters, acts of war, or epidemics;
- time-sensitive research opportunities to study the effects on diversity, health equity, inclusion, or access of unanticipated events affecting alcohol-related behaviors and outcomes; and
- time-sensitive research opportunities to inform state or local organizations of the alcohol-related consequences of new or changing policies, programs, or practices.

Specific Areas of Research Interest: National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS)

NIAMS is interested in applications focused on evaluating time-sensitive natural experiments that concern populations with or at risk for development of NIAMS core-mission diseases (arthritic and other rheumatic, musculoskeletal, and skin disorders. Examples include, but are not limited to, time-sensitive natural experiments of changes to the neighborhood food and physical activity environments on the health of populations experiencing or at risk for NIAMS core-mission diseases. Studies among underserved, vulnerable, diverse and health disparities populations are encouraged.

Specific Areas of Interest: OBSSR, ODP, ORWH

- OBSSR, ODP, and ORWH do not manage or administer grants. Applicants are encouraged to focus applications on the objectives of at least one of the participating NIH Institutes and Centers (IC) listed in the announcement. Offices listed *may* consider opportunities to co-fund projects that align with the mission and priorities of the office; however, these co-funding requests originate from Program Officers at ICs. Office interests are provided below:
- **Office of Behavioral and Social Science Research (OBSSR)**
    - Research that advances the understanding behavioral or social factors and outcomes related to an unexpected and/or time-sensitive event. The OBSSR is particularly interested in research that has broad applicability and has the potential to provide evidence to meaningful inform decision makers and guide healthcare or public health policy and practice.
- **Office of Disease Prevention (ODP)**
    - Research that has strong implications for disease and injury prevention and health equity and that includes innovative and appropriate research design, measurement, and analysis methods. The ODP has a specific interest in projects that develop and/or test preventive interventions. Of particular interest is prevention research addressing leading causes and risk factors for premature morbidity and mortality, dissemination and implementation, and health disparities.
- **Office of Research on Women's Health (ORWH)**
    - Research of relevance to women and individuals assigned female at birth. For this funding opportunity, ORWH is particularly interested in intersectional research into the health impacts of time-sensitive events, policies, programs, or infrastructure changes on women.

Part II:

Peer Review Process

Mark Rubert, PhD
Center for Scientific Review, NIH

NIH
National Institutes of Health
Office of Behavioral and Social Sciences Research

U.S. Department of Health & Human Services

NIH Center for Scientific Review

The Peer Review Process

Pre-Application Webinar
for PAR 22-233

Mark Rubert, PhD
Scientific Review Officer

R61/R33 mechanism

- R61 phase with developmental activities and a R33 phase with expanded activities designed to achieve the full research aims. The R61 phase will be up to one year, and will support developmental, exploratory research, Institutional Review Board approval for human subjects protection, further development of study partnerships, and the collection of baseline data. The R33 phase will build on this initial work for up to four years to include further development, application, follow-up data collection, or implementation as appropriate and relevant to the proposed research questions.

- The application should articulate clear aims and objectives for each phase of the proposed research, with specific discussion of how results from the R61 phase will inform the R33 phase. In addition, applications must delineate explicit milestones for the R61 and R33 phases.

Scored Review Criteria

Overall Impact

- Reviewers will provide an overall impact score to reflect their assessment of the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved, *in consideration of the following review criteria and additional review criteria (as applicable for the project proposed).*

Significance

- Does project address important issue/critical barrier in field?
- Is the prior research that serves as key support for project rigorous?
- If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved?
- How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

Scored Review Criteria

Investigator(s)

- Are the PD(s)/PI(s) well suited to project?
- If Early Stage/Career Investigator, do they have appropriate experience/training?
- If established, have they demonstrated ongoing record of accomplishments that advanced their field(s)?
- If project is collaborative or multi-PD/PI, do investigators have complementary and integrated expertise; is leadership approach, governance and organizational structure appropriate for project?

Innovation

- Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions?
- Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense?
- Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?

Scored Review Criteria

Approach

- Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project?
- Have the investigators included plans to address weaknesses in the rigor of prior research that serves as the key support for the proposed project?
- Have the investigators presented strategies to ensure a robust and unbiased approach, as appropriate for the work proposed? Are potential problems, alternative strategies, and benchmarks for success presented?
- If the project is in the early stages of development, will the strategy establish feasibility and will particularly risky aspects be managed?
- Have the investigators presented adequate plans to address relevant biological variables, such as sex, for studies in vertebrate animals or human subjects?

- *Milestones and timeline:*
  - *Is there a unifying research question that transcends both R61 and R33 phases?*
  - *Does the application provide well described, feasible and quantifiable milestones for the R61 phase and related scientific goals and objectives for the R33 phase? Are those milestones conducive to accomplishing the study aims?*
  - *Are the goals of the R33 phase based, in part, on findings collected during the R61 phase?*
  - *Does the timeline demonstrate baseline data collection within six months of award?*

Scored Review Criteria

Environment

- Will the scientific environment contribute to the probability of success?
- Are the institutional support, equipment and other physical resources available to the investigators for the project?
- Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements?

- *If proposing to investigate time-sensitive opportunities outside the U.S., is there appropriate justification of how the information obtained from the study will have direct implications for US practice and/or policy?*
  - *Is there adequate information provided demonstrating that all the proper logistics, human subjects concerns, and approvals, both domestic and international, can be addressed within the limited time frame outlined in this announcement.*

Additional Review Criteria

These are not given individual scores but will be considered as a part of the overall impact score

Protections for Human Subjects

- If the project involves human subjects and/or NIH-defined clinical research, are the plans to address 1) the protection of human subjects from research risks, and 2) inclusion (or exclusion) of individuals on the basis of sex/gender, race, and ethnicity, as well as the inclusion or exclusion of individuals of all ages (including children and older adults), justified in terms of the scientific goals and research strategy proposed?

Inclusion of Women, Minorities, and Individuals Across the Lifespan

- When the proposed project involves human subjects, the committee will evaluate plans for the inclusion (or exclusion) of individuals based on sex/gender, race, and ethnicity, as well as the inclusion (or exclusion) of individuals of all ages (including children and older adults) to determine if justified in terms of the scientific goals.

- **Vertebrate Animals**

- **Biohazards**

Additional Review Considerations for this PAR

Reviewers will consider the following items, but will not give scores for them, and they are not considered in the overall impact score

- *Reviewers will assess whether or not (i.e., yes/no) applications demonstrate the time sensitivity of the research opportunity; in other words, will an important opportunity for scientific inquiry and data collection be lost if the work is not initiated in an expedited way (i.e., with minimum delay).*
- *It should be clear that the knowledge gained from the proposed study is time-sensitive such that an expedited review and funding are required in order for the scientific question(s) to be answered.*
- *Reviewers are also asked to determine whether or not the event described in the application offers an uncommon and scientifically compelling opportunity that might only be available through this mechanism. Of particular relevance is that an expedited award would facilitate baseline data collection at a critical point in the timeline of the event in question.*

Peer Review Principles

- Review will be conducted by Special Emphasis Panel
- Conflicts will be excluded
- Standard NIH review procedures will be used, and every applicant will receive a written critique (i.e., a “summary statement”)

Impact/Priority Scores

- For reviewers, the NIH score scale is 1-9, in integers, with 1 being the best (highest impact)
- All eligible reviewers on the panel will give an overall impact score for each discussed application.
- The average score is multiplied by 10, and rounded to the nearest integer, giving the priority scores from 10-90, 10 being the best overall score
- Not Discussed applications (about 50%) will not receive priority scores

Review Contact

If you have additional questions specifically about the review process for these applications, please contact:

Mark Rubert, PhD

rubertm@nih.gov

301-806-6596

Part III:

Timeline for Submission, Review, and Selection of Applications

Sarika Parasuraman, PhD
Office of Behavioral and Social Sciences Research (OBSSR)

NIH
National Institutes of Health
Office of Behavioral and Social Sciences Research

Key Dates

- FOA Posted Date: September 1, 2022
- Open Date: November 1, 2022
- Letter of Intent Due Date: 4 weeks prior to application due date
- Application Due Date: Accepted on a rolling basis
- Peer Review Meeting: Applications reviewed within 8 weeks
- Council Review: Expedited review
- Earliest Start Date: Within 4-6 months of application receipt

Contacts

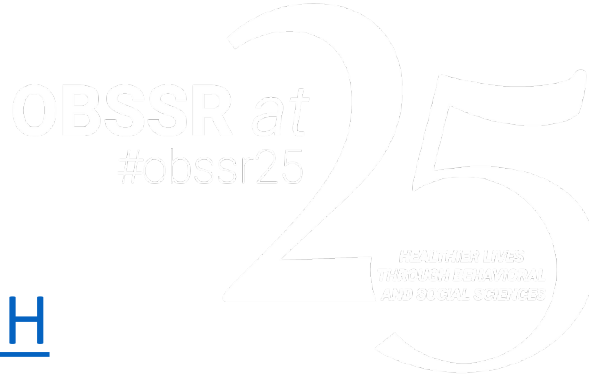
ICO	Contact
OBSSR (General / Triage)	Sarika Parasuraman
NCI	Marissa Shams-White
NIAAA	Gregory Bloss
NIAMS	Stephanie George
NICHD	Layla Esposito
NIDA	Marsha Lopez
NIMHD	Arielle Samantha Gillman
NINR	Karen Kehl
ODP	Bramaramba Kowtha
ORWH	Elizabeth Barr

See Financial/Grants Management contacts in the PAR.

Part IV:
Participant Questions

Submit questions via Q and A button

Stay Connected!



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