Introduction

The COVID-19 pandemic has impacted racial/ethnic minority and underserved communities disproportionately, which is attributable largely to greater exposure risk due to structural inequities. This disproportionate impact of the pandemic has reinforced the importance of working directly with affected communities to understand and apply promising practices to reduce interpersonal and institutional distrust, reduce disparities, and to promote health equity. The long-term goal is to build and maintain trust among underserved communities to address COVID-19 and other conditions with health disparities. Effective community engagement is a key approach to accomplish these goals.

The NIH Community Engagement Alliance (CEAL) Against COVID-19 Disparities seeks to understand and address factors that contribute to the disproportionate burden of COVID-19 in underserved communities and apply Community-engaged strategies to enhance awareness, education, access, trust, and inclusion in the science-based response to COVID-19. CEAL is comprised currently of 11 CEAL research teams working in full partnership with community-based organizations in communities that have a high proportion of racial/ethnic minority groups experiencing a disproportionate burden of COVID-19.

Community Engagement

The Centers for Disease Control and Prevention (CDC) describes community engagement as “the process of working collaboratively with and through groups of people affiliated by geographic proximity, special interest, or similar situations to address issues affecting the wellbeing of those people. It is a powerful vehicle for bringing about environmental and behavioral changes that will improve the health of the community and its members. It often involves partnerships and coalitions that help mobilize resources and influence systems, change relationships among partners, and serve as catalysts for changing policies, programs, and practices (CDC, 1997, p. 9).” Community engagement exists on a continuum from outreach to shared leadership, often involves activities to create awareness, provide education, and build strong bidirectional relationships. Community engagement can occur within or outside of research contexts.

Community-Engaged Research

Community-engaged research is a rigorous approach to studying topics identified by and of importance to the affected communities and combines knowledge generation and action to
improve health outcomes and promote health equity. Community-engaged research also falls along a continuum from consultations with key stakeholders to community-based participatory research (CBPR). The effective application of Community-engaged research among underserved communities requires a specific skill set and appropriate resources. Community-engaged research can and should be conducted using rigorous methodological approaches and is most impactful when the affected groups participate in all phases of the research – from inception to sustained implementation of findings and best practices. Equitable partnerships with multi-sector stakeholders are central to both community engagement and Community-engaged research, as is the appreciation for community assets and needs.

NIH recognizes the need to support the efforts of investigators, collaborators, and partners, who seek to apply principles of Community-engaged approaches to address health disparities within underserved communities of color, particularly during a public health crisis. To that end, the overarching goal of this research opportunity announcement (ROA) is to assist with the rapid development and implementation of a new NIH resource, referred to as the CEAL Consultative Resource (CEACR). This resource will leverage and initially serve as an integral component of the overall CEAL Alliance to provide flexible and tailored guidance around (1) community engagement or (2) community-engaged research within underserved communities of color.

Given the urgency of the pandemic, CEACR will focus initially on COVID-19 community engagement and outreach, such as promoting vaccination acceptance and uptake, addressing vaccine hesitancy, promoting public health mitigation strategies, promoting diagnostic testing, acceptance of effective treatments, and approaches to increase diversity and inclusion in research. CEACR has the potential to expand to address inclusive participation and health disparities within communities of color more broadly. This resource will support the needs of a range of end users seeking to reduce health disparities using community specific approaches.

**CEACR will:**

- Engineer a rapid, flexible, and impactful consultative resource to serve the needs of a variety of end users (e.g., research teams, national organizations, community-based organizations, local government and public health leaders, and the private sector);
- Identify and convene appropriate experts, especially from within the CEAL Alliance, to deliver tailored consultations;
- Provide leadership by training, coaching, and guidance on principles of community engagement and community-engaged research;
- Conduct rapid evaluations across the project period to ensure iteration and adaptation as needed; and
- Provide a framework to evaluate the way a research institution interacts with an underserved community during the research process.

**Scope**

CEACR will coordinate and support a community of practice across the CEAL Alliance. Leveraging the expertise and experience across the Alliance, CEACR will provide support in rapidly convening and exchanging best practices for impactful community engagement, community-engaged research, and inclusive participation. The intensity and flexibility of consultations will match the needs and interests of the end users. Applications should include and describe the following integrative functions:
• Administrative
• Research & Technical Assistance
• Community Partnerships

Administrative: The administrative functions include facilitating the work of CEACR and NIH scientific staff in the overall program management of the initiative. Respondents should expect to work closely with the CEAL Program staff on all coordinating activities and should expect to leverage existing tools, resources and processes as it relates to the deployment of consultations. Possible activities could include, but are not limited to guidance on:

• Leadership and project management for the administrative, coordination, and data coordinating functions
• Identify, recruit, and confirm multi-sector experts, beginning with experts in the CEAL Alliance, to serve as part of a pool of trained panelists which can be constituted into fit-for-purpose panels based on the unique needs of end users
• Develop standard operating procedures for the resource and conduct training across the consultation teams
• Support collaboration and communication among the consultation teams, NIH program staff, the CEAL Alliance Steering Committee,
• Coordinate with CEAL to maintain a CEACR directory (researchers, partners, and community stakeholders)
• Develop and implement processes to conduct intake and needs assessments as requests come in, communication with end users about the services and procedures, and triage end users to the appropriate staff/persons within the consultative teams
• Work with CEAL to coordinate and engage with end users throughout the entire journey of consultation from intake to recommendations, ensuring a high-touch, user-focused approach
• Develop and provide a program evaluation plan to understand end-user satisfaction and evaluate efficacy of the resource
• Establish and administer sub-awards including negotiations, invoicing, and payments, as applicable

Research & Technical Assistance: The research and technical assistance functions will include the delivery of expert guidance on the conduct of Community-engaged research and the mechanics of on-the-ground research. Consultation team members will include researchers, research staff, and other individuals with expertise in building a sustainable partnership with community stakeholders, conducting Community-engaged research and completing program evaluations that serve both the scientific goals and community needs. In addition, end users may seek technical assistance post-consultation to follow-up on the expert guidance, focusing on specific challenges. Consultations will be flexible and tailored to the specific needs of the end user(s) and could include, but are not limited to guidance on:

• Community-engaged research study design, and troubleshooting barriers and challenges to inclusive participation
• Development of culturally specific and/or community competent interventions
• Culturally appropriate measurement strategies and assessment selection, including adapting measures for different populations
• Strategies for appropriate procedures for translation of measures and documents to non-English languages
• Strategies for inclusive participation, data collection, and retention
Community involvement in the interpretation of research findings and collaborating with stakeholders to interpret data
- Return of results to the community
- Ethical considerations, especially related to informed consent and data sharing
- Balancing research versus community needs and interests
- Incorporation of technology to maximize effectiveness
- Ensuring community benefit from research and dissemination of effective communications and/or research findings
- Managing unintended consequences and/or ruptures in community relationships

**Community Partnerships:** The comprehensive communications and community outreach functions will include guidance and expertise on establishing long-term, bidirectional relationships with community organizations and stakeholders who understand the dynamics of, and serve, populations with health disparities. Consultation team members should include individuals with expertise in working within communities as well as community members and advocates. Consultations will be tailored to the specific needs of the end user(s) and could include, but are not limited to guidance on:
- Building and maintaining trust
- Community outreach activities (e.g., awareness and health education campaigns)
- Conducting listening sessions, townhalls, and focus groups
- Collaborating with community health workers and/or promotores
- Identifying appropriate stakeholders and organizations and establishing and maintaining equitable relationships with limited resources
- Establishing and working with community advisory boards, community coalitions, and patient advocacy groups
- Developing comprehensive messages and communication campaigns
- Amplifying community voices

The CEACR seeks to facilitate the work of multi-sector stakeholders (e.g., researchers, community-based organizations, national organizations, congressional/government leaders) seeking to respond to the needs of racial/ethnic minority populations affected disproportionately by the COVID-19 pandemic and other health disparities. Proposals should demonstrate the ability to engineer a CEAL resource that is reproducible, flexible, and effective in supporting community inclusive efforts to address COVID-19 and other health disparities.

**Respondents should describe the following within their applications:**

- Their track record of community engagement research work, including current activities within racial/ethnic minority communities and their record(s) of accomplishments working with various communities such as planning, evaluating, problem solving, user experience, project management, education and training, communication and quality management
- Specific plans to develop and manage a flexible model that can be adapted to meet the needs of a variety of “external users” including research institutions, hospitals and clinics, public health officials, community-based organizations, national organizations and/or other stakeholders with a vested commitment to addressing COVID-19 and other health disparities
- Experience and expertise in community consultations and/or initiatives that advance evidence-based strategies on a variety of topics related to inclusive participation, communications and outreach, vaccine hesitancy and other community topics
The ability to foster relationships, collaborate, and promote health equity with the CEAL Alliance, including CEAL research teams, community partners, network partners, and NIH staff to support the objectives of the CEACR initiative

Experience cultivating and maintaining relationships with community stakeholders to achieve mutually agreed upon objectives

Their track record in dissemination and implementation research or activities resulting in demonstrable positive community impact

**CEAL Consultative Resource: Example Topics for Consultations**

Community engagement and community-engaged research to promote inclusive participation includes a broad spectrum of activities, methods, and solutions to important challenges facing different end users. Respondents may expect to provide consultations on a broad range of topics including, but not limited to the following examples:

*Research & Technical Assistance – Examples:*

- **COVID-19 related topics**, such as:
  - Vaccine hesitancy, acceptance, and uptake
  - Inclusive participation in clinical trials
  - COVID-19 prevention community prevention and mitigation strategies
  - Broad areas of COVID-19 research (observational studies, and post-acute sequelae of COVID-19)

- **Social determinants of health topics**, such as:
  - Access to health care services and digital technologies
  - Health literacy, numeracy, and English language fluency
  - Housing insecurity, neighborhood deprivation, built environment challenges

- **Community-engaged research methodologies and frameworks**, such as:
  - Community-Based Participatory Research and Community Action Research
  - How to address practical and logistical issues (e.g., few resources, changing organizational priorities, staff turnover, timeframe to see impact of service)
  - Selection of appropriate measures and interventions
  - Qualitative methods (e.g., focus groups, structured interviews, town halls, shared experiences, photovoice, risk and asset mapping)
  - Data interpretation and translation of findings with a community lens
  - Incorporating multi-level approaches
  - Applications of the socioecological model, Active Community Engagement Continuum, and other conceptual models

*Community Partnerships – Examples* include guidance on:

- Forming equitable academic-community partnerships
- Framing messages and utilizing formats best suited for content, and strategies for culturally tailoring of communications and materials
- Identifying and partnering with trusted messengers
- Conducting formative evaluations that support communication and outreach efforts
- Effective virtual community engagement
- Structuring and working with community advisory boards and coalitions
- Aligning existing community strengths/assets and enhance resilience
Special Award Terms

Because of the urgency of the public health emergency, the expectation is that the applicant will use their specialized knowledge to develop a specific set of milestones tailored for this unique need. Accordingly, the broad strokes of the milestones below are to be used a guide, however applicants are encouraged to use their creativity and expertise to carefully craft the proposed milestone schedule.

30-days:

- Develop standardized processes for the CEAL consultations
- Identify of impact metrics of the consultations

Additional Milestones of Interest:

- Establish a sustainable and effective CEACR to address COVID-19 and which can be leveraged in the future to address other health disparities, based on NHLBI determination of need and availability of funding
- Identify, recruit, and confirm experts to serve as consultants

Eligibility

Applications are being solicited from individual and organizations with expertise in community engagement and demonstrated experience and interest in working to reduce racial/ethnic COVID-19 and other health disparities. Anticipated eligible organizations will include the following:

- Public/State Controlled Institution of Higher Education
- Private Institution of Higher Education
- Nonprofit with 501(c)(3) IRS Status (Other than Institution of Higher Education)
- Nonprofit without 501(c)(3) IRS Status (Other than Institution of Higher Education)
- Small Business
- For-Profit Organization (Other than Small Business)
- State and Local Government (county, city, township)
- Public health agencies
- Indian/Native American Tribal Government (Federally Recognized)
- Special district governments
- Independent school districts
- Public housing authorities/Indian housing authorities
- Indian/Native American Tribally Designated Organization (Native American tribal organizations (other than Federally recognized tribal governments)
- U.S. Territory or Possession
- Indian/Native American Tribal Government (Other than Federally Recognized)
- Regional Organization

Award Criteria and Selection Information

Applicants are encouraged to be creative and innovative in leveraging their track record of Community-engaged research impact in racial/ethnic minority communities. A single award is
expected. Awardees will be selected through an objective review process that will evaluate the following criteria: 1) proposal responsiveness to the goals of this funding announcement; 2) innovation of the specific proposed strategies; 3) feasibility and rapid potential impact of proposed activities; and 4) value for dollar. For the purposes of budgeting, applicants should assume conducting an average of approximately three (3) consultations per month.

Awardees may be awarded sub-OT agreements pursuant to the NHLBI’s OT authority at 42 USC 285b-3 and the NIH Office of the Director authority at 42 USC 282(n), and funded through contributions from other NIH Institutes and Centers.

The NIH reserves the right to:

- select for negotiation all, some, one, or none of the proposals received in response to this ROA;
- segregate portions of resulting awards into components and their associated budget that differ from those that have been proposed;
- accept proposals in their entirety or to select only portions of proposals for award;
- fund projects in increments and/or with options for continued work at the end of one or more phases;
- fund projects of two or more applicant entities as part of a reorganized, consolidated consortium operating under an article of collaboration, teaming arrangement, or other means acceptable to the NHLBI;
- request additional documentation (certifications, etc.); and
- remove proposers from award consideration should the parties fail to reach a finalized, fully executed agreement, or the proposer fails to provide requested additional information in a timely manner.

Proposal Process

Submission in response to this ROA occurs in two stages. Stage 1 requires submitting a Letter of Request to NHLBI for review (see >$500k process on NHLBI web site). Applicants receiving NHLBI permission to proceed to Stage 2 will then prepare and submit a full proposal through eRA ASSIST.

STAGE 1 – CEAL Consultative Resource Initial Eligibility and Preliminary Review

NHLBI will review and determine whether the applicant should proceed with completing the full proposal submission. The NHLBI may request additional information be provided by the applicant to complete their initial eligibility and preliminary review. These requests will be sent to the applicant via email. Applicants are strongly encouraged to provide the requested information in a timely manner to prevent any potential delays in the review process. Proposals that do not meet the initial CEAL Consultative Resource ROA program and eligibility criteria will be rejected.

Stage 1 will be patterned after the NHLBI >$500K process (https://www.nhlbi.nih.gov/grants-and-training/policies-and-guidelines/applications-with-direct-costs-of-500000-or-more-in-any-one-year) that includes a Letter of Request outlining major elements of the proposed core, personnel, budget, and feasibility.
In order for the NHLBI to make an informed decision about whether to accept a proposed application for review, the Letter of Request (see link above) should not exceed five (5) pages and should include:

- The proposed project title
- The anticipated solicitation (Research Opportunity Announcement)
- The anticipated application receipt date
- The expected start date to launch the CEAL Consultative Resource
- The key personnel (the eRA Commons user id must be included for the PI or contact PI)
- The submitting organization or institution
- Brief description of the overall goals of the CEAL Consultative Resource, the rationale, and how the program will support the overall CEAL research mission
- Brief description of the main CEAL Consultation Resource activities and how they will be accomplished
- Brief description of any prior work or preliminary work in this area
- Brief description of program and project management approach and plan, with particular attention to how objectives will be planned, monitored, reported, and, when appropriate, shared with stakeholders
- Brief description of personnel including their relevant expertise and history in conducting the type of activities necessary goals
- Demonstrated ability to operate in a highly collaborative and flexible manner as required by the Other Transaction mechanism
- Direct and total costs by phase of the project – generally a one-paragraph description of major sources of costs in the study using one of the two tables provided via the following link: https://www.nhlbi.nih.gov/files/docs/500K%20Budget%20Tables_2018-09-17.xlsx
  - Specify (1) any funding provided by other entities (federal agencies, foundations, companies), and (2) any goods or services (and their value) provided by any of these parties.
- A description of any anticipated agreements with third-parties relevant to the proposed project, including details about any provisions or restrictions related to intellectual property, publication, and data sharing.

**STAGE 2 - Full Proposal**

If upon review of the Letter of Request the NHLBI determines the proposed research to be in scope and hold significant promise for achieving the objectives of this ROA, the applicant will be invited to submit a full proposal. The full proposal will be submitted via eRA ASSIST following instructions that will be provided to the applicant.

The full proposal should include information in the following areas:

- **Additional administrative information** about the applicant and institution or organization (name, address, entity and Principal Investigator NIH Commons Registration information), including SAM information and DUN and Bradstreet number, human and animal assurance approvals as appropriate.

- **Project Plan** uploaded as searchable PDF format in a font size of 11 or 12 point and font type of Arial or Times New Romans. Margins must be 1-inch wide (top, bottom, left, and right). The project plan must not exceed 30 pages in length. Biosketches must not exceed five (5) pages in length and are not counted in the page limit. Also excluded from the page limitation are cover sheets, letters from collaborators and consultants, and representation and certification documents.
Application Contents

Technical Proposal

The Technical section of the proposal should not exceed 10 pages and should include:

- The proposed project title
- Description of the team structure and identification of each entity that makes up the state team
- The expected start date to launch the study (with the expectation of launching immediately upon funding)
- The key personnel (the eRA Commons user id must be included for the PI or contact PI)
- The submitting organization or institution
- Demonstrated ability of the group or history of the investigators in conducting Community-engaged research and outreach
- Brief description of the rationale for and importance of the proposed consultative resource research question(s), particularly from a community engagement perspective, describing how the consultative resource will rapidly and flexibly identify and address factors that impact the disproportionate burden of COVID-19 in communities that are underserved
- Plans to collaborate with other community partners and organizations including utilization, as appropriate, of common data elements and other relevant infrastructure and studies.
- Specify (1) any funding provided by other entities (federal agencies, foundations, companies), and (2) any goods or services (and their value) provided by any of these parties.

Budget

The Budget section is not subject to page limitations and must provide a realistic, fully justified budget and cost for performing the work over a 12-month period of performance (1 June 2021 – 31 March 2022).

Provide the overall expected cost for each of the following categories:

- Personnel
- Equipment
- Travel
- Subawards/subcontracts/consultants
- Other direct costs
- Total cost (with indirect costs included)
- Proposed Cost Share contribution

Submission and Contact Information

For best consideration, Letters of Request in stage 1 shall be emailed to NHLBI_OTA@mail.nih.gov by May 3, 2021, by 5 PM EDT. If invited to submit a full application in stage 2, proposals will be submitted under OTA-21-016 via ASSIST. Detailed system instructions for submitting your stage 2 full application will be provided by the NHLBI Agreements Officer.
Financial and administrative questions should be addressed to Erynn Huff, JD, NHLBI Agreements Officer at NHLBI OTA@mail.nih.gov.

Questions about the scientific scope of the studies, programs, consultation services should be addressed to:

Catherine M. Stoney, PhD,
Deputy Director, Center for Translation Research and Implementation Science, NHLBI.
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