Department of Health and Human Services

Part 1. Overview Information

Participating Organization(s)	National Institutes of Health (NIH (http://www.nih.gov))
Components of Participating Organizations	Office of Strategic Coordination (Common Fund (https://commonfund.nih.gov/))
	This notice of funding opportunity (NOFO) is developed as a Common Fund initiative (http://commonfund.nih.gov) through the NIH Office of the NIH Director, Office of Strategic Coordination (https://dpcpsi.nih.gov). All NIH Institutes and Centers participate in Common Fund initiatives. The NOFO will be administered by the National Cancer Institute (NCI/NIH) (https://www.cancer.gov) on behalf of the NIH.
Funding Opportunity Title	Community Partnerships to Advance Science for Society (ComPASS): Health Equity Research Hubs (UC2 Clinical Trial Optional)
Activity Code	UC2 (//grants.nih.gov/grants/funding/ac_search_results.htm?text_curr=uc2&Search.x=0&Search.y=0&Search_Type=Activity) High Impact Research and Research Infrastructure Cooperative Agreement Programs
Announcement Type	New
Related Notices	• **August 28, 2023** - Notice of Technical Assistance Webinar for RFA-RM-23-012. See Notice NOT-RM-23-023 (https://grants.nih.gov/grants/guide/notice-files/NOT-RM-23-023.html). • **August 31, 2022**- Implementation Changes for Genomic Data Sharing Plans Included with Applications Due on or after January 25, 2023. See Notice NOT-OD-22-198 (https://grants.nih.gov/grants/guide/notice-files/not-od-22-198.html). • **August 5, 2022**- Implementation Details for the NIH Data Management and Sharing Policy. See Notice NOT-OD-22-189 (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-22-189.html).
Notice of Funding Opportunity (NOFO) Number	RFA-RM-23-012
Companion Funding Opportunity	None
Number of Applications	See Section III. 3. Additional Information on Eligibility.
Assistance Listing Number(s)	93.310
Funding Opportunity Purpose	The purpose of this Notice of Funding Opportunity (NOFO) is to invite applications from eligible organizations that can serve as Health Equity Research Hubs (Hubs) for awarded community-led health equity structural intervention (CHESI) projects within the Community Partnerships to Advance Science for Society (ComPASS) Program (https://commonfund.nih.gov/compass). The Hubs will serve as a centralized research resource, providing tailored scientific, technical, and collaborative support for sustainable community engagement, research capacity building, and training to assigned CHESI projects that address SDOH and structural factors to improve health outcomes. The Hubs are one of three complementary initiatives under the ComPASS Program, which also include the CHESI projects and the ComPASS Coordination Center.

Key Dates

Posted Date	August 24, 2023
Open Date (Earliest Submission Date)	September 30, 2023
Letter of Intent Due Date(s)	September 30 , 2023

Application Due Dates			Review and Award Cycles		
New	Renewal / Resubmission / Revision (as allowed)	AIDS - New/Renewal/Resubmission/Revision, as allowed	Scientific Merit Review	Advisory Council Review	Earliest Start Date
October 31, 2023	Not Applicable	Not Applicable	March 2024	May 2024	July 2024

All applications are due by 5:00 PM local time of applicant organization.

Applicants are encouraged to apply early to allow adequate time to make any corrections to errors found in the application during the submission process by the due date.

No late applications will be accepted for this Notice of Funding Opportunity (NOFO).

Expiration Date November 01, 2023

Due Dates for E.O. 12372 Not Applicable

Required Application Instructions

It is critical that applicants follow the instructions in the Research (R) Instructions in the How to Apply - Application Guide (https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400) , except where instructed to do otherwise (in this NOFO or in a Notice from NIH Guide for Grants and Contracts (//grants.nih.gov/grants/guide/url_redirect.htm?id=11164)).

Conformance to all requirements (both in the Application Guide and the NOFO) is required and strictly enforced. Applicants must read and follow all application instructions in the Application Guide as well as any program-specific instructions noted in Section IV. When the program-specific instructions deviate from those in the Application Guide, follow the program-specific instructions.

Applications that do not comply with these instructions may be delayed or not accepted for review.

There are several options available to submit your application through Grants.gov to NIH and Department of Health and Human Services partners. You **must** use one of these submission options to access the application forms for this opportunity.

1. Use the NIH ASSIST system to prepare, submit and track your application online.

   Apply Online Using ASSIST

2. Use an institutional system-to-system (S2S) solution to prepare and submit your application to Grants.gov and eRA Commons (https://public.era.nih.gov/commons/) to track your application. Check with your institutional officials regarding availability.

3. Use Grants.gov (https://www.grants.gov/web/grants/applicants/download-application-package.html#search=true&oppNum=RFA-RM-23-012) Workspace to prepare and submit your application and eRA Commons (http://public.era.nih.gov/commons/) to track your application.

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Part 2. Full Text of Announcement

Section I. Notice of Funding Opportunity Description

Key Definitions and Terms for this NOFO

Community Organization: A non-federal, non-academic, non-research organization that provides goods, services, support, resources, or advocacy to members of a defined community. Examples include community or faith-based organizations, local businesses, neighborhood authorities and associations, labor unions, patient or consumer advocacy groups, public health departments, regional/local and public healthcare systems, school districts, law enforcement or criminal/juvenile justice agencies, social service agencies, or departments of commerce, labor, transportation, housing, and recreation. Governmental organizations at the local, state, regional, or tribal level fall within this definition.

Community Engaged Research: Research that requires working collaboratively with and through those who share similar situations, concerns, or challenges in the research process (NAM, 2022 (https://nam.edu/assessing-meaningful-community-engagement-a-conceptual-model-to-advance-health-equity-through-transformed-systems-for-health/)).

Approaches to community engagement include participatory action research, community-based participatory research, team science, empowerment evaluation approaches, community asset mapping, and citizen science.

Data Justice: Data justice examines the use of data as well as the methods of data collection, analysis, sharing, and dissemination to ensure equitable interpretation, representation, and accountability to participants and communities that have been historically disenfranchised.

Health Disparity: A health disparity is an avoidable health difference that adversely affects disadvantaged populations, based on one or more of the following health outcomes (Minority Health and Health Disparities: Definitions and Parameters (https://www.nimhd.nih.gov/about/strategic-plan/nih-strategic-plan-definitions-and-parameters.html)):

- Higher incidence and/or prevalence and earlier onset of disease
- Higher prevalence of risk factors, unhealthy behaviors, or clinical measures in the causal pathway of a disease outcome
- Higher rates of condition-specific symptoms, reduced global daily functioning, or self-reported health-related quality of life using standardized measures
- Premature and/or excessive mortality from diseases where population rates differ
- Greater global burden of disease using a standardized metric

Health Equity: Health equity is when every person has a fair and just opportunity to attain their "full health potential" and no one is "disadvantaged from achieving this potential because of social position or other socially determined circumstances" (Health Equity | CDC (https://www.cdc.gov/chronicdisease/healthequity/index.htm)). Applying the principle of health equity requires that barriers to promoting good health are removed and resources are allocated among populations and/or communities proportional to their need(s). Additionally, applying a health equity lens requires intentional efforts to ensure that research is designed explicitly to promote fairness, opportunity, quality, and social justice in access, interventions, and outcomes. These efforts include meaningful engagement of community collaborators and members at each stage of program development or research design, implementation, and dissemination (What is Health Equity | NIMHD, 2023 (https://www.nimhd.nih.gov/resources/understanding-health-disparities/health-equity.html)).

Multidisciplinary Expert Panels (MEPs): As an integral resource, MEPs will be established by Hubs, and comprised of broad scientific, methodological, statistical, and ad hoc CHESI-relevant subject matter experts convened to support all Hub activities.

NIH-designated Populations that Experience Health Disparities: Racial and ethnic minority populations, less privileged socioeconomic status (SES), underserved rural communities, sexual and gender minority (SGM) groups (Minority Health and Health Disparities: Definitions and Parameters (https://www.nimhd.nih.gov/about/strategic-plan/nih-strategic-plan-definitions-and-parameters.html)).

Research Capacity Building: Processes for developing and strengthening sustainable skills, abilities and resources that enable individuals, organizations, and communities to perform high quality research.

Social Determinants of Health (SDOH): Social determinants of health (SDOH) are the conditions in which people are born, grow, learn, work, play, live, and age, and the wider set of structural factors shaping the conditions of daily life. These structural factors include social, economic, and legal forces, systems, and policies that determine opportunities and access to high quality jobs, education, housing, transportation, built environment, information and communication infrastructure, food, and health care; the social environment; and other conditions of daily life. See https://www.ninr.nih.gov/researchandfunding/nih-sdohrcc (https://www.ninr.nih.gov/researchandfunding/nih-sdohrcc) for additional detail on the NIH SDOH Conceptualization.

Structural Interventions: Interventions that attempt to change the social, physical, economic, or political environments through, for example, system and policy changes that may shape or constrain health behaviors and outcomes, altering the larger social context by which health disparities emerge and persist (Structural Interventions to Reduce and Eliminate Health Disparities (https://ajph.aphapublications.org/doi/full/10.2105/AJPH.2018.304844)).

Purpose

The purpose of this Notice of Funding Opportunity (NOFO) is to invite applications from eligible organizations that can serve as Health Equity Research Hubs (Hubs) for awarded community-led health equity structural intervention (CHESI) projects within the Community Partnerships to Advance Science for Society (ComPASS) Program. The Hubs will serve as a centralized research resource, providing tailored scientific, technical, and collaborative support for sustainable community engagement, research capacity building, and training to assigned CHESI projects that address SDOH and structural factors to improve health outcomes. The Hubs are one of three complementary initiatives under the ComPASS Program, which also include the CHESI projects and the ComPASS Coordination Center. This NOFO seeks to fund up to five Hubs.

Background

Despite longstanding investments to reduce and eliminate health disparities, racial and ethnic minority populations and other NIH-designated populations that experience health disparities continue to bear a disproportionate burden of adverse health outcomes across disease and health conditions. Health disparities are long-standing and deeply rooted in structures, systems, and policies that create social and economic advantage and disadvantage, limiting the optimization of health for underserved racial and ethnic groups and other populations experiencing health disparities. These reinforcing and inequitable systems and structures are the fundamental causes of poor and differential health outcomes and thus must be addressed to make meaningful and sustained improvements in health. Ultimately, a paradigm shift is required to eliminate health disparities, achieve health equity, and create a healthier nation for all.

Addressing fundamental, structural causes of health disparities offers the greatest opportunity to advance health equity, improve health outcomes and is the focus of the ComPASS Program.

Structural Interventions and Multi-Sectoral Partnerships

To advance health equity, innovative structural interventions that attempt to alter the social, physical, and/or economic environments that influence health behaviors and outcomes are critical (Brown, et al., 2019). Such innovative intervention approaches provide opportunities to address the broader systemic, societal factors and conditions that influence the ability to live healthy lives. Structural interventions might include addressing the root causes of economic instability, limited educational and employment opportunities, and lack of community resources. Research efforts must squarely focus on the structural drivers of health disparities that contribute to the disproportionate burden of disease. Structural interventions must be created in partnership with those sectors and systems, such as education, housing, transportation, commerce, agriculture, recreation, economic and urban development, justice, human and social services, healthcare, digital information and communications, and public health. Multi-sectoral partnerships that transcend historical silos maximize the opportunity to address structural factors and advance health equity.

Community-Led Research

Community engaged approaches are recognized as a continuum of effective research strategies to address health disparities and advance health equity (CDC, 2011; Key et al., 2019). Communities and researchers working collaboratively as equal partners throughout all phases of the research process enhances the quality of research and interventions, and ensures research questions, methods, and approaches are responsive to community needs, values, practices, and priorities. Research developed, implemented, disseminated,

and sustained by the community changes the process by which research has traditionally been conducted and presents new opportunities to advance the health of populations experiencing health disparities.

Community-led research requires transforming the processes and practices that govern research engagement. The traditional approach is one that involves academic organizations leading research efforts, which may or may not include engagement from community partners. This research initiative is intended to foster community-led research, which includes community identification and prioritization of the research questions, and implementation of structural health solutions in collaboration with researchers and other relevant partners. This unique approach of community organizations leading efforts to intervene on structural contributors to disease aligns with the NIH goal of achieving sustainability of community-accepted and effective interventions to optimize health.

The Community Partnerships to Advance Science for Society (ComPASS) Program

The Community Partnerships to Advance Science for Society (ComPASS) Program is intended to accelerate health promotion and disease prevention among populations experiencing health disparities. The impetus for ComPASS is the increasing recognition that advancing health equity is a complex challenge that extends beyond the reach of traditional healthcare settings, organizations, or research agendas. This NIH-wide program was created to foster efforts to address structural causes and pathways of differential health outcomes, with the goal of reducing health disparities across diseases and conditions among populations that experience them.

ComPASS aims to be catalytic and cross-cutting in its integration of multi-sectoral partnerships, comprised of community organizations; local, state, Tribal, and federal governments; academic institutions and research organizations; and the private sector to address structural inequities that enable persistent health disparities. The program is transformative in its community-led approach and its focus on structural health equity interventions. Given the documented impact of structural inequities on health outcomes, ComPASS emphasizes cultivating community trust and partnerships, building research capacity among community and relevant partners, and enhancing community organization readiness and competitiveness for future funding that will contribute to greater participation in research by populations that experience health disparities and inclusion of minority health and health disparity populations in research. ComPASS will serve as an initial launch to a longer-term and sustained NIH commitment to eliminating health disparities and advancing health equity through development, testing, and implementation of community-led structural interventions.

ComPASS Program Goals and Objectives
The ComPASS Program has two overall goals: 1) to catalyze, develop, and rigorously assess community-led, health equity structural interventions that leverage multi-sectoral partnerships to advance health equity; and 2) to develop a new health equity research model for community-led, multi-sectoral structural intervention research across NIH and other federal agencies.
The ComPASS Program includes three initiatives to achieve these goals:

1. **The Community-Led, Health Equity Structural Intervention (CHESI**) projects will develop, implement, assess, and disseminate community-led, health equity structural interventions that intervene on structural factors that produce and perpetuate health disparities. These intervention projects will be co-created in partnership with research organizations and multi-sectoral members of their local Health Equity Research Assembly (HERA).
   Local HERAs will be established by the CHESI projects, based on consultation from the National HERA and their identified needs. Each intervention project will have a local HERA of relevant collaborators, including but not limited to, regional federal agency representatives, non-governmental partners, policymakers, community organizations, non-profit organizations, foundations, public and private sector and healthcare organizations. The local HERA provides tailored and contextualized guidance and advice to the CHESI projects during the development, implementation, assessment, dissemination, and sustainability stages of the interventions.
   Approximately 20-25 CHESIs will be awarded in FY 2023.
2. **The ComPASS Coordination Center (CCC)** will lead overall program management and coordination of administrative, data, capacity building, partnership, training, and the National HERA activities.
   The National HERA will comprise an invited group of federal and non-federal members such as those in the transportation, housing, urban planning, and public health sectors to provide vital consultation on the development and implementation of the CHESI projects. These national level representatives will facilitate successful research collaborations and opportunities, as well as consult on the sustainability of the interventions and their potential policy implications .
   A single Coordination Center will be awarded in FY 2023.
3. **The Health Equity Research Hubs (Hubs)** will provide tailored scientific, technical, and collaborative support for sustainable community engagement, research capacity building, and training for the awarded CHESI projects.
   A Multidisciplinary Expert Panel (MEP) will be established by each Hub and serve as an integral resource for the Hub's assigned CHESI projects. Comprised of broad scientific, methodological, statistical, and ad hoc CHESI-relevant subject matter experts, a MEP will be convened and integrated within the Hub's structure to support all Hub functions and activities. Core subject matter expertise will include structural and multilevel intervention study design, sampling and data collection, implementation science, team science, data science, biostatistics and econometrics, community engagement, ethical, legal, and social implications (ELSI), and health disparities research. Additional expertise will be obtained based on the identified needs of the assigned CHESI projects and may come from other Hubs and/or from researchers within and outside the ComPASS Program.
   Up to five Hubs will be awarded in FY 2024.

Through these three initiatives, the ComPASS Program objectives are to:

- Support community organizations and their research partners in co-creating and evaluating community-led, health equity structural interventions.
- Engage multi-sectoral partnerships, both locally and nationally, in advising, guiding, and sustaining the community-led health equity structural interventions.
- Build research capacity and sustainability among community organizations and their research partners to conduct structural intervention, implementation, and community-led research.
- Enhance research methods for collecting SDOH information and collecting and analyzing data to evaluate outcomes from the CHESI projects.
- Disseminate promising approaches resulting from the CHESI projects.

ComPASS Health Equity Research Hubs (Hubs) – This Opportunity
The Health Equity Research Hubs (Hubs), the focus of this NOFO, will serve as a centralized research resource for awarded CHESI projects. Each Hub will support four (4) to six (6) awarded CHESI projects and connect them to a wide range of scientific and technical resources. Hub assignment of CHESI projects will be based on thematically organized SDOH/structural factors. For a description of the CHESI project themes, visit the ComPASS website: https://commonfund.nih.gov/compass (https://commonfund.nih.gov/compass).

The Hubs will provide tailored scientific, technical, and collaborative support for sustainable community engagement, research capacity building, and training to their assigned CHESI projects based on their expertise and focus on SDOH/structural factors. They will play a critical role during the implementation and dissemination phases of the CHESI projects (Phase II and Phase III) and will employ strategies that are responsive and adaptive to the needs of the projects and the various communities they serve. The Hubs are expected to have and draw on established experience working with populations that experience health disparities , as well as an understanding of the potential barriers to and

strategies for implementing structural interventions in underserved communities. Each Hub will be responsible for providing expertise to assigned CHESI projects based on their needs and may leverage expertise within and outside of the ComPASS Program, as needed, including from other Hubs, Project Scientists, consultants, and the local or national HERAs. The Hubs will also apply an intersectional health equity lens to support the research foci and thematic emphasis of their assigned CHESI projects. Each Hub will engage and integrate their MEP across all Hub functions and activities, including the development and use of evidence-based and community-informed approaches that promote active, meaningful engagement of community collaborators, academic researchers, and multi-sector partners at every phase of the research process from intervention design through dissemination.

The Hub investigative team must demonstrate significant expertise and experience coordinating complex consortia and collaborative efforts that involve communities and populations that experience health disparities, researchers, and multi-sectoral partners. The Hub investigative team will leverage prior coordination and team science experience to ensure effective partner engagement with their assigned CHESI projects, augment the core scientific and technical expertise provided to the CHESI projects based on identified needs via the Hub's MEP, and collaborate with the CCC to facilitate respective scientific progress and data compliance. NIH anticipates that changes in CHESI project assignments to Hubs or to the thematic emphasis of awarded Hubs may be necessary as the ComPASS Program evolves. Any changes will be informed by identified scientific, capacity building, training, resource, and partnership needs, as well as any emerging scientific opportunities as determined by the ComPASS Program recipients and NIH Program Staff.

The Hubs will support the research efforts of their assigned CHESI projects and extend the work of the CCC. The primary responsibilities of the Hubs are to: 1) enhance the scientific rigor of their assigned CHESI projects to address SDOH/structural factors; 2) support effective partner engagement by leveraging a multidisciplinary expert panel (MEP); and 3) collaborate with the CCC to provide localized and tailored support based on the needs of their assigned CHESI projects.

Each Hub must include at least four units: 1) Administrative and Coordinating Unit; 2) Research Methods and Data Management Unit; 3) Research Capacity Building and Training Unit; and 4); Community Engagement and Health Equity Practice Unit. These units are described below.

1. The **Administrative and Coordinating Unit** will provide overall leadership, expertise, and organizational infrastructure to support the entire scope of Hub activities. This Unit is charged with assuring active, systematic, and responsive engagement with assigned CHESI projects. Specific responsibilities will include, but are not limited to the following:

- Provide leadership, administrative infrastructure, management, and operational support for all Hub activities, including activities related to the assigned CHESI projects and CCC collaboration (e.g., organizational chart, roles and responsibilities, SOPs, formal agreements, communications).
- Identify, establish, and coordinate the MEP to provide an integrated, synergistic, and responsive infrastructure that actively addresses the scientific, partnership, and research capacity needs of the assigned CHESI projects. MEP subject matter expertise may include broad scientific, statistical, methodological, team science, data science, health disparities, and other relevant subject areas. As an integral resource, the MEP's core expertise may evolve to ensure that the Hub provides ongoing scientific input, guidance, and adds value across all Hub activities.
- Develop a plan for actively engaging assigned CHESI projects and relevant partners in meaningful interactions to support CHESI project and Hub unit activities, as well as establish the Hub as an accessible, valuable and trustworthy research resource.
- Develop a Hub-specific health equity logic model and assessment plan that describes the resource inputs, activities and processes (including the MEP), projected outputs, outcomes and impacts across the Hub Units and functions. The logic model and assessment plan should be aligned with the thematic emphasis of the assigned CHESI projects and consider the contextual factors that may influence achievement of the Hub's goals and intended outcomes (Logic Models | CDC, 2018 (https://www.cdc.gov/evaluation/logicmodels/index.htm)).
- Design and assess a communication plan that includes participation in annual ComPASS meetings, and dissemination of Hub-specific summary reports and updates to the ComPASS consortia, NIH Program Staff, and Project Scientist(s).
- Develop and implement plans to monitor Hub progress, timelines, milestones, and deliverables across all Hub units and functions.
- Collaborate with the CCC to ensure efficient, timely, and responsive coordination, communication, and reporting of ComPASS activities, as needed.

2. The **Research Methods & Data Management Unit** will be responsible for collaborating with the assigned CHESI projects to provide tailored scientific support and intervention-related technical guidance throughout the research process. Each Hub will also leverage and expand the subject matter expertise within their established MEP based on the scientific needs of the CHESI projects.

CHESI project-specific support and collaboration:

Each Hub will serve as a centralized research resource for their assigned CHESI projects and will provide scientific support and technical assistance for research activities as needed, including, but not limited to, the following:

- Study Design
  - Develop, modify, and/or adapt the proposed study design and sampling plan (including power calculations and sample size estimations) for the assigned CHESI projects as needed.
  - Develop, modify, and/or adapt plans for intervention monitoring and assessment, as needed.
  - Identify strategies for optimal measurement of health outcomes, assessing mechanisms of intervention effectiveness, and impact of relevant structural and contextual factors across interventions, settings, and populations.
- Intervention Implementation:
  - Support implementation of the structural intervention, including adaptation and conduct of rigorous methodological approaches that minimize bias.
  - Assist with the identification and implementation of effective approaches to reach, recruit, engage, and retain research participants from populations that experience health disparities using an equity lens.
  - Apply implementation science and other relevant frameworks and models to identify effective strategies across interventions, settings, and populations to improve health outcomes.
- Data Management (Note: Responsibilities described below refer to management of data generated by the assigned CHESI projects).
- Support development, evaluation and/or adaption of data collection, data handling, data access, data annotation, data quality assurance, and data sharing processes of the assigned CHESI projects, as needed, to ensure effective coordination with the CCC and harmonization across CHESIs and the overall ComPASS Program.
- Data Analysis & Interpretation
  - Develop and expand existing plans for statistical data analysis and interpretation of the outcomes for assigned CHESI projects.
  - Identify and apply statistical and methodological approaches (e.g., decision science, value of information) and metrics (e.g., health economic metrics) to inform decision-making and quantify the expected value of research and benefits at multiple levels.
  - Ensure the integrity of CHESI projects, including randomization and quasi-experimental designs, and establish interim analyses and early stopping rules for safety, futility, and reducing the potential risk for re-identification.
  - Apply appropriate analytical approaches using a health equity lens, such as within-group analyses/centering the margins (Doucet, 2019

(https://files.eric.ed.gov/fulltext/ED609713.pdf)), approaches for missing data and data disaggregation (Urban Institute, 2021 (https://www.urban.org/sites/default/files/publication/104512/ethics-and-empathy-in-using-imputation-to-disaggregate-data-for-racial-equity_1.pdf)), and best practices for using statistics on small sample populations (NASEM, 2018 (https://nap.nationalacademies.org/catalog/25112/improving-health-research-on-small-populations-proceedings-of-a-workshop)).
    - Ensure and promote data justice (i.e., processes for the equitable interpretation of study results so CHESI project participants and communities are represented and treated fairly and without bias) to include providing guidance on obtaining community feedback on and understanding the implications of research findings.
- Research Dissemination
- Support assigned CHESI projects as needed in complying with data submission and data sharing requirements established by the CCC.
- Design (e.g., plain language, message development, data visualization) and dissemination of research results based on audience, preferred formats (e.g., research briefs, blogs, spotlights, infographics), media platforms (e.g., social media, local newspapers, news outlets, peer-reviewed journals) and other communications best practices to ensure accessibility and relevance to community members and multi-sectoral partners.
    - Support CHESI projects in manuscript development, serving as lead authors, submission for publication, and execution of research dissemination plans as appropriate.

CCC-related collaboration:

In collaboration and coordination with the CCC, Hub responsibilities include management of Hub-relevant data/resources and provision of scientific support and technical assistance to their assigned CHESI projects with data collection, management, quality control, dissemination, and security, as needed. Specific responsibilities will include the following:

- Data Collection and Management: Support the implementation of data systems, resources, and linkages to foster systematic data collection, data harmonization, and data sharing for assigned CHESI projects, in accordance with NIH policy.
    - Support assigned CHESI projects in implementing/adapting Data Safety Monitoring Plans as needed.
    - Collaborate with other Hubs in designing and coordinating any Hub-generated data or informational resources that may include, but are not limited to ongoing needs, assets, and resource assessments; administrative processes and outcomes; aggregated CHESI project data, including results from decision science, value of information, and/or health economic analyses; research capacity building and training activities; community engagement and health equity metrics; and other best practices, guidelines or other developed tools/products.
    - Collaborate with other Hubs in identifying externally available data, repository, and management resource assets and their utility assessments for addressing the needs of the CHESIs.
- Common Data Elements: Support CHESI projects in the selection, coordination, collection, and adaptation of standardized common data elements (CDEs), including implementation of processes to ensure CDE harmonization and interoperability as advised by the CCC. Collaborate with the CCC to identify, collect, and analyze Hub-specific CDEs. The use of CDEs (https://cde.nlm.nih.gov/) supports the 2023 NIH Data Management and Sharing Policy (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-013.html) by making data from different studies more interoperable.
- Data Analysis and Interpretation: Collaborate with CCC to create and implement an infrastructure for collecting information on cross-Hub activities to assess their effectiveness in supporting CHESI projects.
    - Refine, as necessary, and assist with data analysis plans of the assigned CHESI projects (e.g., descriptive, comparative, cross-intervention, and mechanistic).
    - Assess the scientific and methodologically focused research capacity building and training activities conducted by the Hubs.
    - Contribute to and participate in the design and implementation of any cross-Hub analyses under the coordination of the CCC.
    - Fulfill any queries regarding Hub-generated data, participation in joint activities and/or analyses.
- Data Quality: Coordinate with the CCC to develop and implement infrastructures that will support quality control of the data generated by the assigned CHESI projects and the Hub, including entry, verification, data validation (data checking and query resolution), and data integrity.
- Research Dissemination: Assist with the dissemination and accessibility of information generated by the assigned CHESI projects and Hubs to various audiences, including lay community within and outside the ComPASS Program.
    - Collaborate with the CCC to develop a state-of-the-art, secure, password-protected portal for use, limited to Hub recipients to facilitate controlled access to Hub-generated data, collaboration, information sharing, and partnership activities.
    - Prepare Hub-specific internal and public-facing data reports and summaries for distribution to consortia members, NIH staff, other identified partners, and the public
    - Describe the expected outcomes of the proposed dissemination strategies and activities.
- Data Security: Collaborate with the CCC to monitor and manage security for Hub-generated data. Data security encompasses confidentiality, data integrity, availability, and use. Data security protection and proper stewardship of human, clinical, and other sensitive information stored and distributed is of the utmost importance. The NIH security best practices and provisions (https://sharing.nih.gov/sites/default/files/flmngr/NIH_Best_Practices_for_Controlled-Access_Data_Subject_to_the_NIH_GDS_Policy.pdf) should be implemented to protect the privacy and confidentiality of CHESI participants and prevent unauthorized data access.

3. The **Research Capacity Building and Training Unit** will coordinate, design, and deliver tailored research and training support for their assigned CHESI projects. Based on needs identified throughout the planning, implementation, and assessment phases of the CHESI projects and in collaboration with the CCC, each Hub will leverage, expand, and deploy the subject matter expertise available within their established MEP to provide localized scientific and technical assistance, skills training, and sustainability planning. The activities of this Unit will strengthen the capacity of the CHESI projects to sustainably identify and address the conditions that affect the health and well-being within their local communities.

CHESI project-specific support and collaboration:

Hub-specific responsibilities focused on the scientific, technical, and collaborative support to their assigned CHESI projects include, but are not limited to, the following:

- Develop/adapt, implement, and assess research capacity building and training plans based on prior assessments and evolving needs to enhance sustainability of the assigned CHESI projects.
    - Research capacity building and training activities are expected to cultivate and enhance CHESI partners' and team members' skills across a range of topics, thereby strengthening the sustainability of the CHESI projects and future structural interventions.
        - Each of the proposed research capacity building and training strategies and activities should have clearly described objectives, components, and expected outcomes.
        - Trainings should be team-based, multidisciplinary in focus, and may be online or in-person. Acknowledgment of participation can include receipt of a certificate of completion, documentation to demonstrate training competency, or provision of experiential, continuing education, and other professional development experience.

        - Topics of research capacity building and training activities may focus on implementation research; health equity structural intervention design, approaches, frameworks, and conceptual models; structural racism; cultural and implicit bias; participant recruitment and retention strategies; scientific writing and presenting; program evaluation; policy analysis; effective science and health communication; and study design and analytic approaches to assess multilevel interventions.
        - Additionally, activities may focus on topics that bolster the organizational capacity of community partners and team members to sustain structural interventions, such as asset mapping, identifying and implementing evidence-based programs; skill building related to staff and volunteer recruitment and retention; designing and responding to community and organization readiness assessments; and developing leadership succession plans, among others.
- Establish and facilitate local Learning Communities, or similar models, that connect multidisciplinary and multi-sectoral partners aligned by shared goals, metrics, and commitment to accelerate progress and ensure sustainability of CHESI projects.
    - Identify content area foci for Learning Community activities (e.g., participatory action research, research governance, grant writing) and incorporate individuals with lived experiences, as appropriate and relevant to the CHESI projects.
    - Connect and provide Learning Communities with opportunities for bi-directional experiences, continuing education, and peer mentorship that extend beyond traditional training methods.

CCC-related collaboration:

Hub responsibilities focused on coordination and collaboration with the CCC include, but are not limited to, the following:

- Contribute to the development and evaluation of ongoing research capacity building and training needs assessments across the ComPASS Program.
- Assist in the development of resources, trainings and curricula that are informed by SDOH and health equity frameworks for dissemination across the ComPASS Program.
- Comply with plans to ensure that ComPASS-developed trainings and curricula are available to assigned CHESI projects and across all Hubs.
- Work with the CCC to ensure that Hub-generated resources will be innovative, novel, add value and be ready for rapid uptake, dissemination and/or adaptation by other Hubs/components of the ComPASS Program.

4. The **Community Engagement and Health EQuity (CEEQ) Practice Unit** will provide scientific, technical, and collaborative support for their assigned CHESI projects and liaise with the national and local HERAs, to facilitate and assess active and meaningful community engagement, research collaboration, and community translation using a health equity lens. By leveraging or expanding their established MEP, activities conducted within the CEEQ will also seek to ensure sustainability of community-led interventions that are informed by, responsive to, and ultimately serve populations that experience health disparities .

CHESI project-specific support and collaboration:

Specific responsibilities, include but are not limited to the following:

- Support assigned CHESI projects in the co-development, collection, and assessment of metrics of success and measures of community engagement, health equity, and partnership effectiveness.
- Facilitate engagement with the MEP to assist CHESI projects in the design, packaging, and dissemination of promising approaches, best practices, and other resources to be made available in the ComPASS-wide structural intervention repository.
- Assist in implementing effective community outreach and engagement strategies, including roundtables to discuss research findings and potential use of data for decision-making in policy and practice.
- Work with assigned CHESI projects to ensure that dissemination of project-related information is culturally appropriate, accessible, relevant, and actionable to various communities and partners.
- Design, implement, and assess a mentored Community Engagement and Health EQuity (CEEQ) Scholars Program. The CEEQ Scholars program will increase the pipeline of community engagement and health equity scholars by fostering co-learning and community action opportunities with community, research, and multisectoral partners. The Scholars will be integrated within the CCC's efforts to develop and facilitate Communities of Practice that bring together leaders and partners to gain greater knowledge of and expertise on a topic through regular interactions.
    - Work with the MEP, community partners, local and National HERA to design core content, competencies, learning objectives, outcomes, interactive and innovative models of curriculum delivery.
    - Certificates of completion or other documentation to demonstrate training competency should be provided.

CCC-related collaboration:

Specific responsibilities, include but are not limited to the following:

- Contribute to cross-Hub activities that advance the science and practice of community engagement in research, including understanding processes, outcomes, and contextual factors that support effective, equitable, and sustainable research collaborations.
- Collaborate with the CCC in development, implementation, and evaluation of cross-Hub activities that facilitate networking, engagement, synergy, and resource sharing among the CEEQ Scholar Programs.
- Collaborate with the CCC in the expansion of common data elements (CDEs) that capture community engagement and health equity practice indicators, such as power and control, decision-making, influence, data justice, responsibility, mutual benefit, resource-sharing, and ownership, as well as other contextual factors influencing meaningful engagement where communities are viewed as equal partners and leaders (e.g., history, trust, trustworthiness, relationship building, mutual respect, and transparency).

First Year Planning Activities and Deliverables

At the end of the first year, Hub deliverables resulting from initial planning activities, will include, but are not limited to:

- An operational management plan for administrative oversight, processes, and governance of all Hub activities and integration with assigned CHESI projects.
- A communication plan that ensures seamless coordination, ongoing communication, and interactions across Hub units, assigned CHESI projects, and the MEP, while minimizing burden and duplication of effort with the CCC.
- A plan that describes strategies for meaningful, ongoing, and active engagement and establishes the Hub as a valuable and trustworthy research resource for the assigned CHESI projects.
- A plan describing the identification, integration, coordination, utilization, and assessment of the MEP as an integral component of the Hub. This plan would also outline the logistics, infrastructure(s), governing principles, and procedures to facilitate and sustain the MEP.
- A plan describing how the Hub will provide scientific support and technical assistance to assigned CHESI projects in developing and refining their intervention study design, implementation strategies for intervention activities, statistical analysis, and outcome assessment.
- A plan for implementing research capacity building, networking, and training activities that are based on ongoing and coordinated assessment of the assigned CHESI

projects' needs and research stages. The plan will also describe implementation of the proposed Learning Communities, potential topic areas, audiences and intended outcomes.
- A plan for the conduct and assessment of community engagement activities, including liaison activities with the local, national HERAs, and leveraging the MEP resource using a health equity lens.
- An implementation plan for the Hub CEEQ Scholars Program, including but not limited to supporting attachments and details regarding application requirements, eligibility and selection criteria, as well as CEEQ program activities and experiences that are aligned with the Hub functions and desired outcomes.
- A plan for collaboration with the CCC on activities including, but not limited to, delivery of technical assistance in the implementation of CCC-developed planning guides, tools, trainings, and resources; participation in annual ComPASS Consortium meetings .
- A plan for collaboration with and support of the assigned CHESI projects regarding data aggregation, collection, management, sharing, storage, access, quality control, analysis of CHESI project common data elements (CDEs).
- A comprehensive health equity logic model and assessment plan covering all Hub activities.
- A detailed timeline with concrete milestones for all Hub goals, objectives, and Unit activities.
- Proposed criteria to justify any potential restructuring of the thematically organized CHESI projects or shifts in Hub thematic areas, as necessary and in coordination with the CCC, NIH Program Staff and Program Scientist(s).

Formation and Governance of the ComPASS Consortium
The consortium comprises the three ComPASS initiatives: the CCC, CHESI projects, and the Hubs. Immediately following the award, the PDs/PIs and NIH Program Staff will form the ComPASS Steering Committee (SC). Consortium governance rests with the Steering Committee and the SC is subject to oversight by the NIH Common Fund. Consortium members are expected to participate in the development of consortium-wide policies and abide by all policies developed by the SC and approved by NIH staff. The SC, and in particular the co-chairs of the SC, will work cooperatively and interactively, during all phases of the ComPASS program to promote collaboration, information and resource sharing across the ComPASS Program.

- **ComPASS Consortium (or Program):** The consortium structure is meant to efficiently and effectively guide all the funded projects to meet the overall goals of the ComPASS Program. This structure includes all ComPASS recipients the NIH Working Group, other relevant scientists and groups the SC agrees to include within the consortium.
- **ComPASS Program Steering Committee (SC):** The ComPASS Steering Committee will be coordinated and administrated by the ComPASS Coordination Center (CCC) and will govern the activities of the program recipients. The Health Equity Research Hub awards begin 1 year after the formation of the SC. The PIs of the Health Equity Research Hubs will join the ComPASS Steering Committee (SC), comprised of the PIs of the ComPASS Community-led, Health Equity Structural Intervention, the CCC, and involved NIH staff acting as ComPASS Program Officers (POs), Project Scientists (PSs) and the OSC Program Leader. The SC will work cooperatively and interactively, during all phases to promote collaborations, as well as information and resource sharing across the ComPASS Program. The co-chairs will be independently appointed by the NIH in collaboration with the ComPASS SC. The SC co-chairs will preside at all SC meetings. Scientific direction will comply with NIH research policies and procedures. Consortium governance rests with the SC and the SC is subject to oversight by the NIH Common Fund. The governance structure will be co-created by SC members and NIH staff. For votes, the Health Equity Research Hub awards will together have one vote. The Hubs will be convened by the CCC, as needed, to address and determine majority vote on governance-related issues in advance of SC meetings. The CCC award will have one vote, and each Community-Led Health Equity Structural Intervention award will have one vote. All Federal staff together will have one vote. The SC decisions will be made by a majority vote.

Technical Assistance Webinar
All applicants are strongly encouraged to contact NIH Staff to discuss the alignment of their proposed work with the goals of this NOFO and the overall ComPASS Program. A Technical Assistance Webinar will be held for potential applicants at a future date and time to be communicated in an updated Notice to this announcement. NIH staff will be available to answer questions related to this NOFO. Webinar information will be shared on the ComPASS (https://commonfund.nih.gov/compass) website and slides will also be made available for those unable to attend. A list of frequently asked questions (FAQs) related to this NOFO, and the ComPASS Program will also be available on the ComPASS (https://commonfund.nih.gov/compass) website. The information session is open to all prospective applicants and participation in the Technical Assistance Webinar is not required to apply to this funding opportunity.

Applications with the following specifics will be considered non-responsive and will not be reviewed:

- PDs/PIs who do not commit at least 2.0 person months of effort to the application per year for the life of the award.
- Applications that do not include at least four of the identified Hub units.
- Applications that do not describe the proposed structure, composition, and function of the multidisciplinary expertise panel (MEP) resource.
- Applications that do not describe the proposed structure, function, and outcomes of a mentored Community Engagement and Health EQuity (CEEQ) Scholars Program.

See Section VIII. Other Information for award authorities and regulations.

Investigators proposing NIH-defined clinical trials may refer to the Research Methods Resources (https://researchmethodsresources.nih.gov/) website for information about developing statistical methods and study designs.

Section II. Award Information

Funding Instrument	Cooperative Agreement: A support mechanism used when there will be substantial Federal scientific or programmatic involvement. Substantial involvement means that, after award, NIH scientific or program staff will assist, guide, coordinate, or participate in project activities. See Section VI.2 for additional information about the substantial involvement for this NOFO.
Application Types Allowed	New The OER Glossary (//grants.nih.gov/grants/guide/url_redirect.htm?id=11116) and the SF424 (R&R) Application Guide provide details on these application types. Only those application types listed here are allowed for this NOFO.
Clinical Trial?	Optional: Accepting applications that either propose or do not propose clinical trial(s). Need help determining whether you are doing a clinical trial? (https://grants.nih.gov/grants/guide/url_redirect.htm?id=82370)

Funds Available and Anticipated Number of Awards	The NIH Common Fund (Office of Strategic Coordination) intends to commit approximately $3,750,000 in FY2024, and $7,500,000 per year for FY2025 through FY2028. Approximately five (5) awards are anticipated, contingent upon NIH appropriations and submission of a sufficient number of meritorious applications.
Award Budget	Application budgets must reflect the actual needs of the proposed project.
Award Project Period	The project period cannot exceed 5 years.

NIH grants policies as described in the NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.htm?id=11120) will apply to the applications submitted and awards made from this NOFO.

Section III. Eligibility Information

1. Eligible Applicants

Eligible Organizations

Higher Education Institutions

- Public/State Controlled Institutions of Higher Education
- Private Institutions of Higher Education

The following types of Higher Education Institutions are always encouraged to apply for NIH support as Public or Private Institutions of Higher Education:

- Hispanic-serving Institutions
- Historically Black Colleges and Universities (HBCUs)
- Tribally Controlled Colleges and Universities (TCCUs)
- Alaska Native and Native Hawaiian Serving Institutions
- Asian American Native American Pacific Islander Serving Institutions (AANAPISIs)

Nonprofits Other Than Institutions of Higher Education

- Nonprofits with 501(c)(3) IRS Status (Other than Institutions of Higher Education)
- Nonprofits without 501(c)(3) IRS Status (Other than Institutions of Higher Education)

For-Profit Organizations

- Small Businesses
- For-Profit Organizations (Other than Small Businesses)

Local Governments

- State Governments
- County Governments
- City or Township Governments
- Special District Governments
- Indian/Native American Tribal Governments (Federally Recognized)
- Indian/Native American Tribal Governments (Other than Federally Recognized)

Federal Government

- U.S. Territory or Possession

Foreign Institutions

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 in the *NIH Grants Policy Statement* (//grants.nih.gov/grants/guide/url_redirect.htm?id=11118), **are not** allowed.

Required Registrations

Applicant Organizations

Applicant organizations must complete and maintain the following registrations as described in the SF 424 (R&R) Application Guide to be eligible to apply for or receive an award. All registrations must be completed prior to the application being submitted. Registration can take 6 weeks or more, so applicants should begin the registration process as soon as possible. The NIH Grants Policy Statement Section 2.3.9.2 Electronically Submitted Applications (//grants.nih.gov/grants/guide/url_redirect.htm?id=82423) states that failure to complete registrations in advance of a due date is not a valid reason for a late submission.

- System for Award Management (SAM) – (https://grants.nih.gov/grants/guide/url_redirect.htm?id=82390) Applicants must complete and maintain an active registration, **which requires renewal at least annually**. The renewal process may require as much time as the initial registration. SAM registration includes the assignment of a Commercial and Government Entity (CAGE) Code for domestic organizations which have not already been assigned a CAGE Code.
  - NATO Commercial and Government Entity (NCAGE) Code (//grants.nih.gov/grants/guide/url_redirect.htm?id=11176) – Foreign organizations must obtain an NCAGE code (in lieu of a CAGE code) in order to register in SAM.
  - Unique Entity Identifier (UEI) - A UEI is issued as part of the SAM.gov registration process. The same UEI must be used for all registrations, as well as on the grant application.
- eRA Commons (https://grants.nih.gov/grants/guide/url_redirect.htm?id=11123) - Once the unique organization identifier is established, organizations can register with eRA Commons in tandem with completing their Grants.gov registration; all registrations must be in place by time of submission. eRA Commons requires organizations to identify at least one Signing Official (SO) and at least one Program Director/Principal Investigator (PD/PI) account in order to submit an application.
- Grants.gov (//grants.nih.gov/grants/guide/url_redirect.htm?id=82300) – Applicants must have an active SAM registration in order to complete the Grants.gov registration.

Program Directors/Principal Investigators (PD(s)/PI(s))

All PD(s)/PI(s) must have an eRA Commons account. PD(s)/PI(s) should work with their organizational officials to either create a new account or to affiliate their existing account with the applicant organization in eRA Commons. If the PD/PI is also the organizational Signing Official, they must have two distinct eRA Commons accounts, one for each role. Obtaining an eRA Commons account can take up to 2 weeks.

Eligible Individuals (Program Director/Principal Investigator)

Any individual(s) with the skills, knowledge, and resources necessary to carry out the proposed research as the Program Director(s)/Principal Investigator(s) (PD(s)/PI(s)) is invited to work with their organization to develop an application for support. Individuals from diverse backgrounds, including underrepresented racial and ethnic groups, individuals with disabilities, and women are always encouraged to apply for NIH support. See, Reminder: Notice of NIH's Encouragement of Applications Supporting Individuals from Underrepresented Ethnic and Racial Groups as well as Individuals with Disabilities, NOT-OD-22-019 (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-22-019.html).

For institutions/organizations proposing multiple PDs/PIs, visit the Multiple Program Director/Principal Investigator Policy and submission details in the Senior/Key Person Profile (Expanded) Component of the SF424 (R&R) Application Guide.

2. Cost Sharing

This NOFO does not require cost sharing as defined in the NIH Grants Policy Statement. (//grants.nih.gov/grants/guide/url_redirect.htm?id=11126)

3. Additional Information on Eligibility

Number of Applications

Applicant organizations may submit more than one application, provided that each application is scientifically distinct.

The NIH will not accept duplicate or highly overlapping applications under review at the same time, per NIH Grants Policy Statement Section 2.3.7.4 Submission of Resubmission Application (//grants.nih.gov/grants/guide/url_redirect.htm?id=82415). This means that the NIH will not accept:

- A new (A0) application that is submitted before issuance of the summary statement from the review of an overlapping new (A0) or resubmission (A1) application.
- A resubmission (A1) application that is submitted before issuance of the summary statement from the review of the previous new (A0) application.
- An application that has substantial overlap with another application pending appeal of initial peer review (see NIH Grants Policy Statement 2.3.9.4 Similar, Essentially Identical, or Identical Applications (//grants.nih.gov/grants/guide/url_redirect.htm?id=82423)).

Section IV. Application and Submission Information

1. Requesting an Application Package

The application forms package specific to this opportunity must be accessed through ASSIST, Grants.gov Workspace or an institutional system-to-system solution. Links to apply using ASSIST or Grants.gov Workspace are available in Part 1 of this NOFO. See your administrative office for instructions if you plan to use an institutional system-to-system solution.

2. Content and Form of Application Submission

It is critical that applicants follow the instructions in the Research (R) Instructions in the How to Apply - Application Guide (https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400) except where instructed in this notice of funding opportunity to do otherwise. Conformance to the requirements in the Application Guide is required and strictly enforced. Applications that are out of compliance with these instructions may be delayed or not accepted for review.

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.

By the date listed in Part 1. Overview Information, prospective applicants are asked to submit a letter of intent that includes the following information:

- Descriptive title of proposed activity
- Name(s), address(es), and telephone number(s) of the PD(s)/PI(s)
- Names of other key personnel
- Participating institution(s)
- Number and title of this funding opportunity

The letter of intent should be sent to:

Amanda Acevedo, Ph.D.
National Cancer Institute (NCI)
Email: CFComPASS@od.nih.gov (mailto:CFComPASS@od.nih.gov)

Page Limitations

All page limitations described in the SF424 Application Guide and the Table of Page Limits (https://grants.nih.gov/grants/guide/url_redirect.htm?id=61134) must be followed.

Instructions for Application Submission

The following section supplements the instructions found in the SF424 (R&R) Application Guide and should be used for preparing an application to this NOFO.

SF424(R&R) Cover

All instructions in the SF424 (R&R) Application Guide must be followed.

SF424(R&R) Project/Performance Site Locations

All instructions in the SF424 (R&R) Application Guide must be followed.

SF424(R&R) Other Project Information

All instructions in the SF424 (R&R) Application Guide must be followed, with the following additional instructions:

- **Hub Investigative Team:** A one-page attachment must be included listing which personnel will fulfill the required and strongly encouraged areas of experience listed under SF424 (R&R) Senior/Key Personnel. The filename must be labeled “Hub Team.pdf”.
- **Multidisciplinary Expertise Panel (MEP) Resource:** This attachment must describe the core scientific and technical team of experts that will comprise the MEP resource

proposed in this application, the process of recruiting and identifying core or ad hoc expertise, plans for integration and synergy across the scope of Hub activities, and approaches for providing support to the assigned CHESI projects. Examples of additional scientific expertise that may be needed includes, but is not limited to structural racism; cultural and implicit bias; scientific writing and presenting; community-led and -engaged research; program evaluation; policy analysis; health communication; and specific study design and analytic approaches to assess multilevel interventions (e.g., group- or cluster-randomized trials, stepped wedge group- or cluster-randomized trials, group- or cluster regression discontinuity designs, econometrics, interrupted time-series, pragmatic and adaptive study designs and others). The filename must be labeled "Multidisciplinary Expertise Panel Resource.pdf".

- **Milestones and Timeline:** This attachment must include the Hub timeline and major milestones. This attachment supplements, but does not replace, the Milestones section of the Research Strategy. The filename must be labeled as "Milestones and Timeline.pdf".

SF424(R&R) Senior/Key Person Profile

All instructions in the SF424 (R&R) Application Guide must be followed. The additional instructions apply:

The Hub Program Director(s)/Principal Investigator(s) (PD(s)/(PI(s)) or other senior/key personnel must describe their expertise in structural and multilevel intervention study design, team and implementation science, biostatistics and research methods, community engagement, and health disparities research, as well as experience in research capacity building and training. Additionally, Hub PDs/PI(s) and senior/key personnel and staff must demonstrate significant experience and qualifications:

- Leading and coordinating complex consortia and productive trans-/multidisciplinary collaborations that involve communities and populations that experience health disparities, scientific teams, and multisectoral partners.
- Managing large complex projects and teams, including multidisciplinary experts, knowledge of workflow and research team practices.
- Managing successful collaborations to design, implement, and complete large, complex, community-engaged/led intervention research/clinical trials across varied settings, communities, and geographical regions.
- Implementing a broad range of research study designs (i.e., experimental, quasi-experimental design and implementation) and statistical expertise (e.g., econometrics), particularly with health disparity, health equity and community-engaged/led intervention research.
- Familiarity with planning, developing, and executing any special consent and/or IRB procedures needed for the conduct of structural-level and community-engaged/led intervention research.
- A history of successful recruitment and retention of participants to community-engaged/led intervention research/clinical trials.
- Designing data collection and management systems, including distributed data entry, and capabilities and experience with research performance and data quality control systems.
- Coordinating communication and engagement strategies using appropriate technology, including creation and maintenance of online/digital collaborative spaces/platforms, project management tools, and organization systems.
- Developing, implementing/organizing and evaluating virtual and in-person community and scientific meetings, community outreach activities, partner engagement activities, webinars/workshops, research capacity building and mentored training programs and materials.
- Using and evaluating effectiveness of community engaged methods, strategies, and programs, including impact, policy, and sustainability assessments.

Participation of individuals from diverse backgrounds, including underrepresented racial and ethnic groups, persons with disabilities, and women is encouraged at all levels of leadership and conduct of the Hub. See https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-031.html (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-031.html).

R&R Budget

All instructions in the SF424 (R&R) Application Guide must be followed.

- Each applicant should submit base budget estimates for all years. PDs/PIs are expected to commit a minimum of at least 2.0 person months of effort per year for the life of the award. Applicants proposing Multiple PDs/PIs must have a minimum combined PD/PI effort of 2.0 person months.
- In addition to PDs/PIs, budgeted costs may include effort for senior/key personnel such as a Hub Administrator to manage day-to-day operations, Hub Unit Leads, members of the Multidisciplinary Expert Panel (MEP), and biostatistical and data science support for data activities.
- Budgeted funds to support collaborative activities of the Hub may include participation in ComPASS Steering Committee meetings, CCC-coordinated cross-Hub collaborative and governance-related activities, and conference call coordination with assigned CHESI projects.
- The budget should include in-person travel support for Hub-related activities, including but not limited to, costs for Hub PDs/PIs, key personnel, and CEEQ Scholars to attend annual ComPASS Consortium meetings in the Bethesda, MD area.
- The CEEQ Scholars Program budget may include costs such as Scholar stipends, mentor support, and attendance at scientific meetings.

R&R Subaward Budget

All instructions in the SF424 (R&R) Application Guide must be followed.

PHS 398 Cover Page Supplement

All instructions in the SF424 (R&R) Application Guide must be followed.

PHS 398 Research Plan

All instructions in the SF424 (R&R) Application Guide must be followed, with the following additional instructions:

Overview

Provide a succinct description of the overall vision, as well as the scientific, technical, and collaborative goals and objectives of the proposed Hub. This overarching statement should address the:

- SDOH/structural factor theme(s) for which the applicant can serve as a centralized research resource to assigned CHESI projects.
- Organizational structure and operational plan to provide tailored support for sustainable community engagement, research capacity building, and training to awarded CHESI projects.
- Expected outcomes and potential impact should the goals of the Hub be achieved.
- Overall approach for integration and synergy of Hub activities and the MEP.
- Proposed engagement strategies that will support the promotion, establishment, and robust use of the Hub as a valuable and trustworthy research resource.
- Principles and application of community engagement and health equity to all Hub activities.
- Hub's added value and its role in advancing the goals and objectives of the ComPASS Program.

Research Strategy

Applicants must organize the Research Strategy into the sections/subsections identified below. Applicants may include other sections as needed but must include the information requested.

Section 1: Administrative and Coordinating Unit

- Identify the PD(s)/PI(s), senior/key personnel and administrative infrastructure for the Hub.
- Propose overall structure of the Hub, including its leadership, governance and management structure (e.g., subawards and consultants), integration of components and any possible subcontracts (especially with community-based organizations and multisector partners) needed to manage and facilitate the Hub Units.
- Provide an organizational chart of the tasks to illustrate to be accomplished overall and for each Hub Unit, the staff needed for each task and their respective roles and responsibilities.
- Describe plans to coordinate, manage and provide operational, collaborative, communications, and dissemination support for all Hub Units, activities, and generated resources.
- Describe the composition and desired expertise of the MEP, proposed activities, and coordination of the MEP, plans to augment core scientific and technical expertise as needed, and integrate the resource across all Hub Units, functions, and activities.
- Describe the engagement strategy to be employed ensure effective working relationships with assigned CHESI projects and relevant partners.
- Provide a brief description of strategies for connecting and integrating the Hub with the broader ComPASS Program in collaboration with the CCC.
- Explain overall plans to manage/monitor Hub progress, timelines, milestones, and deliverables across all Hub units and functions.
- Propose plans to participate in annual ComPASS meetings, CCC-coordinated and cross-Hub collaborative efforts, and contribute to ComPASS Program activities.

Section 2-4: This section should describe the Research Strategy for each of the remaining Hub Units and be organized into sub-sections as outlined below. Applicants may include other sections as needed but must include the information requested.

Sub-section A: Specific Aims

- Briefly state the specific aims for each Unit, including a concise statement regarding how the work of each Unit will contribute to the SDOH/structural factor theme(s) and success of the assigned CHESI projects.

Sub-section B: Significance

- Describe the major challenges/needs that the Unit plans to address related to the SDOH/structural factor theme(s) and the rationale for proposed integration and synergy of the MEP.
- Describe how the Hub will be nimble, responsive, and adapt to the dynamic and varying needs of the assigned CHESI projects and overall ComPASS Program during all phases of the funding period.
- Identify any anticipated challenges the assigned CHESI projects might encounter and propose strategies for how the Unit will address these challenges.
- Describe how the proposed approaches, methods, resultant strategies, findings, and products may be relevant to or tailored for use by communities and populations that experience health disparities.
- Discuss plans for ensuring sustainability of the valuable resources generated by the Hub and likelihood to advance health equity.

Sub-section C: Innovation

- Describe the proposed scientific, technical and/or team science innovation(s) that the Hub will employ including, but not limited to, novel approaches, data science methods, engagement and coordination strategies, technologies, and collaborations to support assigned CHESI projects.
- Describe how these innovative aspects will advance the Unit's aims and improve use of the Hub as centralized research resource.
- Describe how use of innovative, adaptive, or responsive research methods will advance the design and implementation of high-quality community-led structural intervention research.
    - Describe the prior experience and relevant expertise of identified Unit Lead(s)' in coordinating and managing complex consortia, specifically executing activities of the Hub Unit.
- Discuss plans to ensure that Hub-generated resources will be innovative, novel, add value, and be ready for rapid uptake, dissemination and/or adaptation by other Hubs/components of the ComPASS Program.

Sub-section D: Approach (general)

- Demonstrate the availability of infrastructure, capabilities, resources, and institutional support needed to achieve the goals of the Hub (e.g., Information Technology capacities to effectively perform data activities and develop and disseminate virtual training modules). The plan should also demonstrate that the infrastructure and personnel (e.g., coordinating and contracting outside the entity) are readily available and accessible to accomplish the objectives and activities of the Hub.
- Describe and demonstrate prior experience in leadership and oversight of community-based/ engaged/led clinical trials and projects; development of data resources, management platforms, data analysis, common data elements, and data repositories; experience in capacity-building and training related to health disparity and community-engaged intervention research; and management of administrative logistics and outreach/dissemination activities
- Describe the structure, processes, and strategies for how the proposed Hub will fulfill its overall and Unit functions across the multi-year time frame, including leading and coordinating the support activities with the assigned CHESI projects and collaboration activities with the CCC.
- Describe plans to leverage, expand, and integrate the MEP, including specific ways the MEP will be effectively engaged to enhance the scope of Unit activities and relevant outcomes. This should include a plan to liaise with the local and national HERAs.
- Describe specific ways the Hub will identify and provide tailored scientific, technical, and collaborative support for sustainable community engagement, research capacity building, and training to assigned CHESI projects as described in Section I. The plan should also address Unit-specific elements, including, but not limited to, the following:
    - Provide intervention-related technical guidance based on the scientific needs and research stages of the CHESI projects, including assisting with data coordination, collection, management, statistical analysis and interpretation, outcome assessment and dissemination. Note that describing how the Hub will support the managing and sharing of data generated by the assigned CHESI projects should be included in this sub-section.
    - Establish and facilitate local Learning Communities that connect multidisciplinary and multisectoral partners to accelerate progress and ensure sustainability of the assigned CHESI projects, including specified content areas, activities, and strategies to engage various partners and allies.
- Increase the pipeline of community engagement and health equity practitioners through the design and assessment of a Community Engagement Scholars Program, including eligibility and selection of CEEQ Scholars, outreach and engagement with different types of institutions and organizations, research and engagement learning opportunities that will be developed, mentor identification and training, proposed Scholar products and outcomes, and the benefits to the assigned CHESIs and overall

ComPASS program.
    - Explain ways the Unit will intersect and interact with other Units within the Hub, and how they will foster communications and interactions among assigned CHESI projects, academic, community, multisector partners, local and national HERAs, across other Hubs, and with the CCC as appropriate.
    - Describe efforts to coordinate, disseminate, track performance, and improve relevance of Hub-generated resources to different audiences.
- Describe the rationale for including or not including a Resource Sharing Plan.

Sub-section E: Monitoring and Assessment of Hub Activities

The overall approach to monitoring and assessing Hub activities should be discussed in this section. Note that all plans for data management and sharing of Hub generated data should be described in the Other Plan(s), Data Management and Sharing Plan section.

- Describe how the Hub will assess CHESI project activities, develop a health equity logic model and assessment plan, and disseminate resources and tools for developing, implementing, and assessing structural interventions to address health disparities and advance health equity.
- Describe plans to identify CHESI project needs, monitor and assess Hub Unit activities, including outcomes related to utilization, engagement, satisfaction, effectiveness, impact, and steps taken to improve/optimize support provided to the assigned CHESI projects.
- Propose plans to assess barriers to facilitating and sustaining Hub Unit activities, including research capacity building and training activities.

Milestones and Timeline: In addition, a timeline including milestones is required for all applications. Milestones are intermediate steps towards the completion of concrete goals. They must include clear and quantitative criteria for success. Yearly specific and quantitative milestones are required to provide clear indicators of a project's continued success or emergent difficulties and will be used to evaluate the application not only in peer review, but also in consideration of the awarded project for funding of non-competing award years. The milestones should not be an exhaustive list of every task to be performed. Rather, milestones should be small in number and represent significant accomplishments that inform the go/no-go decision points, along with timelines for assessing progress. The milestones and timeline should be included as an attachment, filename labeled as "Milestones and Timeline.pdf" and submitted under the Other Attachments section of the R&R Other Project Information form.

Letters of Support

Include letters of support from partnering institutions, appropriate leaders of institutional component services, MEP members, potential CEEQ mentors, or outside collaborators/subcontractors with clear statement of roles/responsibilities. The application must include a statement from the applicant's institution (senior institutional official) describing the commitment to the planned program, investigators, all proposed staff, and infrastructure needed. Submitted letters should directly demonstrate the ability of the proposed Hub to fulfill the roles and responsibilities specified in this NOFO.

Resource Sharing Plan:

Individuals are required to comply with the instructions for the Resource Sharing Plans as provided in the SF424 (R&R) Application Guide, with the following additional instructions.

Submission of the Resource Sharing Plan or a rationale for not including one is required. The Resource Sharing Plan will be evaluated as part of the Approach criterion. In the Resource Sharing Plan, applicants should indicate a statement of willingness to abide by all policies related to resource sharing developed by the ComPASS Coordination Center, Steering Committee and approved by NIH Program Staff. ComPASS Hub recipients are expected to develop such policies as members of the ComPASS Steering Committee in collaboration with NIH and should indicate their willingness to participate in the development of such policies and to abide by them. These policies will remain consistent with NIH policies on resource sharing.

NIH's vision for the Hubs is that it will become a long-term research resource with added value to the larger biomedical and behavioral science community. It is therefore important that the Hubs are built to be portable and sustainable. Programmatic preference will be given to designs that can easily be transferred and maintained beyond the funding cycle. Applicants are asked to describe a vision for how the valuable resources generated by the Hubs can be maintained beyond the funding period as part of the application. Applicants must also provide an overall description of any anticipated resources generated by the Hubs, as well as plans to make them available and accessible , consistent with the goals of the ComPASS Program.

After initial review, NIH staff will conduct an administrative review of the Resource Sharing Plan and may negotiate modifications to the plan with the prospective recipients. The final negotiated plan will become a term and condition of award.

Other Plan(s):

Note: Effective for due dates on or after January 25, 2023, the Data Management and Sharing Plan will be attached in the Other Plan(s) attachment in FORMS-H application forms packages.

All instructions in the SF424 (R&R) Application Guide must be followed, with the following additional instructions:

- All applicants planning research (funded or conducted in whole or in part by NIH) that results in the generation of scientific data are required to comply with the instructions for the Data Management and Sharing Plan. All applications, regardless of the amount of direct costs requested for any one year, must address a Data Management and Sharing Plan.
- **Public Access:** The NIH Common Fund intends to maximize the availability of publications and the sharing of underlying data and resources for the ComPASS Program and encourages publication of preprints and the use of open access journals. Hub applicants should describe plans to work with the CCC to make resulting publications and to the extent possible, the associated data immediately and broadly available to the public or provide a justification if such sharing is not possible. Underlying primary data are expected to be made as widely and freely available as possible while safeguarding the privacy of participants and protecting confidential and proprietary data.
- **Data Security:** Data security encompasses confidentiality, data integrity, and availability. Confidentiality includes managing data access to maintain data security and making data accessible to authorized users only for authorized purposes. Data security protection and proper stewardship of Hub-generated data and other sensitive information stored and distributed is of the utmost importance. The NIH security best practices and provisions (https://www.ncbi.nlm.nih.gov/projects/gap/pdf/dbgap_2b_security_procedures.pdf) should be implemented to protect the privacy and confidentiality of research participants and prevent unauthorized access to data. Investigators are expected to develop policies and procedures for notifying NIH, managing, and mediating any loss of data or compromise of data confidentiality.
- **FAIRness:** Implementation of FAIR (Findable, Accessible, Interoperable, Reusable) Principles is essential for the success of ComPASS. Consistent with achieving these principles, the NIH expects that information such as collected data, technical protocols, and any other metadata collected under this NOFO is to be rapidly deposited as appropriate into the ComPASS Coordination Center (CCC) and in a recognized and reusable format. Applicants should describe their plan for collaborating with the CCC to share and document data, metadata, protocols, software code and algorithms, while ensuring that privacy and confidentiality of participants. The CCC will serve as the central access point for information regarding data and tools being developed by the ComPASS Consortium. Hub applicants should describe plans to work with the CCC to

ensure any developed tools, schema, and standards are being implemented appropriately to assess FAIRness and ensure data and resources from ComPASS are interoperable with other Common Fund resources. In addition, NIH staff will work closely with ComPASS recipients to leverage other NIH initiatives such as the Researcher Auth Service (https://datascience.nih.gov/researcher-auth-service-initiative (https://datascience.nih.gov/researcher-auth-service-initiative)).

Appendix:

Only limited Appendix materials are allowed. Follow all instructions for the Appendix as described in the SF424 (R&R) Application Guide.

PHS Human Subjects and Clinical Trials Information

When involving human subjects research, clinical research, and/or NIH-defined clinical trials (and when applicable, clinical trials research experience) follow all instructions for the PHS Human Subjects and Clinical Trials Information form in the SF424 (R&R) Application Guide, with the following additional instructions:

If you answered "Yes" to the question "Are Human Subjects Involved?" on the R&R Other Project Information form, you must include at least one human subjects study record using the **Study Record: PHS Human Subjects and Clinical Trials Information** form or **Delayed Onset Study** record.

Study Record: PHS Human Subjects and Clinical Trials Information

All instructions in the SF424 (R&R) Application Guide must be followed.

Delayed Onset Study

Note: Delayed onset (https://grants.nih.gov/grants/glossary.htm#DelayedOnsetStudy) does NOT apply to a study that can be described but will not start immediately (i.e., delayed start). All instructions in the SF424 (R&R) Application Guide must be followed.

PHS Assignment Request Form

All instructions in the SF424 (R&R) Application Guide must be followed.

3. Unique Entity Identifier and System for Award Management (SAM)

See Part 1. Section III.1 for information regarding the requirement for obtaining a unique entity identifier and for completing and maintaining active registrations in System for Award Management (SAM), NATO Commercial and Government Entity (NCAGE) Code (if applicable), eRA Commons, and Grants.gov

4. Submission Dates and Times

Part I. Overview Information contains information about Key Dates and times. Applicants are encouraged to submit applications before the due date to ensure they have time to make any application corrections that might be necessary for successful submission. When a submission date falls on a weekend or Federal holiday (https://grants.nih.gov/grants/guide/url_redirect.html?id=82380), the application deadline is automatically extended to the next business day.

Organizations must submit applications to Grants.gov (//grants.nih.gov/grants/guide/url_redirect.htm?id=11128) (the online portal to find and apply for grants across all Federal agencies). Applicants must then complete the submission process by tracking the status of the application in the eRA Commons (https://grants.nih.gov/grants/guide/url_redirect.htm?id=11123), NIH's electronic system for grants administration. NIH and Grants.gov systems check the application against many of the application instructions upon submission. Errors must be corrected and a changed/corrected application must be submitted to Grants.gov on or before the application due date and time. If a Changed/Corrected application is submitted after the deadline, the application will be considered late. Applications that miss the due date and time are subjected to the NIH Grants Policy Statement Section 2.3.9.2 Electronically Submitted Applications (//grants.nih.gov/grants/guide/url_redirect.htm?id=82423).

Applicants are responsible for viewing their application before the due date in the eRA Commons to ensure accurate and successful submission.

Information on the submission process and a definition of on-time submission are provided in the SF424 (R&R) Application Guide.

5. Intergovernmental Review (E.O. 12372)

This initiative is not subject to intergovernmental review. (https://grants.nih.gov/grants/policy/nihgps/html5/section_10/10.10.1_executive_orders.htm)

6. Funding Restrictions

All NIH awards are subject to the terms and conditions, cost principles, and other considerations described in the NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.htm?id=11120).

Pre-award costs are allowable only as described in the NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.htm?id=11143).

7. Other Submission Requirements and Information

Applications must be submitted electronically following the instructions described in the SF424 (R&R) Application Guide. Paper applications will not be accepted.

Applicants must complete all required registrations before the application due date. Section III. Eligibility Information contains information about registration.

For assistance with your electronic application or for more information on the electronic submission process, visit How to Apply – Application Guide (https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400). If you encounter a system issue beyond your control that threatens your ability to complete the submission process on-time, you must follow the Dealing with System Issues (https://grants.nih.gov/grants/how-to-apply-application-guide/due-dates-and-submission-policies/dealing-with-system-issues.htm) guidance. For assistance with application submission, contact the Application Submission Contacts in Section VII.

Important reminders:

All PD(s)/PI(s) must include their eRA Commons ID in the Credential field of the Senior/Key Person Profile form**.** Failure to register in the Commons and to include a valid PD/PI Commons ID in the credential field will prevent the successful submission of an electronic application to NIH. See Section III of this NOFO for information on registration requirements.

The applicant organization must ensure that the unique entity identifier provided on the application is the same identifier used in the organization's profile in the eRA Commons and for the System for Award Management. Additional information may be found in the SF424 (R&R) Application Guide.

See more tips (//grants.nih.gov/grants/guide/url_redirect.htm?id=11146) for avoiding common errors.

Upon receipt, applications will be evaluated for completeness and compliance with application instructions by the Center for Scientific Review and responsiveness by Office of Strategic Coordination (OSC), NIH. Applications that are incomplete, non-compliant and/or nonresponsive will not be reviewed.

Post Submission Materials

Applicants are required to follow the instructions for post-submission materials, as described in the policy (//grants.nih.gov/grants/guide/url_redirect.htm?id=82299)

Any instructions provided here are in addition to the instructions in the policy.

Section V. Application Review Information

1. Criteria

Only the review criteria described below will be considered in the review process. Applications submitted to the NIH in support of the NIH mission (//grants.nih.gov/grants/guide/url_redirect.htm?id=11149) are evaluated for scientific and technical merit through the NIH peer review system.

A proposed Clinical Trial application may include study design, methods, and intervention that are not by themselves innovative but address important questions or unmet needs. Additionally, the results of the clinical trial may indicate that further clinical development of the intervention is unwarranted or lead to new avenues of scientific investigation.

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).

Scored Review Criteria

Reviewers will consider each of the review criteria below in the determination of scientific merit and give a separate score for each. An application does not need to be strong in all categories to be judged likely to have major scientific impact. For example, a project that by its nature is not innovative may be essential to advance a field.

Significance

Does the project address an important problem or a critical barrier to progress in the field? Is the prior research that serves as the key support for the proposed 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?

In addition, for applications involving clinical trials

Are the scientific rationale and need for a clinical trial to test the proposed hypothesis or intervention well supported by preliminary data, clinical and/or preclinical studies, or information in the literature or knowledge of biological mechanisms? For trials focusing on clinical or public health endpoints, is this clinical trial necessary for testing the safety, efficacy or effectiveness of an intervention that could lead to a change in clinical practice, community behaviors or health care policy? For trials focusing on mechanistic, behavioral, physiological, biochemical, or other biomedical endpoints, is this trial needed to advance scientific understanding?

Specific to this NOFO:

- To what extent, are the proposed approaches likely to yield important contributions applicable to a range of populations that experience health disparities ?
- To what extent, will successful completion of the aims contribute to or complement community-led efforts to design and implement structural interventions that advance health equity within their local communities?
- How well will the proposed Hub activities contribute to the success of the CHESI projects and overall ComPASS Program?
- How well will successful integration and synergy of the Hub Units and MEP facilitate the ability of the Hub to provide tailored and responsive support to their assigned CHESI projects?

Investigator(s)

Are the PD(s)/PI(s), collaborators, and other researchers well suited to the project? If Early Stage Investigators or those in the early stages of independent careers, do they have appropriate experience and training? If established, have they demonstrated an ongoing record of accomplishments that have advanced their field(s)? If the project is collaborative or multi-PD/PI, do the investigators have complementary and integrated expertise; are their leadership approach, governance, and organizational structure appropriate for the project?

In addition, for applications involving clinical trials

With regard to the proposed leadership for the project, do the PD/PI(s) and key personnel have the expertise, experience, and ability to organize, manage and implement the proposed clinical trial and meet milestones and timelines? Do they have appropriate expertise in study coordination, data management and statistics? For a multicenter trial, is the organizational structure appropriate and does the application identify a core of potential center investigators and staffing for a coordinating center?

Specific to this NOFO:

- How relevant is the experience of the Hub PD(s)/PI(s), senior/key personnel, and Unit Leads to provide scientific and technical support, including statistics and/or methodological expertise to assigned CHESI projects?
- How well do the Hub PD(s)/PI(s) demonstrate evidence of experience and training working productively and effectively in collaborative environments (especially with communities and multisectoral partners who have varying research experience)?
- Is the scientific and technical expertise of the proposed MEP appropriate?
- How well do the Hub PD(s)/PI(s), senior/key personnel, and Unit Leads demonstrate significant experience, flexibility, and accomplishments in managing complex team science research with populations experiencing health disparities?
- How well will the organizational structure, the proposed leadership and team science approaches support and contribute to the overall effectiveness of the Hub's scientific and collaborative activities?
- How extensive and applicable is the PD(s)/PI(s)' prior experience in the design, conduct, assessment, data collection, and analysis, data management and security, data repository development, and oversight, capacity-building/training of major collaborative, community-based intervention research projects to lead the Hub as a centralized research resource?

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?

In addition, for applications involving clinical trials

Does the design/research plan include innovative elements, as appropriate, that enhance its sensitivity, potential for information or potential to advance scientific knowledge or clinical practice?

Specific to this NOFO:

- How well does the applicant demonstrate that the proposed consultation, coordination, methodological support, data management, capacity-building and training, and

community engagement strategies can adapt to the changing and varying needs of the research consortium through all phases of the ComPASS Program?
- How feasible and appropriate are plans for integrating community partners or fostering relationships between scientific experts and assigned CHESI projects?
- Do the proposed Hub activities have the potential to enhance the translation of research into the community, research capacity building, training, and sustainability of community and research collaborations?
- What is the likelihood that the resources generated by the Hub be innovative, novel add value and be ready for rapid uptake, dissemination, or adaptation by other Hubs/components of the ComPASS Program?

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?

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?

In addition, for applications involving clinical trials

Does the application adequately address the following, if applicable

Study Design

Is the study design justified and appropriate to address primary and secondary outcome variable(s)/endpoints that will be clear, informative and relevant to the hypothesis being tested? Is the scientific rationale/premise of the study based on previously well-designed preclinical and/or clinical research? Given the methods used to assign participants and deliver interventions, is the study design adequately powered to answer the research question(s), test the proposed hypothesis/hypotheses, and provide interpretable results? Is the trial appropriately designed to conduct the research efficiently? Are the study populations (size, gender, age, demographic group), proposed intervention arms/dose, and duration of the trial, appropriate and well justified?

Are potential ethical issues adequately addressed? Is the process for obtaining informed consent or assent appropriate? Is the eligible population available? Are the plans for recruitment outreach, enrollment, retention, handling dropouts, missed visits, and losses to follow-up appropriate to ensure robust data collection? Are the planned recruitment timelines feasible and is the plan to monitor accrual adequate? Has the need for randomization (or not), masking (if appropriate), controls, and inclusion/exclusion criteria been addressed? Are differences addressed, if applicable, in the intervention effect due to sex/gender and race/ethnicity?

Are the plans to standardize, assure quality of, and monitor adherence to, the trial protocol and data collection or distribution guidelines appropriate? Is there a plan to obtain required study agent(s)? Does the application propose to use existing available resources, as applicable?

Data Management and Statistical Analysis

Are planned analyses and statistical approach appropriate for the proposed study design and methods used to assign participants and deliver interventions? Are the procedures for data management and quality control of data adequate at clinical site(s) or at center laboratories, as applicable? Have the methods for standardization of procedures for data management to assess the effect of the intervention and quality control been addressed? Is there a plan to complete data analysis within the proposed period of the award?

Specific to this NOFO:

- How feasible and appropriate is the Hub's proposed approach to support the implementation and measurement of community led health equity structural interventions?
- To what extent will the proposed structure effectively support promote collaboration in a timely manner across leadership, Hub Units, MEP, CHESI projects, relevant partners and the CCC?
- To what extent will the proposed strategies for the Hub functions enhance collaboration, synergy, and establish the Hub as a valuable and trustworthy research resource?
- How well integrated is the MEP within the Hub structure to scientifically and technically support the assigned CHESI projects?
- To what extent are the Resource Sharing Plans, or the rationale for not sharing resources, reasonable?
- How effective will the Hub's proposed approach be in supporting the development and dissemination of models/frameworks for the design, implementation, and scale-up of disease-agnostic community-led structural-level interventions?
- How effective will the Hub's proposed approach be in supporting sustainable research capacity building, training, and community engagement efforts that are tailored to the needs of their assigned CHESI projects?
- To what extent are the milestones appropriate and feasible to the Hub goals and functions?

Environment

Will the scientific environment in which the work will be done contribute to the probability of success? Are the institutional support, equipment, and other physical resources available to the investigators adequate for the project proposed? Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements?

In addition, for applications involving clinical trials

If proposed, are the administrative, data coordinating, enrollment and laboratory/testing centers, appropriate for the trial proposed?

Does the application adequately address the capability and ability to conduct the trial at the proposed site(s) or centers? Are the plans to add or drop enrollment centers, as needed, appropriate?

If international site(s) is/are proposed, does the application adequately address the complexity of executing the clinical trial?

If multi-sites/centers, is there evidence of the ability of the individual site or center to: (1) enroll the proposed numbers; (2) adhere to the protocol; (3) collect and transmit data in an accurate and timely fashion; and, (4) operate within the proposed organizational structure?

Additional Review Criteria

As applicable for the project proposed, reviewers will evaluate the following additional items while determining scientific and technical merit, and in providing an overall impact score, but will not give separate scores for these items.

Study Timeline

Specific to applications involving clinical trials

Is the study timeline described in detail, taking into account start-up activities, the anticipated rate of enrollment, and planned follow-up assessment? Is the projected timeline feasible and well justified? Does the project incorporate efficiencies and utilize existing resources (e.g., CTSAs, practice-based research networks, electronic medical records, administrative database, or patient registries) to increase the efficiency of participant enrollment and data collection, as appropriate?

Are potential challenges and corresponding solutions discussed (e.g., strategies that can be implemented in the event of enrollment shortfalls)?

Protections for Human Subjects

For research that involves human subjects but does not involve one of the categories of research that are exempt under 45 CFR Part 46, the committee will evaluate the justification for involvement of human subjects and the proposed protections from research risk relating to their participation according to the following five review criteria: 1) risk to subjects, 2) adequacy of protection against risks, 3) potential benefits to the subjects and others, 4) importance of the knowledge to be gained, and 5) data and safety monitoring for clinical trials.

For research that involves human subjects and meets the criteria for one or more of the categories of research that are exempt under 45 CFR Part 46, the committee will evaluate: 1) the justification for the exemption, 2) human subjects involvement and characteristics, and 3) sources of materials. For additional information on review of the Human Subjects section, please refer to the Guidelines for the Review of Human Subjects (//grants.nih.gov/grants/guide/url_redirect.htm?id=11175).

Inclusion of Women, Minorities, and Individuals Across the Lifespan

When the proposed project involves human subjects and/or NIH-defined clinical research, the committee will evaluate the proposed plans for the 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) to determine if it is justified in terms of the scientific goals and research strategy proposed. For additional information on review of the Inclusion section, please refer to the Guidelines for the Review of Inclusion in Clinical Research (//grants.nih.gov/grants/guide/url_redirect.htm?id=11174).

Vertebrate Animals

The committee will evaluate the involvement of live vertebrate animals as part of the scientific assessment according to the following criteria: (1) description of proposed procedures involving animals, including species, strains, ages, sex, and total number to be used; (2) justifications for the use of animals versus alternative models and for the appropriateness of the species proposed; (3) interventions to minimize discomfort, distress, pain and injury; and (4) justification for euthanasia method if NOT consistent with the AVMA Guidelines for the Euthanasia of Animals. Reviewers will assess the use of chimpanzees as they would any other application proposing the use of vertebrate animals. For additional information on review of the Vertebrate Animals section, please refer to the Worksheet for Review of the Vertebrate Animals Section (//grants.nih.gov/grants/guide/url_redirect.htm?id=11150).

Biohazards

Reviewers will assess whether materials or procedures proposed are potentially hazardous to research personnel and/or the environment, and if needed, determine whether adequate protection is proposed.

Resubmissions

Not Applicable.

Renewals

Not Applicable.

Revisions

Not Applicable.

Additional Review Considerations

As applicable for the project proposed, reviewers will consider each of the following items, but will not give scores for these items, and should not consider them in providing an overall impact score.

Applications from Foreign Organizations

Not Applicable.

Select Agent Research

Reviewers will assess the information provided in this section of the application, including 1) the Select Agent(s) to be used in the proposed research, 2) the registration status of all entities where Select Agent(s) will be used, 3) the procedures that will be used to monitor possession use and transfer of Select Agent(s), and 4) plans for appropriate biosafety, biocontainment, and security of the Select Agent(s).

Authentication of Key Biological and/or Chemical Resources:

For projects involving key biological and/or chemical resources, reviewers will comment on the brief plans proposed for identifying and ensuring the validity of those resources.

Budget and Period of Support

Reviewers will consider whether the budget and the requested period of support are fully justified and reasonable in relation to the proposed research.

2. Review and Selection Process

Applications will be evaluated for scientific and technical merit by (an) appropriate Scientific Review Group(s) convened by the Center for Scientific Review, in accordance with NIH peer review policy and procedures (//grants.nih.gov/grants/guide/url_redirect.htm?id=11154), using the stated review criteria (file:///C:/Users/mckenziene/AppData/Local/Microsoft/Windows/INetCache/Content.Outlook/13V4QPZR/Research%20Draft.doc#_1._Criteria). Assignment to a Scientific Review Group will be shown in the eRA Commons.

As part of the scientific peer review, all applications will receive a written critique.

Applications may undergo a selection process in which only those applications deemed to have the highest scientific and technical merit (generally the top half of applications under review) will be

discussed and assigned an overall impact score.

Appeals (https://grants.nih.gov/grants/policy/nihgps/html5/section_2/2.4.2_appeals_of_initial_scientific_review.htm)of initial peer review will not be accepted for applications submitted in response to this NOFO.

Applications will be assigned on the basis of established PHS referral guidelines to the appropriate NIH Institute or Center. Applications will compete for available funds with all other recommended applications submitted in response to this NOFO. Following initial peer review, recommended applications will receive a second level of review by the appropriate national Advisory Council or Board. The following will be considered in making funding decisions:

- Scientific and technical merit of the proposed project as determined by scientific peer review.
- Availability of funds.
- Relevance of the proposed project to program priorities.

3. Anticipated Announcement and Award Dates

After the peer review of the application is completed, the PD/PI will be able to access his or her Summary Statement (written critique) via the eRA Commons (https://grants.nih.gov/grants/guide/url_redirect.htm?id=11123). Refer to Part 1 for dates for peer review, advisory council review, and earliest start date.

Information regarding the disposition of applications is available in the NIH Grants Policy Statement Section 2.4.4 Disposition of Applications (//grants.nih.gov/grants/guide/url_redirect.htm?id=82416).

Section VI. Award Administration Information

1. Award Notices

If the application is under consideration for funding, NIH will request "just-in-time" information from the applicant as described in the NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.htm?id=82418).

A formal notification in the form of a Notice of Award (NoA) will be provided to the applicant organization for successful applications. The NoA signed by the grants management officer is the authorizing document and will be sent via email to the recipient's business official.

Recipients must comply with any funding restrictions described in Section IV.6. Funding Restrictions. Selection of an application for award is not an authorization to begin performance. Any costs incurred before receipt of the NoA are at the recipient's risk. These costs may be reimbursed only to the extent considered allowable pre-award costs.

Any application awarded in response to this NOFO will be subject to terms and conditions found on the Award Conditions and Information for NIH Grants (https://grants.nih.gov/grants/policy/nihgps/HTML5/part_ii_subpart_b.htm) website. This includes any recent legislation and policy applicable to awards that is highlighted on this website.

Individual awards are based on the application submitted to, and as approved by, the NIH and are subject to the IC-specific terms and conditions identified in the NoA.

ClinicalTrials.gov: If an award provides for one or more clinical trials. By law (Title VIII, Section 801 of Public Law 110-85), the "responsible party" must register and submit results information for certain “applicable clinical trials” on the ClinicalTrials.gov Protocol Registration and Results System Information Website (https://register.clinicaltrials.gov (https://register.clinicaltrials.gov/)). NIH expects registration and results reporting of all trials whether required under the law or not. For more information, see https://grants.nih.gov/policy/clinical-trials/reporting/index.htm (https://grants.nih.gov/policy/clinical-trials/reporting/index.htm)

Institutional Review Board or Independent Ethics Committee Approval: Recipient institutions must ensure that all protocols are reviewed by their IRB or IEC. To help ensure the safety of participants enrolled in NIH-funded studies, the recipient must provide NIH copies of documents related to all major changes in the status of ongoing protocols.

Data and Safety Monitoring Requirements: The NIH policy for data and safety monitoring requires oversight and monitoring of all NIH-conducted or -supported human biomedical and behavioral intervention studies (clinical trials) to ensure the safety of participants and the validity and integrity of the data. Further information concerning these requirements is found at http://grants.nih.gov/grants/policy/hs/data_safety.htm and in the application instructions (SF424 (R&R) and PHS 398).

Investigational New Drug or Investigational Device Exemption Requirements: Consistent with federal regulations, clinical research projects involving the use of investigational therapeutics, vaccines, or other medical interventions (including licensed products and devices for a purpose other than that for which they were licensed) in humans under a research protocol must be performed under a Food and Drug Administration (FDA) investigational new drug (IND) or investigational device exemption (IDE).

2. Administrative and National Policy Requirements

All NIH grant and cooperative agreement awards include the NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.htm?id=11120) as part of the NoA. For these terms of award, see the NIH Grants Policy Statement Part II: Terms and Conditions of NIH Grant Awards, Subpart A: General (//grants.nih.gov/grants/guide/url_redirect.htm?id=11157) and Part II: Terms and Conditions of NIH Grant Awards, Subpart B: Terms and Conditions for Specific Types of Grants, Recipients, and Activities (//grants.nih.gov/grants/guide/url_redirect.htm?id=11159), including of note, but not limited to:

- Federal-wide Standard Terms and Conditions for Research Grants (https://grants.nih.gov/grants/policy/nihgps/HTML5/section_3/3.1_federalwide_standard_terms_and_conditions_for_research_grants.htm)
- Prohibition on Certain Telecommunications and Video Surveillance Services or Equipment (//grants.nih.gov/grants/guide/url_redirect.htm?id=82417)
- Acknowledgment of Federal Funding (https://grants.nih.gov/grants/policy/nihgps/HTML5/section_4/4.2.1_acknowledgement_of_federal_funding.htm)

If a recipient is successful and receives a Notice of Award, in accepting the award, the recipient agrees that any activities under the award are subject to all provisions currently in effect or implemented during the period of the award, other Department regulations and policies in effect at the time of the award, and applicable statutory provisions.

Should the applicant organization successfully compete for an award, recipients of federal financial assistance (FFA) from HHS will be required to complete an HHS Assurance of Compliance form (HHS Assurance of Compliance form (HHS 690 (https://ocrportal.hhs.gov/ocr/aoc/instruction.jsf)) in which the recipient agrees, as a condition of receiving the grant, to administer programs in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, age, sex and disability, and agreeing to comply with federal conscience laws, where applicable. This includes ensuring that entities take meaningful steps to provide meaningful access to persons with limited English proficiency; and ensuring effective communication with persons with disabilities. Where applicable, Title XI and Section 1557 prohibit discrimination on the basis of sexual orientation, and gender identity, The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. See https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html (https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.hhs.gov%2Fcivil-rights%2Ffor-providers%2Fprovider-obligations%2Findex.html&data=05%7C01%7Ccarrie.mitchell%40nih.gov%7Ce8bc304bfdb644bb556e08dac343ad36%7C14b77578977342d58507251ca2dc2b06%7C0%7C0%7C638036992699511
and https://www.hhs.gov/civil-rights/for-individuals/nondiscrimination/index.html (https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.hhs.gov%2Fcivil-rights%2Ffor-individuals%2Fnondiscrimination%2Findex.html&data=05%7C01%7Ccarrie.mitchell%40nih.gov%7Ce8bc304bfdb644bb556e08dac343ad36%7C14b77578977342d58507251ca2dc2b06%7C0%7C0

HHS recognizes that research projects are often limited in scope for many reasons that are nondiscriminatory, such as the principal investigator’s scientific interest, funding limitations, recruitment requirements, and other considerations. Thus, criteria in research protocols that target or exclude certain populations are warranted where nondiscriminatory justifications establish that such criteria are appropriate with respect to the health or safety of the subjects, the scientific study design, or the purpose of the research. For additional guidance regarding how the provisions apply to

NIH grant programs, please contact the Scientific/Research Contact that is identified in Section VII under Agency Contacts of this NOFO.

- For guidance on meeting the legal obligation to take reasonable steps to ensure meaningful access to programs or activities by limited English proficient individuals see https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html (https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html) and https://www.lep.gov (https://www.lep.gov/).
- For information on an institution's specific legal obligations for serving qualified individuals with disabilities, including providing program access, reasonable modifications, and to provide effective communication, see https://www.hhs.gov/civil-rights/for-individuals/disability/index.html (https://www.hhs.gov/civil-rights/for-individuals/disability/index.html).
- HHS funded health and education programs must be administered in an environment free of sexual harassment, see https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html (https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html). For information about NIH's commitment to supporting a safe and respectful work environment, who to contact with questions or concerns, and what NIH's expectations are for institutions and the individuals supported on NIH-funded awards, please see https://grants.nih.gov/grants/policy/harassment.htm (https://grants.nih.gov/grants/policy/harassment.htm).
- For guidance on administering programs in compliance with applicable federal religious nondiscrimination laws and applicable federal conscience protection and associated anti-discrimination laws see https://www.hhs.gov/conscience/conscience-protections/index.html (https://www.hhs.gov/conscience/conscience-protections/index.html) and https://www.hhs.gov/conscience/religious-freedom/index.html (https://www.hhs.gov/conscience/religious-freedom/index.html).

Please contact the HHS Office for Civil Rights for more information about obligations and prohibitions under federal civil rights laws at https://www.hhs.gov/ocr/about-us/contact-us/index.html (https://www.hhs.gov/ocr/about-us/contact-us/index.html) or call 1-800-368-1019 or TDD 1-800-537-7697.

In accordance with the statutory provisions contained in Section 872 of the Duncan Hunter National Defense Authorization Act of Fiscal Year 2009 (Public Law 110-417), NIH awards will be subject to the Federal Awardee Performance and Integrity Information System (FAPIIS) requirements. FAPIIS requires Federal award making officials to review and consider information about an applicant in the designated integrity and performance system (currently FAPIIS) prior to making an award. An applicant, at its option, may review information in the designated integrity and performance systems accessible through FAPIIS and comment on any information about itself that a federal agency previously entered and is currently in FAPIIS. The Federal awarding agency will consider any comments by the applicant, in addition to other information in FAPIIS, in making a judgement about the applicant's integrity, business ethics, and record of performance under Federal awards when completing the review of risk posed by applicants as described in 45 CFR Part 75.205 and 2 CFR Part 200.206 "Federal awarding agency review of risk posed by applicants." This provision will apply to all NIH grants and cooperative agreements except fellowships."

Cooperative Agreement Terms and Conditions of Award

The following special terms of award are in addition to, and not in lieu of, otherwise applicable U.S. Office of Management and Budget (OMB) administrative guidelines, U.S. Department of Health and Human Services (HHS) grant administration regulations at 45 CFR Part 75 and 2 CFR Part 200, and other HHS, PHS, and NIH grant administration policies.

The administrative and funding instrument used for this program will be the cooperative agreement, an "assistance" mechanism (rather than an "acquisition" mechanism), in which substantial NIH programmatic involvement with the recipients is anticipated during the performance of the activities. Under the cooperative agreement, the NIH purpose is to support and stimulate the recipients' activities by involvement in and otherwise working jointly with the recipients in a partnership role; it is not to assume direction, prime responsibility, or a dominant role in the activities. Consistent with this concept, the dominant role and prime responsibility resides with the recipients for the project as a whole, although specific tasks and activities may be shared among the recipients and NIH as defined below.

The PD(s)/PI(s) will have the primary responsibility for:

- Providing scientific leadership and administrative oversight for all aspects of the Hub, including determining/modifying approaches, designing protocols, proposing project milestones for the core Hub functions, and overseeing the conduct of the Hub activities.
- Coordinating project activities technically, scientifically, and administratively at the recipient institution and at other sites that may be supported by the award.
- Working with the CHESI PIs to establish a data collection timeline and maintain quality control.
- Participating in meetings of the ComPASS Program Steering Committee, National HERA, and other subcommittees or Work Groups as needed, one of which is an annual meeting (conditions permitting) in Bethesda, MD.
- Collaborating with ComPASS Program recipients in preparing abstracts, presentations, and publications and on making the public and research and academic professionals aware of the program.
- Establishing reporting timelines and providing periodic reports and data in a timely fashion and in standard format, as agreed upon by the CCC, ComPASS Program Steering Committee, and NIH.
- Adhering to the NIH policies regarding intellectual property, data security and release, and other policies that might be established during the ComPASS Program.
- Submitting updates to NIH Program Officers(s), Project Scientist(s), and the Common Fund on progress and problems.
- Contributing as voting member(s) of the ComPASS Program Steering Committee.
- Participating in CCC-coordinated, cross-Hub collaborative and governance-related activities.
- Implementing guidelines and procedures developed by the ComPASS Program Steering Committee.
- Participating in teleconferences with NIH program staff, as needed.
- Being prepared for annual administrative site visits or virtual visits by NIH staff.
- Agreeing to participate in the collaborative activities of the consortium and agreeing not to disclose confidential information obtained from other members of the consortium including, without limitation, unpublished data, informatics tools, protocols, data analysis, confidential exchanges between members of the consortium, as well as any confidential information received by third party collaborators.
- Supporting the registration of clinical trial studies through ClinicalTrials.gov (https://clinicaltrials.gov/ (https://clinicaltrials.gov/)).
- Recipients will retain custody of and have primary rights to the data and software developed under these awards, subject to Government rights of access consistent with current HHS, PHS, and NIH policies.

In addition to standard annual Research Performance Progress Report (RPPR) submissions, Principal Investigators may be expected to supply additional progress-related information to the National Cancer Institute (NCI).
Common Fund and NCI program staff will have substantial programmatic involvement that is above and beyond the normal stewardship role in awards, as described below:

Definitions:

- **ComPASS Consortium (or Program):** The consortium structure is meant to efficiently and effectively guide all the funded projects to meet the overall goals of the ComPASS Program. This structure includes all ComPASS recipients, the NIH Working Group, other relevant scientists and groups the SC agrees to include within the consortium.
- **ComPASS Program Steering Committee (SC):** The ComPASS Steering Committee will be coordinated and administrated by the ComPASS Coordination Center (CCC) and will govern the activities of the program recipients. The Health Equity Research Hub awards begin 1 year after the formation of the SC. The PIs of the Health Equity Research Hubs will join the ComPASS Steering Committee (SC), comprised of the PIs of the ComPASS Community-led, Health Equity Structural Intervention, the CCC, and involved

NIH staff acting as ComPASS Program Officers (POs), Project Scientists (PSs) and the OSC Program Leader. The SC will work cooperatively and interactively, during all phases to promote collaborations, as well as information and resource sharing across the ComPASS Program. The co-chairs will be independently appointed by the NIH in collaboration with the ComPASS SC. The SC co-chairs will preside at all SC meetings. Scientific direction will comply with NIH research policies and procedures. Consortium governance rests with the SC and the SC is subject to oversight by the NIH Common Fund. The governance structure will be co-created by SC members and NIH staff. For votes, the Health Equity Research Hub awards will together have one vote. The Hubs will be convened by the CCC, as needed, to address and determine majority vote on governance-related issues in advance of SC meetings. The CCC award will have one vote, and each Community-Led Health Equity Structural Intervention award will have one vote. All Federal staff together will have one vote. The SC decisions will be made by a majority vote.

NIH staff have substantial programmatic involvement that is above and beyond the normal stewardship role in awards, as described below:

- NIH Program Officers (PO): The PO will be from NIH/NCI and will be responsible for the normal scientific and programmatic stewardship, including monitoring progress and compliance with general statutory, regulatory, or policy requirements; discussing and approving milestones and significant changes to the project; and technical assistance to correct performance and facilitate interactions. The PO must approve in advance and in writing annual milestones and any significant changes to the award. The PO also has the option to recommend, following consultation with the Project Scientist(s), or the NIH Working Group, restricting an award based on progress towards milestones and implementation of policies or collaboration between members of the consortium, or generation of data or resources for use by consortium members or the wider community. The PO will not co-author publications with the Hub PIs. The NCI PO will: have programmatic authority, including fiscal oversight, over the Hubs; be responsible for making funding recommendations and otherwise providing programmatic approvals and recommendations, following consultation with the NIH Working Group; and closely monitor progress of all the awards made in their initiative and report back as part of the Work Group meetings.
- NIH Project Scientists (PS): NIH Program Staff will serve as Project Scientists (PSs) for the Hubs. There will be at least one PS for each Hub. The PSs will serve as the scientific representatives of the NIH to the investigators under the policies and procedures of the other transactions and cooperative agreement mechanisms. The PSs will provide substantial NIH scientific, programmatic involvement to the recipients during the performance of the activities supported by a cooperative agreement, including reviews of milestones. The Hub PSs will work closely with the POs and other PSs of the ComPASS Program, and PIs of the CHESI projects to maximize progress towards the overall goals of the program. It is expected that the PSs will participate in teleconferences with PDs/PIs and key personnel of the Hubs and attend relevant ComPASS meetings in-person or virtually. Consistent with NIH Institute/Center/Office publication policies, PSs may contribute, as appropriate, to scientific manuscripts and other scholarly activities (e.g., oral presentations, poster presentations) resulting from the ComPASS Program.
- Additionally, an agency program official or IC program director will be responsible for the normal scientific and programmatic stewardship of the award and will be named in the award notice.
- The NIH Program Official(s) may recommend the termination or curtailment of an activity in the event the proposed activities fail to evolve within the intent and purpose of this initiative.

Areas of Joint Responsibility include:

Close interaction among the participating investigators will be required, as well as significant involvement from the NIH, to manage, assess, and support the ComPASS program. As part of the Consortium's Steering Committee, all ComPASS recipients agree to governance, through voting and decision-making. There will be monthly meetings of the Steering Committee. One of these meetings must be an in-person meeting, travel conditions permitting, in Bethesda, MD or surrounding areas. Frequency of meetings in succeeding years may be adjusted by the Steering Committee at the beginning of each budget period. The Hubs leadership will be required to accept and implement policies approved by the Steering Committee.

Dispute Resolution:

Any disagreements that may arise in scientific or programmatic matters (within the scope of the award) between recipients and NIH may be brought to Dispute Resolution. A Dispute Resolution Panel composed of three members will be convened: a designee of the Steering Committee chosen without NIH staff voting, one NIH designee, and a third designee with expertise in the relevant area who is chosen by the other two; in the case of individual disagreement, the first member may be chosen by the individual recipient. This special dispute resolution procedure does not alter the recipient's right to appeal an adverse action that is otherwise appealable in accordance with PHS regulation 42 CFR Part 50, Subpart D and HHS regulation 45 CFR Part 16.

3. Data Management and Sharing

Note: The NIH Policy for Data Management and Sharing is effective for due dates on or after January 25, 2023.

Consistent with the NIH Policy for Data Management and Sharing, when data management and sharing is applicable to the award, recipients will be required to adhere to the Data Management and Sharing requirements as outlined in the NIH Grants Policy Statement (https://grants.nih.gov/grants/policy/nihgps/HTML5/section_8/8.2.3_sharing_research_resources.htm#Data). Upon the approval of a Data Management and Sharing Plan, it is required for recipients to implement the plan as described.

4. Reporting

When multiple years are involved, recipients will be required to submit the Research Performance Progress Report (RPPR) (//grants.nih.gov/grants/rppr/index.htm) annually and financial statements as required in the NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.htm?id=82419).

A final RPPR, invention statement, and the expenditure data portion of the Federal Financial Report are required for closeout of an award, as described in the NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.htm?id=82420). NIH NOFOs outline intended research goals and objectives. Post award, NIH will review and measure performance based on the details and outcomes that are shared within the RPPR, as described at 45 CFR Part 75.301 and 2 CFR Part 200.301.

The Federal Funding Accountability and Transparency Act of 2006 (Transparency Act), includes a requirement for recipients of Federal grants to report information about first-tier subawards and executive compensation under Federal assistance awards issued in FY2011 or later. All recipients of applicable NIH grants and cooperative agreements are required to report to the Federal Subaward Reporting System (FSRS) available at www.fsrs.gov (//grants.nih.gov/grants/guide/url_redirect.htm?id=11170) on all subawards over $25,000. See the NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.htm?id=82420) for additional information on this reporting requirement.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and 2 CFR Part 200.113 and Appendix XII to 45 CFR Part 75 and 2 CFR Part 200, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts from all Federal awarding agencies with a cumulative total value greater than $10,000,000 for any period of time during the period of performance of a Federal award, must report and maintain the currency of information reported in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (currently FAPIIS). This is a statutory requirement under section 872 of Public Law 110-417, as amended (41 U.S.C. 2313). As required by section 3010 of Public Law 111-212, all information posted in the designated integrity and performance system on or after April 15, 2011, except past performance reviews required for Federal procurement contracts, will be publicly available. Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75 and 2 CFR Part 200–

Award Term and Conditions for Recipient Integrity and Performance Matters.

Section VII. Agency Contacts

We encourage inquiries concerning this funding opportunity and welcome the opportunity to answer questions from potential applicants.

Application Submission Contacts

eRA Service Desk (Questions regarding ASSIST, eRA Commons, application errors and warnings, documenting system problems that threaten submission by the due date, and post-submission issues)

Finding Help Online: https://www.era.nih.gov/need-help (https://www.era.nih.gov/need-help) (preferred method of contact)
Telephone: 301-402-7469 or 866-504-9552 (Toll Free)

General Grants Information (Questions regarding application instructions, application processes, and NIH grant resources)
Email: GrantsInfo@nih.gov (mailto:GrantsInfo@nih.gov) (preferred method of contact)
Telephone: 301-637-3015

Grants.gov Customer Support (Questions regarding Grants.gov registration and Workspace)
Contact Center Telephone: 800-518-4726
Email: support@grants.gov (mailto:support@grants.gov)

Scientific/Research Contact(s)

Amanda Acevedo, Ph.D.
National Cancer Institute (NCI)
Telephone: 240-276-5896
Email: amanda.acevedo@nih.gov (mailto:amanda.acevedo@nih.gov)

Peer Review Contact(s)

Center for Scientific Review (CSR)
Email: FOAReviewContact@csr.nih.gov (mailto:FOAReviewContact@csr.nih.gov)

Financial/Grants Management Contact(s)

Crystal Wolfrey
National Cancer Institute (NCI)
Telephone: 240-276-6277
Email: crystal.wolfrey@nih.gov (mailto:crystal.wolfrey@nih.gov)

Section VIII. Other Information

Recently issued trans-NIH policy notices (//grants.nih.gov/grants/guide/url_redirect.htm?id=11163) may affect your application submission. A full list of policy notices published by NIH is provided in the NIH Guide for Grants and Contracts (//grants.nih.gov/grants/guide/url_redirect.htm?id=11164). All awards are subject to the terms and conditions, cost principles, and other considerations described in the NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.htm?id=11120).

Authority and Regulations

Awards are made under the authorization of Sections 301, 402, and 405 of the Public Health Service Act as amended (42 USC 241, 282, and 284) and under Federal Regulations 42 CFR Part 52 and 45 CFR Part 75 and 2 CFR Part 200.

Weekly TOC for this Announcement (/grants/guide/WeeklyIndex.cfm?08-25-23)
NIH Funding Opportunities and Notices (/grants/guide/index.html)

Note: For help accessing PDF, RTF, MS Word, Excel, PowerPoint, Audio or Video files, see Help Downloading Files (/grants/edocs.htm).