

**Community Partnerships to Advance Science for Society (ComPASS) Program:
Community-Led, Health Equity Structural Intervention Initiative (OT2)**

Research Opportunity Announcement

UPDATED January 20, 2023

Overview Information

Participating Organizations(s)	National Institutes of Health (NIH)
Components of Participating Organizations	This Other Transactions (OT) Research Opportunity Announcement (ROA) is developed as a Common Fund initiative through the NIH Office of the Director, Office of Strategic Coordination (OD-OSC). All NIH Institutes and Centers participate in Common Fund initiatives. The research opportunity will be administered by the OD-OSC on behalf of the NIH as part of the Community Partnerships to Advance Science for Society (ComPASS) program.
Research Opportunity Title:	Community Partnerships to Advance Science for Society (ComPASS) Program: Community-Led, Health Equity Structural Intervention Initiative (OT2)
Activity Code	Other Transactions (OT2) Award mechanism. This funding opportunity will use the Other Transactions Authority (OTA) governed by 42 U.S. Code § 282 (n)(1)(b) . OT awards are not grants, cooperative agreements or contracts and use an OTA, provided by law. Policies and terms for individual OTs may vary between awards. Each award is therefore issued with a specific agreement, which is negotiated with the recipient and may be expanded, modified, partnered, not supported, or later discontinued based on program needs, changing research landscape, performance and or availability of funds.
Research Opportunity Announcement (ROA) Number	OTA-22-007
Related Notice	RFA-RM-23-001, Community Partnerships to Advance Science for Society (ComPASS): Coordination Center (U24-Clinical Trial Optional)
Research Opportunity Purpose	The purpose of this Research Opportunity Announcement (ROA) is to solicit applications from community organizations to develop, implement, assess, and disseminate co-created community-led, health equity structural interventions, in partnership with research organizations, that intervene upon structural factors that produce and perpetuate health disparities. This goal will be accomplished in three (3) phases: 1) the intervention planning and development phase; 2) the intervention implementation phase; and 3) the intervention assessment, dissemination and sustainability phase. During Phase I, community organizations will establish multisectoral partnerships, determine multiple health outcomes of interest, and solidify the structural factors to target, all of which will culminate with the development of a draft structural intervention strategy. Phase II will involve implementing the structural intervention and Phase III will involve assessing and disseminating structural intervention results and implementing research capacity and structural intervention sustainability plans.

Objective Review	NIH will engage appropriate expertise and convene an appropriate review to evaluate applications. See the Objective Review section of this opportunity for further details.
Eligibility	See the Eligibility section of this opportunity for further details.
Funds Available and Anticipated Number of Awards	The planned budget for the ComPASS Program is approximately \$153 million over a 5-year period including this Community-Led, Health Equity Structural Intervention Initiative. NIH anticipates making 20-25 awards. However, NIH Common Fund procedures and OT mechanisms allow for significant flexibilities and adjustments, where necessary, to pursue catalytic and transformative initiatives. Award levels may change over time based on programmatic needs, funding availability and recipient performance.
Award Project Duration	Initial project duration is expected to be 5 years, but individual projects may be extended or curtailed based on programmatic objectives, performance and available funds.
Application Submission Instructions	<p>Applicants invited to submit a full application must submit via the NIH eRA Commons ASSIST system by 5:00 PM local time on the due date (see Key Dates below). Use OTA-22-007 in the Funding Opportunity Announcement field. Here are instructions for submitting via the NIH eRA ASSIST system. Technical assistance is available from the eRA Service Desk.</p> <p>To submit a full application via ASSIST, the applicant organization must be registered in eRA Commons (See Submission Instructions). If you are invited to submit a full application, you must be registered in eRA Commons, which may take six (6) weeks or more to complete, applicants should therefore begin the registration process as soon as possible.</p> <p>On the eRA Commons home page, select the “Register Organization” link for more details.</p> <p>To complete registration, if you have not done so already, you may need to register for the following:</p> <ul style="list-style-type: none"> • System for Award Management (SAM) – 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. • Unique Entity Identifier (UEI)- A UEI is issued as part of the SAM.gov registration process. SAM registrations prior to fall 2021 were updated to include a UEI. The same UEI must be used for all registrations, as well as on the other transactions application. • eRA Commons - Once the unique organization identifier (UEI after April 2022) is established, organizations can register with eRA Commons in tandem with completing their full SAM and Grants.gov registrations; all registrations must be in place by time of submission of the full application. eRA Commons requires organizations to

	<p>identify at least one Signing Official (SO) and at least one Program Director/Principal Investigator (PD/PI) account in order to submit an application.</p> <p>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 guidance.</p>
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Key Dates

Release Date	September 12, 2022
Informational Webinar Date (optional)	October 2022. Informational webinar information and specific dates will be posted on the ComPASS Program website, http://www.commonfund.nih.gov/compass
Letter of Intent Due Date	November 18, 2022 A Letter of Intent is required. See Letter of Intent section.
Invitation to Submit Full Application	<i>December 16, 2022-NEW DATE</i> Select LOI submitters will be invited to submit a full application. See Letter of Intent section.
Application Due Date	<i>February 6, 2023-NEW DATE</i> Invited full applications must be submitted via ASSIST. See Application Submission Instructions.
Review	March 2023
Award Negotiations begin	April 2023. Attend videoconferences or teleconferences as requested
Earliest Start Date	September 2023
Kickoff Meeting (mandatory)	A ComPASS Program kickoff meeting will be held in November or December 2023 (virtually)

Agency Contacts

NIH encourages inquiries concerning this announcement and welcomes the opportunity to answer questions from potential applicants.

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Outline of this Opportunity

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Key Definitions

Key Definitions for this ROA

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, regional/local and public healthcare systems, school districts, law enforcement or criminal/juvenile justice agencies, or social service agencies. Governmental organizations at the local, regional, Tribal, or state level and their respective departments of public health, commerce, labor, transportation, housing, and recreation fall within this definition. It is important to note that academic research centers, academic healthcare organizations, and private healthcare organizations do not fall within this definition and would not be eligible for this opportunity.

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

Health Disparity: A health disparity is a 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](#)):

- 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](#)).

NIH-designated Populations that Experience Health Disparities: Racial and ethnic minority populations, less privileged socioeconomic status (SES) populations, underserved rural populations, sexual and gender minorities (SGM) and any subpopulations that can be characterized by two or more of these descriptions ([Minority Health and Health Disparities: Definitions and Parameters](#)).

Social Determinants of Health (SDOH): Social determinants of health (SDOH) encompass both structural and individual factors. Structural factors include the conditions and environments in which people are born, live, learn, work, play, worship, and age that affect a wide range of health, functioning, and quality-of-life outcomes and risks. Healthy People 2030 groups SDOH into five domains: economic stability; education access and quality; health care access and quality; neighborhood and built environment; and social and community context ([Healthy People 2030](#)).

Structural Interventions: Interventions that attempt to change the social, physical, economic, or political environments 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](#)).

Background

Despite longstanding investments to reduce and eliminate health disparities, racial and ethnic minority populations (see NIH-designated populations that experience health disparities definition) continue to bear a disproportionate burden of adverse health outcomes across diseases and 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 racial and ethnic groups and other populations experiencing health disparities. These reinforcing and inequitable systems are the fundamental causes of poor and differential health outcomes and thus must be addressed to make observable and sustained improvements in health. Ultimately, a paradigm shift to advance health equity is required. In absence of this, we will continue to fall short in eliminating health disparities and creating a healthier nation for all.

Social determinants of health (SDOH) are a major contributor to health disparities and operate on a continuum from fundamental structural causes to individual and family circumstances. Structural SDOH reflect the economic and social resources and opportunities that influence an individual's access to health-promoting living and working conditions and to healthy choices ([Braveman, 2011](#)). Research identifies the conditions and environments in which people are born, grow, live, work, age, and play as critical SDOH that influence health outcomes across the life course. Meanwhile, individual-level SDOH comprise individual and family social and economic circumstances such as income, educational attainment, and housing. **Addressing fundamental, structural causes of health disparities offers the greatest opportunity to advance health equity and eliminate health disparities and are consequently 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, economic, and/or political environments that influence health behaviors and outcomes are critical ([Brown, et al., 2019](#)). Such innovative intervention approaches provide opportunities to address the broader system and 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. To accelerate progress toward reducing health disparities and advancing health equity, research efforts must squarely focus on the structural drivers of health disparities that contribute to the disproportionate burden of disease among populations experiencing health disparities. Because structural factors span multiple sectors and systems, interventions must be created in partnership with organizations such as those within the areas of education, housing, transportation, commerce, agriculture, economic and urban development, justice, human and social services, clinical care and public health. Multi-sectoral partnerships that transcend historical siloes maximize the opportunity to address structural factors and advance health equity.

Examples of structural interventions that have the potential to influence health outcomes include, **but are not limited to**:

- Criminal justice system policy changes to address structural racial/ethnic and socioeconomic discrimination (e.g., in police stops, arrests, bail systems and pre-trial detainment/diversion, sentencing, and probation and parole practices);
- Universal basic income programs and policies to address issues of economic instability;
- High-speed broadband internet expansion to enhance internet connectivity and telehealth access in rural and other underserved communities;
- Child tax credits to address access to early childhood education;
- Housing voucher programs to improve access to safe, quality housing;
- Community revitalization investment projects to enhance neighborhood and community resources and facilitate health promoting behaviors;
- Food program policies to improve access to and affordability of fresh produce; and
- Opportunities that leverage changes to policies, programs, and practices at the local, state, and/or federal levels.

The above examples are not exhaustive, and applicants are encouraged to propose structural interventions that are feasible and prioritized within their respective communities.

Structural interventions may be combined with other types of interventions to improve health behaviors and health outcomes. However, interventions that solely help individuals manage the consequences of structural inequities, without intervening directly to change the structures themselves, are not a priority for this initiative.

Community-Led Research

Community engaged approaches are recognized as key research strategies to address health disparities and advance health equity. Communities and researchers working collaboratively as equal partners, in all phases of the research process, enhances the quality of interventions and better ensures research questions, methods, and approaches are responsive to community needs, values, practices, and priorities. Research developed, implemented, and disseminated by community, changes the process by which research has traditionally been conducted and presents new opportunities to advance health for the most impacted populations experiencing health disparities.

Community-led research requires a transformation in the processes and practices that govern research engagement. The traditional approach is one that involves academic organizations leading research efforts with engagement from community partners. This research opportunity is intended to foster community-led prioritization of research and structural health solutions in collaboration with researchers and other relevant partners. This unique approach of community organizations identifying and intervening on structural contributors to disease aligns with NIH's goal to enhance acceptability and sustainability of effective interventions to improve health and sustain positive impacts.

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

The Community Partnerships to Advance Science for Society (ComPASS) Program is intended to make greater advances in promoting health and preventing disease among disproportionately impacted populations. The impetus for ComPASS is the increasing recognition that advancing health equity is a complex challenge that extends beyond the reach of traditional health care settings, organizations, or research agendas. Rather than tackling health disparities by disease and condition or in a single population group, an NIH-wide strategy has been created within ComPASS to foster efforts to address structural causes of differential health outcomes, which will impact multiple diseases and conditions through several pathways.

ComPASS aims to be catalytic and cross-cutting in its integration of multisectoral 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 health disparities to persist. The program is transformative in its focus on structural health equity interventions given the evidenced impact of structural inequities on health outcomes. ComPASS will focus on cultivating community trust and partnerships, building research capacity among community and relevant partners, and enhancing community organization readiness and competitiveness for future funding, contributing to greater diversity and inclusion in research. ComPASS is intended to serve as an initial launch to a longer-term and sustained commitment to eliminating health disparities and advancing health equity through development, testing and implementation of structural interventions.

ComPASS Goals and Objectives

The first overall goal of the ComPASS Program is to catalyze, develop, and rigorously assess community-led, health equity structural interventions that leverage multisectoral partnerships to advance health equity. A second overall goal of ComPASS is to develop a new health equity research model for community-led, multisectoral structural intervention research across NIH and other federal agencies.

Three initiatives will be used to achieve the ComPASS Program goals:

- **The Community-Led, Health Equity Structural Interventions (CHESIs)** will develop, implement, assess, and disseminate co-created community-led, health equity structural interventions in partnership with research organizations, by intervening upon structural factors that produce and perpetuate health disparities.
- **The ComPASS Coordination Center (CCC)** will lead overall program management and coordination of administrative, data, capacity-building, partnership, training, and the National Health Equity Research Assembly (HERA) activities.
- **The Health Equity Research Hubs (Hubs)** will be funded in FY 2024 and provide localized technical assistance and scientific support, as well as partnership support and research capacity-building and training previously designed in collaboration with the CCC.

Through these initiatives, the ComPASS goals will be achieved by:

- Supporting community organizations and their research partners in co-creating research to evaluate community-led, health equity structural interventions;

- Engaging multisectoral partnerships, both locally and nationally, in advising, guiding, and sustaining the community-led health equity structural interventions;
- Building the research capacity in structural intervention research and implementation, community-led research, and sustainability among community organizations and their research partners;
- Developing methods for capturing social determinants of health information, and collecting and analyzing data to evaluate outcomes from community-led health equity structural interventions; and
- Disseminating promising approaches resulting from the community-led health equity structural interventions.

Community-Led, Health Equity Structural Interventions (This Opportunity)

This ROA invites applications from community organizations to work in collaboration with their research partners to develop, implement, assess, disseminate and sustain a community-led health equity structural intervention.

The community-led health equity structural intervention initiative has three (3) phases. It starts with a two-year intervention planning, development, piloting (as appropriate) and partnership building phase (Phase I). It will be followed by a six-year intervention implementation phase (Phase II). It will conclude with a two-year assessment, dissemination and sustainability phase (Phase III). Receipt of an award for the intervention planning, development, piloting (as appropriate) and partnership phase (Phase I) does not guarantee a recipients' continuation to the intervention implementation phase (Phase II) or the assessment, dissemination and sustainability phase (Phase III) of the ComPASS Program. See [Phase I to Phase II Transition](#) for more details.

The OT award mechanism allows significant ongoing involvement from NIH Program Staff and provides the NIH with the flexibility to alter the course of projects in real-time to meet overarching ComPASS Program goals. This may mean an awarded activity could be expanded, modified, or discontinued based on program needs, achievement of agreed-upon activities, or availability of funds. During the funding period, performance will be reviewed on an ongoing basis with course corrections being made where necessary. As a result, the NIH reserves the right to fund projects in increments and/or options for continued work at the end of each phase.

Structural interventions must be designed to intervene upon one or more structural factors (e.g., systems, policies or practices) that produce and perpetuate health disparities. It is expected that community organizations and their research partners will collaborate with multi-sectoral partners, as appropriate, to enact changes to the systems, policies, and practices that produce and perpetuate the structural factors and not just involve those who are directly experiencing the structural factors.

Generally, structural interventions must incorporate intervention strategies that span across the community and societal socioecological domains of influence in order to improve health, reduce health disparities, and advance health equity. Examples of domains in which structural factors

may occur include, but are not limited to, the physical/built environment and sociocultural environment. Meanwhile, the structural intervention is expected to have effects at multiple levels of influence (e.g., individual, interpersonal, community, etc.) through multiple pathways, including influencing individual-level health outcomes across multiple health conditions and diseases. To guide the planning and development of their health equity structural intervention, community organizations and their research partners are encouraged to use the [NIMHD Research Framework](#) and its adaptations, or other socio-ecological frameworks. Additionally, projects are expected to propose appropriate units of analysis and a sufficient sample size to detect and assess the effects of the structural intervention. To enable a more equitable and sustainable partnership, research activities must be embedded within a community-engaged research framework. Research partners must have the requisite expertise and experience to scientifically inform the development, implementation and assessment of the community-led health equity structural intervention.

Phase I: Intervention Planning, Development and Partnership (Years 1- 2)

During Phase I, the community organization, in collaboration with their research partner, will plan, develop, and establish multi-sectoral partnerships, conduct a structural intervention-related community assessment, determine multiple health outcomes of particular interest and confirm the structural factors to target, all of which will culminate with the submission to NIH of a draft structural intervention research strategy. The draft structural intervention research strategy must include, but is not limited to, the research study design, statistical analysis plan and outcome assessment plan.

The ComPASS Coordination Center (CCC) will provide technical assistance in the areas of intervention planning and research capacity-building and training to the community organizations and their research partners during Phase I. Beginning in Year 2 of Phase I, the Health Equity Research Hubs will extend the scientific and partnership support and services previously designed in collaboration with the CCC and provide community organizations and the research partners with technical assistance in the areas of research study design, statistical analysis and outcome assessment.

Community organizations and their research partners are also expected to establish a local Health Equity Research Assembly (HERA) of relevant collaborators, including but not limited to, regional federal agency representatives (e.g., Housing and Urban Development (HUD), Substance and Mental Health Services Administration (SAMSHA), Indian Health Service (IHS), Department of Justice (DOJ), Department of Transportation (DOT), Department of Education, U.S. Department of Agriculture (USDA) Food and Nutrition Service, Department of Veterans Affairs, Department of Labor, Department of the Interior, Centers for Medicare & Medicaid Services, Administration for Children & Families (ACF), Centers for Disease Control and Prevention (CDC), Health Resources and Services Administration (HRSA), Agency for Healthcare Research and Quality (AHRQ), Food and Drug Administration), non-governmental partners, policymakers, community organizations, non-profit organizations, foundations, public and private sector organizations, and health care organizations. Members of the local HERA will provide tailored and contextualized guidance and advice to community organizations and their research partners, throughout all phases of the project.

To facilitate the co-creation of the draft structural intervention research strategy, the community organization, with their research partner, are encouraged to utilize an appropriate, systematic,

community engaged intervention planning process/approach (e.g., Intervention Mapping, PRECEDE-PROCEED, etc.).

The community organization and their research partner are expected to actively participate in the ComPASS Consortium data-related planning activities, which will include, but are not limited to, identifying and sharing Common Data Elements (CDEs) and health outcomes to be collected across all CHESI sites in accordance with NIH Policy for Data Management and Sharing.

Specific activities during the two-year intervention planning, development, piloting (as appropriate) and partnership phase (Phase I) that the community organization and their research partner are expected to participate in will include, but are not limited to:

- Communicating regularly with the ComPASS Coordination Center and in fiscal year 2024, the Health Equity Research Hubs
- Serving as a member of the ComPASS Steering Committee
- Initiating partnerships with multisectoral entities to establish a local Health Equity Research Assembly (HERA)
- Planning and identifying a process for the multisectoral partnership and governance structure for collaboration towards the structural health intervention
- Collaborating with partners in the selection and prioritization of structural intervention targets and health outcomes of particular interest
- Selecting and prioritizing intervention strategies, as appropriate, that build on the strengths, resources, and assets that exist within the community
- With technical assistance provided by the ComPASS Coordination Center, actively participate in community-engaged research training based on identified training priorities
- Identifying a local institutional review board (IRB) and submitting their IRB application for approval
- Hosting a public community forum(s) or engaging in other communication approaches to share and discuss intervention planning findings and structural intervention ideas
- Receiving technical assistance and scientific support from the ComPASS Coordination Center, and in Year 2, the Health Equity Research Hubs, in developing a research design, statistical analysis plan, and outcome assessment plan
- Participating in the ComPASS Consortium's data-related planning activities
- Work with the ComPASS Coordination Center to include ComPASS Consortium Common Data Elements (CDEs) in the experimental design, where appropriate
- In consultation with the local HERA, co-creating a draft structural intervention research strategy for a health equity structural intervention that addresses structural inequities and disparities, based on the community planning findings and anticipated health outcomes. The draft structural intervention research strategy is submitted to NIH for review
- With technical assistance from the Health Equity Research Hubs, pilot research activities and strategies, as appropriate.

Phase I to Phase II Transition

An administrative review of the submitted draft structural intervention research strategy will be conducted by NIH Program staff to evaluate whether the community organization and their research partner will be considered for transition from Phase I to Phase II. Community organizations and their research partners should understand that transition to Phase II will occur only if an administrative review process recommends forward movement/project continuation

based on the successful completion of the planning, development, piloting (as appropriate) and partnership activities.

Phase II: Intervention Implementation (Years 3 - 8)

In Phase II community organizations and their research partners, along with their local HERA, will implement the structural interventions or leverage changes in policies, programs and practices (as appropriate), to examine the impact on health and draft dissemination and sustainability activity plans.

Early in Phase II, the Health Equity Research Hubs will provide technical assistance to the community organizations and their research partners in finalizing the structural intervention's research study design, statistical analysis plan, and outcome assessment plan. The Health Equity Research Hubs will also support the piloting (as appropriate) of research activities and strategies, and assessing the feasibility of leveraging changing policies, programs and practices. Later in Phase II, the Health Equity Research Hubs will support the implementation and data collection of the structural interventions.

In preparation for Phase III, community organizations and their research partners will develop a dissemination plan and a sustainability activity plan. For the dissemination plan, the Health Equity Research Hubs will provide technical assistance to community organizations and their research partners in documenting and packaging promising approaches for the ComPASS structural intervention repository. With advice from the local HERA, the dissemination plan will also include a list of audiences (e.g., policymakers, community coalitions, local chambers of commerce, etc.) and media platforms (e.g., social media, local newspapers, peer-reviewed journals, etc.) relevant for communicating the structural intervention results.

With advice from the local HERA, the sustainability activity plans will include identifying local resources and potential partners that can be leveraged to maintain and/or scale-up structural intervention activities post NIH funding. Sustainability activity plans will also list a forecast of funding opportunities for community organizations to apply for in Year 9, budgetary measures necessary for maintaining research capacity supported by NIH funding and include a process for monitoring structural intervention-related policy, system, program and practice changes.

Specific activities during the six-year intervention implementation phase (Phase II) will include, but are not limited to:

- Conducting regular meetings with the local HERA
- Piloting (as appropriate) of research activities and strategies, and assessing the feasibility of leveraging changing policies, programs and practices as detailed in the draft structural intervention research strategy
- Refining and finalizing the structural intervention research strategy based on results of the feasibility and pilot activities
- Receiving technical assistance from the Health Equity Research Hubs on finalizing the structural intervention's research study design, statistical analysis plan and outcome assessment plan
- Implementing the structural intervention

- Receiving technical assistance from the Health Equity Research Hubs and input from the local HERA in developing draft dissemination and sustainability activity plans
- Working with the ComPASS Coordination Center and ComPASS Steering Committee to identify Common Data Elements (CDEs), including health outcomes, that will be used across different sites
- Collecting and submitting to the ComPASS Coordination Center, the ComPASS Steering Committee's agreed-upon CDEs and health outcome data, as appropriate

Phase III: Assessment, Dissemination, and Sustainability (Years 9 -10)

During Phase III, projects will assess the proximal health outcomes of the structural intervention, disseminate results, and implement sustainability activities. Examining how and whether the structural intervention achieved its goals of changing structural factors (e.g., system, policies, programs, practices, etc.) and improving health outcomes. Dissemination and sustainability activity plans developed during Phase II will be implemented in Phase III by community organizations, and their research partners, with technical assistance from the Health Equity Research Hubs.

Specific activities during the two-year assessment, dissemination, and sustainability phase (Phase III) will include, but are not limited to:

- Analyzing outcome data collected from the structural intervention
- Participating in outcome assessment activities
- Disseminating structural intervention research findings
- Ensuring scientific data generated is shared according to NIH Policy for Data Management and Sharing and per guidance from the ComPASS Coordination Center
- Documenting and packaging promising approaches for submission to the ComPASS structural intervention repository
- Applying for funding opportunities to maintain and/or scale-up structural intervention research activities
- Monitoring changes (e.g., systems, policies, programs, practices) relevant to the structural intervention

Frequently Asked Questions

Response to Frequently Asked Questions about this ROA will be posted here:

<http://www.commonfund.nih.gov/compass>

Eligibility

The Community-Led, Health Equity Structural Interventions initiative expects community organizations to lead research efforts in collaboration with research partners. For the purposes of this opportunity announcement, a community organization is defined as a non-Federal, non-academic or 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, Tribal serving organizations, neighborhood authorities and

associations, labor unions, patient or consumer advocacy groups, regional/local and public healthcare systems, school districts, law enforcement or criminal/juvenile justice agencies, or social service agencies. Non-federal governmental organizations are eligible, and this includes local, regional, Tribal, or state level governments and their respective departments of public health, commerce, labor, transportation, housing and recreation. Academic research centers, academic healthcare organizations, and private healthcare organizations are *not eligible* for this opportunity. These organizations may be identified partners in the application, however.

This opportunity invites applications from a broad range of community organizations including non-traditional industry and non-profit organizations. NIH is particularly interested in applications led by organizations that have a core mission to serve underrepresented or underserved groups impacted by health disparities. Applications must meet the below corresponding eligibility requirements:

Organizations

Academic research centers, academic healthcare organizations, and private healthcare organizations **are not** eligible to apply. Non-domestic (non-U.S.) Entities (Foreign applicants) **are not** eligible to apply. Non-domestic (non-U.S.) components of U.S. Organizations **are not** eligible to apply. Foreign components **are not** allowed.

Applicant organizations may submit more than one application, provided that each application is scientifically distinct. Individuals not affiliated with an organization, or who want to submit an application independently of their current organization, **may not** apply.

The following entities are eligible to apply under this ROA:

Non-profits Other Than Institutions of Higher Education

- Non-profits with 501(c)(3) IRS Status (Other than Institutions of Higher Education)
- Non-profits without 501(c)(3) IRS Status (Other than Institutions of Higher Education), including but not limited to:
 - Faith-based or community-based organizations
 - Tribal serving organizations
 - Patient or consumer advocacy groups
 - Social service organizations
 - Healthcare systems and providers (including Federally Qualified Health Centers)
 - School districts
 - Law enforcement and criminal/juvenile justice agencies
 - Neighborhood associations
 - Labor unions

For-Profit Organizations

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

Governments

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

- American Indian/Alaska Native Tribal Governments (Other than Federally Recognized)

Multiple Principal Investigators

More than one individual may be named as Principal Investigator (PI) in the application. All PIs must be employed by or affiliated with community organizations that meet eligibility requirements. One individual must be identified as the Contact PI. If a multiple PI proposal is submitted, a leadership plan is required.

Financial and Risk Assessment

Proposers may be subject to financial analysis and risk assessment conducted by NIH staff.

Plan for Enhancing Diverse Perspectives

NIH recognizes that diverse teams working together and capitalizing on innovative ideas and distinct perspectives outperform homogeneous teams (see [Notice of NIH's Interest in Diversity](#)). Scientists and trainees from diverse backgrounds and life experiences bring different perspectives, creativity, and individual enterprise to address complex scientific problems. There are many benefits that flow from a diverse NIH-supported scientific workforce, including: fostering scientific innovation, enhancing global competitiveness, contributing to robust learning environments, improving the quality of the research, advancing the likelihood that underserved or health disparity populations participate in, and benefit from health research, and enhancing public trust.

Developing Applications

Letter of Intent

A Letter of Intent (LOI) must be submitted by the due date shown in this notice. The LOI will be used to select community organizations who will be invited to submit a full application. If invited to submit a full application by NIH staff, the organization's Recipient Business Official/Signing Official and Contact PI will be notified and provided with guidance on submission. LOIs are not binding and will be used only to determine which community organizations are invited to submit full applications.

An NIH internal subject matter expert panel will be convened to review LOIs for responsiveness based on the below criteria. Only eligible and responsive LOI submitters will be invited to submit a full application. LOIs that are non-responsive to indicated criteria will not be invited to submit a full application for this opportunity. The NIH is not responsible for providing feedback on the LOI and will not accept an appeal of the decision.

Interested applicants should submit a Letter of Intent (LOI) of no more than 4 pages, outlining the following elements:

Descriptive Information

- Community organization's mission statement
- Description of the community organization's research and/or programmatic experience using community-engaged approaches

- Name and description of the established community partnerships that will help conduct the proposed structural intervention, including the date at which the established community partnership came into existence
- Description of at least one project/strategy/significant initiative that the community organization has participated in related to addressing health disparities with community partners

Project Information

- The project's descriptive title
- Name of project's Principal Investigator(s)
- NIH-designated population(s) experiencing health disparities in the U.S. to be the focus of the proposal
- Project's geographic area(s) where the proposed structural intervention would take place
- Health outcomes impacted by proposed structural intervention
- Structural factors for potential intervention as part of a full application
- At least one potential research organization/research investigator, who has agreed to support and participate in the community organization's full application. The research organization(s)/research investigator(s) can be academic or non-academic institutions and must include the individual researcher's name, title, institution/organization, phone number, and e-mail address

Fiscal Management Information

- Description of the community organization's organizational capacity and fiscal experience, and/or expertise available, with managing program costs of over \$250,000.

LOIs will be considered non-responsive to the opportunity if they:

- Do not have experience working with other established community partners on a health problem
- Do not demonstrate experience participating in at least one health disparity project
- Do not propose a project that focuses on one or more NIH-designated population(s) experiencing health disparities
- Do not describe the health outcomes impacted by proposed structural intervention
- Do not describe structural factors for potential intervention
- Do not propose at least one research organization/research investigator who has agreed to support and participate in the community organization's full application
- Do not have the organizational capacity and fiscal experience and/or expertise available to manage a program greater than \$250,000.

Letters of Intent (LOIs) must be submitted as a .pdf attachment and received by 11:59 PM Eastern Time on or before the due date by the organization's Recipient Business Official/Signing Official. E-mail LOIs to Yvonne Owens Ferguson, Ph.D., M.P.H. at CFComPASS@od.nih.gov. The contact Principal Investigator must be copied on the e-mail. Applicant organizations that submit their LOI by November 18, 2022, will be notified by *December 16, 2022*, if they are invited to submit a full application.

Application Submission Instructions and Contact Information

Full Application Format

Full applications will be accepted only from organizations listed in the Eligibility section of this announcement that submit a responsive LOI, and that are invited to apply. Applications must be prepared and submitted using NIH's [ASSIST](#) no later than the "application due date" shown under the "Key Dates" section of this announcement. The NIH will not review and will return applications submitted from organizations not included in the Eligibility section and those who were not invited to submit a full application. Complete applications must be submitted by the Recipient Business Official/Signing Official. The organization must be registered in eRA Commons with one person designated as the Principal Investigator (PI) and one person designated as the Signing Official (SO). The SO's signature certifies that the applicant has the ability to provide appropriate administrative and scientific oversight of the project and agrees to be fully accountable for the appropriate use of any funds awarded and for the performance of the OT award-supported project or activities resulting from the application.

Full applications must be submitted by the due date, in text-recognizable PDF (Adobe) format, use 11-point font with 1" margins and be single-spaced. The sections of the application should be loaded as separate attachments and should be titled as specified in each section (title included in parentheses following each section).

Cover ("Cover.pdf"; no more than 1 page)

- Number and title of this Research Opportunity Announcement
- Project Title
- Principal Investigator(s) (PI) first and last name, title, organization/, mailing address, email address and phone number. If multiple PIs are named, the Contact PI is clearly identified.
- Name and address of the submitting community organization and name of other involved organizations
- Recipient Business Official/Signing Official first and last name, title, organization, mailing address, email address and phone number
- Structural factors, health outcomes, and Health-disparity population(s) of interests
- Geographical region where the study will be implemented

Abstract ("Abstract.pdf"; no more than 250 words)

- A summary of the application

Specific Aims ("SpecificAims.pdf"; no more than 1 page)

- Do not list specific objectives of the proposed research. Instead, the specific aims page must contain a section entitled, "Significance, Innovation and Impact". The section should provide a cogent overview of your proposed structural intervention.
- *Significance, Innovation, and Impact*: What is the challenge or opportunity that is the focus of your proposed structural intervention? Why is this significant for health disparities or health equity research? What is the overall approach you are proposing? What are the most original or innovative aspects of your application? What would the

impact be on our scientific understanding of health disparities and advancing health equity?

Senior/Key Personnel and Other Significant Contributors (“Senior/Key.pdf”; no more than three (3) pages in length per individual)

At a minimum, the information in the biosketch should include the name and position title, education and/or other training, list of positions and employment in chronological order (including dates); and a personal statement that briefly describes the individual’s role in the project and why they are well-suited for the role. The format used for an NIH grant application is acceptable, but not a required format, as Other Transactions are not grants. [Biosketch Format Pages, Instructions and Samples | grants.nih.gov](https://grants.nih.gov/grants/other_transactions/biosketch_format.html)

Application Research Plan (“Application.pdf”; no more than 10 pages including any charts or figures. Bibliography not included in page limit) should be organized into the following sections to facilitate review:

Significance

- Describe the health problems being addressed by the proposed project using local-level data (e.g., state, regional, county, or city data), community health assessment data, and/or other relevant data sources
- Discuss the structural factors contributing to the NIH-designated population(s) experiencing health disparities
- Describe the proposed project’s potential impact on changing structural-level systems, policies, and/or practices

Community Investigators

- Identify key personnel, community partners, other personnel and consultants
- Describe the research partner(s) and their specific role on the proposed project (e.g., describe their expertise and experience of the research partner(s) and explicitly state how the partner will scientifically contribute to the proposed project)
- Describe the community partners and their specific role on the proposed project (e.g., describe their expertise and experience of the community partner(s) and explicitly state how the partner will contribute to the proposed project)
- Include relevant past performance for the team and any prior experience working together
- Describe the team’s prior experiences, research or practice, in addressing health disparities and/or advancing health equity
- Describe the team’s prior experience in participating in community engaged research

Organizational Capacity

- Describe the team’s experience working within partnerships to address health
- Demonstrate the organizational commitment to support the proposed research through a letter of support from the community organization’s leadership
- Outline the organization’s fiscal management processes, including subcontracting

Structural Intervention Research Planning Process

- Describe the structural factors of focus for the proposed intervention, how they will be measured, and how the structural factors influence the NIH-designated population(s) experiencing health disparities (subject to change per community assessment findings)
- Describe the proposed health outcomes impacted by the proposed structural intervention and plans for how they will be measured (subject to change per community assessment findings)
- Describe the potential participant reach of the structural intervention within the proposed geographic area(s)
- Describe plans for community partner engagement and collaboration during the structural intervention research planning process
- Describe an approach for planning and developing the proposed structural intervention (e.g., conducting the community assessment relevant to the proposed structural intervention, use of appropriate conceptual models and frameworks, identifying and engaging additional community partners, developing intervention strategies, prioritizing structural factors, intervention strategies, etc.)
- Describe plans for sustainability of research capacity and structural intervention efforts post NIH funding

Multiple Principal Investigator (PI) Leadership Plan (“Leadership Plan.pdf”; no more than 1 page)

- For multiple Principal Investigators (PIs), in the Leadership Plan, describe a rationale for choosing a multiple PI approach, the governance and organizational structure, communication plans, processes for making decisions on the project and resolving conflicts.

Data Management and Sharing Plan (“Data Plan.pdf”; no more than 2 pages)

- In accordance with [NIH Policy for Data Management and Sharing](#), describe how the proposed data generated from the project will be managed and shared. For elements to include in the Data Management and Sharing Plan, please see [Data Management & Sharing Policy Overview](#), [Writing a Data Management & Sharing Plan | Data Sharing \(nih.gov\)](#) and [NOT-OD-21-014: Supplemental Information to the NIH Policy for Data Management and Sharing: Elements of an NIH Data Management and Sharing Plan](#). NIH respects and recognizes Tribal sovereignty and American Indian and Alaska Native (AI/AN) communities’ data sharing concerns. For research teams working with Tribes and AI/AN communities, please refer to [NOT-OD-22-064: Supplemental Information to the NIH Policy for Data Management and Sharing: Responsible Management and Sharing of American Indian/Alaska Native Participant Data](#).

PHS Human Subjects and Clinical Trials Information (“Human Subjects.pdf”)

- All projects submitted for this funding opportunity involve human subjects research and are designated as clinical trials. Answer “Yes” to the question, “Are Human Subjects Involved?” on the [\(R&R\) Other Project Information Form](#)
- Because a definite research strategy cannot be described in the application, the proposed project is required to be designated a [Delayed Onset Study](#). Follow the SF424 (R&R) Application Guide’s [Delayed Onset Study instructions](#) to complete the required Delayed Onset Study Justification attachment.

- For this funding opportunity, the applicant is responsible for identifying a local institutional review board (IRB) for the project site(s). Applicants are encouraged to leverage their research partner IRB or utilize the services of an independent IRB. The ComPASS Coordination Center will support award recipients in preparing their IRB protocol for submission.

Plan for Enhancing Diverse Perspectives (PEDP) (“PEDP.pdf”; no more than 1 page)

- Applicants must include a summary of strategies to advance the scientific and technical merit of the proposed project through expanded inclusivity. The PEDP should provide a holistic and integrated view of how enhancing diverse perspectives is viewed and supported throughout the application and can incorporate elements with relevance to any review criteria (significance, community investigators, organizational capacity, structural intervention research planning process). The PEDP will vary depending on the proposed project, expertise required, the environment and the proposed structural intervention sites. Examples of items that advance inclusivity in research and may be part of the PEDP can include, but are not limited to:
 - Discussion of engagement with different types of institutions and organizations (e.g., research-intensive, undergraduate-focused, minority-serving, community-based).
 - Description of any planned partnerships that may enhance geographic and regional diversity.
 - Plan to develop transdisciplinary collaboration(s) that require unique expertise and/or solicit diverse perspectives to address research question(s).
 - Outreach and planned engagement activities to enhance recruitment of individuals from diverse groups as research participants including those from under-represented backgrounds.

Additional information to include in the submission:

- Organizational Letter of Support (“**Organizational Support.pdf**”): A letter of support from the applicant’s organization indicating institutional commitment for the project and to enter into negotiated OT agreements.
- Letters of support from proposed research partners, collaborators, consultants, Tribal communities and partnering community organizations, as appropriate, with clear statement of roles/responsibilities on the project (“**Letters of Support.pdf**”, no page limitations).
- A bibliography (“**Bibliography.pdf**”; no more than 1 page)
- A copy of the applicant organization’s “Invitation to Submit” email received from NIH (“**Invitation.pdf**”; no more than 1 page).

[Budget Details](#)

The NIH may elect to negotiate any or all elements of the proposed budget.

Budget (“Budget.pdf”; no page limitations)

- The Budget section must provide a realistic, fully justified annual budget and cost proposal for performing the work over the three (3) described phases. The budget

should address costs associated with the community organization, community partners, the research partner(s), consultants, subcontracts, and any collaborators.

- The budget should also address costs and fees associated with the research partner's organization/institution providing support for administration of the project's institutional review board (IRB) review or utilizing the services of an independent IRB.
- The budget should also include costs for the Principal Investigator(s) and the research partner(s) to attend in-person annual COMPASS consortium meeting to be held in Bethesda, Maryland.
- Applicants must complete the SF424 budget. Do not complete the budget form in the ASSIST module, instead download and complete the relevant forms found here: <https://commonfund.nih.gov/OTforms>
- Budgets for individual awards are expected to vary, depending on the proposed scope of the project. Annual budgets are expected not to exceed \$750,000 total costs in Year 1 and Year 2, expected not to exceed \$1.5 million total costs in Year 3 - Year 8 and expected not to exceed \$750,000 total costs in Year 9 and Year 10.
- Budgets must adhere to latest NIH salary limitation notice (See [NOT-OD-22-076](#), Guidance on Salary Limitation for Grants and Cooperative Agreements).

The Budget should provide the overall expected cost for each of the following categories:

- Personnel
- Travel
- Subawards/subcontracts/consultants: For research partners and community partners
- Institutional Review Board-associated costs
- Other direct costs
- Total costs (with indirect costs included)

Applicants must provide a budget justification for all budget items. Subawards need to provide details of cost breakdown.

Objective Review

Proposals to Other Transactions Research Opportunity announcements such as this one, are not reviewed by the standard NIH peer review process, but using custom processes referred to as Objective Review. Objective review will involve the submission of written critiques by subject matter experts against the Review Criteria described below, and interactive individual discussions between those experts and NIH program staff. Responsive, full applications submitted in response to the solicitation, will be reviewed by subject matter experts via an objective review process. The subject matter experts will include NIH staff, other federal staff, and individuals external to federal government. The composition of subject matter experts will be demographically diverse in terms of race/ethnicity, gender and geographic region. Of note is the inclusion of review members with expertise working within community organizations, being a part of community partnerships, and being individuals with lived experiences relevant to the applications under review.

The review will facilitate dialogue between applicants and subject matter experts so that applications are improved by the review process. The outcome of each review is therefore intended to be a modified work plan for each applicant. Components of the applications may be

accepted into the final plan in whole, in part, or may be omitted. The modified work plan, as shaped by the objective review process, will serve as a blueprint for the final negotiated terms and milestones for the resulting awards. Applicants will receive written feedback outlining the strengths and weaknesses of the proposed research. However, the NIH will not accept an appeal of the objective review or funding decision outcomes.

Review Criteria

Overall Potential Impact (1 High – 9 Low)

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

1. Significance (15 points)

- Does the applicant's proposed project address an important problem/structural barrier to health?
- Is there inclusion of local, community-level data describing the problem/structural barrier to health?
- How does the applicant describe the proposed project's impact on health outcomes?

2. Community Investigator(s) (30 points)

- Does the applicant and their research partners have the requisite expertise and experience to ensure the successful conduct of a structural intervention?
- How well does the expertise and experience of the research partner align with the scientific requirements of the proposed research?
- Does the research team demonstrate appropriate experience in addressing health disparities or advancing health equity?
- To what extent will the efforts described in the Plan for Enhancing Diverse Perspectives strengthen and enhance the expertise required?

3. Organizational Capacity (25 points)

- To what extent has the applicant adequately described their collaboration experience?
- Does the applicant adequately describe their expertise in building and working in community partnerships?
- Does the applicant provide an adequate description of their fiscal management processes, including subcontracting experience?
- Does the applicant's organizational leadership demonstrate commitment and support of the proposed project?

4. Structural Intervention Planning (30 points)

- How well does the applicant describe the structural factors of interest and its impact on health outcomes?
- Does the applicant include an appropriate intervention planning approach?
- Is the potential participant reach compelling?

Funding decisions will be based on the outcome of the objective review. Agreements for all awards will be negotiated with eligible entities whose applications are determined to provide the best value to the NIH in achieving the overall ComPASS Program goals. Funding decisions will also consider achieving a balance of awards representing the diversity of NIH-designated populations that experience health disparities in the U.S., the geographic diversity across the U.S., and the diversity of the proposed structural intervention ideas, topics, and approaches to maximize potential public health impact of ComPASS. Appeals of funding decisions will not be accepted.

Special Award Terms and Information

The administrative and funding instrument used for this program will be the Other Transaction, OTA mechanism, in which active oversight and management by the NIH is expected during the performance of the activities. Under an OT, the NIH purpose is to support and stimulate the recipients' activities by involvement in and otherwise working jointly with the award recipients. OTs offer considerable flexibility to renegotiate or terminate agreements when necessary to promote the overall objectives of the program. The award and post-award negotiations will reinforce program objectives and, if necessary, adjust conditions by which progress is assessed.

The awardees from the ComPASS Program must participate actively (allocate time and effort) to work with the ComPASS Consortium (e.g., in monthly calls with other awardees) and respond in a timely manner to communications and requests from the NIH, ComPASS Coordination Center, and the Health Equity Research Hubs.

NIH Staff Involvement

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

Definitions:

- NIH Working Group (WG): Consists of NIH program staff from multiple Institutes, Centers, and Offices (ICOs) of the NIH as well as the Office of the Director. The WG will primarily be responsible for the stewardship of the ComPASS Program and will participate as non-voting members in the Consortium committees. The WG is co-chaired by the Directors of the National Institute of Nursing Research, National Institute of Mental Health, National Institute on Minority Health and Health Disparities, the Office of Research on Women's Health, and the Tribal Health Research Office. The WG reports to the Directors of the Office of Strategic Coordination (OSC)/Common Fund and the Division of Program Coordination, Planning, and Strategic Initiatives for final funding decisions.
- ComPASS Steering Committee (SC): The PIs of the ComPASS Community-led, Health Equity Structural Intervention (CHESI), the ComPASS Coordination Center (CCC) awards (the Health Equity Research Hubs in Year 2) and involved NIH staff acting as Program Officials (POs), Project Scientists (PSs) and the NIH OSC/Common Fund Program Leader will form the ComPASS Steering Committee which will govern the activities of the program recipients. The ComPASS Steering Committee will be coordinated and administrated by the CCC. 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 consultation with the ComPASS

SC. The SC co-chairs will preside at all SC meetings. Scientific direction will be in compliance with NIH research policies and procedures. The governance structure will be co-created by SC members and NIH staff. For votes, 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 will review and approve policies and procedures developed by the SC. The SC decisions will be made by a majority vote. The SC will include the Health Equity Research Hubs, which, together, will have one vote. The Health Equity Research Hub awards begin 1 year after the formation of the SC.

- **ComPASS Consortium:** ComPASS awardees, the NIH Working Group and other relevant scientists and groups the SC agrees to include within the consortium. The consortium structure is meant to efficiently and effectively guide all the funded projects to meet the overall goals of the ComPASS Program.
- **National Health Equity Research Assembly (HERA):** The National HERA is an invited group of federal and non-federal members convened as part of the ComPASS Coordination Center (CCC) to provide vital consultation on structural interventions, data resources, grant activities and innovations for implementation and policy impact. These National level representatives will facilitate successful research collaborations and opportunities as well as implementation and sustainability of programs to inform policy. The National HERA is advisory to the CCC and convened at the national level by the CCC.

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

- **NIH Program Officer –** The Program Officer (PO) from the Office of Strategic Coordination (OSC) is 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), External Program Consultants or the NIH Working Group, restricting an award based on progress towards milestones, to incentivize rapid development 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 Program Officer will not co-author publications with the CHESI PIs. The Program Officer will be responsible for making funding recommendations and otherwise providing programmatic approvals and recommendations. POs will have programmatic authority, including fiscal oversight, over the CHESI and receive input from other NIH staff acting as Project Scientists (PSs). POs will closely monitor progress of all the awards made in their initiative and report back as part of the WG meetings.
- **NIH Project Scientist -** One or more NIH Program Staff will serve as Project Scientists (PSs), for each CHESI, as appropriate. 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. If there is more than one PS, one of them will be

designated as the Lead PS. The PSs will provide substantial NIH scientific, programmatic involvement with the awardees that is anticipated during the performance of the activities supported by other transactions and cooperative agreements, including reviews of milestones. The PSs will work closely with the PO, the Steering Committee, and the PIs of their assigned CHESI projects, as appropriate, to maximize progress towards the goals of the project and the program. The PS will attend Steering Committee meetings, as needed. It is expected that the PSs will participate in teleconferences with the PIs and key personnel of CHESI projects and attend relevant ComPASS meetings in-person or virtually. Consistent with NIH Institute, Center and Office publication policies, PSs may contribute, as appropriate, to scientific manuscripts and other scientific and scholarly activities (e.g., oral presentations, poster presentations) resulting from the ComPASS Program.

NIH Discretion

The OT award mechanism allows significant ongoing involvement from NIH Program and Project Managers and provides the NIH the flexibility to alter the course of awarded activity in real-time to meet the overarching program goals. This may mean that an awarded activity could be expanded, modified, or discontinued based on program needs, emerging methods or approaches, performance, or availability of funds. Performance during the award period will be reviewed on an ongoing basis and course corrections will be made as necessary. As a result, the NIH reserves the right to:

- Fund projects in increments and/or with options for continued work at the end of one or more phases;
- Fund projects of two or more entities (potentially across different proposals) as part of a reorganized collaboration, teaming arrangement, or other means acceptable to the government;
- Request additional documentation (certifications, etc.); and
- Remove participants from award consideration should the parties fail to reach a finalized, fully executed agreement prior to a date determined by the NIH, or the proposer fails to provide requested additional information in a timely manner.

Proposals selected for award negotiation may or may not result in the issuance of an OT award, dependent on the outcome of negotiations, the nature of the work proposed, changing external conditions, and other factors. The NIH reserves the right and sole discretion to engage in negotiation with the selectees applying under this solicitation during all phases of the proposal lifecycle.

Award Governance

The NIH will actively engage with award recipients to establish a vision and capabilities for the ComPASS Program and to oversee the effort of individual awards to achieve the vision.

NIH Roles and Responsibilities:

1. **Agreements Officer:** NIH individual responsible for legally committing the government to an OT award and to the agreement through which terms and conditions are established, and for the administrative and financial aspects of the award. The Agreements Officer (AO) is the focal point for receiving and acting on requests for NIH prior approval and is the only NIH official authorized to change the funding, duration, or other terms and conditions of award.

2. Agreement Specialist: A designee of the AO for administrative and financial aspects of the award.
3. Program Official: Individual within NIH who provides day-to-day programmatic oversight of individual awards, working closely with the AO and with the Office that manages the Common Fund.

OT Agreement Governance

OT awards are not grants, cooperative agreements, or contracts. They are used by NIH for particular purposes as authorized by Congress, including in the execution of certain programs supported by the Common Fund. They provide considerable flexibility in establishing policies for the awards. Each award is therefore issued with a specific Agreement, which is negotiated with the recipient and details specific terms and conditions for that award. Policies and terms for individual OT awards may vary between awards, which may be expanded, modified, partnered, not supported, or later discontinued based on program needs, changing research landscape and or availability of funds. Program and administrative policies and the terms and conditions of individual awards are intended to supplement, rather than substitute for, governing statutory and regulatory requirements. Awards or a specified subset of awards also may be subject to additional requirements, such as those included in executive orders and appropriations acts, including the Other Transactions-authorizing legislation cited in the Notice of Award (NoA), as well as all terms and conditions cited in the NoA and its attachments, and conditions on activities and expenditure of funds in other statutory or regulatory requirements, including any revisions in effect as of the beginning date of the next funding segment. The terms and conditions of the resulting OT awards are intended to be compliant with governing statutes.

For the awards funded under this Research Opportunity Announcement, the NIH will engage in negotiations (before, during, and at the end of award) and all agreed upon terms and conditions will be incorporated into the Agreement. A bilateral agreement will be used as the official Agreement and the Notice of Award (NoA) will be solely used for funding obligations. The signature of the Signing Official on the bilateral agreement will certify that the organization complies, or intends to comply, with all applicable terms and conditions, policies, and certifications and assurances referenced (and, in some cases, included) in the application instructions.

Intellectual Property

Specific terms with respect to intellectual property will be negotiated at the time of award; however, any negotiation will consider other laws (as relevant) that affect the government's issue and handling of intellectual property, such as the Bayh-Dole Act (35 U.S.C. 200-212); the Trade Secrets Act (18 U.S.C. 1905) the Freedom of Information Act (5 U.S.C. 552); 10 U.S.C. 130; 28 U.S.C. 1498; 35 U.S.C. 205 and 207-209; and the Lanham Act, partially codified at 15 U.S.C. 1114 and 1122.

Budget

The OT award provides funds for the budget period as appropriate for the negotiated and agreed upon work. Subsequent funding periods represent projections of future funding levels contingent on the availability of funds, achievement of agreed-upon activities, and continued alignment with programmatic goals.

Payment

The OT award will use the Payment Management System (PMS) operated by the DHHS Program Support Center. Payments by PMS may be made by one of several payment methods,

including SMARTLINK II/ACH, cash request, or by cash request on a reimbursement basis as specified in the terms of the Agreement.

Generally, payments align with achievement of milestones and a payment schedule will be negotiated prior to issuance of the award to minimize the amount of time elapsing between the transfer of funds from the Federal Government and disbursement by the recipient.

Reporting

The terms and conditions of award will address this criterion as appropriate based upon the final negotiated and agreed upon budget.

1. Financial and Progress Reports:
 - Recipients will be asked to provide regular progress reports to the Program Officer and Agreements Officer. The frequency and types of technical and financial reports (e.g., Federal Financial Reports) required will be specified in the Agreement document, and will include, as a minimum, financial status reports that will establish the burn rate for the project and a bi-annual status report.
 - A final report that summarizes the project and tasks will be required at the end of the Agreement period. The reports shall be prepared and submitted in accordance with the terms and conditions requirements.
2. i-Edison: Agreement terms and conditions will contain a requirement for patent reports and notifications to be submitted electronically through the i-Edison Federal patent reporting system at <https://www.nist.gov/iedison>.

Management Systems and Procedures

Recipient organizations are expected to have systems, policies, and procedures in place by which they manage funds and activities. Recipients may use their existing systems to manage OT award funds and activities as long as they are consistently applied regardless of the source of funds and across their business functions. To ensure that an organization is committed to compliance, recipient organizations are expected to have in use clearly delineated roles and responsibilities for their organization's staff, both programmatic and administrative; written policies and procedures; training; management controls and other internal controls; performance assessment; administrative simplifications; and information sharing.

Financial Management System Standards

Recipients must have in place accounting and internal control systems that provide for appropriate monitoring of other transaction accounts to ensure that obligations and expenditures are congruent with programmatic needs and are reasonable, allocable, and allowable. A list of unallowable costs will be included in the terms and conditions of the award. In addition, the systems must be able to identify unobligated balances, accelerated expenditures, inappropriate cost transfers, and other inappropriate obligation and expenditure of funds, and recipients must notify NIH when problems are identified. A recipient's failure to establish adequate control systems constitutes a material violation of the terms of the award.

Property Management System Standards

Recipients may use their own property management policies and procedures for property purchased, constructed, or fabricated as a direct cost using NIH OT award funds. The terms and conditions of award will address this criterion as appropriate based upon the final negotiated and agreed upon budget. Procurement System Standards and Requirements
Recipients may acquire a variety of goods or services in connection with an OT award-supported project, ranging from those that are routinely purchased goods or services to those

that involve substantive programmatic work. Recipients must acquire goods and services under OT awards in compliance with the organizations established policies and procedures. The terms and conditions of award will address this criterion as appropriate based upon the final negotiated and agreed upon budget.

Organizational Conflicts of Interest (OCIs)

Applicants are required to identify and disclose all facts relevant to potential OCIs involving subrecipients, consultants, etc. Under this section, the proposer is responsible for providing this disclosure with each Detailed Plan. The disclosure must include the PI/Collaborators', and as applicable, proposed member's OCI mitigation plan. The OCI mitigation plan must include a description of the actions the proposer has taken, or intends to take, to prevent the existence of conflicting roles that might bias the proposer's judgment and to prevent the proposer from having an unfair competitive advantage.

The government will evaluate OCI mitigation plans to avoid, neutralize, or mitigate potential OCI issues before award issuance and to determine whether it is in the government's interest to grant a waiver. The government will only evaluate OCI mitigation plans for proposals that are determined selectable. The government may require applicants to provide additional information to assist the government in evaluating the proposer's OCI mitigation plan. If the government determines that a proposer failed to fully disclose an OCI or failed to reasonably provide additional information requested by the government to assist in evaluating the proposer's OCI mitigation plan, the government may reject the Detailed Plan and withdraw it from consideration for award.

Monitoring

Recipients are responsible for managing the day-to-day operations of OT award-supported activities using their established controls and policies. However, to fulfill their role in regard to the stewardship of federal funds, the program team will monitor their OT awards to identify potential problems and areas where technical assistance might be necessary. This active monitoring is accomplished through review of reports and correspondence, audit reports, site visits and other information, which may be requested of the recipient. The names and contact information of the individuals responsible for monitoring the programmatic and business management aspects of awards will be provided to the recipient at the time of award.

Monitoring of a project or activity will continue for as long as NIH retains a financial interest in the project or activity as a result of property accountability, audit, and other requirements that may continue for a period of time after the OT award is administratively closed out and NIH is no longer providing active OT award support.

Record Retention and Access

For OT awards, the 3-year record retention period will be calculated from the date of the Federal Financial Report (FFR) for the entire competitive segment is submitted. Therefore, recipients must retain the records pertinent to the entire competitive segment for 3 years from the date the FFR is submitted to NIH. If any litigation, claim, financial management review, or audit is started before the expiration of the 3-year period, the records must be retained until all litigation, claims, or audit findings involving the records have been resolved and final action taken. These record retention policies apply to both paper and electronic storage of applicable information, including electronic storage of faxes, copies of paper documents, images, and other electronic media.

Audit

NIH OT recipients for the ComPASS Program are subject to the audit requirements of OMB 2 CFR 200, Subpart F-Audit Requirements, as implemented by DHHS 45 CFR Subpart F. In general, 45 CFR 75, Subpart F-Audit Requirements requires a state government, local government, or non-profit organization (including institutions of higher education). Please consult the provisions within Subpart F to determine requirements for the program specific audit requirements.

For-profit organizations have two options regarding the type of audit that will satisfy the audit requirements. The recipient either may have (1) a financial-related audit (as defined in, and in accordance with, the Government Auditing Standards (commonly known as the “Yellow Book”), GPO stock 020-000-00-265-4, of a particular award in accordance with Government Auditing Standards, in those cases where the recipient receives awards under only one DHHS program, or (2) an audit that meets the requirements of 45 CFR 75, Subpart F-Audit Requirements.

Noncompliance or Enforcement Actions: Suspension, Termination, and Withholding of Support

If a recipient has failed to materially comply with the terms and conditions of award, NIH may take one or more enforcement actions, which include disallowing costs, withholding of further awards, or wholly or partly suspending the OT award, pending corrective action. NIH may also terminate the OT award.

NIH may suspend (rather than immediately terminate) an OT award and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination decision; however, NIH may decide to terminate the award if the recipient does not take appropriate corrective action during the period of suspension. NIH may immediately terminate an OT award when necessary, such as to protect the public health and welfare from the effects of a serious deficiency.

An NIH OT award also may be terminated, partially or totally, by the recipient. If the recipient decides to terminate a portion of an OT award, NIH may determine that the remaining portion of the award will not accomplish the purposes for which the award was originally made. In any such case, NIH will advise the recipient of the possibility of termination of the entire OT award and allow the recipient to withdraw its termination request. If the recipient does not withdraw its request for partial termination, NIH may initiate procedures to terminate the entire award for cause.

If the NIH decides to terminate an OT award, the termination of the award will be considered a unilateral change and the recipient **will not have the right to appeal**. Although a decision is made to terminate an award, the recipient must continue to comply with the Record Retention and Access requirements.

Recovery of Funds

NIH may identify and administratively recover funds paid to a recipient at any time during the life cycle of an OT award. Debts may result from cost disallowances, unobligated balances, unpaid share of any required matching or cost-sharing, funds in the recipient’s account that exceed the final amount determined to be allowable, or other circumstances.

Debt Collection

The debt collection process is governed by the Federal Claims Collection Act, as amended (Public Law [P.L.] 89-508, 80 Stat. 308, July 19, 1966); the Federal Debt Collection Act of 1982 (P.L. 97-365, 96 Stat. 1749, October 25, 1982); the Debt Collection Improvement Act (P. L.104-

134, 110 Stat. 1321, April 26, 1996); and, the Federal Claims Collection Standards (31 CFR Parts 900-904), which are implemented for DHHS in 45 CFR 30. NIH is required to collect debts due to the Federal Government and, except where prohibited by law, to charge interest on all delinquent debts owed to NIH by recipients.

Closeout

The requirement for timely closeout is a recipient responsibility. Closeout includes ensuring timely and accurate submission of all required reports and adjustments for amounts due to the recipient or NIH. Terms and conditions of award will outline the specific timeline requirements for submission of the Final Federal Financial Report, the Final Progress Report, Final Invention Statement and Certification, and any other documentation or deliverables negotiated for award.

Public Policy Requirements and Objectives

NIH intends to uphold high ethical, health, and safety standards in both the conduct of the research it funds and the expenditure of public funds by its recipients. The signature of the Signing Official on the application certifies that the organization complies, or intends to comply, with all applicable policies, certifications, and assurances.

The policies, certifications and assurances listed may or may not be applicable to the project, program, or type of applicant organization. This list is not intended to be comprehensive and other laws may be determined to apply generally to all NIH OT awards, or specifically to a particular award depending on the terms of the OT.

- Animal Welfare Requirements (PHS Policy on Humane Care and Use of Laboratory Animals)
- ClinicalTrials.gov Requirements
- Comptroller General Access
- Debarment and Suspension
- Dissemination of False or Deliberately Misleading Information
- Federal Information Security Management Act
- Financial Conflict of Interest
- Fly America Act
- Gun Control
- Human Embryo Research and Cloning Ban
- Human Fetal Tissue Research
- Human Subjects Protections
- Human Stem Cell Research (NIH Guidelines)
- Lobbying Prohibition
- Metric System
- National Environmental Policy Act
- Pro-Children Act of 1994
- Prohibition on Promotion or Legalization of Controlled Substances
- Research Involving Recombinant or Synthetic Nucleic Acid Molecule
- Research on Transplantation of Human Fetal Tissue
- Restriction of Abortion Funding
- Restriction on Distribution of Sterile Needles
- Restriction of Pornography on Computer Networks
- NIH Salary Cap/Salary Limitation
- Research Misconduct
- Select Agents

- Trafficking in Persons
- USA Patriot Act