



Research Opportunity Announcement
OTA-20-014-C
IMPROVE Community Implementation Program (IMPROVE-CIP)
Solicitation for Research Coalitions

Purpose

The purpose of this new research opportunity announcement is to advance the goals of the NIH Implementing a Maternal health and PRenancy Outcomes Vision for Everyone ([IMPROVE](#)) Initiative. IMPROVE aims to understand the biological, behavioral, environmental, sociocultural, and structural factors that affect pregnancy-related and pregnancy-associated morbidity and mortality and build an evidence base for improved care and outcomes. The initiative promotes research to address health disparities associated with pregnancy-related and pregnancy-associated morbidity and mortality.

This Research Opportunity Announcement (ROA) intends to stimulate dissemination and implementation research on innovative approaches built on evidence-based findings from foundational research on factors that ultimately contribute to reducing maternal mortality (MM) and severe maternal morbidity (SMM). This ROA will support the development and testing of promising community-based implementation strategies to inform integrated efforts to increase adoption, uptake, scale up and scale out of evidence-based interventions to improve pre-pregnancy, pregnancy, perinatal, and postpartum care and advance maternal health and maternal health equity in disproportionately impacted and underserved communities. Leveraging community partners will advance a holistic and inclusive approach to identify, develop, and conduct promising community-engaged implementation research for the delivery and uptake of evidence-based interventions, at both the individual and community levels. Applications are expected to include a strong focus on community partnerships. Detailed plans to engage with relevant community organizations as full partners in the project are required for these implementation projects.

IMPROVE-CIP is a phased mechanism. Phase I is for conducting formative work as described below and is not intended for formal testing and evaluation of dissemination and implementation strategies. Tests of clinical effectiveness are also not appropriate for Phase I. Phase II is intended for the fully-powered testing of dissemination and implementation approaches. This ROA is for support of Phase I only. Availability of funds for full-scale testing of the most promising of these implementation strategies from the Phase I awardees will be considered at a later phase (Phase II), under a separate funding opportunity and subject to the availability of funds [Note: Phase II is not to be proposed, budgeted for, or awarded under this Phase I funding announcement, except as described below in the Application Requirements/Evaluation Criteria section].

Background

The maternal mortality (MM) rate has been rising in the U.S. and is now higher than any developed country in the world. Approximately 700 individuals die each year from conditions related to or associated with pregnancy or childbirth. At the height of the pandemic in 2020,

there were approximately 860 maternal deaths in the United States^{1,2}. In addition, severe maternal morbidity (SMM)³, considered a “near miss” for MM, affects more than 65,000 individuals in the U.S. per year. Individuals experiencing SMM are at increased risk for future adverse health (e.g., cardiovascular disease, diabetes, mental health conditions, strokes, and heart disease). Causes of SMM and MM are multifaceted. In the U.S., the leading causes are cardiovascular disease, infection, overdose, hypertensive disorders, thromboembolism, and hemorrhage. Birthing individuals with underlying disease such as kidney disease, lupus and others also increase risk for MM/SMM. Significant contributing factors include comorbid conditions (e.g., obesity, diabetes, mental health, and substance use disorders) as well as interpersonal (e.g., intimate partner violence), structural and social (e.g., policies, neighborhood characteristics), and health care system factors (e.g., mistrust of the healthcare system, access to care, quality of care). It is estimated that 60 to 70 percent of maternal deaths in the U.S. are preventable.

Several factors affect MM/SMM, including, age, disabilities, geographical location, and social determinants of health (SDOH), education, structural racism and discrimination, neighborhood and built environment, housing stability, and social and community context. Psychosocial factors, stress, social isolation, mental health, intimate partner violence, substance use, quality of life, and SDOH contribute to pregnancy-related and pregnancy-associated morbidity and mortality, particularly among women from racial/ethnic minority groups, less privileged socioeconomic status groups, and other underserved populations such as rural populations, and sexual and gender minorities. Structural racism and discrimination (e.g., residential segregation and homelessness which restrict access to healthcare and healthy living environments) have profound negative impacts on maternal health and well-being outcomes during pregnancy and up to one year postpartum. Structural factors that contribute to negative impacts include occupational segregation and barriers which limit access to health insurance, sick or maternity leave, and healthy working conditions (inclusive of contributing policies and human behavior in the workplace that impact these barriers) and criminal justice inequities that lead to a greater risk of incarceration or fewer legal protections for people who experience violence or trauma, amongst others. Therefore, implementing multifaceted strategies to address preventable contributors to MM/SMM in populations that experience health disparities (HDP) and conducting novel systems research examining the health care and community approaches to maternal wellbeing have the potential to drastically reduce pregnancy-related maternal deaths and decrease maternal morbidity.

High rates of pregnancy-related and pregnancy-associated morbidity and mortality disproportionately affect Black/African American and American Indian/Alaskan Native individuals. Mortality rates for Black women (55.3 mortality incidences per 100,000 live births) were nearly three times higher than White women (19.1)². Most recently available AI/AN population data indicate mortality incidences are significantly higher than White women (2007-2016 average 29.7 mortality incidences per 100,000 live births)⁴. Additionally, there are disparities in maternal health outcomes by age and geographic region such as increased barriers

¹ <https://www.cdc.gov/reproductivehealth/maternalinfanthealth/severematernalmorbidity.html>

² <https://stacks.cdc.gov/view/cdc/113967>

³ <https://www.acog.org/clinical/clinical-guidance/obstetric-care-consensus/articles/2016/09/severe-maternal-morbidity-screening-and-review>

⁴ https://www.cdc.gov/mmwr/volumes/68/wr/mm6835a3.htm?s_cid=mm6835a3_w

to care in more rural and medically underserved areas⁵.

To understand the impacts and vulnerability of populations most affected by MM/SMM, broad engagement with communities is essential⁶. Community-engaged research provides the opportunity and ability to discern community-level and individual-level impacts. Community-engaged research for maternal health enables/facilitates identifying relevant community-level factors that could improve maternal health and informs the development of locally-driven solutions that are effective and sustainable in addressing the disproportionate effects of MM/SMM in/on the engaged communities. Therefore, community involvement and voices will be critically important to advance solutions for addressing challenges associated with MM/SMM. Because key subgroups of the individuals at risk for negative health outcomes during pregnancy are part of marginalized populations (e.g. substance users), plans for engaging so-called “hidden” populations are needed.

IMPROVE-CIP seeks to empower communities across the US to be full partners in community-engaged research and to contribute assets to understand factors that contribute to health disparities related to maternal health; to measure the needs and priorities of the impacted communities across multiple sectors (such as health care and community settings) that would benefit most from improved maternal health; implement effective strategies to assess community knowledge; address misinformation and disinformation in the community; and finally, build trust and strong partnerships across various stakeholders that encourage maternal health.

The NIH-wide IMPROVE initiative supports research on how to mitigate preventable MM, decrease SMM, and promote health equity. IMPROVE is a multipronged, innovative research initiative designed to understand and eliminate health disparities among populations disproportionately affected by severe maternal morbidity and mortality, including Black/African American, American Indian/Alaska Native, Asian American, Native Hawaiian/Pacific Islander, Hispanic/Latina populations, rural and geographically underrepresented populations, sexual and gender minorities, very young individuals, individuals of advanced maternal age, and people with disabilities.

Although there is much to be done for developing new interventions, numerous evidence-based prevention interventions currently exist that are not routinely taken up and delivered in many communities. As part of the IMPROVE initiative, this Research Opportunity Announcement (ROA) seeks applications that propose implementation science projects to mitigate preventable MM, decrease SMM, and promote health equity. Implementation science is the scientific study of methods to promote the integration of research findings and evidence-based interventions into health care practice and policy. The core of implementation science is not to ask what intervention should be used, but rather which strategies are most effective at improving uptake and adoption of interventions of known effectiveness while considering local context. Taking a life-course approach and addressing the structural, social, environmental, healthcare system, and behavioral factors associated with health disparities is fundamental to identifying and implementing sustainable approaches that can prevent MM and SMM for all birthing individuals across the country. Among critical factors that contribute to preventable maternal morbidity and mortality are those associated with healthcare system access and availability, community-level

⁵ <https://www.cdc.gov/reproductivehealth/maternal-mortality/pregnancy-mortality-surveillance-system.htm#urban-rural>

⁶ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7497354/>

resources, provider-level constraints, and social determinants of health.

While NIH continues its strong support of research on identifying and testing the efficacy and effectiveness of interventions for addressing conditions such as eclampsia, pre-eclampsia, hypertensive disorders of pregnancy, mental health disorders, substance use, and gestational diabetes, it is also essential to ensure that existing evidence-based interventions promoting health before, during, and after pregnancy are being delivered, accepted, and utilized for all individuals. The overall goal of this ROA is to study the use of strategies to adopt and integrate interventions of known efficacy and effectiveness into community settings to improve maternal health outcomes before and during pregnancy and post-partum, specifically within populations experiencing health disparities as listed above.

Authority

This Research Opportunity Announcement (ROA) is issued with the goal of establishing a subaward to the “other transactions” agreement NHLBI awarded to Westat under OT2HL158287 pursuant to 42 U.S.C. § 285b-3.

Objectives

Within this ROA, NIH invites applications to plan and carry out projects to disseminate and implement evidence-based interventions or practices into community settings (e.g., workplace, school, place of worship) to advance a holistic approach to improve maternal health and maternal health equity in populations disproportionately impacted by MM/SMM. Applicants are encouraged to propose studies that include interventions with demonstrated efficacy for the target populations and demonstrated effectiveness in real-world settings. Strategies should include plans to identify and overcome barriers and facilitators and adapt to local contexts. Applications that test implementation strategies outside of the traditional clinic setting will be of higher programmatic priority.

Evidence-based practice areas of interest include behavioral interventions; prevention, early detection, diagnostic, treatment, and management interventions; and quality improvement programs, with emphasis on culturally and linguistically appropriate strategies for NIH-designated HDPs (<https://www.nimhd.nih.gov/about/overview/>). Of particular interest are evidence-based practices with demonstrated effectiveness that address MM/SMM related to structural-, social-, psychosocial-, cardiovascular-, metabolic-, infectious-, mental health-, substance use-, and infection and immunity-related causes.

Multidisciplinary, systems, and community-partnered implementation science approaches utilizing existing community-engaged partnerships to reduce severe morbidity and mortality related to and associated with pregnancy encompassing the pre-pregnancy, pregnancy and post-partum periods are encouraged. Innovative approaches that substantially incorporate trusted community partners, organizations, or institutions, such as public libraries, are encouraged.

The overarching vision of this ROA is to (1) engage organizations, networks, and researchers that are firmly connected to, actively working with, and/or embedded in communities with maternal health disparities, and (2) provide funding for the conduct of early-phase studies of community-engaged research to test implementation strategies related to the adoption, integration, scale up, and sustainability of implementation of interventions known to improve the health of birthing

people of reproductive age. **IMPROVE-CIP coalitions are expected to work collaboratively with other coalitions and as appropriate with additional IMPROVE programs.** This includes but is not limited to working with the IMPROVE Centers of Excellence, IMPROVE Implementation Science Hub, and the IMPROVE Data Innovation and Coordinating Hub. Coalitions should anticipate a set of common data elements and/or common outcome measures may be expected from all projects.

Implementation of evidence-based interventions

Areas of interest include but are not limited to:

- Testing strategies for implementing effective, multiple evidence-based maternal health care practices (e.g., Alliance for Innovation on Maternal Health (AIM) patient safety bundles) within community settings, and health care models to address structural determinants of health and health disparities of complex patients, diverse systems of care, for at-risk, NIH-designated health disparity populations.
- Testing multi-level strategies for improved dissemination of evidence-based maternal health prevention, screening, early detection, and diagnostic interventions, as well as effective treatments, clinical procedures, or dissemination of culturally tailored evidence-based guidelines into existing health care systems.
- Testing strategies to incorporate community-identified needs and patient reported outcomes (PROs) and patient preference information (PPI) of pre-pregnancy, pregnant, and post-partum individuals in the design, implementation, and dissemination of pregnancy- and maternal health care-related practices.
- Implementation studies addressing different components of the health care models (e.g., health care system organization, clinician decision support, clinical information system, patient self-management support, delivery system design) which may include care coordination and linkage to treatment/services (e.g., behavioral health, Substance Use Disorders, mental health).”
- Testing strategies that target organizational structure, climate, culture, and processes to enable dissemination and implementation of clinical/public health information and effective interventions to improve maternal health and maternal health equity and reduce structural racism and discrimination among high-risk populations.
- Development and testing of dissemination and implementation strategies to improve maternal health and outcomes that are risk-specific for NIH-designated U.S. HDPs, which currently include Blacks/African Americans, Hispanics/Latinos, American Indians/Alaska Natives, Asian Americans, Native Hawaiians and other Pacific Islanders, socioeconomically disadvantaged populations, underserved rural populations, and sexual and gender minorities (<https://www.nimhd.nih.gov/about/overview/>).

Examples of evidence-based interventions include:

Implementation of any evidence-based intervention must be done in close partnership with the community and incorporate the needs, preferences, and cultural norms of the community in which the intervention is being delivered. This list is not exhaustive, but meant to illustrate some examples which could also include individual level, family or community level interventions.

- Pre-pregnancy counseling:
<https://www.acog.org/clinical/clinical-guidance/committee->

[opinion/articles/2019/01/prepregnancy-counseling](https://www.aafp.org/about/policies/all/preconception-care.html)

- Pre-pregnancy healthcare:
<https://www.aafp.org/about/policies/all/preconception-care.html>
- Screening for gestational diabetes:
<https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/gestational-diabetes-mellitus-screening>
- Screening and prevention of preeclampsia:
<https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/low-dose-aspirin-use-for-the-prevention-of-morbidity-and-mortality-from-preeclampsia-preventive-medication> and
<https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/preeclampsia-screening>
- Achieving optimal health in modifiable risk factors (e.g., weight management, smoking cessation): <https://www.nap.edu/catalog/12584/weight-gain-during-pregnancy-reexamining-the-guidelines>,
https://journals.lww.com/greenjournal/Fulltext/2013/01000/Committee_Opinion_No_548_Weight_Gain_During.47.aspx, and
<https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/tobacco-use-in-adults-and-pregnant-women-counseling-and-interventions>
- Antihypertensive therapy for mild chronic hypertension in pregnancy:
<https://www.acog.org/clinical/clinical-guidance/practice-advisory/articles/2022/04/clinical-guidance-for-the-integration-of-the-findings-of-the-chronic-hypertension-and-pregnancy-chap-study>
https://www.sfm.org/publications/439-smfm-statement-antihypertensive-therapy-for-mild-chronic-2-hypertension-in-pregnancy-the-chap-trial?fbclid=IwAR07cIW9QePMF6v_IJgkmoFJ5dShBFUy1viaaNZW315g6tMQ-fVH8XhAZ54
- Appropriate use of safety bundles (e.g., Alliance for Innovation on Maternal health patient safety bundles):
<https://safehealthcareforeverywoman.org/council/patient-safety-bundles/maternal-safety-bundles/>
- Stress management in low-income pregnant women:
<https://www.sciencedirect.com/science/article/abs/pii/S0306453018308552?via%3Dihub>
- Rheumatic and Musculoskeletal Conditions
<https://www.rheumatology.org/Portals/0/Files/Reproductive-Health-Guideline-Final-2020.pdf>
- Pharmacotherapies for Opioid Use Disorder
<https://www.cdc.gov/pregnancy/opioids/treatment.html>

Other subject areas such as kidney disease, substance abuse and overdose are welcome and encouraged. It is incumbent on the applicant to demonstrate the subject area and corresponding intervention(s) have sufficient evidence to improve maternal health and are ready move to implementation.

Applications should not propose studies that are duplicative of implementation science projects funded by other federal agencies such as HRSA, AHRQ, and CDC.

Key Considerations

Collaborative Research. Given the range of expertise that may be needed for conducting dissemination and implementation research, applicants are encouraged to leverage multidisciplinary teams of scientists and stakeholders.

Community Engagement. Investigators proposing implementation projects must engage community partners at the onset and throughout the project who can successfully partner, advise, and provide feedback to implementation strategy development and testing teams. This type of involvement must include advice from the community, partnership in research, and shared leadership.

All projects are encouraged to leverage existing resources and expand community partnerships (e.g., Tribal governments and agencies, academic, private, safety-net health systems, other health systems, grassroots organizations, public health departments, community and faith-based organizations, and schools or childcare settings) to complete the study aims. Approaches such as team science, community-engaged research, participatory action research, and related approaches may be used to engage stakeholders and underserved populations throughout the research process. Study budgets should include funds for the community partners to be fully engaged and successfully participate in research design and implementation.

Key characteristics of dissemination and implementation (D&I) research:

- Consider and characterize the multi-level context and environment in which the proposed research will be conducted.
- Develop and/or use appropriate D&I related outcomes, measures, and analyses. Applicants are encouraged to review available resources and use standard measures and validated instruments where possible, rather than developing their own measures for each study.
- Incorporate outcomes relevant to patients, consumers, families, practitioners, administrators, and/or policymakers as applicable.

All applications must address how the proposed research impacts maternal health in HDPs and how it may contribute to achieving maternal health equity. Studies that examine or address multiple levels and domains of influence affecting maternal health, care, and access are strongly encouraged. (See the NIMHD research framework: <https://www.nimhd.nih.gov/about/overview/research-framework/nimhd-framework.html> as an example). Projects are expected to incorporate research strategies to address individual and structural factors (<https://health.gov/healthypeople/objectives-and-data/social-determinants-health>) that present barriers to adequate and timely health care.

To accelerate research, NIH encourages investigators to leverage ongoing significant investments made on domestic resources, cohorts, and research infrastructure studying pregnant individuals. NIH expects that investigators supported through this ROA will share their findings, approaches, methods and results including with the other anticipated new NIH initiatives established under [IMPROVE](#) to advance maternal health and maternal health equity and ultimately contribute to reducing MM and SMM. Indeed, results and lessons learned from the coalitions funded under this ROA could potentially help inform and shape the execution of other new IMPROVE initiatives, including the IMPROVE [Centers of Excellence in Maternal Health Research](#).

The NHLBI, on behalf of the NIH Maternal Morbidity and Mortality Task Force (MMTF), is soliciting applications to award several (approximately 4) coalitions under Phase I of IMPROVE-CIP. These implementation science research coalitions (RCs) are envisioned to be comprised of community-based entities [including but not limited to, academic institutions, community-based health systems including Federally Qualified Health Centers (FQHCs), Indian Health Services (IHS) clinics, community primary care centers or networks, community-based participatory research centers, faith-based organizations, and other community-based organizations] that will work together to develop approaches for testing implementation strategies to address maternal health disparities within their communities. It is expected that disproportionately impacted communities will vary in terms of the causes and potential solutions to the maternal health disparities. The implementation strategies for uptake of evidence-based interventions must be developed in close coordination with community partners.

Additionally, RCs selected for Phase I should expect that there will be some harmonization of a minimal set of common data elements and at least one shared outcome measure even if the individual projects are not powered on that outcome measure. RCs selected for Phase I will be expected to work closely with the Westat Administrative Coordinating Center ([ACC](#)), a component of the Community Engagement Technical Assistance Center (CETAC) other transaction authority agreement, as sub-OT awardees.

The purpose of this Research Opportunity Announcement (ROA) is to support the preliminary work necessary to demonstrate the readiness and capacity of RCs to undertake investigations of community-informed and community-engaged implementation strategies focused on prevention and reduction of disparities in maternal morbidity and mortality. *The preliminary work (Phase I, under this award) entails mobilizing research teams and community partners with existing and relevant expertise to complete all of the following activities specifically focused on disparities in maternal morbidity and mortality:*

- Community-informed assessments including:
 - Needs Assessment to demonstrate unmet need in the community.
 - Community Priorities Assessment to align evidence-based interventions with what is most important to the community.
 - Asset Maps that provide a landscape analysis of existing community resources which can be leveraged to address MM/SMM.
- Identification of opportunities and barriers to acceptance, delivery, uptake of, and adherence to evidence-based interventions and practices to address maternal morbidity and mortality.

Definitions

For the purpose of this ROA, note the following definitions.

“**Structural discrimination**” refers to macro-level conditions (e.g., residential segregation) that limit opportunities, resources, and well-being of less privileged groups (Healthy People 2020, <https://www.healthypeople.gov/2020/topics-objectives/topic/social-determinants-health/interventions-resources/discrimination>).

“**Structural racism and discrimination (SRD)**” refers to structural discrimination on the basis of race/ethnicity and/or other statuses, including but not limited to gender, sexual orientation, gender identity, disability status, social class or socioeconomic status, religion, national origin,

immigration status, limited English proficiency, or physical characteristics or health conditions. <https://grants.nih.gov/grants/guide/rfa-files/rfa-md-21-004.html>

“**NIH-designated Populations with Health Disparities**” (HDPs) refers to racial and ethnic minorities, socioeconomically disadvantaged populations, underserved rural populations, and sexual and gender minorities in the U.S. (see <https://www.nimhd.nih.gov/about/overview/>). Health NIH-designated U.S. health disparity populations include Blacks/African Americans, Hispanics/Latinos, American Indians/Alaska Natives, Asian Americans, Native Hawaiians and other Pacific Islanders, socioeconomically disadvantaged populations, underserved rural populations, and sexual and gender minorities^{7,8}. This initiative also targets populations disproportionately impacted by maternal mortality including very young individuals, individuals of advanced maternal age, and individuals with disabilities.

“**Health care models**” refers to the different existing or newly proposed models of patient-centered care. Examples of existing health care models include the Chronic Care Model, the eHealth Enhanced Chronic Care Model, the Community-Based Transition Model, the Nurse Management Model, the Home-Based Model, the Integrated Delivery Systems Model, the Patient-Centered Model and the Value-Based Care Models.

“**Multi-level**” refers to the multi-dimensional framework of determinants relevant to understand minority health and address health disparities. This concept is further described under the NIMHD Research Framework (<https://www.nimhd.nih.gov/about/overview/research-framework/>).

“**Dissemination research**” is defined as the scientific study of targeted distribution of information and intervention materials to a specific public health or clinical practice audience. The intent is to understand how best to communicate and integrate knowledge and the associated evidence-based interventions. Gaps include missing critical information about how, when, by whom, and under what circumstances evidence spreads throughout communities, organizations, front line workers, and consumers of public health and clinical services.

“**Implementation research**” is defined as the scientific study of the use of strategies to adopt and integrate evidence-based health interventions into clinical and community settings to improve individual outcomes and benefit population health. Implementation research seeks to understand the behavior of practitioners and support staff, organizations, consumers and family members, and policymakers in context as key influences on the adoption, implementation, and sustainability of evidence-based health interventions and guidelines (e.g., Community Guide to Preventive Services, U.S. Preventive Services Task Force, and clinical and professional societies' recommendations and guidelines).

For additional resources on dissemination and implementation research, including information on D&I training opportunities, funded studies, key references, past workshops and conferences, visit:

<http://cancercontrol.cancer.gov/is/> and

<https://prevention.nih.gov/research-priorities/dissemination-implementation>.

For additional information on MM/SMM and the IMPROVE initiative at NIH, please visit:

<https://orwh.od.nih.gov/mmm-portal> and

<https://www.nih.gov/research-training/medical-research-initiatives/improve-initiative>.

⁷ <https://www.nimhd.nih.gov/about/overview/>

⁸ <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-19-139.html>

Scope

The RCs will leverage existing infrastructure and community partners and identify and develop promising community-engaged dissemination and implementation research in disproportionately impacted and underserved communities. The purpose is to set the stage for the conduct of future investigations to more definitively test implementation strategies for the delivery and uptake of evidence-based interventions, at both the individual and community levels. Interventions are expected to address areas known to impact MM/SMM before, during, or after pregnancy.

This ROA is not intended to replace traditional NIH research funding mechanisms (e.g., R01, R21). The Period of Performance of this initial phase (also referred to in this announcement as “Phase I”) is expected to last for 2 years from the notice of award. Availability of funds for full-scale testing of the most promising of these implementation strategies from the Phase I awardees will be considered at a later phase (Phase II), under a separate funding opportunity and subject to the availability of funds [*Note: Phase II is not to be proposed, budgeted for, or awarded under this Phase I funding announcement, except as described below in the Application Requirements/Evaluation Criteria section*].

Eligibility

Eligible applicants include, but are not limited to, domestic public or private entities, including academic institutions, community-based health systems including Federally Qualified Health Centers (FQHCs), Indian Health Services (IHS) clinics, community primary care centers or networks, community-based participatory research centers, faith-based organizations, and other community-based organizations, and tribal organizations. For-profit entities are not eligible to apply to this initiative, but may serve in a consultant role or be engaged as a contractor to eligible applicant entities. In these cases, the eligible applicant may use awarded funds from this initiative to pay a for-profit entity for services it receives in the conduct of its eligible work.

Applications are expected to:

- Include researchers with experience in implementation science, community- engaged research approaches, and health research activities with a demonstrated record of successful maternal morbidity and mortality research, particularly in populations experiencing maternal health disparities.
- To reflect collaborative efforts and shared leadership, individuals from community partners should be identified as Key Personnel including a description of their contributions to the project.
- Demonstrate an understanding of the potential barriers to testing implementation strategies within their defined health disparity communities.
- Have an established infrastructure in place to support the development, implementation, and evaluation of the proposed implementation strategies.
- Have an identified coalition/collaborative made up of a multidisciplinary group of researchers with specific expertise noted above, as well as clinicians, public health experts, community-based organization representatives, and local leaders, identified as partners in this effort to test promising strategies for implementation within their communities.
- Demonstrate a history of successful partnership efforts and/or research collaborations, that is reflective of shared leadership and shared resources, with at least two or more member organizations comprising the coalition, including a

description of relevant projects.

Application Responsiveness

Examples of projects that will be considered **responsive to this announcement include:**

- Studies that focus on communities which have a disproportionate burden of severe maternal morbidity and mortality.
- Proposals to plan studies that will test multiple potentially effective implementation strategies to improve uptake and adoption of evidence-based interventions.
- Proposals that include a broad research team of community engagement researchers and key community members, with at least one PI and/or key personnel from a non-academic institution, a community-based organization or other community partners.
- Proposals that focus on maternal health issues or contributors to these problems that are a priority for the community being studied.
- Proposals focused on testing implementing strategies for evidence-based interventions relevant to IMPROVE.

Examples of projects that will be considered **unresponsive to this announcement include:**

- Proposals that do not include a needs assessment study, community priorities assessment, and asset map.
- Proposals to test implementation of outdated guidelines or practices.
- Proposals to test implementation of interventions that are not evidence-based.
- Proposals to test efficacy of interventions. [Testing effectiveness of interventions is only allowed in the context of a Hybrid Type 2 or Type 3 Effectiveness-Implementation design⁹. Type 1 Hybrid designs are not responsive.]
- Studies to conduct research in a community without high burden of MM/SMM.
- Studies that are not focused on a health disparity population as defined above.
- Studies which do not include key personnel, and/or Co-Investigator or Multiple Principal Investigator from a community-based organization or community partner.

Application Requirements/Evaluation Criteria

The application should include the following:

- The identified target population and geographic region for its proposed project and a description of the maternal health disparity in this population.
- Data that demonstrate the need for the proposed project; the project must address needs not being adequately met by current resources, infrastructure and implementation tools.
- A description of the coalition/collaborative structure and members, including existing and potential new members. Coalitions are required to include academic partners/researchers who have conducted community engaged research within those communities.
- A Project Plan with goals and objectives for the proposed project that align with the

⁹ Curran, G. M., Bauer, M., Mittman, B., Pyne, J. M., & Stetler, C. (2012). Effectiveness-implementation hybrid designs: combining elements of clinical effectiveness and implementation research to enhance public health impact. *Medical care*, 50(3), 217–226. <https://doi.org/10.1097/MLR.0b013e3182408812>

initiative's goals and objectives; innovative approaches and the potential for sustainable strategies are desirable. The plan should propose a vision that clearly articulates how the approaches and findings from Phase I could be more fully tested in a potential Phase II at a later stage [as noted above, Phase II is not part of the funding of this current announcement].

- A plan to conduct a needs assessment, community priorities assessment, and asset map to identify barriers and facilitators to adoption of the evidence-based practice/intervention and to inform or refine proposed implementation strategies.
- A description of the evidence-based intervention(s) to be implemented within the community setting(s). Interventions may include programs, practices, processes, policies and guidelines.
- The proposed implementation strategies (systematic processes, methods or techniques to enhance adoption, acceptance, spread, adherence, and/or sustainability) to be tested within specific settings. Includes what the strategy intends to change; the level targeted (individuals, inner setting, outer setting, processes); and the proposed barriers and facilitators of adoption and implementation.¹⁰
- A plan for low health literacy and limited-English proficiency as it impacts implementation within the community identified.
- The underlying theoretical framework or model (e.g., Diffusion of Innovations, Consolidated Framework for Implementation Research; RE-AIM),¹¹ and a description of how implementation outcomes (e.g., feasibility, acceptability, fidelity, scalability, and the potential for sustainability) will be measured.
- The study design¹² proposed to test and evaluate the implementation strategies and allowing for community engagement throughout the project.
- Resources requested, including research lead(s) and other staff, and their roles.
- Letters of commitment from key coalition/collaborative members that demonstrate a clear understanding of their roles as key personnel and/or partners in this project.
- A milestone-driven project plan to accomplish the goals of the project, as per the SOM (below), including risk management for disasters and public health emergencies.

Statement of Objectives and Milestones (SOM)

The applicant's approach to achieving the following milestones will be described in the Project Plan and in the draft milestone-based workplan.

1. Project Management

The following project management activities are required:

- Develop a milestone-based workplan to be reviewed and potentially modified by the ACC, including proposed metrics of successful completion for each milestone.
- Participate in monthly teleconferences with the ACC and provide updates on status of milestone completion, including assessment of risks and challenges.
- Drawing on the workplan, as per direction by the ACC, compile and submit data and

¹⁰ Leeman et al. Beyond "implementation strategies": classifying the full range of strategies used in implementation science and practice. *Implementation Science* (2017) 12:125 Doi: 10.1186/s13012-017-0657-x

¹¹ <https://dissemination-implementation.org/>

¹² Brown CH, Curran G, Palinkas LA, et al. An overview of research and evaluation designs for dissemination and implementation. *Annual Rev of Public Health*. 2017; 38:1 –22. Doi: 10.1146/annurev-publhealth-031816-044215

benchmarks indicating achievement of the required key milestones; likely on a monthly basis to coincide with the monthly teleconferences with the ACC.

- Participate on the ACC Steering Committee (SC); assume at least two members participating in quarterly teleconference meetings.
- Participate in the convening of meetings of project partners as needed to accomplish the proposed project; e.g., patient advocacy groups involved in RCs may have the opportunity to participate in a sub-committee with other patient- or community-based organizations.
- Participate in data collection activities conducted by the ACC in support of the evaluation of the RCs, including a mid-course portfolio evaluation of overall project and individual RCs as well as a summative comprehensive evaluation. The evaluation may include a site visit from NIH and/or ACC staff to be conducted (either virtual or in-person).
- Data Sharing Plan: Consistent with achieving the goals of this program, the NIH expects that information such as collected data, technical protocols, and any other metadata collected under this ROA is to be deposited as appropriate into existing, publicly available data repositories that are easily accessible, and in machine readable format. Where appropriate, applicants should identify such repositories and plans for deposition. If applicants are proposing research within Indian Country or tribal communities, they must propose a data sharing plan that respects and enforces principles and practices of Tribal data sovereignty. The applicant is required to propose a data sharing plan that includes a description of how the Maternal Health Centers of Excellence will work with PD's/PI's and respect sovereignty-based data management and sharing requirements.

2. Study Design and Development

The following milestones are required to be completed during Phase I the award. Milestones may not be completed in Phase II (if awarded):

- Complete an acceptable community needs assessment, community priorities assessment and asset map.
- Identify and/or develop promising implementation strategies based on specific community needs and strengths.
- Refine and finalize Phase II study design, including recruitment/enrollment plan, data collection methods and measures, and analysis plans for quantitative and qualitative data.
- Identify potential barriers and mitigation plans related to achievement of the study aims within the specified community.
- Confirm the adequacy of study sample for Phase II.
- Apply for and obtain any required approvals (IRB, etc.) for Phase II.
- Finalize agreements pertaining to the execution of the initial work (e.g., letters of commitment, data use agreements, partnership agreements, etc.).

If pilot testing of implementation strategies and/or intervention refinement is planned during Phase I, the additional following milestones are required to be completed before the end of Phase I:

- Obtain IRB and other required approvals for Phase I testing.
- Implement early/pilot testing of identified implementation strategies and/or intervention refinement; collect and analyze pilot data on relevant outcomes including feasibility, acceptability, fidelity, scalability, and the potential for sustainability.

- Deliver report of results of the pilot test to the ACC intermittently upon request and at the close of the period of performance.

NIH Assumptions

- NIH assumes that the RCs will maintain key personnel with qualifications equivalent to those who were included in its final negotiated proposal throughout the duration of the award.
- NIH assumes the RCs will maintain fiduciary records in compliance with all appropriate professional standards and federal regulations (as applicable) and in such a format as can be accessed by the government for review at any time.
- NIH assumes that each RC will seek and obtain Institutional Review Board (IRB) approval at their local institution(s), as may be required, and provide evidence of approval to NIH and/or the ACC upon request. Applicants proposing human subjects' research must offer assurance that a Federal-wide Assurance (FWA) is in place.

Award and Selection Information

Awardees will be selected through an objective review process subject to NHLBI review and approval. Cost sharing is allowable and encouraged. The level of funding for any award(s) made will depend on the quality and scope of the proposals received and availability of funds. Agreements for awards will be negotiated and managed by the NHLBI-funded Westat CETAC with eligible entities whose proposals are determined through the review to be the most advantageous and provide the best value to the government.

The NHLBI, through Westat CETAC, reserves the right to:

- Select for negotiation all, some, one, or none of the proposals received in response to this ROA;
- Accept proposals in their entirety or to select only portions of proposals for award;
- Fund proposals in increments and/or with options for continued work at the end of one or more phases, which can consist of more than one milestone;
- Require proposers to coordinate and share data with the CETAC and with other research programs to be identified by the NHLBI;
- Request additional documentation (certifications, etc.); and remove proposers from award consideration should the parties fail to reach a finalized, fully executed agreement, or the proposer fails to provide requested additional information in a timely manner.

CETAC

Awardees of this funding opportunity are required to work as subawardees with Westat, Inc., NHLBI's awardee serving as the Community Engagement Technical Assistance Center (CETAC). The purpose of the CETAC is to provide overall administrative management, support, technical assistance, and community engagement resources to increase the capacity of the NIH funded community engagement research initiatives and programs and to ensure that the research teams can convene as an alliance to synergize and benefit from cross-learning. The CETAC will support IMPROVE-CIP research teams by assigning site liaisons to monitor workplan progress, identify challenges and gaps, and assist awardees to compile data using timely and low-burden submission processes.

Special Award Terms

The complete terms and conditions of each sub-OT award issued under this ROA are subject to

negotiation and will be contained in the Agreement entered between Westat (on behalf of NHLBI) and the IMPROVE-CIP awardee. This Special Award Terms section is provided for informational purposes only in order to provide prospective applicants with an understanding of key expectations and terms that may differ from traditional NIH award mechanisms.

Lower Tier Agreements

The IMPROVE-CIP awardee will be expected to issue sub-awards to entities identified in their proposals and approved by NHLBI under this ROA.

Payment Schedule

NHLBI funds issued under the sub-OT Agreement will be disbursed through Westat (CETAC) based upon submission of monthly progress report to the CETAC with demonstrated progress towards work-plan milestones as well as attendance at regularly scheduled CETAC Liaison meetings.

Milestone-Based Workplan

All IMPROVE-CIP research teams are required to submit a draft milestone-based workplan in response to this ROA. The workplan should include a description of operational milestones, completion criteria, and expected start and completion dates. An “Operational Milestone” is an objective, measurable event that is indicative of project progress occurring as proposed in the application. NHLBI, with the assistance of the CETAC, will review and approve the milestone-based work plan for inclusion in the sub-OT Agreement.

Quarterly Outcome Reporting

All IMPROVE-CIP teams will report on the following team outcomes to the ACC on a quarterly basis, as applicable to IMPROVE-CIP project activities.

- The number and basic demographic characteristics of participants engaged in each proposed activity to date.
- Outreach and ongoing collaboration activities with community partners
- Collect and submit common data elements to the ACC

Proposal Submission Process and Award Criteria

Required sections of the proposal (PROJECT PLAN, BIOSKETCHES, BUDGET, SITE AGREEMENT) will be submitted via the application page at www.MaternalHealthCIP.org. You must create a user account to upload your application. If you intend to submit a proposal, please create this account at least one business day in advance to ensure adequate time for your account to be activated. To create your account, please visit www.MaternalHealthCIP.org and click “Register.”

The PROJECT PLAN and BUDGET should clearly and fully demonstrate the proposer’s capabilities, knowledge, and experience, and the budget proposed to accomplish the SOM. Use the Budget Template available at www.MaternalHealthCIP.org to prepare the project budget. Additional information on requirements for these two sections is provided below.

BIOSKETCHES should be combined into a single PDF file and uploaded separately.

A draft SITE AGREEMENT has been developed to facilitate the award process and is available for download via the application page at www.MaternalHealthCIP.org. Please download and review this agreement and make any necessary edits as required by your institution. The agreement, with any tracked changes, should be uploaded separately.

All components should be uploaded in searchable PDF format, single spaced, with a font size of 11 or 12 point and font type of Arial or Times New Roman. Margins must be 1-inch wide (top, bottom, left, and right).

PROJECT PLAN. The project plan must include the following:

A. Understanding/need (3 page maximum; 15%)

This section describes the maternal health need, target population, and geographic region for its proposed IMPROVE CIP project, including data that demonstrate the need for the proposed project.

B. Investigative team and key personnel (4 page maximum per biosketch; 20%)

Proposers must demonstrate experience of key personnel, including community partners, supporting the planning and implementation of activities described in the SOM. Please describe staff who will be assigned to manage performance and supervise the work for each task and subtask (as appropriate), and identify the person who will serve as the primary logistical point of contact.

This section should also address the management/staffing plan, including how the proposer will provide the necessary project administration, organization, and staff to ensure quality control, compliance with SOM expectations, and necessary staffing adjustments. The applicant's experience with and approach to conflict resolution, consensus building, shared leadership, and bilateral engagement in similar community-based projects should be emphasized.

A biosketch (preferred) or CV is required for key personnel; each **must not exceed 4 pages** in length. The NIH will review these biosketches/CVs to evaluate whether the individuals possess the required experience to perform the specific tasks.

C. Technical approach/scientific plan (12 page maximum; 40%)

The proposer must explain the technical methods and approaches it will take in accomplishing the goals of the ROA, including a description of the proposed study design. The proposer must demonstrate its understanding of the SOM by clearly showing a grasp of the range and the complexity of the tasks and how each will be accomplished. Proposers should demonstrate a conceptual understanding of the challenges specific to the tasks in the SOM and suggestions for overcoming these.

D. Resources and Environment (no page limit; 15%)

In this section, the applicant should describe the resources available to the project and environment in which the activities will be performed.

E. Additional required components of Project Plan

- Draft detailed milestone-based workplan (**2 page maximum; 5%**)
- Description of Phase II potential (**1 page maximum; 5%**)

BUDGET. Please use the budget template to prepare your project budget. This template is available for download via the application page at www.MaternalHealthCIP.org. The budget should reflect the proposed milestone-based payment schedule and total cost proposed, accounting for cost share amounts offered by the applicant. If proposing F&A, include a negotiated federal rate approval. There is no page limit for the budget. Proposers shall assume an award term of up to 24 months.

The budget justification should be aligned with the goals and responsibilities outlined in the proposal. The budget justification should include the specific roles, responsibilities, and percent effort of personnel. Cost sharing is allowable and encouraged.

The direct costs, subcontract F&A (if any), and total costs for each year/partial year of the proposed project (funds and value of goods or services provided as cost share and by third-party contributors) must also be included. A statement about any proposed third-party support, the estimated commitment level, and possible contingency plans in the event that the cost share or third-party support is terminated during the research project should also be provided.

Applications must provide a realistic, fully justified budget and cost proposal for performing the work over a specified period of performance needed to accomplish project objectives. Provide the overall expected cost for each of the following categories:

- Personnel
 - Equipment
 - Travel
 - Subawards/subcontracts/consultants
 - Other direct costs
 - Total cost (with indirect costs included)
 - Proposed Cost Share contribution
- Plan for issuing timely payments to community partners. The plan should detail how processes may differ for different partner types/agreements.
 - Description of community partners, including partner type (such as public health departments, community service organizations, tribal organizations, academia, grassroots organizations, social service systems, health systems, safety-net clinics, schools, and other partners). Information on community partners should be provided in the following table format:

Partner Name	Agreement Type (e.g. consultant agreement, sub contract, MOU)	Partner Type (see examples above)	Brief Description of Role on Project	New or Established Partner	Included in Budget (Y/N)

Roles and Responsibilities

The IMPROVE-CIP Awardee will:

- Develop and address project specific milestones and anticipated outcomes of the proposed research.
- Collect metrics to demonstrate impact and outcomes throughout the project period of performance as well as the potential for sustainability beyond the project time frame.
- Provide representatives to participate in ACC Steering Committee meetings, Work Groups, Interest Groups and other ad-hoc meetings.
- Submit monthly and quarterly reports as requested by the ACC.
- Participate in monthly project monitoring meetings with the ACC.

The ACC (CETAC) will:

- Support IMPROVE-CIP awardees by monitoring workplan progress; identifying challenges and gaps and identifying resources to address challenges as appropriate.
- Provide technical assistance/support in evaluation, and communications.
- Provide scientific and logistical support to NHLBI and this project as a whole on emerging scientific needs related to these topics, including convening working groups and committees.
- Provide technical assistance/support in evaluation and communications to advance the milestone- driven phases of project execution for IMPROVE-CIP awardees.
- Oversee IMPROVE CIP sub-OT awards, including distribution of tranche funding tied to submission of monthly reports.
- Conduct an evaluation of the overall project and individual IMPROVE-CIP awardees.

NHLBI (NIH) will:

- Provide ultimate oversight, guidance, and monitoring of IMPROVE-CIP projects.

Submission and Contact Information

Submission in response to this ROA requires creating a user account and submitting a full and complete proposal using the Maternal Health Community Implementation Project (MH-CIP) website, www.MaternalHealthCIP.org.

Proposals received by **6 PM EDT on December 16, 2022** will be reviewed by February 17, 2023

Proposals received by **6 PM EDT on February 17, 2023** will be reviewed by April 14, 2023.

Proposals received after February 17, 2023 will be reviewed on an ad hoc basis.

Questions:

Financial and administrative questions should be addressed to Erynn Huff, JD, NHLBI Agreements Officer at: erynn.huff@nih.gov with a copy to: NHLBI_OTA@mail.nih.gov.

Technical questions should be addressed to Dave Clark, DrPH., NHLBI Scientific Program Director at Dave.Clark@nih.gov.