



*Implementing a Maternal
health and PRegnancy
Outcomes Vision for Everyone
(IMPROVE) Initiative*



National Institutes of Health

IMPROVE Community Implementation Program (IMPROVE-CIP): Pre-Application TA Webinar

November 16, 2022

Housekeeping

- You are muted upon entry
- Please add your questions to the chat
- We will answer questions as time allows at the end of this webinar
- A recording of the webinar, slides, and Frequently Asked Questions (FAQs) will be made available at www.maternalhealthcip.org.



Agenda

- Other Transaction Authority (OTA) Framework
- Overview of IMPROVE-CIP
 - Key points
 - Eligibility
 - Responsiveness
- Administrative Details
 - Application submission process
- Questions
- Concluding Remarks and Resources



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Other Transaction Authority (OTA) Framework

OTA Framework

*An Other Transaction Authority provides the NIH greater flexibility to identify and engage nontraditional research partners, to **engage traditional partners in new ways**, and negotiate terms and conditions that will **concentrate researchers' efforts, spur innovation, and facilitate collaborative problem solving.***



Defined in the negative

- Not a grant
- Not a contract
- Not a cooperative agreement



Defined in the positive

- Is an agreement between the government and a legal entity
- Is used primarily for R&D
- Is funded from the NIH or other HHS component



OTA Proposal Framework



• Proposal Formatting

- OTA review prioritizes content of proposal and focuses evaluation on requirements as outlined in the Research Opportunity Announcement (ROA).
- Responses should focus on addressing the requirements spelled out in the ROA; note that the format requirements do not limit you to requirements associated with a grant application (such as an R01).
- With this mechanism, if not otherwise specified, you have flexibility to make formatting decisions as long as the content requirements are addressed. For example, the key personnel requirement could be satisfied by submitting a standard NIH biosketch template, resume, or CV.



• Proposal Content

- The ROA provides guidance on what must be addressed by the proposal.
- Additional content in the proposal such as appendixes, or letters of support will not count towards page limits.



Frequently Asked Questions

- What statutory/regulatory/policy constraints apply to OTs?
- What other unique features of OTs should we take note of?



Submitting Additional Questions



For any questions related to the **OT mechanism or other administrative matters**, please reach out to Erynn Huff, JD, NHLBI Agreements Officer at erynn.huff@nih.gov

Copy NHLBI_OT@mail.nih.gov and MaternalHealthCIP@westat.com



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Overview of IMPROVE-CIP

Overview of IMPROVE-CIP

- IMPROVE-CIP is supported by the NIH IMPROVE (Implementing a Maternal health and PRegnancy Outcomes Vision for Everyone) Initiative
- **Purpose:**
 - To support the preliminary work necessary to demonstrate the readiness and capacity of Research Coalitions (RCs) to undertake investigations of community-informed and community-engaged implementation strategies focused on prevention and reduction of disparities in maternal morbidity and mortality.



Background: Implementation Science

- 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.



Background

- Research Opportunity Announcement (ROA) seeks applications that:
 - Propose implementation science projects to mitigate preventable maternal mortality, decrease severe maternal morbidity, and promote health equity.
 - **Use 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**
 - Ensure that existing evidence-based interventions promoting health before, during, and after pregnancy are being delivered, accepted, and utilized for all individuals.



IMPROVE-CIP Phase I

- Phase I
 - Is for conducting formative work
 - 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 in the Application Requirements/Evaluation Criteria section].



Phase I Scope

- 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.
- Interventions are expected to address areas known to impact MM/SMM before, during, or after pregnancy.
- 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.
- 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.



Phase I Work

- 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



Milestone Driven Workplan with ACC Oversight

- Develop a milestone-based workplan to be reviewed and potentially modified by the Administrative Coordinating Center (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 benchmarks indicating achievement of the required key milestones



Important Dates

- October 12, 2022: ROA Release
- November 16, 2022: Technical Assistance Webinar
- Application Receipt Date 1: 12/16/2022
- Application Receipt Date 2: 2/17/2023
- Application Receipt Date 3: Rolling



Eligibility IMPROVE-CIP (Applicants)

- 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.



Eligibility IMPROVE-CIP (Responsive Application)

- 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 nonacademic 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



Eligibility IMPROVE-CIP (Non-Responsive Application)

- Studies to conduct research in a community without high burden of severe maternal morbidity and mortality
- Studies that are not focused on a health disparity population.
- Studies which do not include key personnel, and/or Co-Investigator or Multiple Principal Investigator from a community-based organization or community partner.



Eligibility IMPROVE-CIP (Non-Responsive Application) continued...

- Proposals that do not include a needs assessment study, community priorities assessment, and asset map.
- Proposals to test implementation of outdated guidelines or practices or 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 design
 - Type 1 Hybrid designs are not responsive.



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Administrative Details

Application Due Dates

- **Due Dates**

- Rec'd by 6 PM EDT **December 16, 2022**: Reviewed by February 17, 2023
- Rec'd by 6 PM EDT **February 17, 2023**: Reviewed by April 14, 2023
- Rec'd after February 17, 2023: Reviewed on an ad hoc basis



Application Process

- Required sections should be submitted via the application page at www.MaternalHealthCIP.org.
- Create a user account to upload your application, at least one business day in advance to ensure time for account activation. To create your account, please visit www.MaternalHealthCIP.org and click “Register.”
- Use the Budget Template available at www.MaternalHealthCIP.org to prepare the project budget.
- A draft site/sub OT agreement is available for download via the application page at www.MaternalHealthCIP.org. 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.
- Biosketches should be combined into a single PDF file and uploaded separately.
- All components should be uploaded in searchable PDF format, single spaced, 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).



Review Criteria - Project Plan

- A. Understanding/need (3 page maximum; 15%)
- B. Investigative team and key personnel (4 page maximum per biosketch; 20%)
- C. Technical approach/scientific plan (12 page maximum; 40%)
- D. Resources and Environment (no page limit; 15%)
- E. Additional required components
 - Draft detailed milestone-based workplan (2 page maximum; 5%)
 - Description of Phase II potential (1 page maximum; 5%)

In addition to the Project Plan (A-E), applicants must also submit a **budget**



Budget

- Must use budget template available for download at: <http://www.maternalhealthcip.org/>
- Milestone-based payment schedule
- If proposing F&A, include NICRA
- Assume award term of 24 months
- No page limit



Budget

- **Expected Cost per Categories**

- Personnel
- Equipment
- Travel
- Subaward/subcontracts/consultants
- Other direct costs
- Total cost (with indirect costs included)
- Proposed cost share contribution

- **Budget Narrative**

- Cost categories
- Description of community partners, plan for issuing timely payments to community partners, and detail how the plan differs for different partner types/arrangements (see community partner table provided in the ROA)



Resources

- To view the ROA:
 - www.nhlbi.nih.gov
 - www.maternalhealthcip.org
- A recording of the webinar will be available along with Frequently Asked Questions (FAQs) at www.maternalhealthcip.org.



Submitting Additional Questions



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Questions