TCC for Health Disparities Research
Pilot Project Program
Frequently Asked Questions (FAQs)

Q: What are the ideal attributes of a strong pilot project proposal?

A: Pilot project proposals must demonstrate collaboration; scientific merit; solid policy relevance; high potential for policy impact; scalability; sustainability; and potential to obtain future funding.

Q: What is the purpose of the Letter of Intent (LOI), and am I required to submit one?

A: The LOI is an opportunity to formally present your project's purpose, specific aims, and research plan (or activities) in order to obtain feedback before submitting a full proposal. The LOI allows us to assess the merits of prospective proposals and assist applicants in strengthening their final proposals. LOIs are not required; however, they are strongly recommended.

Please also note that following the LOI deadline (Monday, December 21, 2015) we are unable to respond to any requests to review proposal drafts, summaries, abstracts, or proposal sections prior to submission. After the LOI deadline we will only respond to questions related to the completion of application materials.

Q: Where, or to whom should I direct my questions as I prepare my application?

A: There are several ways to get your questions answered. We encourage you to submit questions through the Pilot Project Portal located at http://www.msmtcc.org/pilot. Please allow up to 48 hours for a response. Also, we will be answering questions during the Technical Assistance webinar hosted on Wednesday, February 10, 2016 at 1:00 pm EST.

Q: What documents need to be submitted to complete my application?

A: You must complete the NIH SF424 (R&R) application packet. In addition to completing the required form fields, you must attach all corresponding documents (in PDF). The following sections constitute a complete SF424:
   a. SF 424 (R&R) Form
   b. PHS 398 Research Plan
   c. PHS 398 Cover Page Supplement
   d. Research and Related Senior/Key Person Profile
   e. Research and Related Other Project Information
   f. Project/Performance Site Locations
   g. Research & Related Budget
   h. R&R Subaward Budget (if applicable)

i. Planned Enrollment Report

The following documents will be submitted under "Additional Requirements"
- Data Safety Monitoring Plan
- Indirect Cost Agreement documentation
- CITI Certifications, or equivalent
- Organizational status documentation (e.g. 501 (c) 3)

If your application is recommended for funding, you will be asked to submit additional items to prepare your application for NIMHD review and final approval. These items may include, but are not limited to:
- Federalwide Assurance (FWA) Number
- IRB letter of record
- IRB approval notice

All application components must be completed before your application is submitted to NIMHD for review and final approval. **Therefore, we STRONGLY recommend you start the FWA and IRB processes as early as possible to prevent administrative delays and expedite the review process**. Please consult the [pilot project application checklist](#) for reference.

Q: What expenses are allowed?

A: The following expenses are allowable under the Pilot Project mechanism:
- *Personnel:* Salary support and fringe benefits for investigators and key personnel should not exceed 25% of total budget, unless approved in advance. Please include full name, role on project, base salary, FTE on the project (based on calendar-months), salary requested, fringe benefits, and total cost for all investigators. Indicate names, role on project, qualifications, and specific role on proposed project for each personnel in the budget justification page(s).
- *Consultant Costs:* Please include expenses associated with all consultants, collaborators, and other parties who will serve a role in the execution of the project (e.g. evaluators, statisticians, etc.). Please note that stipends are not allowable expenses; all consultants must be paid by invoicing fees for services provided. Provide full justifications for all consultants in the budget justification page.
- *Equipment:* Please include all durable equipment that is essential to the completion of the project scope of work. Items costing $5,000 or more shall be listed as "equipment" and are subject to approval.
- *Supplies:* Disposable office supplies, printing and copying, research related supplies, educational supplies, etc. Items costing below $5,000 or less shall be listed as "supplies".
- *Travel:* Mileage, transportation costs, and domestic travel when necessary to carry out the proposed research (please consider including travel expenses to attend the TCC Health Policy Research Summit in April 2016).
- *Inpatient/Outpatient Care Costs*: Care-related expenses directly related to carrying out the project scope of work.
- *Other Expenses*: Other allowable expenses necessary to carry out the project scope of work such as telephone service, survey costs, participant incentives, publication costs including reprints, development of policy briefs and other disseminable deliverables, etc.

Q: What budget items or expenses are NOT allowable?

A: The following expenses are NOT allowable:
- Secretarial/administrative personnel not directly tied to project scope of work (should be included in indirect costs).
- Student tuition and stipends
- Foreign travel, and travel not directly associated with the proposed project scope of work
- Rental or office/laboratory space
- Membership fees and dues
- Honoraria and travel expenses for visiting lecturers
- Per diem charges for hospital beds
- Purchasing and binding of periodicals and books
- Office and laboratory furniture

Q: I plan to apply for a Developmental Seed Award. Is it necessary to complete a six page narrative?

A: No. You are allotted up to six (6) pages maximum for both awards. We expect grantees to be **concise** yet thorough in writing their narrative sections. Please use your own discretion in determining the space needed to clearly describe your plans for the developmental seed award. If you feel that you can get your point across in less than six pages, please do so.

Q: Do I need to propose research activities to be eligible for the Developmental Seed Award?

A: No. The seed award is specifically designed to support faculty investigators and organizations' efforts to build capacity and carry out formative activities that will prepare them to develop a quality pilot research project proposal. These activities include, but are not limited to policy scans, brief needs assessments, environmental scans, research/policy training for key personnel, focus groups, brief surveys, etc. **Please note that all research activities involving human subjects will require IRB approval prior to final approval by NIMHD.** To determine whether or not your proposed activities qualify as "human subjects research" please access the NIH decision tree here.

Q: What information are you looking for in the PHS 398 Research Plan Section?

A: The following sections should be addressed in the Research Plan section found in the SF 424 application packet. Please adhere to the page limits provided.

- *Specific Aims (1 page limit):*
    - State the overarching goals for your proposed research project, and describe at least two specific aims to be achieved by the end of the project performance period.

- *Research Plan (6 pages limit)*
    - *Background and Significance:* Describe the community served by the pilot project and the community-identified health disparity, its causes and possible solutions. Also, describe the impact of the health problem in the community. This may include epidemiological or population surveillance data, findings from policy and environmental scans, findings from community needs assessments, and review

of relevant literature on the community and/or health disparity of interest. Explain how your proposed project will serve to further explore and/or address the health disparity in the community or settings identified.

- *Innovation:* Explain how your proposed project is innovative and makes a meaningful contribution to health policy research devoted to addressing health disparities and promoting health equity.

- *Preliminary Work:* Describe all previous work and formative research conducted that informs the proposed project, if any.

- *Experience, and Organizational Capacity:* Describe how the principal investigator and key personnel are qualified to carry out the proposed research, and how the organizations involved are strategically positioned to support the proposed research activities. Describe prior experience working with community-based organizations and/or academic institutions to effectively communicate the success of interventions utilizing high-impact, population-wide approaches that improve population health of those impacted by health disparities.

- *Research Strategy/Approach:* Describe in detail the project's specific population of interest, research approach/methods, data collection and management plan, statistical analysis and evaluation plan, dissemination and implementation plan, and timeline.

- *Anticipated community benefits and policy impacts:* Describe how the targeted community will benefit from the project, and how you anticipate the project will inform and influence health policy

Q: Can you please explain the Application Review Process in more detail?

A: There are generally two stages of the review process; Initial Application Review, and NIH Final Review.

Initial Application Review: Upon the submission deadline, all applications will be screened for eligibility and then assigned to the review team. A panel of experienced reviewers from diverse constituencies of the regional community will review all proposals. A multidisciplinary review committee will be drawn from among the consortium partners involved in the TCC. The pilot project co-directors will solicit additional reviewers from the pool of expertise across regional consortium.

Proposals will be carefully evaluated to determine scientific merit, relevance to the elimination of health disparities, and health policy and practice implications. The review process will follow the NIH peer- review format with at least three independent reviewers assigned to each application. Proposals will be scored using the NIH 9-point rating scale. For reference, please refer to the following links:

http://grants.nih.gov/Grants/peer_review_process.htm
https://www.youtube.com/watch?v=fBDxI6l4dOA.
http://grants.nih.gov/grants/peer/guidelines_general/scoring_system_and_procedure.pdf

After excluding individuals with potential conflicts of interest, expert reviewers will be assigned to review project proposals. Reviewers will score each proposal based on structured criteria and provide written critiques to substantiate their scores. The following criteria will be used:

- *Overall Impact:* Reviewers will provide an overall impact/priority score to reflect their assessment of the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved, in consideration of the following review criteria, and additional review criteria (as applicable for the project proposed)
- *Significance*: Does the project address an important problem or a critical barrier to progress in the field? If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?
- *Investigators*: Are the PD/PIs, collaborators, and other researchers well suited to the project? If Early Stage Investigators or New Investigators, or in the early stages of independent careers, do they have appropriate experience and training? If established, have they demonstrated an ongoing record of accomplishments that have advanced their field(s)? If the project is collaborative or multi-PD/PI, do the investigators have complementary and integrated expertise; are their leadership approach, governance and organizational structure appropriate for the project?
- *Innovation:* Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense? Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?
- *Approach:* Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Are potential problems, alternative strategies, and benchmarks for success presented? If the project is in the early stages of development, will the strategy establish feasibility and will particularly risky aspects be managed? If the project involves clinical research, are the plans for 1) protection of human subjects from research risks, and 2) inclusion of minorities and members of both sexes/genders, as well as the inclusion of children, justified in terms of the scientific goals and research strategy proposed?
- *Environment:* Will the scientific environment in which the work will be done contribute to the probability of success? Are the institutional support, equipment and other physical resources available to the investigators adequate for the project proposed? Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements?

Additional Review Criteria: As applicable for the project proposed, reviewers will evaluate the following additional items while determining scientific and technical merit and in providing an overall impact/priority score, but will not give separate scores for these items: Protections for Human Subjects; Inclusion of Women, Minorities, and Children; Vertebrate Animals; Biohazards Resubmission; Renewal; Revision

Additional Review Considerations: As applicable for the project proposed, reviewers will consider each of the following items, but will not give scores for these items and should not consider them in providing an overall impact/priority score: Applications from Foreign Organizations; Select Agent; Resource Sharing Plans; Budget and Period Support.

Following independent peer review, the review team will convene as a panel to discuss the merits of each application and generate a rank order list of applicants recommended for funding.

Applicants will receive decision letters indicating whether or not they have been recommended for funding no later than 45 business days following the applicant submission deadline. Decision letters will include reviewer scores and comments. **Please note: All proposals recommended for funding will be subject to NIMHD review and final approval prior to funds being disbursed.**

NIMHD Review and Approval: All prospective grantees recommended for funding must respond to all proposal and budget revisions requested by the Scientific Review Committee. In addition, prospective grantees must fulfill additional federal requirements before their proposals can be submitted and reviewed by NIMHD. These requirements include, but are not limited to:

- Federalwide Assurance (FWA) Number and supporting documentation
- Institutional Review Board (IRB) approval for research involving human subjects
- IRB Letter of Record
- HIPAA compliance certifications, if necessary

Dr. Divine Offoegbu, TCC Program Manager will assist all prospective grantees in securing these items in an expedient fashion. Please make all accommodations necessary to obtain and submit additional proposal items by Monday, May 16, 2015 at 5:00pm EST to prevent administrative delays. **We strongly suggest that you plan ahead to address the additional requirements prior to Monday, May 16th, 2015. Administrative delays may result in loss of recommendation status.**

Upon receiving proposal revisions and all supporting documentation, applications will be submitted to NIMHD for review and approval. Grantees will be notified of their final approval by e-mail.

Q: Do we receive the full balance of our award upon final approval and contract execution?

A: No. Our institution does not allow "up front" payments. To receive initial payment you will be asked to participate in an orientation webinar, complete a time-phased work plan, and submit your first invoice. Invoice processing generally occurs within 45 days. Subsequent payment(s) will be based on completion of key milestones and deliverables delineated in the time-phased work plan.

Q: Are Pilot Project Program awards renewable?

A: All approved grantees are funded for one year. Opportunities for pilot project renewals will be based on favorable progress towards project aims and availability of funds. Developmental seed award recipients are encouraged to apply for a pilot project award during the next TCC RFA cycle.

Q: Can you please share a detailed timeline of important events and dates for the Pilot Project Program?

A: Timeline is below. Please note that timeline is subject to change. Please check the TCC Pilot Project Portal regularly for updates at: **http://www.msmtcc.org/pilot**.

Date	Activity
Monday, November 16, 2015	Official release of 2015 Pilot Project RFA
Monday, December 21, 2015	Letter of Intent Due (optional)
Monday, January 4, 2016	LOI responses sent to applicants
Wednesday, February 10, 2016	Technical Assistance Webinar
Wednesday, February 24, 2016	**Proposal Submissions Due**
Wednesday, March 30, 2016	Scientific Review complete; decisions letters sent to applicants
Friday, May 20, 2016 (or earlier)	Prospective grantee proposals sent to NIH for final review
Monday, August 1, 2016 (or earlier)	Anticipated NIH approval date, execution of grantee contracts.

BEST OF LUCK IN COMPLETING YOUR LETTERS OF INTENT (LOI) AND APPLICATIONS!!!!!