Tropical Medicine Research Centers (TMRC) Network



Opportunity Fund 2023 Call for Submissions

Release Date: February 17, 2023

SUBMISSION AND REVIEW DATES

Call for Research Concept Release	February 17, 2023
Webinar for Opportunity Fund	February 23, 2023 (8am EST)
Deadline for Questions	March 8, 2023
Response to Questions Available	March 15, 2023
Research Concept Deadline	April 3, 2023
Research Concept Presentations to the	June 20, 2023
Scientific Advisory Group	June 26, 2023
Distribution of Invitation for Full White Paper for Selected Applications	June 30, 2023
Deadline for Full White Paper Application	August 28, 2023
Notification of Award	September 18, 2023

Call for Research Concepts 2023: Synopsis

The TMRC Network Opportunity Fund supports, trains, and mentors the next generation of neglected tropical disease (NTD) researchers. This program will help develop capacity for NTD research around the world.

The Opportunity Fund is meant to leverage the expertise, established field sites, specimens and data collected by the TMRCs to expand up the currently funded TMRC project and/or conduct pilot studies which will provide preliminary data to develop future larger grant applications. The scope of research will be limited to the NTD that is being study at the collaborating TMRC for this submission.

https://tmrc-network.org/opportunity-fund

tmrc-info@rti.org

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1. Opportunity Fund Overview

1.1 Background

The Tropical Medicine Research Centers Network (TMRC Network) is made up of 7 geographically diverse Research Centers (RCs) where NTDs are critical public health concerns and a Coordinating Center (CC)The TMRCs are intended to advance NIAID's global research effort by targeting research endeavors to: a) develop novel diagnostic, prevention and therapeutic strategies adapted for the unique needs of low and middle-income countries (LMICs), as classified by the World Bank; b) create and sustain incountry research capacity; c) stimulate scientific collaboration and global partnerships; and c) facilitate sample sharing to support translational research to develop or evaluate new drugs, diagnostics, vaccines, and/or vector control strategies. For more information about the TMRC Network, please visit its website (https://tmrc-network.org/). For more information on the neglected tropical diseases being studied as part of the TMRC Network, please visit the NTD page on the website (https://tmrc-network.org/). For more information on the website (https://tmrc-network.org/). For mo

Current TMRC Research Centers

- <u>Philippines TMRC:</u> Biomarkers for Risk for Progression of S. Japonicum Associated Hepatic Fibrosis with Point of Care Test Development
 - Rhode Island Hospital Center for International Health Research at Brown University, USA
- <u>Ethiopia, Kenya, Sudan TMRC:</u> Ecotypes Driving Transmission and Pathogenesis of VL and PKDL in Eastern Africa
 - Ohio State University, USA
- <u>Peru TMRC:</u> One-Health Approach to Study Human Fasciola Hepatica Transmission and Inform Strategic Control
 - University of Texas Medical Branch, Galveston, USA
- Brazil TMRC: Sao Paulo-Minas Gerais Center for Chagas Disease Treatment (SaMi-Trop)
 - o Fundacao Faculdade de Medicina, Brazil
- Vietnam TMRC: Tropical Medicine Research Center for Talaromycosis in Vietnam
 - Duke University, USA
- <u>Uganda TMRC</u>: Uganda Schistosomiasis Multidisciplinary Research Centre (U-SMRC)
 - o Uganda Virus Research Institute (UVRI), Uganda
- <u>India TMRC (Pending award):</u> Changing the Landscape of Soil Transmitted Helminths in India using a One Health Approach
 - Christian Medical College Vellore, India

TMRC Coordinating Center

The TMRC Coordinating Center (TMRC CC), led by RTI International, serves as the operational hub for the TMRC Network and supports administration of the Opportunity Fund.

1.2 Objectives and Research Priorities

The TMRC Network Opportunity Fund supports, trains, and mentors the next generation of NTD researchers. The Opportunity Fund is meant to leverage the expertise, established field sites, specimens and data collected by the TMRCs to conduct pilot studies which will provide preliminary data to develop future larger grant applications. The scope of research will be limited to the NTD that is being studied at the collaborating TMRC for each submission.

Examples of types of research this program would consider include the following:

- Retrospective study using already captured clinical data (secondary human subjects research) or other experimental data for publication.
- Behavioral/social science studies on unique aspects of a particular cohort that are nested within a parent study.
- Characterizing pathogens or pathogen diversity from previously collected animal or vector specimens.
- Purchasing reagents or lab equipment to conduct additional analyses on existing, stored specimens.
- Supporting study results dissemination and manuscript publication.

Human Subjects Research:

- This program is not designed to support submission of new human subjects research, given the length of time required to receive Institutional Review Board (IRB) approval for new studies. Nor does this program support clinical trials. However, human subjects research is allowed within a limited scope, including research applications nested within a parent study with an IRB approval already in place and requiring only an amendment for the additional sub-study. Research involving stored specimens from human subjects is allowed provided the specimens are deidentified and cannot be linked back to the subjects.
- As part of the Application, see detailed instructions on page 8.
- For more information on human subjects research, please visit the National Institutes of Health (NIH) website: https://grants.nih.gov/policy/humansubjects.htm.

This program will not fund:

- Human subjects research requiring a new IRB approval (rather than a modification of an existing IRB approval).
- Clinical trials: Please see this website for more information on the definition of clinical trials (https://grants.nih.gov/policy/clinical-trials/definition.htm).
- Animal study requiring a new IACUC approval (rather than modification of an existing IACUC approval).
- Other areas outside of funding priorities include specific HIV/AIDS-only and other topics not within scope of the TMRC Network (e.g., brain disorders, addiction).
- Research that falls within the categories of United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern
 (https://www.phe.gov/s3/dualuse/Pages/InstitutionalOversight.aspx) or within the United States Department of Health and Human Services Framework for Guiding Funding Decisions about Proposed Research Involving Enhanced Potential Pandemic Pathogens (HHS P3CO Framework) (https://www.phe.gov/s3/dualuse/Pages/p3co.aspx).
- Conduct/attendance of workshops or trainings.
- Salary supplement.

1.3 Eligibility

The TMRC Opportunity Fund is designed for researchers who are in the early stage of their careers, including applicants from lower- and middle-income countries (LMICs) who are poised to lead research

studies and postdoctoral fellows and investigators who fit within the NIH definition of New Investigator. Submissions will be completed by the TMRC Research Center (each center may submit only one application) with the named investigator being an existing collaborator on the TMRC's currently funded project.

Both international and U.S. (domestic) researchers are eligible to apply. Candidates from high-income countries must have a clinical or research doctorate (including PhD, MD, DO, DVM, ScD, DNS, PharmD, or equivalent doctoral degrees), and LMIC candidates must have at least a master's degree or equivalent and 4+ years of relevant research experience, with some exceptions.

Each submission is limited to two performance sites for their project.

1.4 TMRC Engagement

<u>Submissions will be completed by the primary TMRC that is currently funded. Each center may submit only one application.</u> TMRCs are encouraged to consider diversity, equity, and inclusion goals in their selection of applicants to move forward.

The application process is considered part of the capacity-building process for applicants. As a result, TMRCs are expected to work closely with selected applicants on their application package to provide support on grantsmanship, biostatistics, and other application needs.

<u>As part of the submission</u>, each applicant must include a Letter of Collaboration from the affiliated TMRC. The Letter of Collaboration must address the following questions:

- Does this applicant and their proposed research study build the capacity at the Research Site for the TMRC?
- How will the TMRC contribute to the development and success of the applicant?
- Will the proposed research study allow the applicant to expand their skill set?
- Will the proposed research study lead to a conference abstract or publication?
- What is the long-term vision of the applicant as it relates to TMRC research priorities, in-country research needs and capacity, or other?

1.5 Funding

Awards will be made to the institution managing the award in the applicant's name. These will be subawards made by RTI International as part of its prime TMRC CC NIAID award. Budget requests need to reflect the actual needs of the proposed project. If two applicants apply as Co-PIs, if selected, their institutions would each receive a subaward, with the total funding for the combined award across both institutions not exceeding \$20,000.

Туре	Period of Performance	Maximum Total Cost (Direct and Indirect)
Grant with milestones	12 months	\$10,000 USD

2. Application Process

All interested TMRC investigators are invited to attend an informational webinar about the Opportunity Fund application process. In summary, each TMRC will identify one early career investigator that they will work with to submit a research concept and associated presentation. The junior investigator will

present the concept to the TMRC Scientific Advisory Group (SAG) during a virtual meeting. Following review of the concept and presentation, selected investigators will be invited to submit a complete white paper and associated budget.

All concepts and white papers must include the following elements (as applicable) in the order listed below. Page limits are noted where applicable. Failure to include a required element may result in the application not being reviewed. All applications must be in English.

2.1 Informational Webinar

The TMRC CC will host an informational webinar on Zoom for interested TMRC applicants. The TMRC CC will use this live webinar to discuss the Opportunity Fund award process in detail and will include time for questions from participants. The webinar will be recorded and posted to the Opportunity Fund webpage on the TMRC website for those unable to participate in the live session. The TMRC CC will share a Zoom link to access the webinar.

Questions about the application process will be received until March 8, 2023, by email to tmrcinfo@rti.org. The TMRC CC will respond to the inquiry directly and post all questions and responses on the TMRC Network website (https://tmrc-network.org/opportunity-fund) by March 15, 2023.

2.2 Research Concept Submission

Each TMRC is invited to collaborate with an early-stage researcher to submit one Research Concept. The Research Concept should include:

- 1. Title
- 2. Investigator(s) names and institution
- 3. Affiliated TMRC
- 4. One to two paragraph description of the proposed research project
- 5. High level budget description (1 paragraph maximum)

At the time of Research Concept submission, the applicant must also submit a slide presentation of the concept. A template for the slide presentation will be made available on the Opportunity Fund webpage. The junior investigator will present the concept to the TMRC Scientific Advisory Group (SAG) during the virtual protocol review meetings, which will be scheduled for June 2023.

2.3 Application Format and Deadline

Only applicants invited by the SAG are eligible to submit a full application (white paper and budget). All white papers should be submitted as a single PDF file, except for the full budget and budget justification PDF form, which **should be a separate file.** All text should be in Calibri with a font size of no less than 11, with normal text spacing required. All margins should be at least one inch. Inclusion of URLs to

All final white papers must be submitted via email as a single PDF and separate budget with justification no later than 5:00 PM Eastern Time, Monday, August 7, 2023

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provide additional information is prohibited in all sections. All required templates will be available on the TMRC Network website: https://tmrc-network.org/opportunity-fund.

2.4 Full Application Submission Requirements

The full application consists of the following components.

Item	Description		
Application	Please be su	re to include information on the organization managing the funds for	
Cover Sheet	the award. The cover sheet includes an abstract that will be used for public		
(Template	announcements about the program.		
provided)			
Title and Table	Provide the title of the proposed project and a Table of Contents for the full		
of Contents	Application.		
Study Personnel	Demonstrate that the applicant PIs, collaborators, and other researchers are well		
(1-page limit)	suited to the project, and address how the study personnel will work together,		
	including roles and responsibilities for each team member.		
Specific Aims	Per the NIH {	grant format, include a Specific Aims section that summarizes the	
(0.5 page limit)	goals and objectives of your research project. Specific aims and objectives should		
	be clearly defined and sensibly tied to a definite research question. A clear		
	endpoint or set of endpoints should be tied to each objective. Please refer to		
	NIAID guidance on developing specific aims: https://www.niaid.nih.gov/grants-		
	<u>contracts/draft-specific-aims</u>		
Study Rationale		The project should address an area of need targeted by the TMRC	
		Network. All projects must be in line with the scientific mission of	
		the TMRC Network. Priorities specific to this Call for Submissions	
		are included in Section 1.2. See the TMRC website for more	
		information on each TMRC and the Network priorities	
		(https://tmrc-network.org/).	
	2-page	A successful application will describe how the proposed research	
	limit	meaningfully expands on existing research.	
Research	-	The overall strategy, methodology, statistical plan, and analyses	
Methods and		should be well reasoned and appropriate to accomplish the specific	
Approach		aims of the project. A sample size estimate must be included.	
''		Address how potential problems will be resolved, and include	
		benchmarks for success.	
Project Timeline	Investigators need to provide a detailed timeline for their project, including key		
(0.5-page limit)	milestones and activities over the course of the project. Project timelines should		
	consider the possibility of a delayed start due to US Government and regulatory		
	approvals taking significant time. Please consider the impact of a 1-3 month delay		
	in starting your project after the award date.		
Research	A description of all locations should be provided including how each proposed site		
Performance	contributes t	to the study and how the applicant will use these sites to complete	
Sites	the study protocol.		
(0.5-page limit)			

Item	Description
Human Subjects	Include a summary of the parent study and existing IRB approvals for the study.
Research	Please note that the proposed Opportunity Fund work should be covered by the
(1-page limit)	parent TMRC and no recruitment should occur as part of the Opportunity Fund
	award. Only samples and data already collected may be used or analyzed.
	All applicants proposing human subjects research, either exempt or non-exempt, should address the following elements on the Protection of Human Subjects: Risks to the subjects Adequacy of protection against these risks Potential benefits of the research to the subjects and others Importance of the knowledge gained or to be gained Country- / institution-specific ethics / IRB regulations addressed
	For more information on human subjects research, please visit the NIH website: https://grants.nih.gov/policy/humansubjects.htm and Office for Human Research Protections website: https://www.hhs.gov/ohrp/regulations-and-policy/index.html .
	The collaborating TMRC partner should provide additional guidance/support as needed to help applicants navigate this topic.
Research and	If applicable, complete the R&R Other Project Information Form. This form
Other Related	includes questions on use of human subjects, vertebrate animals, and
Project	environmental impact. For guidance on completing the form, please see G.220 -
Information	R&R Other Project Information Form (https://grants.nih.gov/grants/how-to-
(Template	apply-application-guide/forms-e/general/g.220-r&r-other-project-information-
provided)	<u>form.htm</u>).
Research and Related Budget	A full budget, with total costs of no more than \$10,000, must be submitted on the budget form available on the TMRC Network website.
and Budget Justification (Template	 A budget justification which describes direct costs necessary to complete the project must be included here. The budget should reflect direct and indirect costs for the 1-year period of award.
provided)	Foreign institutions should use 8% as the standard indirect rate.
	Because Opportunity Fund is available as a subaward of the prime TMRC CC
Download the	NIAID award, all subawards will be subject to the same policies and restrictions
budget template	as the award for the TMRC CC.
from the TMRC	If your institution does not have adequate funds for a cost-reimbursement
website as it is a	award (with monthly invoicing) and requires pre-payment of funds during the
fillable form and cannot be viewed	award year, please note this in your budget justification and outline a payment
in a web	schedule that will function for your project.
browser.	
Supporting	Start each document on a new page with complete header information. Include
Documentation	only those components described within this Call for Applications; inclusion of
(Templates	items not requested may result in the removal of those items or administrative
provided:	withdrawal of the application.
provided.	withdrawar of the application.

Item Description Biosketch, Biographical Sketch and Other Support. All applications must include: Support) Applicant PI(s) Biographical Sketch (four-page limit) Applicant PI(s) Previous/Current/Pending Support (include funding amount from each support source – no page limit) Key Personnel Biographical Sketches (four-page limit each) Key Personnel Current/Pending Support (no page limit) Please see the NIH website for instructions on completing the Biosketch (https://grants.nih.gov/grants/forms/biosketch.htm) and Other Support form (https://grants.nih.gov/grants/forms/othersupport.htm). NOTE: The TMRC Pilot Program is using the new non-fellowship formats required for applications submitted after January 25, 2022. References Cited (no page limit): List the references cited in the Research Methods (including URLs or DOIs if available) using a standard reference format that includes the full citation (i.e., author[s], year published, title of reference, source of reference, volume, chapter, page numbers, and publisher, as appropriate). List of Abbreviations, Acronyms, and Symbols: Provide a list of all abbreviations, acronyms, and symbols used in the application. Facilities, Existing Equipment, and Other Resources (template provided): Describe the facilities and equipment available for performance of the proposed project and any additional facilities or equipment proposed for acquisition at no cost to the award. Describe how containment facilities are appropriate for the proposed research. Indicate whether Government-furnished facilities or equipment are proposed for use. If so, reference should be made to the original or present Government award under which the facilities or equipment items are now accountable. US Government Foreign Clearance Form (template provided). Applicants must complete the Foreign Clearance form. This form is required by the US Government to gain approval to conduct research at a foreign research site. If your research will be conducted in more than one foreign research site, please fill out a form for each site. Please ensure that the form is correctly filled out with the information about the institution overseeing the implementation of the award and administering the funds for the award, as well as correct information on human and/or vertebrate animal research. If the institution that will oversee the implementation of the award is different from the institution that will administer the funds and are located at separate foreign sites, please complete separate USG Foreign Clearance forms for each and identify their respective roles clearly. Letters of Organizational Support (one-page limit per letter): Provide a letter (or letters, if applicable), signed by the appropriate organization official, reflecting the institution's commitment to the completion of the study, including protected time of the applicant to complete the study, laboratory space, equipment, and other resources available for the project.

Item	Description
	Letter of Collaboration from TMRC PI (one-page limit per letter): Provide a signed
	letter from the collaborating TMRC contact PI that will demonstrate that the PI
	has the support or resources necessary for the proposed work. See Section 1.4 for
	questions the TMRC PI must address in the Letter of Collaboration.
	Submission Checklist: Application (template provided): Please complete and
	submit the submission checklist for the application. The checklist is intended to
	assist applicants to ensure that they submit a complete application package.

3. Research Concept and White Paper Review and Selection Process

3.1 Review Criteria

To determine scientific and technical merit, research concepts and subsequently full applications will be evaluated by the Scientific Advisory Group (SAG). The following criteria will be used in that evaluation. The research concept evaluations will focus on a high-level assessment of rational, significance, & impact as well as research strategy and feasibility.

3.1.1 Rational, Significance & Impact

- Does the project address a need or barrier to progress in the TMRC's primary objectives
- Is the proposed work achievable and will it advance scientific knowledge or technical capacity?
- Does the project fit within the TMRC's overall objectives or expertise?
- Is the TMRC guidance integrated into the project and are the roles and responsibilities between the applicant and the TMRC collaborators complementary?

3.1.2 Research Strategy and Feasibility

- Are the Specific Aims clearly defined and tied to the TMRC's research question(s)?
- Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project?
- Are the potential problems, alternative strategies, and benchmarks for success clearly laid out and sufficiently addressed?
- Is the study, as proposed, likely to be completed in the designated time period and with the available budget?
- Is the statistical plan appropriate for addressing the research questions, given the design of the study? Are the sample size calculations clearly described and is the proposed sample size adequate given the goals of the study? (white paper only)

3.1.3 Personnel

- Do the background and expertise of the PI(s) demonstrate their ability to perform the proposed work?
- Are the levels of effort by the PI(s) and other co-investigators appropriate to ensure the successful conduct of the project?

3.1.4 Environment

- Is the scientific environment appropriate for the proposed research?
- Are the facilities and resources adequate to support the research requirements?
- Are the quality and extent of organizational support appropriate for the proposed research?

3.1.5 Budget

- Is the budget appropriate for the proposed research and within the funding limitations?
- Is there sufficient level of effort for the PI to complete the research study as described?

3.1.6 Protection of Human Subjects

- If they have any participant-facing activities, does the applicant address issues of confidentiality, data management, participant risks, and compensation?
- Does the proposed work require additional IRB approval?

3.1.7 Inclusion of Women, Minorities, and Children

• If the study involves the use of human subjects samples / data, does the sample population involve all relevant populations?

3.2 Programmatic Review

The SAG will make funding recommendations to DMID using the following criteria:

- Evaluation of each concept and white paper based on criteria defined in Section 3.1
- Relevance to the mission of the TMRC Network, as evidenced by the following:
 - Relative impact
 - o Program portfolio composition
 - o Programmatic relevance
 - o Adherence to the intent of the award mechanism
- Availability of funds

Final selection of research awards will be made by DMID.

4. Opportunity Fund Awards

4.1 Award Process Overview

- Award Notification
- · First Quarterly/Kick-Off Meeting
- Subaward Negotiations (~1-3 months)
- Public Award Announcement
- Invoicing
- Data Sharing
- Reporting
- Citing TMRC Network in Scientific Publications

4.2 Award Notification Procedures

Successful applicants will be notified via email by the TMRC CC within the noted program timeline. Upon notice of award, applicants will be required to respond with their acceptance and intent to conduct proposed work within specified timeline.

4.3 U.S. Government Approvals and Foreign Clearance

U.S. Government approvals may be required prior to initiating the Opportunity Fund Award or establishing a subcontract for the award, depending on the scope of the proposed research.

• DMID is required to submit any project foreign components through internal USG systems for approval before awards can be initiated. Applicants submit the USG Foreign Clearance forms as

part of their applications. Awards that include foreign components are subject to U.S. State Department approval. <u>Foreign Clearance may take 1-3 months (or more)</u>, or additional time if <u>awardees require changing any submitted Foreign Clearance information</u>.

• The TMRC CC and/or NIAID may require additional documentation/information as it pertains to planned select agent research.

4.4 Regulatory Approvals and Documentation

4.4.1 Human Subjects Research

The RTI IRB defers oversight of any human subjects research funded by Opportunity Fund awards to the study IRB of record. An <u>IRB Authorization form</u> must be signed by the IRB of record and the RTI IRB before human subjects work can be initiated.

Opportunity Fund awardees must submit <u>all required regulatory documents and approvals</u> to the TMRC CC before funded research can be initiated and no later than 2 months after the award notice. This includes IRB approval, IACUC approval, study protocol, CITI certificates for key personnel, etc., as appropriate. A protocol template will be shared with awardees if needed. If the study has an international component, information on study location, site contacts, and FWA number (for human subjects' research) will be required. For more information on FWA, please see the U.S. Department of Health and Human Services website: https://www.hhs.gov/ohrp/register-irbs-and-obtain-fwas/fwas/index.html

4.5 Subaward Procedures

Once U.S. Government approval criteria and regulatory documentation are met, subawards will be made to each awardee by RTI International (on behalf of the TMRC CC) to the applicant's institution that is administering the funding. These will be subawards issued by RTI International from the prime TMRC CC NIAID award.

If your application is recommended for funding, subaward negotiations will be held between your institution that is managing the subaward and RTI International to establish the scope of the final project. All official negotiations of the budget, terms, and conditions of any resulting subaward will be conducted between the Business Official of your institution and the RTI Subcontracts Specialist. All subawards, and changes to all subawards that result in substantive changes to the budget, including major modifications of the awards and changes across cost categories, require approval from the TMRC CC and DMID.

4.6 Subaward Letters

If needed, RTI will issue initial subaward letters allowing for up to 10% of the total budget to be spent while full subaward negotiations take place, to allow awardees to initiate start-up activities.

4.7 Award Announcements

After a subaward has been executed between RTI and the TMRC, awarded studies will be featured on the TMRC Network website for the Opportunity Fund and through a network wide email. Announcements will include PI, home institution, collaborating TMRC, and a synopsis of the project, based on the application abstract.

4.8 Invoicing

The subaward documents include invoice instructions the awardee institutions can use to submit for payment. Payment schedules will be defined during the subaward negotiations, which may include prepayment, monthly invoicing, or quarterly invoicing.

The first invoice will require extra time for payment, especially for first-time awarded foreign institutions, as RTI accounting must conduct accounting set-up and ensure secure payment processing. Please plan accordingly and anticipate approximately one month processing time for first-time invoice payment.

4.9 Data Sharing

Sharing unpublished data among network collaborators is one of the core principles of the TMRC Network. Awardees are encouraged to work with their mentor and the TMRC CC to establish infrastructure for the sharing of data that is not or will not be made immediately publicly available. For more information about the NIH Data Management and Sharing Policy, which all TMRCs are required to adhere to, see the NIH Scientific Data Sharing website: https://sharing.nih.gov/data-management-and-sharing-policy-overview. ClinEpiDB is an open-access data analysis platform that is recommended by the TMRC Network for data sharing and exploration. Awardees can learn more about this platform via the TMRC Network website: https://tmrc-network.org/secure/clinepi-db.

4.10 Reporting

One interim progress report (6-month) and a final report (12-month) will be required by each awardee. The report template will be provided by the TMRC CC. In addition to written progress reports, oral presentations will be expected at the TMRC Network Annual Meeting and may be requested for Steering Committee meetings.

4.11 Citing TMRC in Scientific Products

Opportunity Fund awardees are required to cite the TMRC CC award number and the assigned Opportunity Fund subaward number in all scientific products resulting from the work funded through this program, including conference presentations and posters, peer-reviewed journal articles, and other scientific endeavors.