

MITS Surveillance Alliance MITS Mortality Surveillance Program Awards Request for Proposals

Letters of intent due to MITSAllianceGrants@rti.org by Friday, March 18, 2022, 6:30 pm U.S. Eastern Time (23:30 UTC)

Please email MITSAllianceGrants@rti.org with questions or for clarification by Friday, April 8, 2022

Proposals due to MITSAllianceGrants@rti.org by Friday, April 22, 2022, 6:30 pm U.S. Eastern Time (23:30 UTC)

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of-death (CoD) ascertainment.

High-quality, precise mortality data are important to understand the burden of disease and to inform innovation, health planning, and resource prioritization to improve health outcomes. Pathology-based mortality surveillance using Minimally Invasive Tissue Sampling (MITS) improves the accuracy of cause-

The MITS Surveillance Alliance builds on the work of the Barcelona Institute for Global Health (ISGlobal), and the Child Health and Mortality Prevention Surveillance (CHAMPS) and Country-wide Mortality Surveillance for Action (COMSA) platforms. The outcomes from the initial phase of the MITS Surveillance Alliance (2017-2021) included standardization of MITS procedures and creation of a global forum to share best practices and advance MITS-informed CoD classification. For more information on Phase I, please see the Clinical Infectious Diseases Supplement Minimally Invasive Tissue Sampling (MITS): Accurate Cause of Death Attribution and Surveillance in Low-Resource Settings¹.

The overarching goals of the second phase of the MITS Surveillance Alliance (2022-2025) are to accelerate MITS-informed CoD as a standard tool for mortality surveillance programs, and to ensure data quality across sites. MITS will improve the accuracy of CoD estimates obtained through surveillance systems and verbal autopsy (VA)-based programs to inform health policies and programming to better target efforts aimed at reducing mortality.

Based on the findings and progress made from the initial phase of the MITS Surveillance Alliance, Phase II will advance the incorporation of MITS into mortality surveillance programs in low- and middle-income countries (LMICs) in the next phase. The initiative will focus on identifying up to five surveillance sites that will incorporate MITS into existing mortality surveillance programs.

This Request for Proposals (RFP)outlines the selection criteria and expected terms of reference for this initiative.

2. Request for Letters of Intent (LOI) and Proposals

The goal of this funding is to build capacity, conduct and integrate MITS into mortality surveillance programs to provide improved data for routine decision-making. The objectives include:

- Identify sites with capacity and interest in integrating MITS into an existing mortality surveillance program to provide data for routine decision-making.
- Support existing mortality surveillance programs inclusion of reference MITS cases to calibrate verbal autopsy results.
- Standardize data collected to facilitate contributions to larger initiatives aimed at improving global CoD estimates through shared data repositories, such as a reference death archive.
- Promote sustainability through a requirement for mutual investment (e.g., cost sharing).
- Facilitate transition planning at sites to integrate the use of MITS reference cases into their mortality surveillance program beyond the life of the award.

In support of these objectives, the MITS Surveillance Alliance Secretariat requests letters of intent and proposals for project awards to incorporate MITS into existing mortality surveillance programs.

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¹ https://academic.oup.com/cid/issue/73/Supplement_5



3. Funding and Additional Support

The Secretariat will issue up to five (5) awards through this RFP process to qualifying institutions in the amount of \$300,000 USD per award. The period of performance will be 36 months from award, estimated to be July 1, 2022 – June 30, 2025.

Additional support provided by the Alliance includes:

- Documentation of the procedure to conduct MITS.
- Access to protocols, training materials, model consents, and procedures to implement MITS.
- Travel and per diem costs for theoretical and practical training.
- Up to 300 MITS kits customized to surveillance site program needs containing; biopsy
 needles, formalin jars for tissue samples, PPE, etc. to be used for sample collection. Kits for
 training and backup supplies in case of breakage will also be provided.
- Access to the MITS Alliance website and a web-based Quality Control (QC) process for interpretation of MITS.
- Assistance with data standardization and management.
- Assistance with the development of a CoD attribution process (e.g., panel).
- An invitation to participate in MITS Alliance Community of Practice and Technical Working Groups.
- An invitation for membership and attendance at the annual MITS Surveillance Alliance meeting.

4. Expectations and Minimum Eligibility Requirements

Expectations of Awardees include:

- Participation in MITS sample collection training (travel costs to be provided by the Secretariat, in addition to award).
- Implementation of community sensitization in MITS-naïve populations prior to performing MITS to increase acceptance of the procedure. If the applying institution doesn't have the required staff, it is expected that they have partnerships with organizations capable of supporting community sensitization and engagement.
- Verification that MITS kits have been utilized by logging MITS barcode information into website tracking system.
- Participation in quality assurance and quality control activities including use of the MITS Alliance QC portal and expert review.
- Compliance with data-sharing requirements (see minimum eligibility requirement) and sharing of deidentified data with publicly accessible global repositories.
- Commitment to utilizing common data elements and integrating core questions in mortality surveillance efforts per Secretariat guidance in the areas of MITS, including relevant clinical history and laboratory data.
- Use a standardized process for integrating MITS results and other information (e.g., clinical and laboratory data, verbal autopsy results) to assign immediate, underlying and contributing causes of death per the WHO International Form of Medical Certificate of CoD with Secretariat support.



- Development and commitment to a transition and sustainability plan to integrate MITS into the local standard mortality surveillance program after the award period.
- Participation in the MITS Alliance Community of Practice including Technical Working Groups.
- Participation in the annual MITS Surveillance Alliance meeting.
- Completion of a final report on findings.
- Compliance with the Bill & Melinda Gates Foundation Open Access Policy.

Minimum Eligibility Requirements

Successful awardees must:

- Demonstrate immediate access to a population with an ongoing, active mortality surveillance program
 in a low-and middle-income country (LMIC) and describe how MITS will be incorporated. The current
 mortality surveillance program may vary in size (e.g., district, regional, or other area) and scope (e.g.,
 population-wide or sub-population). It is expected that the MITS cases to be performed would be a
 sample of the deaths registered. Non-LMIC locations will be considered on a case-by-case basis with
 well documented needs and justification.
- Obtain required in-country approvals from the Ministry of Health or other relevant authorities.
- If the applying institution is not based in an LMIC, demonstrate (via Letters of Support) collaboration with partner institutions based in LMICs.
- Demonstrate that the target population has a sufficiently high mortality rate necessary to attain 10-15 MITS cases per month, considering acceptance rates.
- Be willing to comply with cost-sharing requirements of 20% of award (\$60,000 USD). Please see **Section 5** Cost-sharing and Award Payments (below).
- Obtain institutional approval to comply with data-sharing requirements and sign a Data Use Agreement (DUA): If you accept the grant, you agree to share deidentified data regarding cause of death ("CoD") (e.g., MITS data, verbal autopsy, and clinical and laboratory data supporting the CoD determination) for the purpose of secondary analysis. Shared data will be embargoed for a period of time so that project teams may publish their findings before the data is released for secondary analysis. A data sharing agreement will be made available once the data sharing plan is finalized and will be executed before any sharing of data. Before submitting your grant application, please ensure that you have obtained sufficient buy-in from your institution and relevant governance for the anticipated data sharing.
- Be legally registered to operate in the proposed country.
- Be directly responsible for the preparation and management of the surveillance site program, not acting as an intermediary/consultant.
- Be willing to comply with all technical and financial requirements for participation in the program, including reporting and documentation of MITS Kit use.
- Be able to obtain formal Institutional Review Board (IRB) or Ethics approval to conduct MITS in the selected population.
- Provide a letter of support from the applying institution indicating the ability to utilize facilities and staff to conduct MITS.
- Have the minimum requirements for MITS set-up and functioning in a LMIC setting (for facilities,



infrastructure, and equipment requirements, see Table 2 in the article *Building Capacity and Infrastructure at Hospitals Implementing Minimally Invasive Tissue Sampling: Experience and Lessons Learned from Nepal, Rwanda, and Tanzania*) ².

- Have access to histology facilities and equipment that are available and suitable to conduct
 histological sample processing, evaluation, and sample storage as required to achieve surveillance
 site program objectives.
- Have access to molecular microbiology laboratory facilities and equipment that are available and suitable to conduct molecular sample processing, analysis [polymerase chain reaction (PCR)], and sample storage needed for surveillance site program objectives
- Be willing to engage with local authorities and strengthen linkages with civil registration and vital statistics programs to improve mortality statistics. A memorandum of understanding or similar agreement with local authorities is not required but strongly encouraged following award.

5. Cost Sharing and Award Payments

Recipients will be required to participate in cost-sharing of 20% of award (\$60,000 USD). Allowable cost sharing (matching funds) are costs, such as staff salaries and equipment, that directly benefit the surveillance site program and could legitimately be charged to the award but instead are paid by the applying institute as a commitment to the surveillance site program. The MITS Alliance Secretariat may request documentation from the applying institute to verify the value of the shared costs. Please see **Appendix C**. for complete details and an example of 20% cost sharing.

The awards of \$300,000 USD will be paid in four installments upon completion of four milestones.

Table 1. Milestone Timeline and Payment Schedule

Milestone	Description of Milestone	Required Deliverable	Amount (USD)					
I	IRB Approval of the program	IRB Approval Letter	\$75,000					
2	Staff trained in MITS	Training certificate	\$75,000					
3	50% of MITS utilized	Documentation of MITS used and corresponding QC process complete	\$75,000					
4	Program completion report	Program completion report	\$75,000					
	Total \$ 300,000							

6. Application Process

To apply for these awards, an applicant must complete a two-step process that includes the submission of a Letter of Intent (LOI) followed by submission of a full proposal. See the below application and award timeline for further details.

² Table: https://academic.oup.com/view-large/323089998. in https://doi.org/10.1093/cid/ciab780



Table 2. Application and Award Timeline

Request for Proposals released	Monday, February 21, 2022
Letter of Intent (LOI) Due	Friday, March 18, 2022 6:30 pm U.S. Eastern Time (23:30 UTC)
Deadline to submit process or other clarifications to MITSAllianceGrants@rti.org *	Friday, April 8, 2022
Responses to questions posted on https://mitsalliance.org/	Friday, April 15, 2022
Proposals Due **	Friday, April 22, 2022 6:30 pm U.S. Eastern Time (23:30 UTC)
Applicants notified of award decision	Friday, May 13, 2022
Estimated start of award	July 1, 2022
MITS training and community sensitization	July - August, 2022
Estimated start of MITS cases	September, 2022
End of award period of performance	June 30, 2025

^{*} Questions may still be asked after this date, but the responses may not be included in the website post.

7. Letter of Intent (LOI) Submission Instructions

The first step in the application process is to complete a Letter of Intent (LOI), following the below instructions, describing the overall plan to integrate MITS into your site's current practices for CoD attribution.

LOIs will be accepted through Friday, March 18, 2022, 6:30 pm U.S. Eastern Time (23:30 UTC). Only submissions by email will be accepted. All submissions must be sent directly to MITSAllianceGrants@rti.org. Please start the email subject line with "MITS Mortality Surveillance Program Award Letter of Intent:" followed by your proposal title. Please attach the LOI as a .pdf file to the email. Please create the LOI on the applying institutions' letterhead.

Applicants may only submit one LOI per institution. After receiving the LOI, the Secretariat may reach out for further information or clarification.

All institutions that submit LOIs by the due date (March 18, 2022) are expected to submit proposals unless they notify the Secretariat otherwise. Any institutions that decides not to submit a full proposal should inform the MITS Surveillance Alliance Secretariat via email MITSAllianceGrants@rti.org.

Letters of intent must clearly and concisely specify the following:

- Proposed populations (include age ranges) to be studied, including the country and location where
 MITS will be conducted, and whether there will be a focus on specific morbidities
- Number of MITS planned
- Summary of the current mortality surveillance program being conducted into which the addition of MITS is proposed. The current mortality surveillance program may vary in size (e.g., district, regional, or other area) and scope (e.g., population-wide or sub-population). It is expected that the MITS cases to be performed would be a sample of the deaths registered.
- The proposed activity's purpose, objectives, activities and expected impact
- LOIs should confirm that the applying institution and Project Director can meet all expectations and

^{**} The Secretariat may reach out for further clarification or discussion of the proposal prior to award.



minimum eligibility requirements listed in Section 4.

Please see **Appendix A** for a LOI template

After receiving the LOI, the Secretariat may reach out for further information or clarification.

8. Proposal Submission Instructions

All institutions that submit LOIs by the due date (March 18, 2022) are expected to submit a full proposal by April 22, 2022 as the second step in the application process. *Any institutions that decides not to submit a full proposal should inform the MITS Surveillance Alliance Secretariat via email MITSAllianceGrants@rti.org*.

Proposals must include all information in **Appendix B.** Proposal Template and **Appendix C.** Budget and Justification Instructions and Template and address every item in the scoring matrix in **Table 3**. Proposal Evaluation Scoring Matrix. Proposals may vary in length, but the project description and project staffing sections combined should not exceed 10 pages. There is no page limit for organizational information and past performance, letters of support, proposed personnel CVs, and any attached protocols. All responses must be provided in a 11-point size font or greater.

Responses should clearly and concisely explain the proposed activity's purpose, objectives, activities and expected impact. Within the responses, the applicant must ensure that the text;

- provides the information requested under the headings in the Appendix B. Proposal Template and Appendix C. Budget and Justification Instructions and Template and addresses every item in Table 3.
 Proposal Evaluation Scoring Matrix;
- provides full information, as the scoring matrix will be applied solely on the information included in the proposal; and
- is drafted as clearly as possible to enable it to be evaluated.

Only complete proposals will be evaluated. Please ensure all required materials are submitted:

- Proposal Cover Page
- Institutional Information and Past Performance
- **Project Abstract and Proposal** that complies with page limits (10 pages, 11 pt. for the project description and project staffing and facilities description).
- Project Budget Summary, Budget, Cost Share Demonstration, and Budget Justification
- Letter of support from the applying institution indicating 1) the ability to utilize facilities (lab, storage space, etc.) and staff to conduct MITS and 2) the ability to sign a formal data use agreement and share deidentified data regarding cause of death (CoD) (e.g., MITS data, verbal autopsy, and clinical and laboratory data supporting the CoD determination) for the purpose of secondary analysis. LOS are not included in the page limit for the application. (Please see Appendix D. Applying Institution LOS Example)
- Letter of support (LOS) from the in-country implementing organization if the applying institution is not
 in the country where MITS is being conducted, and MITS will be implemented by an in-country
 organization
 - ** Optional <u>but strongly recommended</u>: Provide LOS from any other partner organizations, including hospitals, relevant local authorities, community organizations, local leaders, or others who will support the surveillance site program
- CVs for the project director and all other proposed key staff. Other key staff include the in-country



implementing organization surveillance site program lead (if applicable), lead pathologist, lead microbiologist, and the lead social scientist. CVs should be concise but are not included in the page limit for the application.

**Optional: Any provided mortality surveillance protocols. These are optional, but ideal to include if MITS is being incorporated into an ongoing mortality surveillance program.

After receiving the Proposal, the Secretariat may reach out for further information or clarification.

9. Proposal Evaluation

Once proposals have been received, a committee will be assigned to review the application and will apply the following criteria to scoring the proposals.

The evaluation committee shall verify compliance with the basic instructions set forth in this RFP (e.g., number of pages, font size, format, and attachments). Only complete proposals will be evaluated.

The technical evaluation of the proposal will cover the relevance of the surveillance site program, its merits and effectiveness, and its viability and sustainability. The proposals will be given an overall score out of 100 points in accordance with the breakdown provided below in **Table 3**. Proposal Evaluation Scoring Matrix.



Table 3. Proposal Evaluation Scoring Matrix

•	Area of Assessment	Points
•	I. Applying Institution History and Past Performance	10
	Ability to implement MITS given the institution's size and staffing structure based on experience	10
	implementing projects or programs of a similar size and complexity.	
	2. Project Description	40
	ect approach and strategies	
	MITS is already being conducted or will be integrated into an existing mortality surveillance program that the	
	applying institution can access.	
	Application has a clearly stated project into which MITS will be integrated.	10
	Commitment to utilizing common data elements	
	Appropriate use of MITS, including a plan for how to interpret MITS results and a description of the CoD	
	assignment process.	
	ulation	
	Applicant includes a description of current geographical coverage of current mortality surveillance	
	program and how MITS is appropriate to use in this population. Low- and Middle-Income Countries	10
	(LMIC) are prioritized, however other locations will be considered.	
	Evidence of access to population to meet sample size (e.g., 10 MITS per month) within the period of	
	award performance given local mortality rates and estimated consent rate.	
	nmunity Engagement	_
	Community engagement strategy or demonstrated partnerships with other organizations capable of	5
	community sensitization and engagement.	
	ting Mortality Surveillance	
	Access to and engagement with an existing mortality surveillance program	5
	Demonstrated experience in implementing verbal autopsy.	
Tran	nsition Plan	
•	Share results with local authorities.	
•	Strengthens linkages with civil registration and vital statistics, national bureau of statistics, and other	
	relevant local authorities.	10
•	Establishes a governance structure and sustainability plan to oversee MITS-informed CoD determination	
	after the award ends.	
•	Addresses training and resource allocation for conducting MITS after the award ends.	
	3. Project Staffing and Facilities Description	30
•	Staff description and CVs indicate qualifications and experience are sufficient to: conduct MITS and	
	complete both histological and molecular microbiological analysis (PCR) of samples. Staff should include:	
	pathologist, microbiologist, pathology technician and/or microbiology technician, a social scientist to	15
	support community sensitization, and others necessary to conduct MITS.	13
•	Sufficient level of effort has been allocated via award funds or cost-sharing to support the surveillance site	
	program	
•	Facilities are suitable to conduct MITS (e.g., mortuary), including space for donning PPE, preparing	5
	materials, and a well-lit, ventilated room to conduct MITS with an autopsy table and running water.	
	Histology facilities and equipment are available and suitable to conduct histological sample processing,	5
•		
•	evaluation, and sample storage as required to achieve surveillance site program objectives.	,
•	evaluation, and sample storage as required to achieve surveillance site program objectives. Molecular microbiology laboratory facilities and equipment are available and suitable to conduct molecular	
•		5
•	Molecular microbiology laboratory facilities and equipment are available and suitable to conduct molecular	
•	Molecular microbiology laboratory facilities and equipment are available and suitable to conduct molecular sample processing, analysis (PCR), and sample storage needed for surveillance site program objectives.	5
	Molecular microbiology laboratory facilities and equipment are available and suitable to conduct molecular sample processing, analysis (PCR), and sample storage needed for surveillance site program objectives. 4. Budget and Justification	5
•	Molecular microbiology laboratory facilities and equipment are available and suitable to conduct molecular sample processing, analysis (PCR), and sample storage needed for surveillance site program objectives. 4. Budget and Justification Description of how MITS incentive funds will be used appropriately (e.g., facilities costs, staff, CoD panel).	5
•	Molecular microbiology laboratory facilities and equipment are available and suitable to conduct molecular sample processing, analysis (PCR), and sample storage needed for surveillance site program objectives. 4. Budget and Justification Description of how MITS incentive funds will be used appropriately (e.g., facilities costs, staff, CoD panel). Applicant has documented cost-sharing of $\geq 20\%$ of award. Budgeted sufficient level of effort of all key and other staff to support the surveillance site program.	5
•	Molecular microbiology laboratory facilities and equipment are available and suitable to conduct molecular sample processing, analysis (PCR), and sample storage needed for surveillance site program objectives. 4. Budget and Justification Description of how MITS incentive funds will be used appropriately (e.g., facilities costs, staff, CoD panel). Applicant has documented cost-sharing of ≥ 20% of award. Budgeted sufficient level of effort of all key and other staff to support the surveillance site program. 5. Data-sharing Agreement and Letters of Support	5 10
•	Molecular microbiology laboratory facilities and equipment are available and suitable to conduct molecular sample processing, analysis (PCR), and sample storage needed for surveillance site program objectives. 4. Budget and Justification Description of how MITS incentive funds will be used appropriately (e.g., facilities costs, staff, CoD panel). Applicant has documented cost-sharing of ≥ 20% of award. Budgeted sufficient level of effort of all key and other staff to support the surveillance site program. 5. Data-sharing Agreement and Letters of Support Letter of Support from applying institution, including agreement to share de-identified individual-level data	5
•	Molecular microbiology laboratory facilities and equipment are available and suitable to conduct molecular sample processing, analysis (PCR), and sample storage needed for surveillance site program objectives. 4. Budget and Justification Description of how MITS incentive funds will be used appropriately (e.g., facilities costs, staff, CoD panel). Applicant has documented cost-sharing of ≥ 20% of award. Budgeted sufficient level of effort of all key and other staff to support the surveillance site program. 5. Data-sharing Agreement and Letters of Support Letter of Support from applying institution, including agreement to share de-identified individual-level data around CoD, including MITS data, verbal autopsy, clinical and laboratory data.	5 10 10 5
•	Molecular microbiology laboratory facilities and equipment are available and suitable to conduct molecular sample processing, analysis (PCR), and sample storage needed for surveillance site program objectives. 4. Budget and Justification Description of how MITS incentive funds will be used appropriately (e.g., facilities costs, staff, CoD panel). Applicant has documented cost-sharing of ≥ 20% of award. Budgeted sufficient level of effort of all key and other staff to support the surveillance site program. 5. Data-sharing Agreement and Letters of Support Letter of Support from applying institution, including agreement to share de-identified individual-level data	5 10



Appendix A. Letter of Intent Template

[Institutional letterhead]

[Date]

Subject: Intent to submit a proposal for a MITS Mortality Surveillance Program Award

Dear MITS Surveillance Alliance Secretariat awards administrator,

I am pleased to provide this letter of intent to submit a proposal for a MITS Mortality Surveillance Program Award, in response to your Request for Proposals (RFP) entitled "MITS Surveillance Alliance MITS Mortality Surveillance Program Awards".

Our proposal is entitled "[Proposal Title]". Please find below information summarizing our initial plan for our proposal. I confirm that my proposal and my institution, [Name of the Applying Institution] can meet all expectations and minimum eligibility requirements listed in the RFP.

- [Country] where MITS will be conducted
- **[Other participating institutions if applicable]** *E.g., name of the in-country implementing organization if the applying institution is not in the country where the surveillance site program will be conducted.*
- [Project target population] include age ranges to be studied, including the country and location where MITS will be conducted, and whether there will be a focus on specific morbidities.
- [Mortality Surveillance Program Summary] Summary of the current mortality surveillance program being conducted into which the addition of MITS is proposed. The current mortality surveillance program may vary in size (e.g., district, regional, or other area) and scope (e.g., population-wide or sub-population). It is expected that the MITS cases to be performed would be a sample of the deaths registered.
- [Project Summary] Summary of the proposed project's purpose, objectives, activities and expected impact
- [Number of MITS planned] up to 300
- [Strategic Fit] A few sentences on how this project meets the MITS Surveillance Alliance Phase II Goals.

Thank you very much for your consideration,

[Project Director Signature]

[Project Director Name]
[Project Director Title]
[Address]
[Email]
[Phone]



Appendix B. Proposal Template

Proposal Cover Page: Please include the following information on the proposal cover page (1 page)

- Project Title
- Project Director
- Name of the Applying Institution
- Requested Amount (USD): \$ 300,000
- Requested MITS Kits (Up to 300 MITS kits):
- Total Proposed Cost Share:
- Country where MITS will be conducted:
- Project target population:
- Strategic Fit: 2-3 sentences on how this project meets the MITS Surveillance Alliance Phase II Goals.
- **1. Applying Institution Information and Past Performance** (no page limit)

1 a. Basic Organizational Information

Complete and include the table below in the proposal to provide basic organization information.

Applying Institution's Name	
11 7 3	
Address, including country	
Office Telephone Number(s)	
• • • • • • • • • • • • • • • • • • • •	
Web Address and/or Social Media Address	
Desires Discours	
Project Director	
(Name, Title, Phone, and E-mail Address)	
Contact Person if different from PI (Name,	
· · · · · · · · · · · · · · · · · · ·	
Title, Phone, and E-mail Address)	
NI I TO COLUMN	
Names and Titles of other key staff	
Documentation of legal registration in the	
proposed country	
Applying Institution's authorized signatory	
(Name, Title, Phone, and E-mail Address)	

1 b. Institutional Background and Past Performance

 Please briefly describe the applying institution's mission and goals, and the sector(s) worked in (e.g., development, health, infectious disease), including the target populations (e.g., children under 5) with whom the institution was previously or is current working. Please include a brief



summary of the applying institution's experience implementing projects or programs of a similar size and complexity.

 Provide at least three references for completed projects or programs, funding source and results of the work in the following format:

Sponsor/Client	
Sponsor/Client contact information	Name:
	Phone Number:
Project Title	
Performance Period	
Value of award	\$
Major project or program conducted	
Goals/Aims	
Outcome against goals (publication references, if applicable)	

2. Project Abstract (included in 10 page limit, 11 pt font)

Provide a succinct summary (limit to 300 words) of the proposed project and activities to be supported by the incentive funds.

- State the Problem:
- Describe Participants/Population:
- Approach/Strategies/Methods:
- Conclusions/Results/Implications:

3. Project Description (included in 10 page limit, 11 pt font)

Describe the current or proposed project in the populations of interest and how MITS will be valuable and integrated into this existing population as part of the proposed project.

3a. Project Approach and Strategies

Describe the surveillance site program to which MITS will be integrated. Describe the organs or sample types to be collected, and the analyses planned for the MITS samples. Describe how the histology and molecular biology results of MITS samples will be integrated into CoD assignment. Describe how MITS will be valuable and integrated into existing projects of the applying institution or how MITS is already used.

3b. Population

Describe the population being targeted for this project and reasons for their selection. Please describe why MITS is appropriate to use in this population. Note that priority will be given to LMIC countries. Give evidence of access to a population sufficient to meet sample size (e.g., 10 MITS per month) within the period of award performance given local mortality rates and estimated consent rate.

Please include population information, including gender, age, demographic group, general health status, geographic location (e.g., in-patient or out-patient, clinic, community, rural, urban).

Please include any applicable inclusion or exclusion criteria for the project. Provide a statement that participants must meet all of the inclusion criteria to participate in this study and then list each criterion. List as many criteria as necessary to clearly define your study population. Provide a



statement that all candidates meeting any of the exclusion criteria will be excluded from study participation and then list each criterion.

3c. Community Engagement Strategy, Enrollment, and Follow-up

Community engagement and sensitization strategy. Or include a description of (and Letters of Support from) demonstrated partnerships with organizations capable of supporting community sensitization and engagement.

Describe the method for identifying and recruiting participants and duration of enrollment period and follow-up period, if applicable.

3d. Existing Mortality Surveillance Program

Describe the applying institution's current access to and engagement with an existing mortality surveillance program, including demonstrated experience implementing verbal autopsy. The current mortality surveillance program may vary in size (e.g., district, regional, or other area) and scope (e.g., population-wide or sub-population). It is expected that the MITS cases to be performed would be a sample of the deaths registered.

3e. Transition Plan

Detail a preliminary sustainability and transition plan that includes engagement with and sharing of results with local stakeholders and authorities, strengthening linkages with civil registration and vital statistics, establishes a governance structure, and address ongoing training and resource allocation for continuing support to incorporate MITS reference cases as part of the mortality surveillance program following the completion of the award. This should include a plan with milestones to assess performance toward sustainability and preparation for the transition of work.

3f. Timeline

Please complete the below table to describe demonstrate when the key activities of the proposed project will be conducted. The period of performance is July 1, 2022 – June 30, 2025 (36 months).

Year	Year 1			Year 2			Year 3					
	July-	Oct-	Jan-	April-	July-	Oct-	Jan-	April-	July-	Oct-	Jan-	April-
Activity/Period	Sept	Dec	Mar	June	Sept	Dec	Mar	June	Sept	Dec	Mar	June
	2022	2022	2023	2023	2023	2023	2024	2024	2024	2024	2025	2025
Activity 1												
Activity 2												
Activity 3												
Activity 4												
Activity 5												
Activity 6												

4. Project Staffing and Facilities (included in 10 page limit, 11 pt font)

Describe the staff committed for MITS. Describe their qualifications and experience to conduct MITS and to complete both histological and molecular microbiological analysis (PCR) of samples. Preferred staff should include a pathologist, microbiologist, pathology technician, microbiology technician, a social scientist to support community sensitization, and others that may be necessary to conduct MITS.

Provide a description of facilities and equipment available or proposed to be purchased under this award to conduct MITS, store and process samples, and to conduct histopathological and molecular microbiological (PCR) analysis of MITS samples.



5. Budget Summary, Budget Details, Budget Justification, and Cost Share Demonstration

Please see Appendix C. Budget and Justification Instructions and Template for complete instructions.

6. Letter(s) of Support (no page limit)

Provide a letter of support from the applying institution and any relevant governance indicating the ability to utilize facilities (lab, storage space, etc.) and staff to conduct MITS and the ability to sign a formal data use agreement and share deidentified data regarding cause of death (CoD) (e.g., MITS data, verbal autopsy, and clinical and laboratory data supporting the CoD determination) for the purpose of secondary analysis. Shared data will be embargoed for a period of time so that project teams may publish their findings before the data is released for secondary analysis. A data sharing agreement will be made available once the data sharing plan is finalized and will be executed before any sharing of data. (Please see **Appendix D.** Applying Institution Letter of Support Example)

Provide letters of support from any partner organizations, including hospitals, relevant local authorities, community organizations, local leaders, or others who will support the surveillance site program.

If the applying institution is not in the country where the surveillance site program will be conducted, a letter of support from the in-country implementing organization is required.

Letters of support are not included in the page limit for the application.

7. CVs for the project director and all proposed key staff (no page limit)

Please provide CVs for key staff, including the project director, the lead of the organizations implementing the surveillance site program in-country (if applicable), lead pathologist, lead microbiologist, lead social scientist, and others as applicable to the proposed surveillance site program.

CVs should be concise but are not included in the page limit for the application.



Appendix C. Budget and Justification Instructions and Template

Please provide an award budget summary using the provided template, budget (\$300,000) using the provided template, cost share budget (> \$60,000) using the provided template, and budget justification following the below instructions. Define how the MITS incentive funds will be used (e.g., start-up costs, quality control, analysis fees, facilities' costs, staff, CoD panel). If proposing other uses of incentive funds, please provide details on those activities and how they will benefit the surveillance site program. Applicants will be evaluated based on ability to leverage existing project resources in the implementation of MITS and feasibility of implementation given existing resources and MITS incentive funding.

1. Budget Summary:

Applying Institution Name	
Applying Institution Type (select one)	Non-profit/NGO Government Entity Other private organization For-profit organization U.S. University U.S. College Non-U.S. University or College Multilateral Organization
Proposal Title	
Period of Performance	July 1, 2022 – June 30, 2025 (36 months)
Reporting Cadence (select one) Selecting appropriate time periods for budgeting and subsequent reporting is important to manage the project from a programmatic, financial and administrative perspective. The default is to define the periods as 12-month increments from the beginning of the project. However, you may select a different setup if you prefer and adjust the periods in the budget template as needed. For example, you can choose to align the periods with the calendar year or with your institution's fiscal year.	12 month increments Calendar year Your institution's fiscal year
Applying Institution Indirect Cost Rate: Please be aware of the limitations defined by the BMGF Indirect Cost policy.	%
Will funds be spent in non-USD currencies? (Select one)	Yes No
Will the total cost of this project require contributions of funding from sources other than BMGF? (e.g., either by your institution or others)	Yes No
Is this a new version of a previously approved budget? (e.g., supplement)	Yes No

2. Budget Details

These are instructions for completing the budget. Please also refer to **Table 4.** Budget Template.

Note: Generally speaking, a single line item should not exceed 5% total budget (\$15,000). Where it is not practical or meaningful to break a line item into component parts, you can use the budget justification to explain the nature of the expenditure.



<u>Personnel:</u> When entering personnel items, each line should be for no more than one individual (e.g., multiple individuals should not appear in a given row). If the budget will be broken down by an additional dimension, it is acceptable to budget for fractions of the same individual across multiple dimensions, as needed. The unit cost is the annualized salary (or wage compensation) per full-time equivalent (FTE) position in Period 1. To account for salary increases, an annualized percent increase can be included. Fringe costs (employee benefits) are captured as a percentage on top of salaries in a separate column.

Note: The allocation per period is expressed as a fraction of a full work year. If a period spans 12 months, this corresponds to the fraction of time an individual dedicates to the project. If a period's length is less than 12 months, the value entered needs to be discounted accordingly.

For example, (see below), an FTE dedicating 80% of their time to a project over a six-month period translates into an FTE allocation of 0.40 in the template (e.g., 6/12 * 0.8 = 0.4).

<u>Inflation:</u> For personnel, you can include inflation in the "% Inflation per Period" section. For all other budget categories, if applicable, please include inflation in the cost per item, and explain in the budget justification.

<u>Travel</u>: Line items in the Travel category can be entered in a variety of ways to suit your budgeting preference. Multiple identical trips by multiple people can be reflected in the same line. Travel activity can also be budgeted out line by line (e.g., flight, hotel, per diem, ground transport).

Note: Travel for MITS training will be covered by the Secretariat and should not be included here.

<u>Consultants:</u> The Consultant category includes individuals who are working on the project but are not your employees. Independent contractors are also considered consultants. Contracts with consulting firms that are set up in a fixed fee arrangement or do not have individualized rates are considered sub-awards and are not allowed as part of this award.

One way to enter the requested budget for individual consultants is to express the fees as a daily rate multiplied by the number of days. Alternatively, if the contract is based on another rate, you may populate the template accordingly, but please make sure to always indicate what type of rate is being used in the billing unit/expense column.

<u>Capital Equipment:</u> Capital Equipment includes only items with a unit cost of at least \$5,000 (USD) and a useful life of more than one year. Goods that do not fit this definition should be included under Other Direct Costs. Capital equipment should only include items that are purchased after the execution of the grant agreement for the purposes outlined in the grant proposal and in accordance with the BMGF Indirect Cost policy. For equipment that is shared with work not funded by BMGF, a fractional quantity can be entered. For items purchased before the grant agreement, these items may be used as part of the cost-sharing demonstration (See 4. Cost Sharing).

Other Direct Costs: This category typically includes supplies and equipment with a unit cost generally under \$5,000 USD. It also serves as a place to capture everything that qualifies as a direct cost and does not fit any of the other categories. Avoid line items that represent significant amounts without being specific enough.

<u>Sub-awards</u>: Sub-awards are not allowed as part of this award.

3. Budget Justification

The purpose of the budget justification is to supplement the information provided in the budget table by justifying how the budget cost elements are necessary to implement project outcomes and accomplish the



results. Specifically, the budget justification is:

- A tool to help the MITS Surveillance Alliance fully understand the budgetary needs of the grant applicant
- An opportunity for grantees to provide descriptive information about their budget costs beyond the constraints of the budget spreadsheet
- A means for grantees to articulate the link between project outcomes and direct costs as well as speak to what is covered by the requested indirect cost rate.

Taken together, the budget justification and the budget spreadsheet should combine to provide a complete quantitative and qualitative description of how the budget supports the proposed project plan and target outcomes for the grant.

Ideally, the budget justification should be filled out in tandem with the budget table. The descriptions provided in the budget table should be brief. Please use the budget justification to provide a more thorough explanation of your budget.

The budget justification is organized by expense categories and other topics similar to the budget template, including:

- <u>Assumptions and risks</u> Describe any assumptions considered for the development of the budget. In addition, describe any potential risks in spending as planned and any plans to mitigate those risks.
- <u>Personnel</u> Provide a brief description of personnel budgeted for the grant, including responsibilities as they relate to the project. Also include assumptions made for any staff budgeted which are to-behired, including salary estimates for these personnel.
 - Allowance for Salary Increase (ASI) Include a description of the applying institutions policy of using ASI to account for the change in labor costs over the life of the project.
 - Benefits Describe the components of the benefits column included with the salary costs. For example: pension, health insurance, expatriate costs, etc.
- <u>Inflation</u> Please explain any inflation that was incorporated into the cost per item in any category other than personnel. Inflation in personnel costs should be captured in the ASI.
- <u>Travel</u> Provide the rationale for the travel budgeted and assumptions used to determine appropriate number of trips and personnel required. Include a brief rationale for how travel costs were estimated.

Please indicate any overarching assumptions used in the development of travel estimates including basis of estimate. Please describe your institutions' travel policy.

	Project Year	Number of Trips	Staff Traveling	Origin/ Destination	Trip Duration	Purpose of Trip
	[Project Year]	[Number of trips]	[Staff Name]	[Origin]/ [Destination]	[Trip Duration]	[Description of purpose of trip]
L						
L						

Airfare: The budget incorporates the below estimates for round-trip airfare.

- Domestic travel from [From] to [To], economy, round-trip: \$X,XXX
- International travel from [From] to [To], economy, round-trip: \$X,XXX



Per Diem: The budget incorporates the below estimates for Per Diem. For the purposes of budget estimation, Per Diem rates are budgeted in compliance with the U.S. Department of State published rates as well as Federal Travel Regulations.

Location: \$XXX per day

Ground Transportation: The budget incorporates an estimate of \$XXX per trip for ground transportation expenses.

Taxis To and From Airport: The budget incorporates an estimate of \$XXX per trip for taxis to and from the airport.

• <u>Consultants</u> – Please discuss in detail all consultants budgeted including name, position on the contract, job responsibilities, qualification, basis of daily rate proposed, and location of staff (e.g., headquarters/home office, in-country).

Consultant Name	Position	Daily Rate Proposed	Total Level of Effort	Job Responsibilities
[Staff Name]	[Position]	[Daily Rate]	[LOE]	[Description of job responsibilities]

<u>Capital equipment</u> – Provide a brief justification and description of any items required for the project with a unit cost of greater than \$5,000 (USD) and a useful life of more than one year. Include a detailed description of any minor equipment budgeted including a description of the line item budgeted, unit cost, basis of estimate for unit cost, and number of units budgeted per year. This section can be deleted if no minor equipment is budgeted.

Description	Unit	Unit Cost	Yr I Qty	Yr 2 Qty	Yr 3 Qty	Total Cost
Name I	Each	\$	#			
Name 2						
Name 3						
Name 4						
Name 5						

- Other direct costs Provide a brief description and rationale for items required, including cost assumptions used to develop the budget.
 - Computer Expense: Please include a detailed description of any computer expenses budgeted including a description of the line item budgeted, unit cost, basis of estimate for unit cost, and number of units budgeted per year. This section can be deleted if no computer expenses are budgeted.
 - Shipping & Postage: Please include a detailed description of any shipping & postage expenses budgeted including a description of the line item budgeted, unit cost, basis of estimate for unit cost, and number of units budgeted per year. This section can be deleted if no shipping & postages expenses are budgeted.
 - Telecommunications: Please include a detailed description of any telecommunication expenses budgeted including a description of the line item budgeted, unit cost, basis of estimate for unit



cost, and number of units budgeted per year. This section can be deleted if no telecommunication expenses are budgeted.

- Services Expense: Please include a detailed description of any services expense budgeted including a description of the line item budgeted, unit cost, basis of estimate for unit cost, and number of units budgeted per year. This section can be deleted if no services expense is budgeted.
- Materials & Supplies: Please include a detailed description of any materials & supplies budgeted including a description of the line item budgeted, unit cost, basis of estimate for unit cost, and number of units budgeted per year. This section can be deleted if no materials or supplies are budgeted.

For each of the above types of other direct costs, please detail the budget calculation using the below table as an example.

Description	Unit	Unit Cost	Yr I Qty	Yr 2 Qty	Yr 3 Qty	Total Cost
Name I	Each	\$	#			
Name 2						
Name 3						
Name 4						
Name 5						

- <u>Indirect Cost Rate</u> Briefly explain the indirect cost rate being charged on this project and the rationale and assumptions behind it. Please be aware of the limitations defined by the <u>BMGF Indirect Cost policy</u>.
- <u>Currency exchange (if applicable)</u> Briefly describe any non-US Dollar currency exchange exposure
 with this investment. For example, describe which costs included in the budget are exposed to
 exchange risk (e.g., which expense categories will be spent in non-US Dollar currencies and
 approximately how much do these costs total within the overall project). The budget justification
 should also include a description of how you estimated the exchange rate for each currency. Finally,
 please also describe your institution's experience and policies for managing foreign exchange risks.
- Other sources of support for the project (if applicable) If you are requesting partial funding from the
 MITS Surveillance Alliance for the project and will depend on funds from other sources, please describe
 your contingency plans if full project funding does not become available. If you have applied for
 funding from other sources which overlaps with the funding requested in this proposal, please indicate
 the nature and timing of that potential funding. Any expected in-kind contributions (e.g., drug
 donations, personnel time) should also be included.



Table 4. Budget template

Description	Purpose	Unit Cost	Period I	Period 2	Period 3	Addtl.	Addtl.	Addtl.	Period I	Period 2	Period 3	Total
			7/22 – 6/23	7/23-6/24	7/24-6/25	Info	Info	Info	7/22 – 6/23	7/23-6/24	7/24-6/25	
Personnel						1		1				
Name	Job Title	Annual	Period I	Period 2	Period 3	Total	% ASI	%	Period I	Period 2	Period 3	Total
		Salary	FTE	FTE	FTE	FTE		Benefit	Personnel	Personnel	Personnel	Personnel
								S	Cost	Cost	Cost	Cost
						<u> </u>		Subtotal				
Travel								oub to tu.	l.	I.	<u> </u>	
Description	Purpose	Cost per	Period I	Period 2	Period 3	-	-	-	Period I	Period 2	Period 3	Total Travel
		ltem	No. items	No. items	No. items				Travel Cost	Travel Cost	Travel Cost	Cost
								Subtotal				
Consultants								Jubtotai			l.	l
Consultant	Role	Billing Rate	Period I	Period 2	Period 3	Billing	-	-	Period I	Period 2	Period 3	Total
name			Billable	Billable	Billable	Unit/Ex			Consultant	Consultant	Consultant	Consultant
			units	units	units	pense			Cost	Cost	Cost	Cost
								Subtotal				
Capital Equi	pment							Subtotal				
Equipment	Purpose	Cost per	Period I	Period 2	Period 3	-	-	-	Period I	Period 2	Period 3	Total
Description		item	Quantity	Quantity	Quantity				Equipment	Equipment	Equipment	Equipment
			,	,	,				Cost	Cost	Cost	Cost
								Subtotal				
Other Direc	t Costs							Jubiotai	l		1	l
Item	Purpose	Cost per	Period I	Period 2	Period 3	-	-	l -	Period I	Period 2	Period 3	Total Other
Description	'	item	Quantity	Quantity	Quantity				Other Direct	Other Direct	Other Direct	Direct Cost
			,	,	,				Cost	Cost	Cost	
			<u> </u>				L	Cubassal				
								Subtotal Total				
								Total	Period I	Period 2	Period 3	Total
									renod i	renou z	remod 3	rotai

^{*}ASI – allowance for salary increase



4. Cost Sharing

Proposals must demonstrate cost sharing of 20% of award (\$60,000). Allowable cost sharing (matching funds) are costs, such as the surveillance site program staff salaries and equipment, that directly benefit the surveillance site program and could legitimately be charged to the award but instead are paid by the applying institute as a commitment to the surveillance site program. The MITS Alliance Secretariat may request documentation from the applying institute to verify the value of the shared costs. See **Table 5** for an example and template of how to document 20% cost sharing.

Requirements:

- Costs are verifiable by the applying institute
- Not included as a cost-share or contribution as part of other programs or awards
- Allowable as a direct cost
- Not paid by another award from The Bill & Melinda Gates Foundation
- Not directly billed to this program in any way (no double counting)

Eligible Costs:

- Pro Bono (uncompensated) faculty and staff salaries
- Volunteer services (uncompensated services provided by people outside of the applying institution) that are necessary for the surveillance site program's success
- Materials and Supplies required for the surveillance site program operations
- Services: logistical services, travel, accommodation, meals, lodging during travel for training or implementation
- Equipment (e.g., pathology or microbiology lab equipment, freezers for sample storage etc.) that is purchased for the surveillance site program and not already covered under an institutes' facilities and administration (F&A) rate. For equipment that is purchased and shared with work not funded by this award, a fractional quantity can be entered to reflect a fair cost share.

Non-eligible Costs:

- Institute facilities, laboratory space, or any cost already covered by the facilities and administration (F&A) or indirect rate
- Any item paid for by The Bill & Melinda Gates Foundation via another award or project
- Any items not directly contributing to the outlined scope of work



Table 5. Cost Share Template and Example

Cost Share	Cost Share	Valuation	Unit Description	Year I			Year 2			Year 3			Total
Category	Description Description	Method 1		Unit	Value	Total	Unit	Value	Total	Unit	Value	Total	Cost Share
Salary	5% PI Salary	Proposal budget	Per Year	0.05	\$100,000	\$5,000	0.05	\$100,000	\$5,000	0.05	\$100,000	\$5,000	\$12,500
Salary	5% Project Coordinator Salary	Proposal budget	Per Year	0.05	\$50,000	\$2,500	0.05	\$50,000	\$2,500	0.05	\$50,000	\$2,500	\$7,500
Services	25% Annual Pathology Equipment Maintenance	Past Invoice	Per Year	0.25	\$1,000	\$250	0.25	\$1,000	\$250	0.25	\$1,000	\$250	\$750
Services	25% Annual Microbiology Equipment Maintenance	Past Invoice	Per Year	0.25	\$1,000	\$250	0.25	\$1,000	\$250	0.25	\$1,000	\$250	\$750
Equipment	25% PCR thermal cycler	Past Invoice	Per unit	0.25	\$20,000	\$5,000	0	0	0	0	0	0	\$5,000
Services	50% Pathology Lab Services	Past Invoice	Per biopsy core processed (50% total laboratory fee)	500	\$15	\$7,500	1500	\$15	\$22,500	500	\$15	\$7,500	\$37,500
		ı	,	1	ı			ı	ı	1	ı	Total	\$64,000

^{1.} Indicate how the value of the contribution will be calculated. Documentation of value should be available upon request.



Appendix D. Applying Institution Letter of Support Example

[Institutional letterhead]

		[Date]
Dear MITS Surveillance Alliance Secreta	riat awards administrator,	
Subject: Intent to share mortality data	under a future MITS Alliance Data Use A	greement (DUA).
clinical, laboratory and demographic da	leath, including but not limited to MITS at a supporting the cause-of-death deter embargoed for a period of time so that	data, verbal autopsy, mination for the
A data use agreement will be negotiate available once the details of the data sh		a and will be made
We confirm that our project team and reto such an agreement including but not recommended by stakeholders and dor	limited to inclusion of additional data e	_
Project Director: [Name] [Address] [Email] [Phone]		
Signature		
[Include your signature below and the s wet or typed signature is acceptable. PI present]	ignature of the person/organization wh ease be sure the full contact information	
I certify that the above information is tr	rue and accurate.	
Project Director Signature	Printed Name/Title	Date
Data Owner Signature	Printed Name/Title	Date
Institutional Representative Signature	Printed Name/Title	Date