



Questions/Clarifications for the MITS Incentive Award Program

Responses from the MITS Surveillance Alliance

Concept papers will be accepted from **February 1 to February 28, 2019 by 5:00pm** (Eastern Standard Time). All submissions must be sent directly to MITSAllianceGrants@rti.org

Project/Research Question Clarifications

1. Is it mandatory for the proposed MITS project be integrated into an already existing project? Can it not be an independent research project?

A proposed MITS project can be an independent research project, it does not need to be integrated into existing research. However, due to the award size and structure it is anticipated that most proposals will likely be integrated to leverage the resources of an existing project.

2. Will the study fund qualitative MITS research, such as attitudes and perceptions of relatives or healthcare professional towards MITS?

The Alliance encourages the use of award funds to conduct qualitative research combined with conducting MITS, such as is described in the question. However, the structure of this award funds the collection of samples using MITS kits; thus qualitative research would need to complement the collection and analysis of post-mortem samples.

3. Can concept papers propose to conduct MITS in a community (non-hospital) setting?

Yes; MITS can be proposed for a community setting if appropriate for the population.

4. Are there any age limitations on the population for which MITS is proposed?

No; concept papers may propose any age population for study. If awarded, MITS kits and protocols will be provided for any age, stillbirth through adult.

MITS Kit Clarifications

5. MITS Kits which will be provided contains which items?

MITS kits include all single-use supplies and consumables needed to conduct an external evaluation of the body as well as sample collection and storage for transfer to the laboratory (e.g. needles, syringes, cassettes, jars and vials, labels). MITS kits do not provide personal protective equipment (e.g. gloves, lab coat, goggles), equipment (e.g. camera, scale), reusable labware (e.g. biowaste container, tube racks), or standard decontamination reagents (e.g. ethanol, iodine). Likewise, reagents for processing and analysis of samples are not included in the kit.



6. Would the MITS Surveillance Initiative be interested in a MITS project focused on a new organ?

The Alliance is interested in supporting any postmortem studies that use MITS to improve cause of death classification. The MITS kits to be provided by the Alliance are currently developed using existing available standardized protocols. The sample types available are listed below. The Alliance is open to considering the expansion of MITS kit protocols to new sample types within the resources allotted to the Alliance for this award. Proposals with sample types beyond the below should reference any published literature on the use of post-mortem biopsy or post-mortem minimally invasive techniques for sample collection.

Sample Types with previously-developed MITS protocols:

- Lung/thorax
- Brain parenchyma/central nervous system (occipital, trans-nasal, and fontanelle approaches)
- Liver
- Abdominal Organs (Kidney/Spleen)
- Heart Blood
- Stool
- Cerebral spinal fluid
- Nasopharyngeal/oropharyngeal swab
- Placenta and umbilical cord
- Skin lesions
- Palpable lymph nodes
- Hair
- Bone marrow

7. Can the MITS kits be tailored to meet the objectives of the individual applications?

Yes, the Alliance plans to tailor the kits to the needs of the individual proposals using existing available standardized protocols (see question 4). The Alliance is open to considering the expansion of MITS kit protocols to new sample types within the resources allotted to the Alliance for this award.

Funding Clarifications

8. Is the award only for the MITS? Could the award include complete diagnostic autopsy, if our study model requires it?

The award is intended to support postmortem studies with MITS to improve cause of death classification, which could include validation compared to complete diagnostic autopsy (CDA). MITS kits won't provide supplies for CDA, but award funds could support this if it supports the proposed research objectives. Note that research comparing MITS to CDA in certain populations is available in the published literature. We encourage applicants to make explicit how the proposed research objectives are unique and add to the currently available published literature on MITS.



9. Who will provide the reagents and consumables for sample processing and analysis during the study? Who will pay laboratory fees?

The award funds can be used to cover the costs of molecular or histopathological processing and analysis of the samples collected under this award.

10. Will the award will be paid to the organization (e.g. hospital) or to the investigator?

Incentive award funds can only be issued to the applying organization (e.g. university, hospital, or other institution). The award cannot be issued directly to an individual. The funds can be used as agreed upon by the organization and the investigator. We encourage principal investigators to discuss how the award funding would be accepted and committed to the project with their organization's representative.

11. Funding of a fixed amount per MITS kit would serve those that aim to do in-depth examination of a small number of potentially highly informative cases that still require fixed costs including the infrastructure and staffing less than proposals that include a higher volume of MITS cases and/or less intense examination of samples. In these cases, can the amount of money per MITS kit be increased?

The current RFA is limited to awarding \$1000 per MITS kit completed. However, we understand the value of the small in-depth studies described in this question and encourage investigators to apply for this funding.

12. Proposals may be able to leverage the infrastructure from existing MITS studies and extend those resources to examine new populations, geographies, or contexts. For example, pathologists or pathology technicians may already be trained. In such instances can the money that would have been used for travel and MITS training be repurposed for other aspects of the project?

In the current RFA, funds associated with travel and training cannot be reallocated to the awardee. In this example, we would encourage using the benefits of this award to train additional pathologists or technicians to expand the number of individuals trained to conduct MITS.

13. Is it acceptable to use some funds for salary support to carry out the proposed work?

Yes; the award can be used to cover salary of staff to carry out the proposed work.

14. In the case of multiple institution affiliations, is a letter of support from the Principal Investigator's home institution sufficient or would the Alliance also like letters from in-country collaborators?

Multiple letters of support will be accepted if multiple institutions are collaborating in the proposal. However, the most important letter of support is from the institution closest to the proposed work in-country. This letter should indicate the ability to utilize facilities (lab, storage space, etc.) and staff to conduct MITS.

15. Is the letter of support from the institution separate from the Certification statement?

Yes; the letter of support and certification statement are separate. The Certification statement (*found on page 8 of the RFA*) should be signed by the Principal Investigator and include information on the Principal Investigator's home institution.

16. Can an institution, organization, or applicant submit more than one application?

No; in the current RFA, Section 3.a) states "*Applicants may only submit one Concept Paper per organization.*"