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# Considerations and Lessons Learned in the MITS Consent Process

Prepared by

**RTI International**  
RTI International  
3040 E. Cornwallis Road  
Research Triangle Park, NC 27709



## Acknowledgements

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Introducing and conducting postmortem research studies in vulnerable populations and standardizing the use of minimally invasive tissue sampling (MITS) to determine cause of death encompasses an array of social and behavioral considerations. This document, based on input from existing MITS Alliance member projects, is not intended to displace the established principles and procedures related to Good Clinical Practice and informed consent, nor is it intended to be an implementation guide. Rather, these guidelines are intended to provide users with general considerations and lessons learned for introducing MITS and obtaining consent. The MITS Alliance Secretariat acknowledges and emphasizes that the implementation of postmortem studies is very context specific. The contents in this guide reflect the specific and unique cultural and religious characteristics of the communities in which MITS was implemented. How this guide will be used will vary, and each MITS project will need to review this guide and adapt the contents to suit its own environment and community.

This may also be considered a “living document.” The contents represent the collective knowledge and learning about the MITS consent process that has occurred up until this point. However, as MITS projects continue to grow and evolve and consent processes are evaluated, there is opportunity to refine and amend this document to address new information. Further, as the number of projects implementing MITS grows this document will also evolve to reflect the new cultural and religious contexts in which MITS is being implemented. The goal is to revise this document as necessary to reflect the growing body of knowledge related to MITS consent.

### Formative Research

Most projects within the MITS Alliance dedicate significant resources to the design and implementation of formative research prior to implementing MITS. These are some of the guiding principles used in the design of research studies and lessons learned and key takeaways that emerged as a result of that research.

- Understand community explanations and perceptions of death and what drives the desire to learn the cause of death
- Assess current perceptions and decision making regarding postmortem procedures
- Explore social and structural factors that may impact acceptability and consent
- Seek input and engagement from influential leaders within the community
  - Ensure that communities are knowledgeable and informed
  - Engage a community advisory board
  - Offer 1-day seminars or workshops
- Collect information to inform consent procedure
- Sensitize health care professionals regarding the benefit of determining the cause of death/mortality data
  - Conduct a Health Care Professionals Assessment/Survey
  - Before and during the study, conduct sensitization workshops with health care workers familiarizing them with the study
- Monitor and address local rumors about MITS and cause of death after MITS has been introduced

### Prior to Seeking Consent

The nature of the relationship between family and MITS team members prior to seeking consent varies across projects. In some projects MITS team members are known to the family prior to consent because the death was imminent and they were introduced prior to the death. In other projects the MITS team is only introduced once the death has occurred. Although the former affords more opportunities to build rapport, it is imperative that establishing a good rapport between the MITS team and family be considered when outlining the consent process.

- Build rapport with family members
- Provide family members with a written description of MITS that they can use to inform other family members
- Discuss the tests/examinations/investigations that the patient will undergo as part of normal patient care before mentioning MITS
- Engage members of the primary clinical team to establish trust and serve as a link between the family and the MITS team
- Introduce new or previously unknown members of the MITS team to the patient/family as part of handing over care

<p><b>Timing</b></p> <p>The timing of when a family can be approached varies depending on the population studied and where the study is being conducted. However, all MITS Alliance projects emphasized the importance of giving family members adequate time to grieve.</p>	<ul style="list-style-type: none"> <li>• Allow adequate time for grieving, but approach families before burial preparations begin</li> <li>• Be mindful that in the case of imminent neonatal death the family may still have hope and may not recognize that death is imminent</li> <li>• In the case of imminent neonatal death, begin to sensitize the family to the fact that there is no improvement in the child’s condition but do not discuss the MITS procedure until the death has occurred</li> <li>• Use a 24/7 on-call system for the study team to facilitate the team seeking consent in a timely manner</li> </ul>
<p><b>Setting</b></p> <p>Some projects in the MITS Alliance have specific rooms dedicated to grief counseling and MITS consent, but many projects do not have such resources and have still managed to create appropriate settings for seeking consent.</p>	<ul style="list-style-type: none"> <li>• Seek consent in person and in a quiet, private setting that, when feasible, is not located on the wards</li> </ul>

<p><b>Person Seeking Consent</b></p> <p>The specifics of how the person seeking consent is introduced and integrated into the larger medical team have varied across MITS Alliance projects and are influenced by the structure of the research team, the resources available, and the nature of the study. The recommendations here reflect projects that included a dedicated MITS team and projects where the MITS team was integrated into the existing clinical team.</p>	<ul style="list-style-type: none"> <li>• Use a member of the clinical team who has built a relationship with the family to introduce the person seeking MITS consent</li> <li>• Show sympathy, use simple language, and be willing to respond to questions</li> <li>• Provide an accurate timeline for the procedure and release of the body</li> <li>• Offer the opportunity to see the deceased after MITS is complete</li> <li>• Ensure that the family understands that MITS is completely voluntary</li> <li>• Provide transportation to bring a parent/family member who is not onsite at the hospital and is a key decision maker to support the primary caretaker (usually the mother) in the consent decision; provide phone communication when that key influencer is far away</li> <li>• Provide transportation home and assistance with funeral arrangements (for consenters and nonconsenters alike)</li> </ul>
<p><b>Training</b></p> <p>In addition to the standards of informed consent and Good Clinical Practice, an important aspect of training individuals to obtain consent is ensuring that they are sensitive to families' grieving. Although some projects in the Alliance engage clinicians already experienced in grief counseling, such as Palliative Care Teams, other projects incorporate the topic into training programs and materials for those who will be seeking consent.</p>	<ul style="list-style-type: none"> <li>• Ensure that all counselors are trained in grief counseling</li> <li>• Provide ongoing mentorship/supportive supervision</li> <li>• Offer periodic refresher trainings to provide feedback, address common challenges, and reinforce important aspects of the consent process</li> </ul>

### Who Can Grant Consent

MITS Alliance projects must consider social, legal, cultural, and familial norms, and logistics and timing, when determining who can provide consent for conducting MITS.

- Recognize cultural norms regarding postmortem decision making
- Determine who are the family members and which members should be included in the consent process during initial discussions with the family
- Consider engaging family members who are taking charge and appear calm
- In the case of children, address the parents first; other family members can be involved at the request of parents
- Include other family members as is relevant and appropriate (e.g., in-laws, spouses, grandparents)
- Engage family members who are supportive of MITS to facilitate the conversation when appropriate

<p><b>Describing MITS</b></p> <p>Much of what is explained to a family when describing the MITS procedure will be outlined as part of Good Clinical Practice and informed consent. Depending on the nature of the study, some projects will also describe the differences between conventional autopsy and MITS and acknowledge how conducting MITS will (or will not) impact a family’s ability to carry out traditional postmortem practices.</p>	<ul style="list-style-type: none"> <li>• Use simple language</li> <li>• Frame MITS in a similar manner as other health procedures such as blood draws</li> <li>• Describe differences between MITS and conventional diagnostic autopsy (where applicable)</li> <li>• Describe the use of MITS, including that clinical diagnosis is frequently limited</li> <li>• Describe that the information will be used to improve disease prevention and treatment</li> <li>• Indicate that it is free and a summary report on the cause of death will be provided</li> <li>• Describe that small needles are used, where incisions will be made if they are part of the procedure, and that they will be sutured up afterward</li> <li>• Be sure to answer all questions posed by the family</li> <li>• Indicate that rituals around death such as body washing or viewing will still be possible after the procedure</li> <li>• Explain that by consenting the family is not only getting more accurate information on the cause of death for their family member, but also doing a service to mankind</li> </ul>
<p><b>Family Follow-Up</b></p> <p>Feasibility is the primary consideration in determining whether a MITS team follows up with families after MITS has been conducted via phone, through a home visit, or through a facility appointment.</p>	<ul style="list-style-type: none"> <li>• Communicate a realistic timeline for the report to be issued</li> <li>• Be sure that the report is delivered to the family on time</li> <li>• Share MITS results with the family in person by a clinician trained in grief counseling and when possible offer additional grief counseling as desired</li> <li>• Offer a follow-up meeting with the family if they choose</li> <li>• Establish and follow a protocol for notifying the family if the results are of public health significance (such as HIV infection)</li> </ul>



### Managing Refusals

Regardless of the rationale, within the limitations of the project, MITS Alliance projects are committed to continuing to provide quality care to families who have refused MITS.

- Maintain respect and ensure that professional medical care will still be received
- Provide access to grief counseling and a follow-up visit after 6 weeks if desired

## Appendix A: Bibliography

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