Participant Informed Consent Form – ePOCT+ data collection

Study title: Dynamic clinical decision support algorithms to manage sick children in primary health care settings in Tanzania (DYNAMIC)

Introduction: This health facility is participating in a research study to improve diagnosis and treatment of sick children by health workers. The intervention we are testing is an electronic tool that will guide health workers through the consultation process and help them make a diagnosis and determine the appropriate treatment.

Procedures: Your child will receive the normal care he/she needs from the health care provider. However, you may notice that the health workers are using tablets. If you and your child choose to participate in the study, information will be collected about today's visit and any future visits. After one week, you will be contacted by a study team member via a telephone call or an SMS, to ask if your child is better or not, and if he/she was or is hospitalized.

INTERVENTION ONLY: In addition to the normal lab testing that may be needed for diagnosing your child, we may ask to take an extra small amount of blood (maximum 6 ml, or the equivalent of a teaspoon), stool, urine or collect liquids from your child's nose today, and possibly also in one week or later. These samples will be analyzed at a later stage in a laboratory outside of this facility. This additional testing most likely won't directly benefit your child but will help the Ministry of Health gain a better understanding of illnesses that children have in this area and how to prevent and cure them. If, however, this additional test comes back positive for one of the rare infections, you will be contacted by phone and asked to bring the child back to the health facility for further evaluation and treatment if he/she is still sick. This sample will be kept for 15 years, after which all samples will be destroyed.

Benefits: Your child may have no direct benefit from participating in the study. However, the information we will learn from this study will help manage sick children in this facility and similar health facilities in Tanzania and elsewhere.

Risks: Being in this study is unlikely to bring any risks or discomforts beyond what is normal during an outpatient consultation.

Privacy and confidentiality: All information collected will be done in a way that people outside this health facility are unable to find out who you and your child are and what medical problem he/she has.

Participating in the study: Taking part in the study is not compulsory and you are free to decide if you and your child wish to participate. We are asking to enroll your child into the study for six months, meaning that we will collect data not only about today's visit, but any subsequent visits within the next six months. We will not repeat this consent process, but we will ask you each time you return if you and your child are still comfortable with your choice to participate. Your decision will not affect the care your child will receive in any way. If you choose to participate now but change your mind later, you can stop at any time. In that case, you can choose if the information that has already been collected is kept or discarded.

Study approval: This study has been approved by the national and local Ethical Boards of Tanzania, which are tasked to make sure that research participants are protected from harm. The study has also been approved by the facility in-charge, the district health authorities and the Ministry of Health.

Contact Information

In case you have questions or concerns about the study, you can contact the local investigator listed below. You may also contact the Ethics Committee.

Local Investigators

Mbeya site
Dr. Chacha David Mangu
Tel: +255 769 566 348
Email: cmangu@nimr-mmrc.org

OR

Morogoro site
Dr. Lameck Luwanda
Tel: +255 623 183 606
Email: llameck@ihi.or.tz

Ethics Committee

- IHI ethics committee: Dr Mwifadhi Mrisho; Tel: +255 766675; Email: mmrisho@ihi.or.tz
- National Institute for Medical Research, P.O. Box 9653, Dar es Salaam, Tanzania Tel: +255 22 2121400 / Mobile: +255 758 587885 / Hotline: +255 22 2130770 Email: ethics@nimr.or.tz / nimrethics@gmail.com

Consent and signature

I have read the provided information/the information has been read to me, and I understand the study. I have had the opportunity to ask questions and my questions have been answered to my satisfaction. I agree for my child to take part in this study.

CONSENT GIVEN FOR:

☐ Capturing data about child's health

☐ Specimen collection (intervention only)

Is the child eligible to give assent (aged 12 years or above)? ☐ Yes ☐ No

Name of child	Date	Signature or thumbprint
Name of parent/guardian	Date	Signature or thumbprint
Name of witness**	Date	Signature or thumbprint
Name of person taking consent	Date	Signature or thumbprint

** Only for parent/guardian who CANNOT read and write, signature of a witness is required, certifying that he/she has witnessed that the information has been accurately read to the parent/guardian of the child, he/she has had the opportunity to ask questions, and gave consent freely.

Two copies are required – one for the participant and one for study team

Participant Informed Consent Form – Operational research

Study title: Dynamic clinical decision support algorithms to manage sick children in primary health care settings in Tanzania (DYNAMIC)

Introduction: This health facility is participating in a research study to improve diagnosis and treatment of sick children by health workers. The intervention we are testing is an electronic tool that will guide health workers through the consultation process and help them make a diagnosis and determine the appropriate treatment. We want to learn more about social, economic, and environmental impacts of the project and any facilitators or barriers to its implementation.

Procedures: As part of this study, you may be asked to take part in one or more of the following activities:

☐ *Focus group discussion:* You will join a group discussion with other volunteers where you will be asked to discuss your experience with and perception of the electronic tools and their impacts on health care at this facility or in the district. The focus group discussion should last about one hour and will be audio-recorded. Additionally, a study team member may write down notes during the discussion, but he or she will not write down the name of the person speaking.

☐ *Individual interview/survey:* You will be interviewed or asked to respond to a structured questionnaire about your experience with the project and its impacts on health care at this facility or in the district. The interview will take place in a private location where your responses will not be overheard and should last between 20 and 30 minutes. You do not have to answer any questions that make you feel uncomfortable. The interviews will be audio-recorded. Additionally, a study team member may write down notes during the interview, but he or she will not write down your name and only study staff will be allowed to access your answers or the notes.

☐ *Matched observation / exit interview:* You will be asked to allow a study team member to be present during the consultation visit between a health care provider and your child. He or she will take notes or fill specific checklists about the services provided and the patient/provider interaction but will not interfere with the visit in any way. If you ever feel uncomfortable with the presence of the study team member, you may ask him/her to step out at any time. No names of the patient or provider will be noted, and the notes from the observation will only be accessible to study staff.

For caregiver only: At the end of the consultation, you will be interviewed by a different team member about your experience during the consultation and perception of the quality of care you and your child received.

Benefits: You may not directly benefit from participating in the study. However, the information we will learn will be used to improve the electronic tools used in the study and processes that surround their implementation. As a result, the users of the tools and beneficiaries of the project may benefit from your input in the future.

Risks: There are no risks posed by participating in the study.

Privacy and confidentiality: All information you provide will be kept confidential and only study staff will be allowed access to all collected information.

Participating in the study: Taking part in the study is not compulsory and you are free to decide if you wish to participate. Your decision will not affect you in any way. If you choose to participate but change your mind later, you can stop at any time.

Study approval: This study has been approved by the national and local Ethical Boards of Tanzania, which are tasked to make sure that research participants are protected from harm.

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Consent and signature

I have read the provided information, or it has been read to me, and I understood the study. I have had the opportunity to ask questions about it and any questions I asked have been answered to my satisfaction. I agree to take part in this study.

Name of participant	Date	Signature or thumbprint
Name of witness**	Date	Signature or thumbprint
Name of person taking consent	Date	Signature or thumbprint

** Only for participants who CANNOT read and write, signature of a witness is required, certifying that he/she has witnessed that the information has been accurately read to the parent/guardian of the child, he/she has had the opportunity to ask questions, and gave consent freely.

Two copies are required – one for the participant and one for the study team