**Title:** The feasibility and acceptability of a diagnostic algorithm for timely post-tuberculosis lung disease diagnosis at primary health care facilities in Mbarara, Uganda

**Study area:** Post-Tuberculosis Lung Disease

**Informed Consent Version:** Version 1.1

**Version Date:** July 01st 2025

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**Sponsor/Funder:**

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National Clinical Trial (NCT) Number: **Not yet assigned**

**Study Sites:** Mbarara University of Science and Technology/Mbarara Regional Referral Hospital,

Mbarara District, Uganda

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RESEARCH ETHICS COMMITTEE

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# INFORMED CONSENT FORM

This document outlines the research study and expectations for potential participants. It should be written in layman terms and typed on MUST-REC letterhead.

## Instructions

1. The wording of this document should be directed to the potential participant not MUST-REC.
2. If a technical term must be used, then define it the first time it is used and any acronyms or abbreviations used should be spelled out the first time they are used.
3. All the sections of this document must be completed without any editing or deletions.
4. Please use a typing font that is easily distinguishable from the questions of this form. Preferably the font size should be 12.

**Study title** – This should be the same as on all other documents related to the study.

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| The feasibility and acceptability of a diagnostic algorithm for timely post-tuberculosis lung disease diagnosis at primary health care facilities in Mbarara, Uganda. |

**Principal Investigator(s)**

Dr. Nuwagira Edwin, enuwagira@must.ac.ug

**Organization:** Mbarara University of Science and Technology.

**Introduction**

What you should know about this study:

1. You are being asked to join a research study.
2. This consent form explains the research study and your part in the study.
3. Please read it carefully and take as much time as you need.
4. You are a volunteer. You can choose not to take part and if you join, you may quit at any time. There will

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9be no penalty if you decide to quit the study.

**Brief background to the study**

Tuberculosis remains one the leading causes of mortality and disability in low income settings like Uganda. Despite improvement in the treatment success rate, tuberculosis survivors continue to have respiratory tract (breathing) problems, an impaired quality of life, and reduced functional status compared to people who have never had tuberculosis. The persistent respiratory symptoms after tuberculosis cure with or without structural or functional lung damage is called post-tuberculosis lung disease. Unfortunately, in our setting (Uganda), this has not been well studied, and because of this, there are no guidelines or protocols for diagnosis or care of patients with post- tuberculosis lung disease. Our group has been collecting data among tuberculosis survivors to study the different presentations and trying to figure out how to make a diagnosis of post-tuberculosis lung disease without using sophisticated imaging, that would not even be affordable for may tuberculosis survivors. We started a post- tuberculosis care clinic and here we do more tests such as lung function testing, chest imaging, laboratory tests to make sure there is no tuberculosis reinfection or We have now developed a simple criteria that we can use in screening people who may have post-tuberculosis lung disease, to be referred for care and proper diagnosis at Mbarara regional referral hospital.

**Purpose of the research project**

Include a statement that the study involves research, estimated number of participants, an explanation of the purpose(s) of the research procedure and the expected duration of the subject's participation.

This is a pilot cluster randomized clinical trial which means that we will test the feasibility and acceptability of the clinical algorithm at four selected health facilities in Mbarara district in Uganda. We will enroll patients with previous infection of pulmonary tuberculosis or active pulmonary tuberculosis infection who present with complaints that are related to their breathing. Two health facilities will use the algorithm we will develop, and the other two will use the algorithm that was developed by a consensus meeting at a post-tuberculosis conference. Participants with possible post-tuberculosis lung disease will then be referred to Mbarara regional referral hospital for further tests to confirm the disease. In total, 80 participants will be enrolled and followed up to six months.

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## Why you are being asked to participate?

Explain why you have selected the individual to participate in the study.

You have been invited to participate in this study because you are either a clinician or nurse taking care of patients at a level three health facility or a you previously had drug- susceptible pulmonary tuberculosis and now presenting with symptoms that are consistent with post-tuberculosis lung disease. Your participation is entirely voluntary which means you are free to accept or decline or even withdraw from the study at any time without providing a reason. Your decision to decline or withdraw will not in any way affect we interact with you in the future or how we take care of you, should you ever visit Mbarara Regional Referral Hospital or Mbarara University of Science and Technology.

## Procedures

Provide a description of the procedures to be followed and identification of any procedures that are experimental, clinical etc. If there is need for storage of biological (body) specimens, explain why, and include a statement requesting for consent to store the specimens and state the duration of storage.

If you are able to read, take time and read everything carefully. If you are unable to read, a research assistant is ready to help you read and understand everything fully. Please don't hesitate to ask any questions about the study, especially the benefits and risks. You will be asked to sign on a piece of paper as evidence of acceptance to take part. If you the clinician mentions that you may have post-tuberculosis lung disease, we will request yoy to cme to Mbarara Regional Referral Hospital post-tuberculosis clinic where we will test your lung function using a spirometer (special equipment to test lung function), and do chest imaging to confirm that you either have or don't have post-tuberculosis lung disease. If indeed you have it, there will be some interventions to help you get well. For example, we work with the physiotherapy department and these will take you through a series of breathing exercises to train your breathing muscles sustain or tolerate an exercise with ought much fatigue or breathlessness or coughing. After that visit, you are welcome to keep coming in to our clinic for consultations. You can always come to the hospital at the post-TB clinic in case you have breathing problems for evaluation. We will take a couple of routine measurements which include, your blood pressure, temperature, body weight, height, waist mid-upper arm circumference. We shall also measure your blood pressure, and measure your blood sugar. The health worker will help the research team in identifying and screening patients with post-tb lung disease. We will teach you and show you how to screen for post-tuberculosis lung disease at a primary health facility.

## Risks or discomforts

Describe any reasonably foreseeable risks or discomforts-physical, psychological, social, legal or other associated with the procedure, and include information about their likelihood and seriousness. Discuss the procedures for protecting against or minimizing any potential risks to the subject. Discuss the risks in relation to the anticipated benefits to the subjects and to society.

There are no major risks anticipated in this study except you might spend a little more time at the clinic than you would usually do. You might also feel some discomfort as lung function testing or

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physiotherapy is being done. However, if you want, you will be given sometime during the interviews to relax, and then resume when you are ready.

While having a chest X-ray taken, you are exposed to radiation, but both the exposure and the radiation dose are in the allowable safety range. Having an Xray or CT scan will not increase your chances of having cancer in future.

**Benefits**

Describe any benefits to the subject or other benefits that may reasonably be expected from the research. If the subject is not likely to benefit personally from the experimental protocol note this in the statement of benefits.

This study is of great benefit to you since you followed up, to have a definitive diagnosis for either post-tuberculosis lung disease or not. The lung function results from this study will help us understand how tuberculosis affects the lungs and this will help us plan better to easily diagnose post-tuberculosis lung disease care for future patients who have recovered from pulmonary drug-susceptible tuberculosis. In addition, we hope to use our results to inform policy makers like the ministry of health to add post-tuberculosis lung disease in the tuberculosis treatment guidelines.

**Incentives or rewards for participating**

It is assumed that there are no costs to subjects enrolled in research protocols. Any payments to be made to the subject, e.g., travel expenses, token of appreciation for time spent, must also be stated, including when the payment will be made.

There are no financial gains whatsoever for participating in this study. The study team is enrolling you during your routine visit to the facility. We will however give you a transport refund of 40,000 Uganda shillings (equivalent to 10 United states dollars), ALL laboratory and imaging tests will be done by the study. We will, in addition provide you with a 500ml bottle of drinking water during the interviews. We will not pay you for taking part in this research.

**Protecting data confidentiality**

Provide a statement describing the extent, if any, to which confidentiality or records identifying the subjects will be maintained. If data is in form of tape recordings, photographs, movies or videotapes, researcher should describe period of time they will be retained before destruction. Showing or playing of such data must be disclosed, including instructional purposes.

If you consent to take part in this study, you will be given a unique number which we will use for all your study-related information. Your name will not be displayed on any document or even publication.
All study information that will be collected from you will be kept in a locked cabin and only accessed by study staff. Your records for this research study will be reviewed by the university or any other regulatory authorities to assure the accuracy, quality, and correct conduct of the research

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**Protecting subject privacy during data collection**

Describe how the privacy of the participant will be ensured during the process of data collection.

To protect your privacy during data collection, all interviews and clinical assessments will be conducted in a private setting, such as a designated consultation room, where unauthorized individuals will not be present. Your responses will be recorded using unique participant codes instead of your name or personal identifiers. Only authorized study staff will have access to your data, and all electronic records will be stored on password-protected devices. Paper forms, if used, will be securely locked in cabinets accessible only to the research team. Your personal information will not be shared outside the research team, and any publications or reports from the study will not include information that can identify you.

**Right to refuse or withdraw**

Include a statement that participation is voluntary and that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled.

You have every right to refuse to give your permission to let the researchers collect and test you in preparation for this study. Even if you give your permission now, you can change your mind. Your decision will not affect your current or future relations with Mbarara regional referral hospital, the tuberculosis treatment unit in particular or Mbarara University of Science and Technology.

**What happens if you leave the study?**

Include a statement that the subject may discontinue participation at any time without penalty or loss of benefits.

Your participation in this study is completely voluntary. You are free to withdraw from the study at any time, for any reason, without any penalty or loss of benefits to which you are otherwise entitled. If you choose to leave the study, we will not collect any new information about you, and you may also request that your data collected up to that point not be used in the study. Your decision to withdraw will not affect your medical care, your relationship with the research team, or your access to health services at this facility.

**Who do I ask/call if I have questions or a problem?**

Include contact for the researcher and Chairperson, MUST-REC.

Should you any questions or require further information about the study, you may contact the study principal investigator, Dr. Nuwagira Edwin of Mbarara University of Science and Technology, on 0779096887. If you have questions or concerns regarding your rights during the study, you can contact Associtate Professor Alele Paul the chairperson of the Mbarara University of Science and Technology Research and Ethics Committee on +256-4854- 33795 or 0773573372

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**What does your signature or thumbprint on this consent form mean?**

Your signature on this form means

- You have been informed about this study's purpose, procedures, possible benefits and risks
- You have been given the chance to ask questions before you sign
- You have voluntarily agreed to be in this study

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| Name of adult participant | Signature/Thumbprint of participant/ Parent/Guardian/Next of Kin | Date |
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| Name of person obtaining consent | Signature | Date |
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| Print Name of witness | Signature or thumbprint or mark | Date |

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# CERTIFICATE OF CONSENT

I.....having read and understood the information sheet concerning the Improving Diagnostic Strategies for Post-Tuberculosis Lung Disease in Ugandan Primary Health Care Settings (IMPULSE-TB) study do voluntarily accept to participate in the study. I have been given enough time to fully comprehend what the study is about and all my questions and concerns have been satisfactorily answered. I understand that I may at any time withdraw from the study with or without a reason.

| Participant's name | Participant's signature or thumbprint | Date |
|---|---|---|
| | | |

| Study Staff's Name | Study Staff's Signature | Date |
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Impartial witness in the event that the participant is illiterate

I confirm that I observed the participant being informed about the study. He/She has had a chance to ask questions all of which were answered satisfactorily

| Impartial Witness Name | Impartial Witness Signature or thumbprint | Date |
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