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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.

Metabolic and molecular ecological evolution of opportunistic pulmonary fungal co-infections

Principal Investigator(s)

Dr Herbert Itabangi

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 be no penalty if you decide to quit the study.

Brief background to the study

Lower respiratory infections may be cause by either bacteria fungi or viruses. These organisms can co-exist with each other in the same infection site. However, their interaction mechanisms are not yet well understood. This study therefore will aim to describe these interactions.

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.

1. To determine the burden and profiles of fungal-co-infections among patients with chronic pulmonary disease presenting with TB like symptoms
2. To establish and characterise microbial communities associated with chronic pulmonary disease.

3. To characterise potential interaction relationships established between fungal and bacterial communities

Why you are being asked to participate?

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

You are being asked to participate in this study because you have symptoms or signs for Lower pulmonary infection. Through analysis of collected sputum samples we can demonstrate the definitive cause of your persistent pulmonary symptoms. The results from this study will be used to guide clinicians on improving the management of pulmonary infections.

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.

- Your acceptance to take part of this study will be followed by collecting information regarding social demographics, questions on your medical history and physical examination. In addition, you will be required to provide sputum samples (2 samples will be collected on the first day and one sample early morning of the following day)
- These samples will be collected in a container provided to you with instructions by the study nurse

- The samples will then be processed in the Laboratory to establish the diagnosis and; where diagnosis is not determined immediately you will be requested to return after 3 weeks.

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 more than minimal discomforts and risks if you decide to participate in this study.

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.

The results will inform the clinician on the likely cause of your condition
This will improve on the management and treatment of your condition
This result will inform the policy on management of lower pulmonary infections

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.

You will be reimbursed 10,000 UGX as a transport compensation when you return the morning sample

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.

Your information will be given a unique code, stored securely and only accessible to study team and attending doctor. however, your contacts will be required for accessing you when the need arises.

Protecting subject privacy during data collection

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

The guidelines require that a sputum sample be collected in an open space, however, in as much as possible your privacy will be protected.

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 the rights to decline to participate or withdrawal from the study at any time without suffering any prejudice.

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.

You may discontinue participation at any time without any penalty or loss of benefits

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

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

If you have any questions or concerns about completing the questionnaire or about taking part of this study, you may contact

Dr Herbert Itabangi, PhD
Teaching Assistant
Department of Microbiology, MUST
PO BOX 1410.Mbarara ;
Mobile phone : (+256) 0752381780/ 075554564/ 0789434346

Contact for IRC office

Dr. Francis Bajunirwe
Chairman, MUST-REC
P.O. Box 1410 Mbarara
Tel: 0485433795/0772 576 396

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

_____	_____	_____
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