# Effectiveness of Low-Dose Theophylline for the Management of Biomass-Associated COPD

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# MAKERERE UNIVERSITY COLLEGE OF HEALTH SCIENCES

# SCHOOL OF MEDICINE RESEARCH AND ETHICS COMMITTEE (SOM-REC)

## INFORMED CONSENT TEMPLATE FOR INTENDING RESEARCHERS

**Title of the proposed study:** "Effectiveness of Low-dose Theophylline for the Management of Biomass-associated COPD"

**Investigators :**

1. Trishul Siddharthan MD; tsiddhar@miami.edu
University of Miami
2. William Checkley, MD, PhD; wcheckl1@jhmi.edu,
Johns Hopkins University
3. Bruce Kirenga, MMED; bruce.kirenga@yahoo.com
Makerere University College of Health Sciences
4. Patricia Alupo, MMED; patricia.alupo@gmail.com
Makerere College of Health Sciences
5. Peter Jackson, MD; peter.jackson@vcuhealth.org
Virginia Commonwealth University

**Background and rationale for the study:**

Chronic lung disease affects people like yourself around the world but there are few options for treatment. We are conducting a study to identify

potential treatments that may improve your breathing, be accessible and low-cost.

**A description of sponsors of the research project and the organizational affiliation of the researchers:** National Heart, Lung, Blood Institute, National Institutes of Health, University of Miami, Makerere University

**Purpose:**

The purpose of this research study is to identify treatments for people in your community who have chronic lung problems and experience symptoms such as shortness of breath and tightness in their chest. If you are identified as having any of these respiratory problems, you will be asked if you would like to participate in a study that will try to find out if your condition can be managed with daily pills. This study is being conducted with support from the National Institutes of Health in the United States.

**The estimated duration the research participant will need to commit to take part in the research project:**

100 participants will participate for a total of 12 months. Each participant will have 5 visits. The first set of testing will be completed in no more than two visits. In total, the procedures will take no more than 45 minutes. If you qualify for the study, fieldworkers will follow up every month to provide additional medications and perform additional tests. These follow up tests should take no more than 30 minutes.

**Procedures:**

If you agree to participate, we will ask you to complete a questionnaire about your current health and health history and perform breathing tests. We will also measure your blood pressure, weight, and height. If you are a woman capable of having a child, you will have a pregnancy test done and it must be negative. If you qualify for the study you will be provided with pills for a one-year period. Half of the people that participate in this study will receive a placebo pill (a pill that looks like the study medication but contains no medication.) The other half will receive the medication. The purpose is to determine whether the study drug works.

Neither the field workers nor the study investigators will know which group receives the placebo until the end of the study. We will additionally take blood tests up to three times during the study. You will be provided with a diary to record your symptoms and with a monitor to test air pollution levels in your household during the course of the study.

## Who will participate in the study:

We are asking you to be a volunteer in a research study. You are being asked to participate because you are 40 years of age or older, have full-time residence in Nakaseke or Kampala for more than 6 months, and do not intend to move away from the community in the next 6 months. You do not have to participate if you do not want to. Pregnant women are not allowed to participate.

## Study Procedures and Risks/Discomforts:

### Spirometry

The breathing test ("spirometry") is a special test for assessing how the lungs work. We will ask you to breathe deeply into a small machine. This process is generally safe; however, in older patients it may cause some participants to feel dizzy or lightheaded; some may faint. The administration of an inhaled, short-acting bronchodilator is generally safe, but may cause some nervousness and tremor and may cause your heart to beat fast. To minimize the risk of this test, we will not ask you to perform it if you have a high pulse rate or high blood pressure.

## Theophylline

Theophylline is a once-a-day medication for your breathing. The most frequent side-effects are stomach discomfort, headache, insomnia (difficulty sleeping) and heart palpitations. You should take the study medication once daily, as prescribed. In cases of overdose, (taking too much study drug) the side effects include vomiting, cardiac arrhythmias, (irregular heartbeat) and seizures that are difficult to treat, which can cause death. If that were to happen, you will be provided with a number to call should you have any symptoms and you will be referred to Nakaseke Hospital or Makerere Lung Institute for further management.

## Blood samples

This procedure is quite safe and well tolerated; the risks are of drawing blood pain, discomfort, bruising or infection at the puncture site. For each blood draw (up to 5 teaspoons), disposable material will be used to avoid the risk of infection and will be performed by trained personnel to reduce discomfort.

## Benefits:

Being in this study will not help you directly. But your participation in the study may benefit other people in the future by helping us learn more about treatment for COPD globally. You will receive the results of all health testing, including the breathing test results.

**Confidentiality:** This research is covered by a Certificate of Confidentiality (CoC) from the National Institutes of Health. The researchers with this CoC may not disclose or use information, documents, or biospecimens that may identify you.

## What information is being collected, used, or shared?

To do this research, we will need to collect, use, and share your private health information. By signing this document, you agree that your health care providers may release your private health information to us, and that we may use any and all of your information that the study team believes it needs to conduct the study.

## Who will see, use or share the information?

The results of this study could be presented in journals or scientific conferences, but without your name or any other information that could identify you. Your name will not appear in any publication of this study. People at the and the University of Miami who work on the study or who need to make sure the measurements are being done correctly may see the results from the tests, but this information will not include identifying information. The final decision to share this data will be taken by the principal

investigators. The local Research Ethics Committee (REC) and Uganda National Council for Science and Technology (UNCST) are entities which may have access to private information that identifies the research participants by name. This trial will be registered and may report results on www.ClinicalTrials.gov, a publicly available registry of clinical trials

## Alternatives:

Participation in the study is not mandatory. You have the alternative to continue with the standard of care.

## Cost:

There are no anticipated costs associated with this study. All study medications will be provided to you free of cost during the trial period.

## Compensation for participation in the study:

We will pay 20,000UsH (~$5) per visit in the form of cash to compensate for time requires to complete questionnaires. There will be no reduction in this amount or penalties for not completing the study. No compensation is available if some injury happens because of your participation in this study. The researchers have taken steps to minimize the risks of this study. Even so, you may still have problems or side effects, even when the researchers are careful to avoid them. Please tell the researchers listed about any injuries, side effects, or other problems that you have during this study. You should also tell your regular doctors.

## Reimbursement:

We will conduct all tests in your home. Should you be required to come for a clinic visit for the study, these costs will be reimbursed.

## Questions about the study:

If you have any questions or complaints as a result of being in the study, you may:

## Contact the Local Study Coordinator in Uganda:

Patricia Alupo
Telephone: +256 701124540

## Contact the Principal Study Investigator in USA:

Dr. Trishul Siddharthan
Telephone: +1 305-243-6388

## Statement of voluntariness:

Participation in the proposed study is voluntary and participants may join on their own free will. Participants also have a right to withdraw from the study at any time without penalty.

## Dissemination of results:

Research participants will get feedback on findings and progress of the study. Any new information that affects the study or findings that have relevance to you will be made available to you and your health care providers.

## Ethical approval:

This study has been reviewed by an Institutional Review Board (IRB), a group of people that reviews human research studies in the United States and the Human Subjects Review Committee, a group of people that reviews human research studies in Uganda. The IRB or Human Subjects Review Committee can help you if you have questions about your rights as a research participant or if you have other questions, concerns or complaints about this research study. Please call or contact the Human Subjects Review Committee of Makerere University School of Medicine (Uganda), or the Institutional Review Board of the University of Miami if you have questions about your rights as a study participant, feel that you have not been treated fairly, or if you have other concerns.

**Contact the Human Subjects Review Committee at:**

Secretariat Makerere College of Health Sciences Clinical Research Coordination
Telephone: +256 0414-533541
E-mail: rresearch9@gmail.com or research@chs.mak.ac.ug

**Contact the Institutional Review Board (IRB) at:**

Telephone: +1- 305-243-3195 Email: hsro@miami.edu

**Consent:**

Statement of consent after understanding the study and a signature portion.

## STATEMENT OF CONSENT/ASSENT

..... has described to me what is going to be done, the risks, the benefits involved and my rights regarding this study. I understand that my decision to participate in this study will not alter my usual medical care. In the use of this information, my identity will be concealed. I am aware that I may withdraw at anytime. I understand that by signing this form, I do not waive any of my legal rights but merely indicate that I have been informed about the research study in which I am voluntarily agreeing to participate. A copy of this form will be provided to me.

Name ……

Signature/thumb print of participant …… Date ……

Name……

Signature of witness (if applicable)……Date…….

Name ……

Signature of interviewer/Person obtaining informed consent

…… Date …….