Study Consent Documents

Study Title: A Clinical Risk Score for Early Management of TB in Uganda
(NIH/NIAID R21AI161301, PI: Dr. David Dowdy)

NCT Number: NCT05122624

Date of the document:

- Informed Consent Form for Adults: May 25, 2021
- Informed Assent Form for Adolescents: May 25, 2021
- Informed Consent Form for Parents/Legal Guardians of Adolescents: May 25, 2021
- Informed Consent Form for Care Providers: June 13, 2021

MAKERERE UNIVERSITY COLLEGE OF HEALTH SCIENCES

JOHNS HOPKINS SCHOOL OF PUBLIC HEALTH

CONSENT TO PARTICIPATE IN A RESEARCH STUDY

For adults age ≥18 recruited for the end-phase survey

Study: PredicTB: Validating a clinical risk score for early management of tuberculosis in Ugandan primary health clinics

Participant Study ID:

Is the Participant able to Read and Write? Yes ☐ No ☐

Date the Participant Consented: __ __ /__ __ / 20__ __

Time of Signing the Consent Form __ __: __ __ (24-hour clock)

Did the participant comprehend all the information in the Consent Form? Yes ☐ No ☐

Comments:

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Did the Participant have any questions? Yes ☐ No ☐

If Yes, were they all answered? Yes ☐ No ☐

Comments:

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Principal Investigator (Uganda):
Dr. Achilles Katamba, MBChB PhD
Makerere University College of Health Sciences
Email: axk95@case.edu
Tel: +256-414-530-021, +256-753-040-922

Principal Investigator (USA):
Dr. David Dowdy, MD PhD
Johns Hopkins School of Public Health
Email: ddowdy1@jhmi.edu

Introduction: We are inviting you to take part in a research study to understand how people with tuberculosis (TB) symptoms can be diagnosed for TB and treated. When a person presents to the clinic with TB symptoms (cough, fever, night sweat, or recent weight loss), he/she is asked to provide a sample of sputum to be tested for TB. Clinic staff send the sputum sample to the central lab to test for TB, and the lab returns the test result to the clinic. If the result is positive, he/she is expected to hear from the clinic about the result and treatment availability. This entire process can take more than a week, meaning that he/she has to delay the treatment.

We have trained care providers in this clinic to use a clinical risk score, called the "PredicTB" score, to identify people who might be considered for starting TB treatment on the same day of their clinic visit – before their lab results come back. This score is easy to calculate on the basis of patient characteristics (for example, age and sex) and the presence of TB symptoms. If the score is higher than a certain level, clinicians might decide to start patients on TB treatment immediately, without waiting for lab results – but every patient is different, and clinicians will only use this score as one consideration in deciding how to treat you. All treatment decisions will be made by your treating care provider, based on their assessment of your condition. Whether this score is used or not, a sample of sputum will still be sent to the lab to confirm whether you have TB.

We are now asking you to participate in an additional survey, because your provider asked you to provide a sputum specimen for TB diagnosis – and we are interested in how the "PredicTB" score performed, and also if it can be improved for other patients in the future. If you agree to participate, we would like to ask information about your TB symptoms, risk factors for TB, social and economic status, and opinion about same-day TB treatment, in order to help us understand how people at risk for TB can benefit from this score, and from treatment without delay.

Alternative to participation: You can choose whether or not you want to participate in this survey. Participation in this survey will not affect your clinical care in any way. Even if you choose not to participate in the survey and had a positive TB test, you will still be able to receive treatment for TB. If you have any questions or wish to stop being a part of the survey at any time, you can always ask any member of our study team.

Sponsor: The research study, including this survey, is sponsored by the National Institutes of Health in the United States, and it is being conducted by researchers from Makerere University in Uganda and from Johns Hopkins University in the United States.

Purpose of this study: TB is a common disease in Uganda. Currently, many people who have TB delay starting treatment because they are waiting on results from the lab. We are doing this research study to learn about how we could treat people with TB earlier, before they get more ill or spread TB to others.

What will happen if I agree to participate in this study? We would like to ask you some questions and collect information about your TB symptoms, risk factors for TB, social and economic status, and your opinion about same-day TB treatment, in order to help us understand how people at risk for TB can be benefit of treatment without delay. We will not ask or disclose any identifiable information.

Duration of study: If you choose to participate, completing the series of questions will take about 20 minutes. We can complete it today or schedule it at a more convenient time. We may also ask your treatment team to contact you again if you have confirmed positive TB but have not yet started on treatment for TB.

Risks of participating in this study: You may have a risk of breach of confidentiality. Although the study staff will not record any identifiable data, and the survey will be carried out in a private room, people in the clinic may see that you are taking this survey. This survey is being given to people who are being tested for TB at this clinic, and does not indicate that you actually have TB. You may also experience some discomfort during the interview, as some of the questions may be sensitive. You may choose not to answer any given question if it makes you uncomfortable.

Benefits of participating in this study: Participating in this survey may improve your knowledge about TB but otherwise will not benefit you directly.

Steps we will take to protect your privacy and confidentiality: Research staff will not ask, keep, or release any identifying information about you. To make sure the project follows good research practices, the Makerere University School of Public Health Higher Degree of Research and Ethics Committee, the Johns Hopkins School of Public Health Institutional Review Board, the Ugandan National Council for Science and Technology, or the U.S. National Institutes of Health may look at or copy records that show your study number – but will not keep any records that have your name or identifying information attached. We will comply with all laws that protect your confidentiality.

Voluntary participation: Participating in this survey is voluntary. It is your choice whether to participate or not. You may leave the survey at any time. You may refuse to answer any questions you do not want to answer. If you choose not to participate in the survey, you will still receive health care as you normally would. You may change your mind and leave the survey at any time, even if you agreed earlier. Tell research staff if you are thinking about stopping or if you decide to stop. If you decide after the survey that you do not wish to be in the survey, you can contact the study staff and you will be removed from the survey.

The study staff may also stop you from taking part in this survey at any time if the study is stopped, or if they believe that it is in your best interest.

Costs: You will not be charged for any of the study activities.

Payment: Because we know your time is valuable, we will give you some money to compensate for the inconvenience of participating in the interview or interviews. The interview will take approximately 20 minutes and the study will give you **20,000 (Twenty thousand) shillings.**

Questions: You may ask any questions about this study and survey at any time. You can talk to the study staff about any questions, concerns, or complaints you have about this study. You can also contact Dr. Achilles Katamba, the Principal Investigator on 0772-575-038 or 0753-040-922. If you wish to discuss the study or your rights as a research participant to someone outside the study, or if you wish to voice any problems or concerns you may have about the study, please call Dr. Suzanne Kiwanuka, the chairperson of School of Public Health Higher Degree of Research and Ethics Committee at 0701-273-378.

Consent to Participate

You have been given a copy of this consent form to keep. PARTICIPATION IN RESEARCH IS VOLUNTARY. You have the right to decline to participate or to withdraw at any point in this study without penalty or loss of benefits to which you are otherwise entitled. If you wish to participate in this study, please sign below.

Participant Study ID:

PARTICIPANT

_____	_____	_____
Date	Participant's Name	Participant's Signature or Mark

(Do not date here if participant cannot read and write)

WITNESS – ONLY IF NEEDED

(Only for adult participants who cannot read and write but can communicate)

_____	_____	_____
Date	Name of Witness Attending Consent	Signature of Person Obtaining Consent

RESEARCH STAFF

_____	_____	_____
Date	Name of Person Obtaining Consent	Signature of Person Obtaining Consent

MAKERERE UNIVERSITY COLLEGE OF HEALTH SCIENCES

JOHNS HOPKINS SCHOOL OF PUBLIC HEALTH

ASSENT TO PARTICIPATE IN A RESEARCH STUDY

For adolescents age 15-17 recruited for the end-phase survey

Study: PredicTB: Validating a clinical risk score for early management of tuberculosis in Ugandan primary health clinics

Participant Study ID:

Is the Participant able to Read and Write? Yes ☐ No ☐

Date the Participant Consented: __ __ /__ __ / 20__ __

Time of Signing the Consent Form __ __: __ __ (24-hour clock)

Did the participant comprehend all the information in the Consent Form? Yes ☐ No ☐

Comments:

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Did the Participant have any questions? Yes ☐ No ☐

If Yes, were they all answered? Yes ☐ No ☐

Comments:

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Participant Study ID:

Principal Investigator (Uganda):
Dr. Achilles Katamba, MBChB PhD
Makerere University College of Health Sciences
Email: axk95@case.edu
Tel: +256-414-530-021, +256-753-040-922

Principal Investigator (USA):
Dr. David Dowdy, MD PhD
Johns Hopkins School of Public Health
Email: ddowdy1@jhmi.edu

Introduction: We are inviting you to take part in a research study to understand how people with tuberculosis (TB) symptoms can be diagnosed for TB and treated. When a person presents to the clinic with TB symptoms (cough, fever, night sweat, or recent weight loss), he/she is asked to provide a sample of sputum to be tested for TB. Clinic staff send the sputum sample to the central lab to test for TB, and the lab returns the test result to the clinic. If the result is positive, he/she is expected to hear from the clinic about the result and treatment availability. This entire process can take more than a week, meaning that he/she has to delay the treatment.

We have trained care providers in this clinic to use a clinical risk score, called the "PredicTB" score, to identify people who might be considered for starting TB treatment on the same day of their clinic visit – before their lab results come back. This score is easy to calculate on the basis of patient characteristics (for example, age and sex) and the presence of TB symptoms. If the score is higher than a certain level, clinicians might decide to start patients on TB treatment immediately, without waiting for lab results – but every patient is different, and clinicians will only use this score as one consideration in deciding how to treat you. All treatment decisions will be made by your treating care provider, based on their assessment of your condition. Whether this score is used or not, a sample of sputum will still be sent to the lab to confirm whether you have TB.

We are now asking you to participate in an additional survey, because your provider asked you to provide a sputum specimen for TB diagnosis – and we are interested in how the "PredicTB" score performed, and also if it can be improved for other patients in the future. If you agree to participate, we would like to ask information about your TB symptoms, risk factors for TB, social and economic status, and opinion about same-day TB treatment, in order to help us understand how people at risk for TB can benefit from this score, and from treatment without delay.

Alternative to participation: You can choose whether or not you want to participate in this survey. Participation in this survey will not affect your clinical care in any way. Even if you choose not to participate in the survey and had a positive TB test, you will still be able to receive treatment for TB. If you have any questions or wish to stop being a part of the survey at any time, you can always ask any member of our study team.

Sponsor: The research study, including this survey, is sponsored by the National Institutes of Health in the United States, and it is being conducted by researchers from Makerere University in Uganda and from Johns Hopkins University in the United States.

Purpose of this study: TB is a common disease in Uganda. Currently, many people who have TB delay starting treatment because they are waiting on results from the lab. We are doing this research study to learn about how we could treat people with TB earlier, before they get more ill or spread TB to others.

What will happen if I agree to participate in this study? We would like to ask you some questions and collect information about your TB symptoms, risk factors for TB, social and economic status, and your opinion about same-day TB treatment, in order to help us understand how people at risk for TB can be benefit of treatment without delay. We will not ask or disclose any identifiable information.

Duration of study: If you choose to participate, completing the series of questions will take about 20 minutes. We can complete it today or schedule it at a more convenient time. We may also ask your treatment team to contact you again if you have confirmed positive TB but have not yet started on treatment for TB.

Risks of participating in this study: You may have a risk of breach of confidentiality. Although the study staff will not record any identifiable data, and the survey will be carried out in a private room, people in the clinic may see that you are taking this survey. This survey is being given to people who are being tested for TB at this clinic, and does not indicate that you actually have TB. You may also experience some discomfort during the interview, as some of the questions may be sensitive. You may choose not to answer any given question if it makes you uncomfortable.

Benefits of participating in this study: Participating in this survey may improve your knowledge about TB but otherwise will not benefit you directly.

Steps we will take to protect your privacy and confidentiality: Research staff will not ask, keep, or release any identifying information about you. To make sure the project follows good research practices, the Makerere University School of Public Health Higher Degree of Research and Ethics Committee, the Johns Hopkins School of Public Health Institutional Review Board, the Ugandan National Council for Science and Technology, or the U.S. National Institutes of Health may look at or copy records that show your study number – but will not keep any records that have your name or identifying information attached. We will comply with all laws that protect your confidentiality.

Voluntary participation: Participating in this survey is voluntary. It is your choice whether to participate or not. You may leave the survey at any time. You may refuse to answer any questions you do not want to answer. If you choose not to participate in the survey, you will still receive health care as you normally would. You may change your mind and leave the survey at any time, even if you agreed earlier. Tell research staff if you are thinking about stopping or if you decide to stop. If you decide after the survey that you do not wish to be in the survey, you can contact the study staff and you will be removed from the survey.

The study staff may also stop you from taking part in this survey at any time if the study is stopped, or if they believe that it is in your best interest.

Costs: You will not be charged for any of the study activities.

Payment: Because we know your time is valuable, we will give you some money to compensate for the inconvenience of participating in the interview or interviews. The interview will take approximately 20 minutes and the study will give you **20,000 (Twenty thousand) shillings.**

Questions: You may ask any questions about this study and survey at any time. You can talk to the study staff about any questions, concerns, or complaints you have about this study. You can also contact Dr. Achilles Katamba, the Principal Investigator on 0772-575-038 or 0753-040-922. If you wish to discuss the study or your rights as a research participant to someone outside the study, or if you wish to voice any problems or concerns you may have about the study, please call Dr. Suzanne Kiwanuka, the chairperson of School of Public Health Higher Degree of Research and Ethics Committee at 0701-273-378.

Consent to Participate

You have been given a copy of this consent form to keep. PARTICIPATION IN RESEARCH IS VOLUNTARY. You have the right to decline to participate or to withdraw at any point in this study without penalty or loss of benefits to which you are otherwise entitled. If you wish to participate in this study, please sign below.

Participant Study ID:

ADOLESCENT PARTICIPANT

_____	_____	_____
Date	Participant's Name	Participant's Signature or Mark

(Do not date here if participant cannot read and write)

WITNESS – ONLY IF NEEDED

(Only for adult participants who cannot read and write but can communicate)

_____	_____	_____
Date	Name of Witness Attending Consent	Signature of Person Obtaining Consent

RESEARCH STAFF

_____	_____	_____
Date	Name of Person Obtaining Consent	Signature of Person Obtaining Consent

MAKERERE UNIVERSITY COLLEGE OF HEALTH SCIENCES

JOHNS HOPKINS SCHOOL OF PUBLIC HEALTH

CONSENT TO PARTICIPATE IN A RESEARCH STUDY

For parents/legal guardians of adolescents age 15-17 recruited for the end-phase survey

Study: PredicTB: Validating a clinical risk score for early management of tuberculosis in Ugandan primary health clinics

Participant Study ID:

Is the Parent able to Read and Write? **Yes** ☐ **No** ☐

Date the Participant Consented: __ __ /__ __ / 20__ __

Time of Signing the Consent Form __ __: __ __ (24-hour clock)

Did the parent comprehend all the information in the Consent Form? Yes ☐ **No** ☐

Comments:

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Did the Parent have any questions? **Yes** ☐ **No** ☐

If Yes, were they all answered? **Yes** ☐ **No** ☐

Comments:

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Principal Investigator (Uganda):
Dr. Achilles Katamba, MBChB PhD
Makerere University College of Health Sciences
Email: axk95@case.edu
Tel: +256-414-530-021, +256-753-040-922

Principal Investigator (USA):
Dr. David Dowdy, MD PhD
Johns Hopkins School of Public Health
Email: ddowdy1@jhmi.edu

Introduction: We are inviting your child to take part in a research study to understand how people with tuberculosis (TB) symptoms can be diagnosed for TB and treated. When a person presents to the clinic with TB symptoms (cough, fever, night sweat, or recent weight loss), he/she is asked to provide a sample of sputum to be tested for TB. Clinic staff send the sputum sample to the central lab to test for TB, and the lab returns the test result to the clinic. If the result is positive, he/she is expected to hear from the clinic about the result and treatment availability. This entire process can take more than a week, meaning that he/she has to delay the treatment.

We have trained care providers in this clinic to use a clinical risk score, called the "PredicTB" score, to identify people who might be considered for starting TB treatment on the same day of their clinic visit – before their lab results come back. This score is easy to calculate on the basis of patient characteristics (for example, age and sex) and the presence of TB symptoms. If the score is higher than a certain level, clinicians might decide to start patients on TB treatment immediately, without waiting for lab results – but every patient is different, and clinicians will only use this score as one consideration in deciding how to treat your child. All treatment decisions will be made by your child's treating care provider, based on their assessment of your child's condition. Whether this score is used or not, a sample of sputum will still be sent to the lab to confirm whether your child has TB.

We are now asking your child to participate in an additional survey, because your child's provider asked your child to provide a sputum specimen for TB diagnosis – and we are interested in how the "PredicTB" score performed, and also if it can be improved for other patients in the future. If you agree for your child to participate, we would like to ask information about your child's TB symptoms, risk factors for TB, social and economic status, and his/her opinion about same-day TB treatment, in order to help us understand how people at risk for TB can benefit from this score, and from treatment without delay.

Alternative to participation: You can choose whether or not you want your child to participate in this survey. Participation in this survey will not affect your child's clinical care in any way. Even if you choose for your child not to participate in the survey and your child had a positive TB test, your child will still be able to receive treatment for TB. If you have any questions or wish your child to stop being a part of the survey at any time, you can always ask any member of our study team.

Sponsor: The research study, including this survey, is sponsored by the National Institutes of Health in the United States, and it is being conducted by researchers from Makerere University in Uganda and from Johns Hopkins University in the United States.

Purpose of this study: TB is a common disease in Uganda. Currently, many people who have TB delay starting treatment because they are waiting on results from the lab. We are doing this research study to learn about how we could treat people with TB earlier, before they get more ill or spread TB to others.

What will happen if I agree to participate in this study? We would like to ask your child some questions and collect information about his/her TB symptoms, risk factors for TB, social and economic status, and his/her opinion about same-day TB treatment, in order to help us understand how people at risk for TB can be benefit of treatment without delay. We will not ask or disclose any identifiable information of your child.

Duration of study: If you choose for your child to participate, completing the series of questions will take about 20 minutes. We can complete it today or schedule it at a more convenient time for your child. We may also ask your

child's treatment team to contact your child again if he/she has confirmed positive TB but has not yet started on treatment for TB.

Risks of participating in this study: Your child may have a risk of breach of confidentiality. Although the study staff will not record any identifiable data, and the survey will be carried out in a private room, people in the clinic may see that you are taking this survey. This survey is being given to people who are being tested for TB at this clinic, and does not indicate that you actually have TB. Your child may also experience some discomfort during the interview, as some of the questions may be sensitive. Your child may choose not to answer any given question if it makes you uncomfortable.

Benefits of participating in this study: Participating in this survey may improve your child's knowledge about TB but otherwise will not benefit you directly.

Steps we will take to protect your privacy and confidentiality: Research staff will not ask, keep, or release any identifying information about your child. To make sure the project follows good research practices, the Makerere University School of Public Health Higher Degree of Research and Ethics Committee, the Johns Hopkins School of Public Health Institutional Review Board, the Ugandan National Council for Science and Technology, or the U.S. National Institutes of Health may look at or copy records that show your study number – but will not keep any records that have your child's name or identifying information attached. We will comply with all laws that protect your child's confidentiality.

Voluntary participation: Participating in this survey is voluntary. It is you/your child's choice whether to participate or not. Your child may leave the survey at any time. Your child may refuse to answer any questions he/she does not want to answer. If your child chooses not to participate in the survey, your child will still receive health care at any regular clinic or hospital. Your child may change your/his/her mind and leave the survey at any time, even if you/your child agreed earlier. Tell research staff if you/your child are thinking about stopping or if you/your child decide to stop. If you/your child decide after the survey that you/your child do not wish to be in the survey, you/your child can contact the study staff and your child's information will be removed from the survey.

The study staff may also stop you/your child from taking part in this survey at any time if the study is stopped, or if they believe that it is in your best interest.

Costs: You will not be charged for any of the study activities.

Payment: Because we know your child's time is valuable, we will give your child some money to compensate for the inconvenience of participating in the interview or interviews. The interview will take approximately 20 minutes and the study will give your child **20,000 (Twenty thousand) shillings.**

Questions: You/your child may ask any questions about this study and survey at any time. You/your child can talk to the study staff about any questions, concerns, or complaints you/your child have about this study. You/your child can also contact Dr. Achilles Katamba, the Principal Investigator on 0772-575-038 or 0753-040-922. If you/your child wish to discuss the study or your child's rights as a research participant to someone outside the study, or if you/your child wish to voice any problems or concerns you/your child may have about the study, please call Dr. Suzanne Kiwanuka, the chairperson of School of Public Health Higher Degree of Research and Ethics Committee at 0701-273-378.

Consent to Participate

You have been given a copy of this consent form to keep. PARTICIPATION IN RESEARCH IS VOLUNTARY. You have the right to decline for your child to participate or to withdraw at any point in

this study without penalty or loss of benefits to which you/your child are otherwise entitled. If you wish for your child to participate in this study, please sign below.

ADOLESCENT'S NAME

_____ _____
Date Participant's Name
(Do not date here if participant cannot read and write)

PARENT/LEGAL GUARDIAN

_____ _____ _____
Date Name of Witness Attending Consent Signature of Person Obtaining Consent

WITNESS – ONLY IF NEEDED
(Only for adult participants who cannot read and write but can communicate)

_____ _____ _____
Date Name of Witness Attending Consent Signature of Person Obtaining Consent

RESEARCH STAFF

_____ _____ _____
Date Name of Person Obtaining Consent Signature of Person Obtaining Consent

MAKERERE UNIVERSITY COLLEGE OF HEALTH SCIENCES

JOHNS HOPKINS SCHOOL OF PUBLIC HEALTH

CONSENT TO PARTICIPATE IN A RESEARCH STUDY

For care providers whose clinical activities will be observed in the study clinics

Study: PredicTB: Validating a clinical risk score for early management of tuberculosis in Ugandan primary health clinics

Provider-participant initial:

Date the Participant Consented: __ __ /__ __ / 20__ __

Time of Signing the Consent Form __ __: __ __ (24-hour clock)

Did the participant comprehend all the information in the Consent Form? Yes ☐ No ☐

Comments:

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Did the Participant have any questions? Yes ☐ No ☐

If Yes, were they all answered? Yes ☐ No ☐

Comments:

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Principal Investigator (Uganda):
Dr. Achilles Katamba, MBChB PhD
Makerere University College of Health Sciences
Email: axk95@case.edu
Tel: +256-414-530-021, +256-753-040-922

Principal Investigator (USA):
Dr. David Dowdy, MD PhD
Johns Hopkins School of Public Health
Email: ddowdy1@jhmi.edu

Introduction: We are inviting you to take part in a research study as a health care provider who provides diagnosis or treatment for patients with pulmonary TB in four selected clinics. We have introduced you to a clinical risk score, the "PredicTB" score, designed to evaluate a patient's risk of TB and provide a guide for same-day treatment initiation. All treatment decisions are still ultimately at your discretion, based on your clinical training. We would like to learn how you integrate this score into your routine practice (if at all) and how you use the score.

We are asking you to participate in a direct observation study to see how you use this score, estimate the time required for calculating this score, provide feedback to you as to how you and other providers are using this score, and see whether use of this score changes practice in this clinic (or not).

You can choose whether or not you want to participate in this direct observation. If you choose to participate, our study staff will contact you during each of four subsequent quarterly site visits and directly observe your utilization of the PredicTB and the record keeping process. The site visits will last approximately two days each, during which time study staff will directly observe your activities, attempting to be as non-intrusive as possible, interfering only minimally with your routine workflow. If any of your patients is uncomfortable with the observer, the observer will wait outside the room and ask you to estimate the time you took on the PredicTB score. Observers will not record any patient data.

Alternative to participation: You may choose not to participate in this portion of the study. Your employment will not be affected if you choose not to participate in the study. If you choose not to participate in the direct observation, you are still welcome to use the PredicTB score as you see fit, and our study staff will remain available to you if you have any questions about its use. We will still collect data from the clinic as a whole (for example, the total number of patients started on treatment, and started on treatment on the same day), but none of those data will be linked to you personally. If you have any questions or wish to stop being a part of this direct observation study at any time, you can always ask any member of our study team, and they will stop the observations immediately.

Sponsor: This study is sponsored by the National Institutes of Health in the United States, and it is being conducted by researchers from Makerere University in Uganda and from Johns Hopkins University in the United States.

Purpose of this study: We are doing this research to improve the clinical management of patients with pulmonary TB in highly resource-constrained settings. To the extent that implementation of PredicTB achieves this goal, observing how providers use the PredicTB score and keep corresponding clinical records will help us evaluate the real-world implementation of the PredicTB risk score and – if it is useful – improve it for future use in other clinics.

What will happen if I agree to participate in this study? Our study staff will contact you during each of the four subsequent quarterly site visits and directly observe your utilization of PredicTB and record keeping process. The site visits will last approximately two days each, during which time study staff will attempt to be as non-intrusive as possible, interfering only minimally with your routine workflow.

Duration of study: If you choose to participate, there will be four two-day-long site visits during which feedback will be provided and your workflow observed.

Risks of participating in this study: You may experience some inconvenience as a result of our study staff's presence, even though we will conduct the study activities in such a way as to minimize adverse impact on routine clinic flow. Importantly, we will try to minimize direct engagement between study staff and providers to the extent

possible, by way of preserving the pragmatic nature of this study. The data collected for the study is not meant to evaluate your clinical performance in any way – none of these data will be reported to your superiors or anyone responsible for evaluating your clinical performance. Rather, the goal of this study is only to evaluate the performance of the PredicTB tool in real-world clinical practice. Nonetheless, you may experience some discomfort if you receive negative feedback (e.g., that your record keeping quality is lower than the clinic or study average). We hope that such feedback will ultimately improve clinical care for patients in the clinic, and again emphasize that this feedback will be shared confidentially to you and will not be made available to any of your superiors.

Benefits of participating in this study: Our direct observation followed by feedback may improve your understanding and adoption of the PredicTB score, and may also improve clinical care for your patients in the clinic.

Steps we will take to protect your privacy and confidentiality: No personal identifiers will be collected at any time, though we cannot fully assure anonymity because the number of providers at each clinic is small. Research staff will have access to information about you, but they will not keep or release any identifying information about you to others. To make sure the project follows good research practices, the Makerere University School of Public Health Higher Degree of Research and Ethics Committee, the Johns Hopkins School of Public Health Institutional Review Board, the Ugandan National Council for Science and Technology, or the U.S. National Institutes of Health may look at or copy records that show your study number. We will comply with all laws that protect your confidentiality.

Voluntary participation: Participating in this study is voluntary. It is your choice whether to participate or not. You may leave the study at any time. If you choose not to participate in the study, you will still receive any support you might want in utilizing the PredicTB score. You may change your mind and leave the direct observation study at any time, even if you agreed earlier. Tell research staff if you are thinking about stopping or if you decide to stop. If you decide after the study that you do not wish to be in the study, you can contact the study staff and you will be removed from the study. We will tell you about any new information or changes in the study that may affect your willingness to continue in the study. The study staff may also stop you from taking part in this study at any time if the study is stopped, or if they believe that it is in your best interest.

Costs: You will not be charged for any of the study activities.

Payment: There will be no compensation.

Questions: You may ask any questions about this study at any time. You can talk to the study staff about any questions, concerns, or complaints you have about this study. You can also contact Dr. Achilles Katamba, the Principal Investigator on 0772-575-038 or 0753-040-922. If you wish to discuss the study or your rights as a research participant to someone outside the study, or if you wish to voice any problems or concerns you may have about the study, please call Dr. Suzanne Kiwanuka, the chairperson of School of Public Health Higher Degree of Research and Ethics Committee at 0701-273-378.

Consent to Participate

You have been given a copy of this consent form to keep. PARTICIPATION IN RESEARCH IS VOLUNTARY. You have the right to decline to participate or to withdraw at any point in this study without penalty or loss of benefits to which you are otherwise entitled. If you wish to participate in this study, please sign below.

PARTICIPANT

Date	Participant's Name	Participant's Signature or Mark

(Do not date here if participant cannot read and write)

STUDY STAFF

Date	Name of Person Obtaining Consent	Signature of Person Obtaining Consent