APPENDIX 1 – CONSENT FORMS

ENGLISH CONSENT FORM

Title of Protocol: Use of unmanned air vehicles (medical drones) to overcome geographical barriers to delivery antiretroviral therapy and biological samples

ABBREVIATED TITLE: MEDICAL DRONE PROJECT

Protocol Version this Consent Form Accompanies: Version 1.5

Protocol Date: 10/02/2020

Principal Investigator: Rosalind Parkes-Ratanshi, MBChB, MRCP, PhD

Site Location*: Infectious Disease Institute (IDI), Kampala, Uganda*

Principal Investigator Phone: 041 4307000

Principal Investigator Email: rratanshi@idi.co.ug

Additional Investigator phone: 0752323253

24-Hour Contact: Dickson Masoni 0753030095, **Joan Akullo** 0774670441

Introduction

My name is ……. (Name of consenter)

I am the …… (Job Title) of the medical drones study

CONSENT FOR JOINING DIFFERENTIATED SERVICE DELIVERY MODEL WITH DRONE ART DELIVERY (BUFUMIRA SITES)

INFORMED CONSENT

We are asking you to volunteer for a research study in Kalangala District. We will first explain why we are doing this study, the good and bad about it, and what will be asked of you if you agree to be in the study.

If you decide to be in the research study, we will ask you to sign this consent form or make your mark in front of a witness. We will give you a copy of this form. This consent form might contain some words that you do not know. Please ask us to explain anything you do not understand.

What is a drone?

Drone refers to an unpiloted aircraft or spacecraft. Another term for it is an "unmanned aerial vehicle,"(UAV). A drone is a flying robot that can fly with either a person controlling it or with a computer programme.

What are some of the uses of drones?
Drones are used in a wide range of roles such as in search and rescue, traffic monitoring, weather monitoring and firefighting. Drones are also used for videography, mapping of community boundaries, monitoring fast moving crop pests such as the armyworm and monitoring livestock and wildlife in parks, and for delivery services.

Benefits of drones
They can save lives
In natural and manmade disasters, UAV can be positioned to survey damage, locate stranded and injured victims, deliver emergency drugs/medical supplies and assess ongoing threats without risking the safety of rescue teams and first-responders.
They can provide access to hard-to-reach places
They are very good at providing maps of areas where it is difficult to travel to and in Rwanda, they are used to deliver blood supplies

PURPOSE OF THE STUDY

The purpose of this study is to understand if medical drones are able to help us deliver anti-retroviral drugs (drugs for HIV care) more cheaply and more effectively than using boats. We would like to understand if the medical drones help patients to get an undetectable viral load, stay in care and not get lost to follow up. We will compare the drones to other ways of accessing ART such as pick up at health center, delivery by outreaches and peer support group pickups. We would like to understand how the drones work, what the challenges are and what the costs of using drones are. We will also look at what other medical uses we can use the drones for. We have obtained permission from the Makerere University School of Medicine Ethics Committee and Uganda National Council for Science and Technology for conducting this study.

WHY ARE YOU BEING INVITED TO PARTICIPATE IN THE STUDY? HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

You are being invited to take part in this study because you are an HIV-infected individual on ART or soon initiating and are receiving care at Bufumira HCIV in Kalangala district.

A total of up to 250 people will be participating in this study.

YOUR PARTICIPATION IS VOLUNTARY

Before you learn about the study procedures, it is important that you know these things:

- You do not have to be in this study if you do not want to.
- You may decide to not take part in the study. You may stop being in the study at any time. If you stop, you will not lose any of the benefits of your regular medical care (including community distribution, outreaches, peer support groups etc. if they are available in your landing site)

- If you decide to not take part in the study, you can still join another research study later, if one is available and you qualify.
- If you do not join the study, it will not stop you from receiving ART by drone in the future if it becomes widely available

STUDY PROCEDURES: WHAT WILL HAPPEN TO YOU IF YOU TAKE PART?

If you agree to take part in this research study, you will be asked to read, sign and date the consent form attached to this information sheet. This will happen after the study has been verbally explained to you by your doctor and/or his designee, and all your questions have been answered. A copy of the signed, completed consent form would be given to you for your information and records. If you permit, your doctor will inform your primary care doctor of your participation in this trial.

You may already be taking ART medication at the time of enrollment or will start ART at the same time as the study. The choice of the medication and the decision to start or change medication is not related to this study. The HIV medication is not being made available as a part of this study. HIV medication is provided free of charge as part of your routine care in the health facility.

After joining the study, we will continue with your normal study procedures that you have already consented for including a questionnaire today, in 6 months and in 12 months.

The table below shows the summary of the procedures you will undergo while participating in the study.

Study procedures	Base-line survey	Pre-drone preparation	Drone deployment	Monthly	Month 6	Month 12
Individual Informed Consent for survey/ FGC/ IDI	√					
Evaluation for eligibility DSD models, Formation of ART groups and group consenting		√				
Quantitative surveys undertaken	√		√		√	√
Qualitative FGD/ IDI undertaken	√				√	√
ART delivered by facility visits/ outreaches	√	√	√	√	√	√
Participant consent to join DSD model including drone delivery		√				
ART delivery using at predetermined sites and pic-ups by drone*			√	√	√	√

Follow-up Visits

If you decide to be part of this study, you will get your ART delivery through a community/ peer support group. The ART may be delivered to the group by drone or by boat. If the drone is not available a delivery by boat will be arranged.

In case you miss an appointment
We will call you and may visit your home or call your next of kin to help us identify the reason for this.

WHAT IS REQUIRED OF YOU?
While you are in the study you must:

Agree that your ART will be delivered by the DSD method chosen for your landing site (e.g. peer support community group, village health team led community ART refill)

Agree that your ART can be delivered by drone when they are working well

Accept to disclose your HIV status to the group

The group leader will receive the drone on behalf of the group and distribute the ART

RISKS AND DISCOMFORTS

Safety of drones

Drones feature safety devices to allow them to abandon a pre-planned mission and return to a landing point directly if they experience any problems.

Confidentiality. The greatest risk of this study is that your HIV status may become known to those on your landing site if they see you picking ART from the drone. However, your group leader will manage the drone and you can pick your ART from them at another time so that you are not identified by touching or going near to the drone.

There are no major risks identified from this study. The risk to patients may include temporarily not being able to access medicines by drone due to technical breakdown. There is a small chance that the drone may crash and cause injury to the general public, but this is unlikely as the drone will be flying mainly over water and not over places where people live. All flight paths will be approved by the Ugandan Civil Aviation Authority. There will be no additional medical risks compared to the standard of care at Bufumira HCIV.

There is a small risk of breach of confidentiality, but all data will be collected with a number instead of a name and the tablets/ computers will be kept locked away and password protected.

BENEFITS

In this study you may be able to access your ART through a DSD which may be more convenient for you and can deliver straight to your landing site. Once drone delivery starts you may also receive your medication by drone which can also deliver to your landing site. Also, you or others may benefit in the future from what is learned in this study.

NEW FINDINGS

You will be told any new information learned during this study. It may be important for your health. You may be told when the results of the study may be available and how to learn about them.

COSTS TO YOU

There is no cost to you for being in the study.

REASONS WHY YOU MAY BE WITHDRAWN FROM THE STUDY

You may be removed from the study without your consent for the following reasons:

- If the study is stopped or canceled.
- If the study staff feels that staying in the study would be harmful to you.

- If you become unwell/ pregnant and cannot get your ART by DSD model; you will then need to get your care from a facility health worker at the facility or at an outreach camp.

ALTERNATIVES TO PARTICIPATION

You do not have to participate in this study. If you decide not to participate in the study you will receive the standard of care at the health facility.

REIMBURSEMENT

There is no reimbursement as DSD is a standard delivery ART model.

PARTICIPANT RIGHTS

Participation in this study is entirely voluntary. You have the right to refuse to participate in this study and this decision will not affect your treatment at IDI in any way. If you choose to participate in the study you have the right to withdraw from the study at any time. You may contact the chairman of the Research Ethics Committee if you have any questions regarding your rights as a study participant at any time.

Dr. Suzanne Kiwanuka
School of Public Health
Makerere University
skiwanuka@musph.ac.ug
256-701-888-163/ 256-312-291-397

CONFIDENTIALITY

Efforts will be made to keep your personal information confidential. Information from Medical Drones project will be kept on tablets which will be password protected and locked every evening. Study information about you will be identified only by code. The link between your name and code will be kept in a secure location. Any publication of this study will not use your name or identify you personally. Your personal information will only be disclosed if required by law.

Your study records may be reviewed by study staff and representatives of:

- Infectious Diseases Institute, Makerere University
- The Makerere University School of Public Health IRB
- Uganda National Council for Science and Technology

RESEARCH-RELATED INJURY

The MOH staff will track your health while you are in this study and you can use visit a MOH clinic to get health information if you are unwell. If you have a medical emergency that requires immediate care and you cannot reach the study staff, please go to the nearest clinic that can care for your problem.

IDI does not normally pay for harm done. However, the study doctors will ensure you get care at Kalangala HCIV according to national guidelines.

By signing this consent form and agreeing to be in this study, you are not giving up any of your rights.

PROBLEMS OR QUESTIONS

Dr. Rosalind Parkes-Ratanshi or her designee will explain this study to you. If you have any questions you may ask her designee now or any time during the study. You may ask to speak to:

Dr. Rosalind Parkes-Ratanshi
Infectious Diseases Institute,
Mulago Hospital Complex
Makerere University, Kampala
Email: rratanshi@idi.co.ug
Mobile: 0752323253

INFORMED CONSENT FORM

I have read this form or had it read to me. I have discussed the information with study staff. My questions have been answered. I volunteer to join a DSD model as detailed below. I understand my DSD model may get delivery by medical drone I have been told that my decision whether or not to take part in the DSD is voluntary. I have been told that if I decide to join the Medical Drones study I may withdraw at any time. By signing this form, I do not give up any legal rights that I have as a research participant.

Name of landing site _____

DSD model being used _____

Name of group leader _____

Group number _____

…… …….. ……..

Name of Participant (Print) Signature of participant Phone contact

or if illiterate, make a thumbprint * in the box below

Date ____ /____ /____

Day Month Year

_____ _____

Name of Person Administering Consent (printed) Signature of Person Administering Consent

Date ____ /____ /____

_____

Day Month Year

Position/Title

**If the patient is unable to read and/or write, an impartial witness should be present during the informed consent discussion. After the written informed consent form is read and explained to the participant, and after they have orally consented to their participation in the study, and have either signed the consent form or provided their fingerprint, the witness should sign and personally date the consent form. By signing the consent form, the witness attests that the information in the consent form and any other written information was accurately explained to, and apparently understood by, the patient and that informed consent was freely given by the patient*.

_____ _____

Name of Person Witnessing Consent (printed) Signature of Person Witnessing Consent

Date ____ /____ /____

Day Month Year

ENGLISH CONSENT FORM

Title of Protocol: Use of unmanned air vehicles (medical drones) to overcome geographical barriers to delivery antiretroviral therapy: The Bufumira pilot

ABBREVIATED TITLE: MEDICAL DRONE PROJECT

Protocol Version this Consent Form Accompanies: Version 1.5

Protocol Date: 10/02/2020

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Site Location*: Infectious Disease Institute (IDI), Kampala, Uganda*

Principal Investigator Phone: 041 4307000

Principal Investigator Email: rratanshi@idi.co.ug

Additional Investigator phone: 0752323253

24-Hour Contact: Dickson Masoni 0753030095, **Joan Akullo** 0774670441

Introduction

My name is ……. (Name of consenter)

I am the …… (Job Title) of the medical drones study

QUANTITATIVE AND QUALITATIVE CONSENT FOR PEOPLE LIVING WITH HIV ABOUT MEDICAL DRONES

What is a drone?

Drone refers to an unpiloted aircraft or spacecraft. Another term for it is an "unmanned aerial vehicle,"(UAV). Essentially, a drone is a flying robot that can fly autonomously or be remotely controlled through software-controlled flight plans in their embedded systems, working in conjunction with on-board sensors and GPS.

What are some of the uses of drones?

Drones are used in a wide range of roles such as in search and rescue, surveillance, traffic monitoring, weather monitoring and firefighting. Drones are also used for videography, mapping of community boundaries, monitoring fast moving crop posts such as the armyworm and monitoring livestock and wildlife in parks, and delivery services.

Benefits of drones

They can save lives

In natural and manmade disasters, UAV can be positioned to survey damage, locate stranded and injured victims, deliver emergency drugs/medical supplies and assess ongoing threats without risking the safety of rescue teams and first-responders.

They can provide access to hard-to-reach places

In the delivery of drugs as in aerial photography, drones can be efficiently, economically and safely captured used to capture reliable information.

Reduction of costs of providing services

For instance, the supply of medicines using a boat and a drone.

INFORMED CONSENT

We are asking you to volunteer for a research study in Kalangala District. We will first explain why we are doing this study, the good and bad about it, and what will be asked of you if you agree to be in the study.

If you decide to be in the research study, we will ask you to sign this consent form or make your mark in front of a witness. We will give you a copy of this form. This consent form might contain some words that you do not know. Please ask us to explain anything you do not understand.

PURPOSE OF THE STUDY

The purpose of this study is to understand if medical drones are able to help us deliver anti-retroviral drugs (drugs for HIV care) more cheaply and more effectively than using boats. We would like to understand if the medical drones help patients to get an undetectable viral load, stay in care and not get lost to follow up. We will compare the drones to other ways of accessing ART such as pick up at health center, delivery by outreaches and peer support group pickups. We would like to understand how the drones work, what the challenges are and what the costs of using drones are. We will also look at what other medical uses we can use the drones for. We have obtained permission from the Makerere University School of Medicine Ethics Committee and Uganda National Council for Science and Technology for conducting this study.

WHY ARE YOU BEING INVITED TO PARTICIPATE IN THE STUDY? HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

You are being invited to take part in this study because you are resident on Kalangala and have visited Bufumira HC III or Mazinga HCIII in Kalangala district for your HIV care.

A total of up to 250 people will be participating in this study.

YOUR PARTICIPATION IS VOLUNTARY

Before you learn about the study procedures, it is important that you know these things:

- You do not have to be in this study if you do not want to.
- You may decide to not take part in the study. You may stop being in the study at any time. If you stop, you will not lose any of the benefits of your regular medical care
- If you decide to not take part in the study, you can still join another research study later, if one is available and you qualify.
- If you do not join the study, it will not stop you from receiving medication by drone in the future if it becomes widely available

STUDY PROCEDURES: WHAT WILL HAPPEN TO YOU IF YOU TAKE PART?

If you agree to take part in this research study, you will be asked to read, sign and date the consent form attached to this information sheet. This will happen after the study has been verbally explained to you by your doctor and/or his designee, and all your questions have been answered. A copy of the

signed, completed consent form would be given to you for your information and records. If you permit, your doctor will inform your primary care doctor of your participation in this trial.

After joining the study, you will be asked some questions by a health care worker about your access to medical services, your medical needs and your thoughts about medical drones. This information will be recorded on a computer tablet.

WHAT IS REQUIRED OF YOU?

While you are in the study you must:

Answer the questions from the health worker truthfully

RISKS AND DISCOMFORTS

There are no major risks identified from this study as it is a simple questionnaire. We estimate it will take no longer than 30 minutes.

If you feel uncomfortable with any questions, you do not need to answer.

There is a small risk of breach of confidentiality, but all data will be collected with a number instead of a name and the tablets/ computers will be kept locked away and password protected.

BENEFITS

You or others may benefit in the future from what is learned in this study in planning for medical drones in Kalangala District

NEW FINDINGS

You will be told any new information learned during this study. It may be important for your health. You may be told when the results of the study may be available and how to learn about them.

COSTS TO YOU

There is no cost to you for being in the study.

ALTERNATIVES TO PARTICIPATION

You do not have to participate in this study. If you decide not to participate in the study you will receive the standard of care at the health facility.

REIMBURSEMENT

You will get 10,000 shillings for your time spent filling in the questionnaire.

PARTICIPANT RIGHTS

Participation in this study is entirely voluntary. You have the right to refuse to participate in this study and this decision will not affect your treatment at IDI in any way. If you choose to participate in the

study, you have the right to withdraw from the study at any time. You may contact the chairman of the Research Ethics Committee if you have any questions regarding your rights as a study participant at any time.

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Your study records may be reviewed by study staff and representatives of:

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RESEARCH-RELATED INJURY

The MOH staff will track your health while attending this clinic and you can use visit a MOH clinic to get health information if you are unwell. If you have a medical emergency that requires immediate care and you cannot reach the study staff, please go to the nearest clinic that can care for your problem.

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Email: rratanshi@idi.co.ug
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INFORMED CONSENT FORM

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…… …….. ……..

Name of Participant (Print) Signature of participant Phone contact

Or if illiterate, make a thumbprint * in the box below

Date ____ /____ /____

Day Month Year

_____ _____

Name of Person Administering Consent (printed) Signature of Person Administering Consent

Date ____ /____ /____

_____

Day Month Year

Position/Title

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Name of Person Witnessing Consent (printed) Signature of Person Witnessing Consent

Date ____ /____ /____

Day Month Year

ENGLISH CONSENT FORM

Title of Protocol: Use of unmanned air vehicles (medical drones) to overcome geographical barriers to delivery antiretroviral therapy: The Bufumira pilot

ABBREVIATED TITLE: MEDICAL DRONE PROJECT

Protocol Version this Consent Form Accompanies: Version 1.5

Protocol Date: 10/02/2020

Principal Investigator: Rosalind Parkes-Ratanshi, MBChB, MRCP, PhD

Site Location*: Infectious Disease Institute (IDI), Kampala, Uganda*

Principal Investigator Phone: 041 4307000

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24-Hour Contact: Dickson Masoni 0753030095, **Joan Akullo** 0774670441

Introduction

My name is ……. (Name of consenter)

I am the …… (Job Title) of the medical drones study

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What is a drone?

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Reduction of costs of providing services

For instance, the supply of medicines using a boat and a drone.

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If you decide to be in the research study, we will ask you to sign this consent form or make your mark in front of a witness. We will give you a copy of this form. This consent form might contain some words that you do not know. Please ask us to explain anything you do not understand.

PURPOSE OF THE STUDY

The purpose of this study is to understand if medical drones are able to help us deliver anti-retroviral drugs (drugs for HIV care) more cheaply and more effectively than using boats. We would like to understand if the medical drones help patients to get an undetectable viral load, stay in care and not get lost to follow up. We will compare the drones to other ways of accessing ART such as pick up at health center, delivery by outreaches and peer support group pickups. We would like to understand how the drones work, what the challenges are and what the costs of using drones are. We will also look at what other medical uses we can use the drones for which is why we would like to interview people who do not have HIV to find Your medical needs. We have obtained permission from the Makerere University School of Medicine Ethics Committee and Uganda National Council for Science and Technology for conducting this study.

WHY ARE YOU BEING INVITED TO PARTICIPATE IN THE STUDY? HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

You are being invited to take part in this study because you are resident on Kalangala and have visited Bufumira HC III or Mazinga HCIII in Kalangala district for a medical problem.

A total of up to 100 people will be participating in this study.

YOUR PARTICIPATION IS VOLUNTARY

Before you learn about the study procedures, it is important that you know these things:

- You do not have to be in this study if you do not want to.
- You may decide to not take part in the study. You may stop being in the study at any time. If you stop, you will not lose any of the benefits of your regular medical care
- If you decide to not take part in the study, you can still join another research study later if one is available and you qualify.
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After joining the study, you will be asked some questions by a health care worker about your access to medical services, your medical needs and your thoughts about medical drones.

WHAT IS REQUIRED OF YOU?

While you are in the study you must:

Answer the questions from the health worker truthfully

RISKS AND DISCOMFORTS

There are no major risks identified from this study as it is a simple questionnaire. We estimate it will take no longer than 30 minutes.

If you feel uncomfortable with any questions, you do not need to answer.

There is a small risk of breach of confidentiality, but all data will be collected with a number instead of a name and the tablets/ computers will be kept locked away and password protected.

BENEFITS

You or others may benefit in the future from what is learned in this study in planning for medical drones in Kalangala District

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Dr. Suzanne Kiwanuka
School of Public Health
Makerere University
skiwanuka@musph.ac.ug
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The MOH staff will track your health while attending this clinic and you can use visit a MOH clinic to get health information if you are unwell. If you have a medical emergency that requires immediate care and you cannot reach the study staff, please go to the nearest clinic that can care for your problem.

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Dr. Rosalind Parkes-Ratanshi
Infectious Diseases Institute,
Mulago Hospital Complex
Makerere University, Kampala
Email: rratanshi@idi.co.ug
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…… …….. ……..

Name of Participant (Print) Signature of participant Phone contact

Or if illiterate, make a thumbprint * in the box below

Date ____ /____ /____

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_____ _____

Name of Person Administering Consent (printed) Signature of Person Administering Consent

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Position/Title

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Title of Protocol: Use of unmanned air vehicles (medical drones) to overcome geographical barriers to delivery antiretroviral therapy and biological samples

ABBREVIATED TITLE: MEDICAL DRONE PROJECT

Protocol Version this Consent Form Accompanies: Version 1.5

Protocol Date: 10/02/2020

Principal Investigator: Rosalind Parkes-Ratanshi, MBChB, MRCP, PhD

Site Location*: Infectious Disease Institute (IDI), Kampala, Uganda*

Principal Investigator Phone: 041 4307000

Principal Investigator Email: rratanshi@idi.co.ug

Additional Investigator phone: 0752323253

24-Hour Contact: Dickson Masoni 0753030095, **Joan Akullo** 0774670441

Introduction

My name is ……. (Name of consenter)

I am the …… (Job Title) of the medical drones study

CONSENT FOR MEDICAL DRONES SAMPLE SUB-STUDY

INFORMED CONSENT

We are asking you to volunteer for a research study in Kalangala District. We will first explain why we are doing this study, the good and bad about it, and what will be asked of you if you agree to be in the study.

If you decide to be in the research study, we will ask you to sign this consent form or make your mark in front of a witness. We will give you a copy of this form. This consent form might contain some words that you do not know. Please ask us to explain anything you do not understand.

PURPOSE OF THE STUDY

You are being asked to take part in a medical drones' sample sub-study. You are being asked to participate because you are an adult who is willing to give two additional samples of blood or urine or sputum for the medical drone sample sub-study.

The purpose of this study is to determine the effect of unmanned aerial transport on laboratory test results. Every transport mode such as planes, trains, cars etc. is used for moving laboratory samples. This allows samples to get from small doctor's offices to big labs. Before a new mode of transport

e.g. planes are used to transport patient samples, we have to make sure it does not affect the test results of the sample. Unmanned aerial vehicles are a new form of transportation that will be used to transport samples in the future. We are doing these initial experiments to see if they affect the test results. We have obtained permission from the Makerere University School of Public Health and Uganda National Council for Science and Technology for conducting this study.

YOUR PARTICIPATION IS VOLUNTARY

Before you learn about the study procedures, it is important that you know these things:

- You do not have to be in this study if you do not want to.
- You may decide to not take part in the study. You may stop being in the study at any time. If you stop, you will not lose any of the benefits of your regular medical care (including community distribution, outreaches, peer support groups etc. if they are available in your landing site)
- If you decide to not take part in the study, you can still join another research study later, if one is available and you qualify.
- If you do not join the study, it will not stop you from receiving health services from this facility in the future.

STUDY PROCEDURES: WHAT WILL HAPPEN TO YOU IF YOU TAKE PART?

If you agree to take part in this sub-study, you will be asked to read, sign and date the consent form attached to this information sheet. This will happen after the study has been verbally explained to you by your doctor and/or his designee, and all your questions have been answered. A copy of the signed, completed consent form would be given to you for your information and records. If you permit, your doctor will inform your primary care doctor of your participation in this trial.

Once your sample are taken, one sample will be flown in the drone for a period of time (up to one hour) and the other sample will be driven to a lab or delivered by boat (the usual route). These samples will be then tested and the results will be compared.

The tests will be as follows.

1) Blood - DBS for viral load, Full blood count, Biochemistry
2) Sputum – gene expert for TB
3) Urine – NAAT for STI (gonorrhea/ Chlamydia)
4) Genital swab – NAAT for STI gonorrhea/ Chlamydia)

The samples will be kept to the end of the study period and then destroyed.

WHAT IS EXPECTED FROM THE PARTICIPANT?

If you decide to volunteer for the study, you will be asked to comply with the following procedures:

- After entering the study, we will collect your clinical history on the day of enrolment.
- We shall provide you a specimen bottle for urine and sputum samples and you will be shown where to go and put the sample in the specimen bottle.
- If you have symptoms of a sexually transmitted infection, you will be requested to take a sample from the genital area with a swab (like a large cotton bud). The full procedure will be explained to you by your doctor. If you do not wish to do this, you can still contribute urine or blood or sputum.

BENEFITS

There will be no direct benefits to you. You will continue receiving the routine care from this health facility. This study will benefit the society in general when results are available after the sub-study.

NEW FINDINGS

You will be told any new information learned during this sub-study. It may be important for your health. You may be told when the results of the sub-study may be available and how to learn about them.

COSTS TO YOU

There is no cost to you for being in the study.

REASONS WHY YOU MAY BE WITHDRAWN FROM THE STUDY

You may be removed from the study without your consent for the following reasons:

- If the study is stopped or canceled.
- If the study staff feel that staying in the study would be harmful to you.

REIMBURSEMENT

There is no reimbursement as this is a voluntary research participation.

PARTICIPANT RIGHTS

Participation in this study is entirely voluntary. You have the right to refuse to participate in this study and this decision will not affect your treatment at IDI in any way. If you choose to participate in the study you have the right to withdraw from the study at any time. You may contact the chairman of the Research Ethics Committee if you have any questions regarding your rights as a study participant at any time.

Dr. Suzanne Kiwanuka
School of Public Health
Makerere University
skiwanuka@musph.ac.ug
256-701-888-163/ 256-312-291-397

CONFIDENTIALITY

Efforts will be made to keep your personal information confidential. Information from Medical Drones project will be kept on tablets which will be password protected and locked every evening. Study information about you will be identified only by code. The link between your name and code will be kept in a secure location. Any publication of this study will not use your name or identify you personally. Your personal information will only be disclosed if required by law.

Your study records may be reviewed by study staff and representatives of:

- Infectious Diseases Institute, Makerere University
- The Makerere University School of Public Health IRB
- Uganda National Council for Science and Technology

RESEARCH-RELATED INJURY

The MOH staff will track your health while you are in this study and you can use visit a MOH clinic to get health information if you are unwell. If you have a medical emergency that requires immediate care and you cannot reach the study staff, please go to the nearest clinic that can care for your problem.

IDI does not normally pay for harm done. However, the study doctors will ensure you get care at Kalangala HCIV according to national guidelines.

By signing this consent form and agreeing to be in this study, you are not giving up any of your rights.

PROBLEMS OR QUESTIONS

Dr. Rosalind Parkes-Ratanshi or her designee will explain this study to you. If you have any questions you may ask her designee now or any time during the study. You may ask to speak to:

Dr. Rosalind Parkes-Ratanshi
Infectious Diseases Institute,
Mulago Hospital Complex
Makerere University, Kampala
Email: rratanshi@idi.co.ug
Mobile: 0752323253

INFORMED CONSENT FORM

I have read this form or had it read to me. I have discussed the information with study staff. My questions have been answered. I volunteer to join a DSD model as detailed below. I understand my DSD model may get delivery by medical drone I have been told that my decision whether or not to take part in the DSD is voluntary. I have been told that if I decide to join the Medical Drones study I may withdraw at any time. By signing this form, I do not give up any legal rights that I have as a research participant.

I agree to provide two of the following samples

1) Blood yes/no/NA
2) Sputum yes/no/ NA
3) Urine yes/no/NA
4) Genital (vaginal/urethral swab) yes/no/NA

…… …….. ……..

Name of Participant (Print) Signature of participant Phone contact

Or if illiterate, make a thumbprint * in the box below

Date ____ /____ /____

Day Month Year

_____ _____

Name of Person Administering Consent (printed) Signature of Person Administering Consent

Date ____ /____ /____

_____

Day Month Year

Position/Title

**If the patient is unable to read and/or write, an impartial witness should be present during the informed consent discussion. After the written informed consent form is read and explained to the participant, and after they have orally consented to their participation in the study, and have either signed the consent form or provided their fingerprint, the witness should sign and personally date the*

consent form. By signing the consent form, the witness attests that the information in the consent form and any other written information was accurately explained to, and apparently understood by, the patient and that informed consent was freely given by the patient.

_____ _____

Name of Person Witnessing Consent (printed) Signature of Person Witnessing Consent

Date ____ /____ /____

Day Month Year