Official Study Title: "INcentives and Re**MIND**ers to Improve Long-term Medication Adherence**" (INMIND)**

Date: 24 August 2021

Consent Form for Clients

"INcentives and Re**MIND**ers to Improve Long-term Medication Adherence**" (INMIND) - Phase 2**

Principal Investigator: Dr. Sebastian Linnemayr**,** PhD
Institution of affiliation: Rand Corporation
Address: 1776 Main Street, Santa Monica, CA 90407-2138, US
Phone contact: +1 310 393 0411 ext 6734
Email: slinnema@rand.org

Site Principal investigator: Dr. Barbara Mukasa
Institution of affiliation: Mildmay Uganda
Address: P.O. Box 24985, Kampala; Uganda.
Office: Tel: +256 312 210 200
Mobile: +256772700816
Email: barbara.mukasa@mildmay.or.ug

Sponsor: National Institute of Mental Health, United States of America (US)

INTRODUCTION
I'm [name of the study coordinator]. I work at Mildmay Uganda Hospital that together with the RAND Corporation from the US is conducting a research study to understand what helps people like you remember to take their HIV pills every day on time. This study has been approved by an accredited Ugandan-based Research Ethics Committee, the Mildmay Uganda Research Ethics Committee.

Before you decide whether you want to be in this study, we would like to explain why we are doing it, how it may help you, any risks to you, and what is expected of you. I will then ask you if you want to be part of the study and if yes, you will be asked to sign this Informed Consent form.

STUDY PURPOSE
Many clients at Mildmay Uganda Hospital have trouble remembering to take their HIV pills called ART every day on time. We therefore came up with a study called Incentives and Reminders to Improve Long-term Medication Adherence or "INMIND." The purpose of this study is to learn whether this INMIND program can help clients form **routines** around taking their pills. With INMIND, some people who take their ART regularly and at the same time can win airtime vouchers of up to 10,000 Ugandan Shillings at their monthly visits for the first three months (meaning there will be up to three prize drawings).

STUDY PROCEDURES
After you enroll in the study, we will give you an electronic pill bottle cap that measures how well you are taking your medication. We will also ask you for your mobile phone contact information, as one of the study activities may involve receiving daily text messages. If you decide to participate in the study we will abstract your viral load test information from Mildmay's records, and in rare cases ask you to undergo a viral load test for study purposes.

The next time you come to the clinic, in about one month, we will check whether you are using the pill bottlecap regularly, and we will ask you to update your contact information and begin the intervention. At that time, you may be asked to complete a 45-minute questionnaire. We will also give you a flyer with information about why it is important to build a routine around pill taking and review this information together during that clinic visit. We will then advise and work with you to choose your preferred pill-taking routine.

For three months, we will ask you to come to this research office every month and will download the data from your electronic pill bottle cap, update your contact information, and you may be eligible to participate in a prize drawing. After three months of intervention, you will also be asked to fill out a follow-up questionnaire. Six months after that, you will be asked to fill out this questionnaire again. These questionnaires will include questions about your background, medical history, symptoms, experience with your pill-taking routine, and your attitude to pill taking. Each questionnaire should take about 45 minutes to complete. Whenever possible,

the study activities will be scheduled on days on which you have a visit already scheduled at Mildmay Uganda Hospital so you don't have to come to the clinic just for study-related reasons.

A total of 150 HIV clients from the Mildmay Uganda Hospital who have just begun their ART treatment will take part in the study. You will be assigned to one of the following three groups with an equal (i.e., one in three) chance, as the assignment is decided by chance by the computer, and you will not be able to choose the group you want to be in.

Clients in Group 1 will receive daily text messages to remind them of their pill-taking routine. During the three months of the intervention, we will measure how well you take your ART and send you a text message every day at the same time. That message will not use any words related to Mildmay, HIV, drugs or ART, but instead, will say something like 'Hello this is INMIND. Please take your vitamins every day at the same time.' After those three months, we will stop sending you messages but will keep measuring your adherence for another six months to see how you take your medication during that time.

Clients in Group 2 will receive the same daily text messages, but may also receive small rewards. During the three months of the intervention, every time you visit the clinic, you may be eligible to receive a small prize of up to 10,000 USh if you take your ART pills very regularly, meaning at the same time every day on at least five days every week. After those three months, we will stop sending you messages, and there will be no more prize drawings, but we will keep measuring your adherence for another six months to see how you take your medication during that time.

Clients in Group 3 will NOT receive daily text messages or be eligible for rewards, but will receive the usual standard of care as offered to all clients at Mildmay clinic.

Schedule of Follow-up Study Visits
No matter which group you are assigned to, you will continue to come to Mildmay Uganda Hospital for your HIV care on your regularly scheduled days. If you wish to leave the study and not continue with the scheduled study visits, you are free to do so.

Use of Electronic Cap to Measure Adherence
An electronic pill bottle cap called 'MEMS cap' that records when the bottle is opened will be used to measure your adherence. At your clinic visits, after you get your medication from the pharmacy please bring the medication to me, and I will give you a MEMS cap to place on one of the pill bottles. If the cap does not fit on your pill bottle, you will be given a different bottle to use. You should only remove the ART medication from the bottle when you are about to swallow the medication.

We will discuss how best to fit the use of the MEMS cap into your life so that it does not hurt your pill-taking. I will call you within the first week of using the cap to ask whether you are having difficulties with using it. Please use this cap and bring your ART medication and the electronic cap to each study visit. You cannot participate in the study if you do not want to or cannot use the MEMS cap; at your next visit by checking if you are taking at least 30% of your scheduled ART pills out of the MEMS cap.

Use of the MEMS cap information to determine eligibility in the monthly prize drawings in group 3
In intervention group 2, the monthly prize drawings are based on taking your ART pills according to the routine agreed on at the beginning of the study. We will get this information when we download the data stored on the MEMS cap.

Receiving text messages
If you are assigned to Group 1 or 2, you will receive daily text messages reminding you to take your medication on time. You can only participate in the study if you either own a cell phone or have regular access (at least five days a week) to one and are willing to receive such messages.

RISKS AND DISCOMFORTS

You may not feel comfortable using the cap if, for example, people who don't know your HIV status ask you what it is; in such cases, we have to discuss if we can find a solution that works for you, or we may decide that you cannot participate in the study because of this issue.

Also, someone with access to your phone might read your study text messages; while we will discuss steps with you on how you can respond if someone asks you about these messages, there is a possibility that someone infers that you are part of a study or a client at Mildmay Uganda Hospital. Should that occur and you feel upset, you will be able to receive counseling or be referred to appropriate mental health services.

If you are in group 2, you may be able to participate in prize drawings; you may feel pressure to come to the clinic and take your medications or feel stress when you do not win a prize, or feel upset because of things discussed in the questionnaire. Should that occur, you will be able to receive counseling or be referred to appropriate mental health services.

POTENTIAL BENEFITS TO PARTICIPANTS AND/OR TO SOCIETY
The INMIND study may help you form a daily pill-taking routine to better adhere to your ART medication; therefore, you may receive health benefits from the treatment. However, because the INMIND intervention is currently being tested, we do not know for sure that it will work. Your participation in the program helps us to learn about its effectiveness and may help improve health care for people living with HIV in the future.

COSTS OF AND COMPENSATION FOR PARTICIPATION
There are no costs to you for participating in the study itself. The costs related to ART and procedures that are part of your usual Mildmay clinical care are your responsibility just as they were before you joined the study.

You will receive 30,000 Uganda Shillings as transport refund each time you participate in a survey. If you stop answering the survey for any reason – even if the survey is not yet over - you will still receive the 30,000 USh.

If you are assigned to Group 2, you may have the chance of winning up to three small monthly prizes in the form of cell phone minutes; the prizes are not guaranteed as they are drawn by chance.

CONFIDENTIALITY
Your answers will be kept private. Instead of your name, we will use a number to identify you. All study documents will be kept in a locked office at the Mildmay Uganda Hospital offices in Kampala. Computer files will be protected with a password.

Only researchers will be able to see your answers. Your name will not be used in any reports or articles we publish. We will not tell your family, your doctors, or anyone else outside the research team what you say or do during the study. However, it is possible that your privacy will be broken. We will do everything we can to prevent this. When we talk about the INMIND intervention in reports or articles, we will hide your name and other things about who you are. We will share only study data with other researchers once it is de-identified (meaning it cannot be linked to you), and after carefully checking the objectives of the researcher requesting it.

VOLUNTARY PARTICIPATION AND OPTION TO WITHDRAW
If you do not want to be in the study, you can stop taking part in the intervention at any time. You will still get the same medical care if you decide not to take part in the study. You do not have to answer any question in the questionnaires that you do not want to answer.

DISSEMINATION OF STUDY FINDINGS
You shall receive communication from the study team about the progress and findings of the study during and/or after the study findings are available to the public.

RIGHTS OF RESEARCH PARTICIPANTS
If you do not understand something, or if you want more information, please ask now. If you have questions about your rights as a research participant, please contact Semei Christopher Mukama, Secretary of the MUREC, at 0392174236. If you have any questions or concerns about the research, please contact Dr.

Barbara Mukasa, Site Principal Investigator, at 0772700816 or Mr. Peter Wabukala, the Study Coordinator, at 0785823296

WRITTEN CONSENT OF RESEARCH PARTICIPANT

"I have read (or someone has read to me) the information provided above. I have been given an opportunity to ask questions, and all of my questions have been answered to my satisfaction. I have been given a copy of this form."

I consent to participate in the research as described above.

_____
Name of Participant

_____ _____
Signature / thumbprint of Participant Date

_____
Name of Witness (if unable to read and write)

_____ _____
Signature / of Witness Date

SIGNATURE OF INVESTIGATOR/STUDY INTERVIEWER

I have explained the research to the participant and answered all of his/her questions. I believe that he/she understands the information described in this document and freely consents to participate.

_____
Name of Study Interviewer

_____ _____
Signature of Study Interviewer Date