

**Cover page – Clinicaltrials.gov**

**Study name:** Reducing Time to Spaced-out Appointments for Newly-diagnosed People Living With HIV

**ClinicalTrials.gov Identifier:** NCT04567693

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## **KEY INFORMATION FOR *REDUCING TIME TO SPACED-OUT APPOINTMENTS FOR NEWLY-DIAGNOSED PEOPLE LIVING WITH HIV***

We are asking you to choose whether or not to volunteer for a research study about the best way to schedule appointments for people who are newly diagnosed with HIV. This page is designed to give you key information to help you decide whether to participate. We have included detailed information after this page. Ask the research team questions. If you have questions later, the contact information for the research investigator in charge of the study is below.

### **WHAT IS THE STUDY ABOUT AND HOW LONG WILL IT LAST?**

By doing this study, we hope to learn whether an appointment schedule with fewer appointments will make it easier for patients living with HIV to get their care. We will compare different appointment schedules to understand the costs and benefits of each one. Your participation in this research will last about 1 year.

### **WHAT ARE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?**

You will not receive any direct benefit from participating in this study. However, some participants appreciate knowing they have contributed to research that may benefit others in the future.

For a complete description of benefits, refer to the Consent Document below.

### **WHAT ARE KEY REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?**

You may not want to participate in this study if you are worried about keeping your information absolutely private. In addition, sometimes answering questions about your health can be stressful.

For a complete description of alternate treatment/procedures, refer to the Consent Document below.

### **DO YOU HAVE TO TAKE PART IN THE STUDY?**

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits or rights or access to care you would normally have if you choose not to volunteer.

### **WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?**

The persons in charge of the study are Dr. Gad Murenzi (Rwanda) and Dr. Jonathan Ross (US) If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study his/her contact information is:.

## DOCUMENTATION OF INFORMED CONSENT AND HIPAA AUTHORIZATION

If you are a parent or legal guardian of a child who may take part in this study, permission from you and the assent (agreement) of your child may be required. When the word “you(r)” / “my” / “me” / “I” appears in this consent form, we mean the participant (you or your child); “we” means the research study doctors and research staff.

### **Introduction**

You are being asked to participate in a research study called ***REDUCING TIME TO SPACED-OUT APPOINTMENTS FOR NEWLY-DIAGNOSED PEOPLE LIVING WITH HIV***. Your participation is voluntary -- it is up to you whether you would like to participate. It is fine to say “no” now or at any time after you have started the study. If you say “no”, your decision will not affect any of your rights or benefits or your access to care.

### **Why is this study being done?**

The goal of this study is to understand whether there are benefits or harms from having less frequent appointments for HIV care starting at 6 months after diagnosis. Right now, people living with HIV in Rwanda must come to appointments often for the first 12 months after diagnosis, which can be difficult. We want to test whether having patients come less frequently will have an effect on patients’ adherence to medication or appointments. We think that coming less frequently will not lead to worse adherence.

### **Why am I being asked to participate?**

You are being asked to participate in this study because you are a person living with HIV, are at least 15 years old and are receiving health care from one of the health centers participating in the study. You are being asked to take part because you heard about the study from someone who works at the health center or from the research staff. In total, we expect approximately 90 people from 3 health facilities to take part in this study.

### **What will happen if I participate in the study?**

If you choose to participate, you will be randomized to one of three appointment schedules. Randomization is like a coin flip. We do not control which schedule you will be assigned. The entire study will last for 1 year. In all schedules, you will continue to come to the health center until 6 months have passed since you first enrolled in care.

- In the first schedule, you will have a viral load checked two times between now and the 6-month point. If both viral loads are suppressed, then you will be scheduled to see the nurse every 6 months and come to the pharmacy for medication pick-up every 3 months.
- In the second schedule, you will have a viral load checked once between now and the 6-month point. If the viral load is suppressed, then you will be scheduled to see the nurse every 6 months and come to the pharmacy for medication pick-up every 3 months.
- In the third schedule, you will continue to come to the health center every 3 months to see the nurse and every month to the pharmacy for the entire study period.

As part of this study we will measure a few blood tests at the first and last research visits. These tests are the same tests that you would have done at the health center. To obtain the blood sample, we will wipe the skin on your arm with alcohol to clean it. Then, we will insert a small needle into a vein. Three tubes of blood will be drawn, about 20ml.

A description of this clinical trial will be available on [www.ClinicalTrials.gov](http://www.ClinicalTrials.gov), as required by U.S. law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

As part of this study we will review your medical records and put the information we collect in our research records.

**How many people will take part in the research study?**

You will be one of about **90** people who will be participating in this study.

**Genetic Testing**

This study will not involve genetic research or genetic testing.

**Specimen Banking (Future Use and Storage)**

We will destroy the specimens and information about you when the study is complete. Information about you will be kept as long as required by regulations and institutional policy, but will not be used for future studies.

**Information Banking (Future Use and Storage)**

Information about you will be kept as long as required by regulations and institutional policy, but will not be used for future studies.

**Will I be paid for being in this research study?**

You will receive a total of RWF 24,000 for 3 study visits. You will receive RWF 8,000 in cash at the end of each visit. If you choose to withdraw from the study before all visits are completed, you will be paid only for the visits you completed.

**Will it cost me anything to participate in this study?**

Taking part in this study will not involve added costs to you. All care will be given free of charge as per Government of Rwanda policies.

**Confidentiality**

The researchers and study staff follow US federal and state laws as well as Government of Rwanda laws to protect your privacy. This part of the consent form tells you what information about you may be used and shared in the research described in this form. You do not have to sign this form but, if you do not, you may not participate in the research.

The health information that we may use or disclose for the research described in this form includes information from your entire medical record, such as your name, phone number, email, medical diagnoses, dates, test results, social security number, medical record numbers, etc.

Your information and research records will be kept confidential. Your study information will be kept as long as they are useful for the research described in this form.

The only people who can see your research records are:

- Researchers and other individuals who work with the researchers
- Organizations and institutions involved in this research, including those that fund the research, if applicable
- Groups that review research such as central reviewers, Institutional Review Boards, the Office for Human Research Protections, the US Food and Drug Administration, data coordinating centers, and domestic and foreign agencies that regulate research.

The purposes of these uses and disclosures are to (1) conduct the study and (2) make sure the study is being done correctly. The information covered under this form may no longer be protected by federal privacy laws (such as HIPAA) once disclosed, and those persons who receive your health information may share your information with others without your additional permission. All of these groups have been asked to keep your information confidential.

Medical information collected during the research, such as test results, may be entered into your medical record and will be available to clinicians and other staff who provide care to you.

To maintain the integrity of this research study, you generally will not have access to your research-related personal health information. If it is necessary for your care, your research-related health information will be provided to you or your physician.

**Are there any times you would not keep my data confidential?**

If you give us information that suggests that your child or any other child is being abused, we are required by law to report that information to the Government of Rwanda agencies in charge of child protection. Reporting this information may put you, your family, or others who are involved at risk of questioning and legal action by the authorities.

If you give us information that you are in danger of hurting yourself, hurting someone else, or being hurt by someone else, we might not be able to keep this information confidential, and might need to share this information with social work or mental health staff at the health center in order to help you.

**Certificate of Confidentiality**

As a way to protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health, which is funding this study. If information from this study were requested or subpoenaed by government agencies or the courts, we would use the Certificate to attempt to legally refuse to provide that information. These requests are rare – in only a few cases did researchers have to use the Certificate, and it was honored most of the time, but not every time. There are several kinds of situations to which the Certificate does not apply. For example, we are still required to report child abuse and some diseases, and we must make data available to the government for review or evaluation of our research. The Certificate does not prevent you or a member of your family from voluntarily sharing information. Similarly, if an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

**Are there any risks to me?**

As part of this study you may have fewer regularly scheduled visits to the health center, which may put you at risk of worse adherence to your medications or appointments, or make you feel like you have less support from the health center.

A risk of taking part in this study is the possibility of a loss of confidentiality or privacy. Loss of privacy means having your personal information shared with someone who is not on the study team and was not supposed to see or know about your information. The study team plans to protect your privacy – see the Confidentiality section above for details.

**Questionnaire**

You may feel uncomfortable answering questions about your health, including about HIV. You can choose not to answer questions that make you feel uncomfortable.

**Blood Draw**

Rarely, the vein where we inserted the needle will become sore or red. Sometimes, a temporary harmless “black and blue” may develop. Very rarely, fainting may occur.

**New Findings**

If we learn any significant new findings during the study that might influence your decision to participate, we will contact you and explain them.

**Are there possible benefits to me?**

You may or may not receive personal, direct benefit from taking part in this study. The possible benefits of taking part in this study include coming to the health center less frequently, which may reduce your burden of care.

**What choices do I have other than participating in this study?**

You can refuse to participate in the study. If you decide not to participate, the medical care providers at this facility will still give you all of the standard care and treatment that is appropriate for you.

**Are there any consequences to me if I decide to stop participating in this study?**

No. If you decide to take part, you are free to stop participating at any time without giving a reason. This will not affect your care and you will continue to be treated at this facility. However, some of the information may have already been entered into the study and that will not be removed. The researchers may continue to use and share the information they have already collected.

To revoke (take back) your consent and authorization, you must contact the Principal Investigator in writing at the address on page 1 of this form. However, you may first call or speak to the Principal Investigator and he will stop collecting new information about you. If you take back your consent and authorization, you will not be allowed to continue to participate in this research study.

**Can the study end my participation early?**

In addition, your participation will end if the investigator or study sponsor stops the study earlier than expected.

**CONSENT TO PARTICIPATE**

I have read the consent form and I understand that it is up to me whether or not I participate. I know enough about the purpose, methods, risks and benefits of the research study to decide that I want to take part in it. I understand that I am not waiving any of my legal rights by signing this informed consent document. I will be given a signed copy of this consent form.

Printed name of participant	Signature of participant (not applicable for participants under age 13)	Date	Time
Printed Name of Parent or Guardian (when applicable)	Signature of Parent or Guardian (when applicable)	Date	Time
Printed name of the person conducting the consent process	Signature	Date	Time