Study ID | | | | |

Research Information Sheet and Consent Form for INTUIT-SA intervention development

Title: **Integrating U=U into HIV Counselling in South Africa (INTUIT-SA)**
IRB Number: Pending
Sponsor: U.S. National Institute of Mental Health (NIMH)

Principal Investigator: Dr. Jacob Bor (Boston University)
Principal Investigator: Dr. Dorina Onoya (University of the Witwatersrand)
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NCT04504357

Invitation to participate

Good day, *[interviewer introduces her/himself and the institution/organization]*. We are asking you to be in a research study. A research study is an organized way of collecting information about scientific questions. This form will tell you what you should expect if you agree to be in the study. We are inviting you to participate in this project because you currently receive or provide HIV care at the *[name of the clinic]* that has been selected as a study site for this project.

It is your decision whether or not to join the study. The purpose of this study is to develop and test a mobile application that presents information about HIV treatment as a means of preventing HIV transmission in South Africa. If you agree, you will participate in a **focus group discussion** or **key informant interview.** The discussion/interview will be a single session and will last about one hour.

Please note that taking part in this study is entirely voluntary. If you choose to participate, you are free to stop participating at any time. If you decide not to participate, you will receive the same care from this clinic that you would receive otherwise.

Please read along with me as I read the information below aloud and ask questions about anything you do not understand before deciding whether to participate. If this information and consent form contains any words you do not understand, please ask the study staff to explain them to you.

What is The Purpose of This Study?

Drs. Jacob Bor from Boston University (USA) and Dorina Onoya from the University of the Witwatersrand in Johannesburg are conducting a research study with HIV positive patients at three clinics in Johannesburg. The main aim of the study is to develop and assess the value of a mobile application ("App") with videos to let HIV positive persons know about the benefits of HIV treatment in preventing the transmission of the virus to a sexual partner. Understanding the benefits of treatment in preventing HIV transmission could motivate persons who are HIV-infected to start HIV treatment as early as possible and adhere to their treatment. It could also reduce stigma and take away the fear of infecting a partner during unprotected sex. We believe that such an video-based mobile application will provide information in a way that is easy to understand. Also, such a mobile application will provide much-needed support to counsellors to make sure that their patients are fully informed about the benefits of HIV treatment.

What will happen in this research study?

To conduct this study, we are asking clinic counsellors and adult (>18 years old) HIV positive patients, who are eligible for the study, to participate in the study at the selected study sites.

If you choose to participate in this study, you will be asked to participate in a (CIRCLE ONE) FOCUS GROUP DISCUSSION or KEY INFORMANT INTERVIEW that will last about one hour. The session will be conducted either in-person, by telephone, or by video-conference. The goal of this session is to learn more about what you think about HIV treatment as prevention and to get your feedback on the design and content of the mobile application. We may show you some videos on HIV treatment-as-prevention and will be interested in what the videos make you think about and feel. We may also ask you to answer some survey questions about treatment-as-prevention and related concepts. The discussion or interview will be conducted by study staff in either Zulu, Sotho or English. If you are participating in a focus group, you will be joined by 5-10 other study participants.

The discussion/interview will be audio-recorded and transcribed so that the research team can listen to our conversation again later. We plan to conduct three Focus Group Discussions with a total of 24 participants and 20 one-on-one Key Informant Interviews. The research team will then use the information we collect to help develop and improve the

mobile application. We will also write scientific papers about what we learn.

Are There Risks or Discomforts from Participating?

There are no physical risks involved in participating in this research. The team will do everything possible to decrease other potential risks.

The two main potential risks are violations of your confidentiality and psychological distress. Violation of confidentiality, including accidental disclosure of your HIV status, could occur if the information collected in the interview were disclosed to people outside the study team. There is also always the possibility of a breach of confidentiality when conducting research. However, we will do everything we can to reduce these risks.

There is a risk of unpleasant feelings and psychological distress brought about by study questions regarding your relationships, household, emotional well-being, experiences, and perceptions. Given that you may find answering questions about these issues upsetting, you will be asked these questions in as sensitive a manner as possible. If you experience emotional distress during the interview, the research staff will use their extensive training to handle these situations, and the local project Principal Investigator (Dr Dorina Onoya) will be available to speak with participants if needed. Should the problem go beyond the skills of the study staff and project director, with your permission, you will be referred to the clinic social worker who will follow-up with you to ensure that you receive the help you need. Please remember that you are free to end the interviews and stop participating in the study at any time. There is also the risk of fatigue from interviewing.

How Will My Information Be Protected?

The study team will do everything possible to protect your confidentiality during this study. During the study, your name and contact information will be collected, so that we can reach out to you if there are opportunities for follow-up interviews. ALL documents containing study participant names will be kept in a secure location so that only the study team can access it. Your name and other information that would allow someone outside the study to identify you will never be used in study publications or reports.

In addition to the researchers, the ethics committees of the University of the Witwatersrand and the Office of Human Subject Protection in the U.S. Department of Health and Human

Services are authorized to review study data.

The lead researchers (Drs Jacob Bor and Dorina Onoya) will monitor the study on an ongoing basis. We will report to the ethics committees of the University of the Witwatersrand any breaches in confidentiality identified. In the event of a breach in confidentiality, staff will be retrained on human subjects' protection and confidentiality or removed from the study if the breach is severe or if the staff member cannot be sufficiently retrained. Staff will be made aware of this condition on employment.

Are There Potential Benefits from Participating?

There will not be any direct benefits to participants of the study. The information generated from the study will generate new knowledge that is important to the National HIV program in South Africa.

What Other Choices Do I Have?

The alternative to participating in this study is to not participate. You can continue to receive the usual care and treatment from this clinic or any other clinic as needed.

Are There Any Costs or Payments to Me?

There are no costs to you for participating in this study. We anticipate that the Focus Group Discussion or Key Informant Interview will take about 60 minutes to complete. A small amount (R100) will be paid to participants in appreciation for their time.

Participants' Rights

By consenting to participate in this study, you do not waive any of your legal rights. Giving consent means that you have heard or read the information about this study and that you agree to participate. You will be given a copy of this form to keep.

If you withdraw from this study at any time, you will not suffer any penalty or lose any benefits to which you are entitled.

You may obtain further information about your rights as a research participant by calling the Human Research Ethics Committee (Medical) of the University of the Witwatersrand at (011) 717 2301 or HREC-Medical.ResearchOffice@wits.ac.za. You may also contact the Office of the Institutional Review Board of Boston University Medical Center at +001-617-358-5372 or email medirb@bu.edu.

A member of the research team will try to answer all of your questions. Please contact Dr. Dorina Onoya at 010-001-0639 if you have more questions or concerns (donoya@heroza.org or hero.ethics@heroza.org).

Right to Refuse or Withdraw

Taking part in this study is voluntary. You have the right to refuse to take part in this study. If you decide to be in the study and then change your mind, you can withdraw from the research. Your participation is entirely up to you. Your decision will not affect your ability to get health care at this clinic.

If you choose to take part, you have the right to stop at any time.

Signatures

Signing this consent form indicates that:

- You have read this consent form (or have had it read to you),
- Your questions have been answered to your satisfaction,
- You voluntarily agree to participate in this research study.

You will receive a copy of this consent form to keep.

_____

Participant (Signature and Printed Name) Date

_____

Person Obtaining Consent (Signature and Printed Name) Date