Participant Informed Consent Form for Pilot Study:

Protocol: Developing a Gender-Enhanced PrEP Information-Motivation Workshop for Young South African Women

Thank you for your interest in our research study. Please read this consent form or ask someone to read it to you. We will also explain everything to you verbally and ask you for permission to record our discussion and the information we provide you with.

If you decide to join the study, we will ask you to tell us verbally that you understand the study and agree to participate. We will also ask you to send us a WhatsApp message including your name saying that you agree to be part of the study. We will send you a copy of this form to keep and you can ask us questions about the study.

Key Information

You are being asked to participate in a research study about sexual health. The purpose of the study is to help understand the best ways for women like you to learn about a new HIV prevention method called oral Pre-Exposure Prophylaxis (PrEP). Your participation in this research study is voluntary. If you decide to participate these are the things you will do:

1. Participate in an online group with other women to receive information about and discuss sexual health and PrEP.
2. Complete a confidential questionnaire through an online link sent to your phone **before** and **after** the activity above.
3. You will have the opportunity to speak with our nurse about whether a newly available HIV prevention method, PrEP, or pre-exposure prophylaxis, might be a good option for you.
4. After you complete these online activities, you will be invited to be a Peer Health Advocate and recruit other women to the online group activity.
5. Three month later, you will complete a follow-up questionnaire sent to you via phone.

Purpose and Overview

You are being asked to participate in a research study that aims to help find the best ways to enable young adult women to improve their sexual health, including protecting themselves and their families from HIV, other sexually transmitted infections, and unplanned pregnancy. The purpose of this study is to determine if one educational activity may be more effective than another activity in helping women decide whether to use a newer HIV prevention method called

oral Pre-Exposure Prophylaxis, or PrEP. You will participate in an online WhatsApp® group and workshop developed together with young women. The study is also trying to learn if women recruiting other women to participate in these activities is a good way to engage many women.

The South African Medical Research Council (SAMRC) is working on this study with a group of researchers in the United States at the HIV Center for Clinical and Behavioral Studies at the New York State Psychiatric Institute at Columbia University Irving Medical Center (CUIMC) and at Brown University. This study is funded by a grant from the US National Institute of Mental Health.

You are being asked to participate in the study because you are a young woman who may benefit from knowing about different options to prevent HIV and other sexually transmitted infections, and unplanned pregnancy.

Voluntary
Participation in this research study is voluntary. If you decide not to participate in this study or drop out at any time it will not affect your access to reproductive health services or to participating in other studies conducted by the South African Medical Research Council.

Procedures
If you agree to participate, there are six online activities that are part of this study:

1. You will be invited into a WhatsApp® group with about 6 other young women and 2 trained study staff members who will facilitate a 90-minute online workshop.
   In the WhatsApp® group and workshop the facilitators (study Staff) will engage with you in the group and online workshop and will send you all the necessary documents needed to complete the workshop. You will be able to ask questions about PrEP for the duration of your group which will last a maximum of 1 month. The workshop will be audio-recorded so that the researchers can give feedback to the facilitators about conducting the workshop. (See more information about audio-recording below).

2. Prior to participating in the above activity, you will be asked to complete a set of confidential questions online that will take about 20 minutes. The questions ask about your background, sexual behavior, and your knowledge of and attitudes about specific HIV and sexually transmitted infection prevention methods.

3. After completing the activity (WhatsApp® group and online workshop) you will complete another online questionnaire. It will include some of the same questions as in the first questionnaire, as well as a few additional questions about your reaction to the activity

and your future HIV prevention plans. It will take about 20 minutes to complete.

4. At the end of this questionnaire, you will have the opportunity to state if you would like to speak with the study nurse about whether a newly available HIV prevention method, PrEP, or pre-exposure prophylaxis, might be a good option for you at this time. Speaking with the nurse is not a requirement for participating in the study, and the decision will be yours. If you speak to the nurse, you will be offered an optional HIV-test as part of the counselling about PrEP. You may decide that you want to speak to the study nurse about PrEP at the end of the workshop, at another time, or not at all. (See below for more information about speaking with the nurse to determine if PrEP might be a good option for you).

5. After you complete these study procedures, you and others who participated will be invited to be Peer Health Advocates (PHAs). If you want to be a PHA you will speak about HIV prevention with women you know and invite up to three women to participate in the activity (online WhatsApp group workshop). You will be reimbursed for up to three women you recruit if they are eligible for and participate in the study (see below under Compensation).

6. Three month later, you will complete a follow-up online questionnaire. The questionnaire will take about 20 minutes and will include many of the same questions as before. Some women also will be selected to participate in an in-depth interview at this time.

MORE INFORMATION ON SPEAKING WITH THE NURSE ABOUT WHETHER PrEP MIGHT BE A GOOD OPTION FOR YOU. If, after our online activities, you wish to assess if you are eligible for PrEP, you will be contacted by our study nurse, who will conduct PrEP counselling with you and afterward offer you an optional HIV-test. This will be provided by our nurse free of charge. You can choose if you want to speak with the nurse remotely (online) via WhatsApp or face to face at the MRC Gender and Health Research Unit (GHRU). You can also choose if you want to do HIV self-testing with online guidance from the nurse or if you want to come to the MRC GHRU for HIV testing. HIV testing and counseling is not a requirement of this study. However, it is needed before beginning PrEP because PrEP is a prevention option for people who are HIV-negative. If you qualify for PrEP (i.e., are HIV-negative), it will be your decision regarding whether you want to take PrEP. If you decide to take PrEP, we will refer you to a clinic where you can get some additional tests before starting PrEP and where you can get a prescription for PrEP. This study does not provide PrEP. If the HIV testing and counselling shows that you are HIV-positive, we will refer you to a clinic where you can get care and treatment to help

you stay healthy with HIV.

Audio-recording
The online workshop will be digitally audio-recorded. The purpose of recording is to enable the researchers to give feedback to the facilitators on how they conduct the workshop. The audio-recording will not be shared with anyone beyond the study team at the South African Medical Research Council, Brown University, and the HIV Center in New York. Each recording will be erased within three months of the workshop. The Audio-recording is a required component of the study.

Risks and Inconveniences
There are no physical risks in participating in this study. You may find that the time involved in the group and online workshop is inconvenient. Talking or thinking about relationships, sex, HIV and other sexually transmitted infections, or other personal matters can make some people uncomfortable, embarrassed, or have other feelings. Our study staff is trained to help you deal with the feelings you may have. You can also talk about your feelings with our study nurse, and she can provide a referral to professional services if you need or want one.

There is a risk that the confidentiality of what you answer on study questionnaires, say to the study staff or to other group members could be broken. To protect against this, we follow strict procedures for protecting confidentiality, which are described below.

Benefits
This study is not designed for your benefit. However, you may find it helpful to learn about different options you have to prevent HIV, other sexually transmitted infections, and unintended unplanned pregnancy. Your feedback may help other young women in South Africa by helping us develop new programs to educate women about how they can best protect themselves.

Confidentiality
In the WhatsApp® group and workshop, we ask that everyone participating in the group respect the confidentiality of the other participants. In group activities we will ask everyone to use a made-up name (pseudonym) as their WhatsApp® name rather than a real name, and to make their phone numbers confidential for the duration of the group work. At the beginning of the online workshop, the facilitators will inform all participants not to take pictures/screenshots or repeat what is said in the group to others.

All study staff will be instructed not to discuss any identifying information they learn about you or other study participants with anyone.

All questionnaires will be identified only by individual participant code numbers and will not contain any personal health information or your name. All records will be kept in locked files at the GHRU of the SAMRC and will be kept confidential. A master list matching individual participant names with code numbers will be kept in a separate locked file drawer known only to the key study staff. This master list will be destroyed no later than five years after the end of the study.

The surveys that you complete online will not contain your name, but only your Study ID number. All survey data will be stored in a secure, password-protected online system.

Your information or material will be available only to research staff and to regulatory personnel at the US and South Africa institutions conducting this study and to US Federal and State regulatory personnel, who may review records as part of routine audits to ensure that this study is being done in a professional way that protects your rights.

A description of this clinical trial will be available on 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.

Your private information will not be used for future research studies or distributed to another investigator for future research studies.

Certificate of Confidentiality

As a way to protect your privacy, this research is covered by a Certificate of Confidentiality issued by the National Institutes of Health, which is funding this study. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. This protection includes civil, criminal, administrative, legislative, or other government proceedings. An example would be a court subpoena. There are several kinds of situations where the Certificate does not apply. For example, we are still required to report child abuse, and we must make data available to the funding agency for a 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.

Compensation

Compensation is provided for time, effort, and data bundle costs. You will receive R50 for data bundles prior to the online WhatsApp activities in order to be able to connect into the session. You will receive an additional R200 for completing the questionnaire directly after the workshop and R100 for answering follow up questions 3 months after your online participation. You will

receive R100 for each woman you refer who attends the full workshop, for up to 3 women. You will be paid only if the woman you recruit is eligible for and completes the study activities.

In Case of Injury
U.S. Federal government regulations require that we inform participants about this institution's policy with regard to compensation and payment for treatment of research-related injuries. If you believe that you have sustained an injury as a result of participating in a research study, you may contact the Principal Investigator at 031 242 3749 so that you can review the matter and identify the medical resources that may be available to you.

Questions
We will answer to the best of our ability any questions that you may have today about the research procedures, or about your response to the study procedures. If you have any additional questions or comments in the future, you can call Professor Jill Hanass Hancock, Principal Investigator, 031 242 3749. She will answer your questions to the best of her ability.

The Institutional Review Board at the South African Medical Research Council has approved recruitment for this study.

If you want further information or have any questions about the study, you may contact the study team. If you would like to contact a team member you may contact

Silindile Khumalo
South African Medical Research Council,
491 Peter Mokaba Road, Durban
Kwa-Zulu Natal, South Africa
Tel: 031 242 3605
Email: Silindile.khumalo@mrc.ac.za

If at any time you have any questions regarding your rights as a participant in a study, you may contact Ms. Adri Labuschagne the secretariat of the Ethics Committee on the following address:

SAMRC Ethics Committee
P.O. Box 19070
Tygerberg, Cape Town
Tel: 021-9380687
Fax: 0866854023
E-mail: adri.labuschagne@mrc.ac.za

You also can contact the New York State Psychiatric Institute-Columbia University Irving Medical Center Department of Psychiatry Institutional Review Board at 1051 Riverside Drive, Box 10, New York, NY 10032; Phone +00 1 646-774-7155; Fax +00 1 646-774-7154; Email: IRBMail@nyspi.columbia.edu. The Institutional Review Board is a committee that oversees the protection of people participating in research studies.

You will be given a copy of this consent form to keep.

Documentation of Consent for Pilot Study

I voluntarily agree to participate in the research study described above.

_____ _____

(Print Name) (Date)

_____

(Signature)

I have discussed the proposed research with this participant including the risks, benefits, and alternatives to participation (including the alternative of not participating in the research). The participant has had an opportunity to ask questions and in my opinion is capable of freely consenting to participate in this research.

_____

(Print Name)

_____ _____

(Signature of Person Designated to Obtain Consent) (Date)

Witnesses 1

_____

(Print Name)

_____ _____

Witness 2

_____

(Print Name)

_____ _____