A Comprehensive HIV Prevention Package for South African Adolescent Girls and Young Women: IMARA SA

Pilot Consent form for Adolescent Girls between the ages of 18-19 years, Version 5.0

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APPENDIX B4: CONSENT– UCT HREC APPLICATION

Multilevel Comprehensive HIV Prevention Package for South African Adolescent Girls and Young Women

Short Title: IMARA

Version 5.0: 05 September 2020

Study Implementers: Desmond Tutu Health Foundation, University of Cape Town & University of Illinois at Chicago (USA)

Study Sponsors: USA National Institute of Mental Health

Principal Investigators: Professors Geri Donenberg and Linda-Gail Bekker

INTRODUCTION

Good day, I am …….. a social science interviewer at the Desmond Tutu Health Foundation, University of Cape Town. We would like to ask for your permission to take part in a study that aims to test an HIV Prevention Programs for teen girls and their mothers (or legal guardians and/or primary female caregivers). Before agreeing to participate, it is important that you understand the following explanation on the purpose of the study, the study procedures, benefits, risks, discomforts, and precautions as well as the other procedures that are available to you, and your right to withdraw from the study at any time. You need to understand what is involved before you agree to take part in this study and ask me or other research staff, any questions you may have.

I am now going to explain the study and your rights; once you have understood the study and you decide to take part, we will ask for your written consent to participate. With your written consent, we will also, record our discussions with you. You will

receive a copy of these consent forms for your records. This process is called informed consent. Also, we are asking you to participate with your mother or female caregiver of your choice. Please let us know if you are happy to take part with your mother or another Female Caregiver. Should you not want your mother or another female caregiver to participate, you will unfortunately not be able to take part in the study. Please let us know at the end of our discussion if you are happy to take part with your mother or another female caregiver of your choice. (***Interviewer Note: if the adolescent is not comfortable to take part in the study with the mother or another caregiver, she will not be able to participate in the study***). While you have consented to participate in our study before as per copy [*Interviewer to show participant her consent copy],* this short consent form is to highlight additional activities that were not included in the previous consent. I will explain to each activity, one by one below. First, I would like to thank you for coming for your Month 6 follow-up visit. On this follow up visit, there will be no discussion groups.

[Use text below if the re-consenting process is being completed remotely]

To confirm that I am speaking with _____ *(participant's name and surname)*, could you please give me your date of birth?

When you first gave us permission to take part in the IMARA study, we explained that we would ask you to answer some similar questions as in the first survey 6 months later. Ideally, we would ask you these questions in person, but as you know, our country is facing an unprecedented situation with the COVID-19 virus and is recommending that all citizens stay at home, maintain good hygiene practices and practice social distancing. **We therefore would like your permission to ask you these questions over the phone, since we cannot meet you in person**. If you agree to participate in the phone interview, I will ask you each question and record your answer. In addition to requesting your permission to complete the survey via telephone, I would like to ask for your permission to complete additional activities that were not included in the previous consent. I will explain each activity, one by one below

Why is this study being done?

Young people (15-19 years of age) are likely to engage in behaviors that may put them at risk of getting HIV. They also find themselves sad now and again something that makes them even more vulnerable to poor decision making especially around sex health and sexual behavior. This study aims to teach young people the skills to make better health decision in future. Our program IMARA works to achieve that. This is a prevention program; this means that young people can join the study even if they have never been in a relationship, never had sex, currently living with HIV or without. We want to understand how we can work with adolescent girls and young women, and their female caregivers, to assist them to learn more about HIV/AIDS, sexually transmitted infections and strengthen their relationship in order to make healthy decisions. We also know that programs that provide support from others work well in helping young people engage in positive behavior. For this reason, this study is being conducted to see whether other, such HIV prevention methods can help. So we are testing out new ways that different groups of people can prevent getting HIV and other STIs. These new ways consider who, when and how individuals should speak about HIV/STIs prevention. Families seem to be the best groups where teens like you might benefit most since these are the people you live with and see every day. We shall be asking for your thoughts and feelings about a mother-daughter program and we want to learn more about:

- How to strengthen adolescent and young women abilities when responding to challenges
- How to strengthen the mother-daughter relationship in order to be able to interact with their mothers or female caregivers on topics such as such as sex and, depression, HIV and many more.
- Whether taking part in a group-based program aimed at preventing HIV will help adolescent girls better understand what behaviors put them at risk and in danger of getting infected with HIV and how to protect themselves.

We also want to understand whether young girls like your daughter and female caregivers like yourself will want to take part in health services like taking PrEP, testing for HIV and other sexually transmitted infections (STIs).

This study is voluntary, which means you don't have to participate if you do not want to, however, should you be interested to take part, both you and your mother or caregiver must agree to take part in this study in order for either of you to participate. IMARA is designed to to allow us to learn how families can help their young girls choose healthy and strong relationships and in return remain healthy.

What am I being asked to do and why?

We are asking you to be to take part in this study that will help us find out more about how people your age make healthy future decisions about their sexual health and best ways to prevent HIV and STIs. We are asking you to help with this research because you are between 15 and 19 years of age and female. We will also be asking other young girls like to participate.

Do I have to take part?

You do not have to take part in the study. Your decision to take part in this research study is completely voluntary. You can refuse any part of the study and you can stop participating at any time. You can refuse to answer any question. If you decide to participate and later change your mind, you will not be contacted again or asked for further information. If you decide not to participate, or decide to leave the study after you have agreed to participate, this will in no way affect your ability to receive health services or any other services.

You cannot be in this study if (1) you do not want to participate; (2) you are not 15-19 years old; (3) you do not understand the steps involved to participate in the study and (4) your female caregiver or mother refuses to participate in the study. This is because it's a mother-daughter program

What would I have to do if I agree to take part in the study?

1. First and foremost, you will start by signing a consent form
2. Then you will be asked to complete a baseline survey in a private room at our DTHF Philippi site. The survey questionnaire gathers information on:

   a. Personal information including, for example, age, gender, population group, family life, etc.);

   b. Health including questions on HIV, sexually transmitted infections (STIs) including gonorrhea and chlamydia, knowledge, attitudes, and stigma for pre-exposure prophylaxis (PreP), and mental health;

   c. Strengths when responding to challenges in life; and

   d. How families interact including parenting and communication including around topics such as sex and mental health.

   e. For the first survey, all participants will be their willingness to be tested for HIV, STIs throughout the study and willing to take a pill called Pre-exposure prophylaxis (PrEP) for one month. No participants will be excluded if they refuse to test for HIV, STIs or refuse to take PrEP.

   f. If you agree to test for HIV and STIs, you will provide a finger-prick blood sample and a urine sample. These samples will be used to tested for HIV and other sexually transmitted infections (STIs) only. Results for your HIV will be provided at the end of the first session. You STI results will be provided at your next meeting. No other tests will be conducted on the samples you provide, and these samples will be discarded after. If you are interested in taking PrEP, we will give you a one month's supply and give you a referral to one of our youth-friendly clinics that are now offering PrEP, where our team will meet you at these clinics for further assistance. In addition, we ask you to provide more blood samples that we will use to conduct further tests to ensure that you are safe to carry on taking PrEP. However, you one month supply will be provided immediately.

3. Once the consent and survey are completed, families will be randomly chosen to receive the IMARA program (intervention group) and the other in the control group and will receive FUEL a health program matched for time and attention. Once assigned to a group, you cannot change from one to the other.

The program consists of 2 sessions each completed on a different day. We will schedule you on a day you are able to, to come to our research site where you and your mother or a female caregiver of your choice will be invited to take part in group discussions with other teens and their mothers/female caregivers. These groups will include about 6-8 young girls and their mothers.

Each study visit takes about 6-7 hours. This visit, also called the enrolment visit will take about 6 hours . Day two of the sessions will take about 7 hours.. During group sessions, families usually start off together and then split into two groups with mothers in one room and girls in the other. Only one caregiver/mother per adolecent girl must attend the program. Sessions build on improving knowledge and family communication as well as family bonding in order to address topics such as sex, mental health, and relationships. After each session homework will be given to for each family to do.

We will also ask you to answer some of these questions again 6 months. During this 6-month follow-up visit, just like at the beginning of the study, you will have the option of receiving HIV counseling and testing (HTC), STI testing, and/or PrEP. The STI tests will include chlamydia, gonorrhoea, and trichomonas. The staff members will have in hand your consent form and will remind you of all the clinical procedures and the risks involved before any clinical assessments begin. If you have accepted PrEP from us in the past, we will ask you to provide a blood sample that will be used to test for your adherence to the PrEP medication. Should you have stopped taking PrEP and wish to start again, we will test you afresh before giving you another prescription. The follow

up visit will take about 3-4 hours. We will try to get in touch with you to answer these questions even if you have moved to another area or location.

2) Month 12 follow-up visit

For this consent, we would like to request your permission to complete another follow-up visit at Month 12. What that means is that we have extended the study period for an additional six months. We will continue to contact you on a monthly basis to keep in touch between now and then, and we will schedule the visit with you about one month in advance. Like in the Month 6 visit, when you come in for the Month 12 visit, we will ask you to do the following:

i) Complete a survey once again. During the survey, you will be asked the same types of questions as in the first two surveys—questions about HIV, sexually-transmitted infections, PrEP, mental health, sexual behavior (including questions about sexual partners), and alcohol/drug use. We will also ask about your relationship with your caregiver and communication with your caregiver around topics like sex, along with questions about your experiences during the COVID-19 lock-down.

ii) Complete clinical assesments similar to the ones you have already completed with us. The staff members will have in hand your consent form and will remind you of all the clinical procedures and the risks involved before any clinical assessments begin. You will once again have the option of receiving HTC, STI testing, and PrEP. The STI tests will include chlamydia, gonorrhoea, and trichomonas. If you have accepted PrEP from us in the past, we will ask you to provide a blood sample that will be used to test for your adherence to the PrEP medication. Should you have stopped taking PrEP and wish to start again, we will test you afresh before giving you another prescription.

As you know, our country has been facing an unprecedented situation with the COVID-19 virus. In the event that we are under nationwide lockdown when the Month 12 survey is meant to take place, we may request your permission to complete the survey

via telephone. We will then ask you each question over the phone and record your answer. There is a risk that others may overhear our conversation, but before we begin we will ask you to find a private space where you feel comfortable answering the questions. Only when we are able to, we will ask you to come to the site for the clinical assessments, since all clinical assessments can only happen in person.

[Use text below if the re-consenting process is being completed remotely]

1) **Month 6 follow up visit and clinical assesments:**

Given the current cirmstances with COVID-19, and as explained above, we request your permission to conduct the survey via telephone. However, because all clinical assesments need to be done in person and at the research site, we will conduct these tests only when you can come to the site after the lockdown has been lifted. Just like at the beginning of the study, you will have the option of receiving HIV counseling and testing (HTC), STI testing, and/or PrEP. The STI tests will include chlamydia, gonorrhoea, and trichomonas. The staff members will have in hand your consent form and will remind you of all the clinical procedures and the risks involved before any clinical assessments begin. If you have accepted PrEP from us in the past, we will ask you to provide a blood sample that will be used to test for your adherence to the PrEP medication. We will contact you in good time to schedule a clinic visit.

2) **Month 12 follow-up visit**

We have made changes to our study and have extended the study time to an additional 6 months. Therefore, we would like to request your permission to complete another follow-up visit at Month 12. We will continue to contact you on a monthly basis to keep in touch between now and then, and we will schedule the visit with you about one month in advance. When you come for the Month 12 visit, we will ask you to do the following:

i) Complete a survey once again. During the survey, you will be asked the same types of questions as in the first two surveys—questions about HIV,

sexually-transmitted infections, PrEP, mental health, sexual behavior (including questions about sexual partners), and alcohol/drug use. We will also ask about your relationship with your caregiver and communication with your caregiver around topics like sex, along with questions about your experiences during the COVID-19 lock-down.

ii) Complete clinical assesments similar to the ones you have already completed with us. The staff members will have in hand your consent form and will remind you of all the clinical procedures and the risks involved. You will once again have the option of receiving HTC, STI testing, and/or PrEP. The STI tests will include chlamydia, gonorrhoea, and trichomonas. If you have accepted PrEP from us in the past, we will ask you to provide a blood sample that will be used to test for your adherence to the PrEP medication. Should you have stopped taking PrEP and wish to start again, we will test you afresh before giving you another prescription.

In the event that we are under a nationwide lockdown, we will follow the same procedures as the ones highlighted above for Month 6, where we will complete the survey via telephone and only when we are able to, we will ask you to come in person for clinical assessments.

What if the questions upset me?

Like I indicated earlier, if you feel uncomfortable or do not want to answer any of the questions, this will not affect your participation in the study. You can continue with the study and/or withdraw from the study at any time. On this survey, we will additionally ask you some questions about your experiences during the COVID-19 lock-down. Now that we are requesting to conduct the survey using the telephone, please assess your home situation to find a private space where you feel comfortable answering the questions. [*Interviewer must confirm with the participant regarding availability of a private space to conduct the survey telephonically, otherwise request to postpone the survey until she has found a quiet space*]. Should you feel uncomfortable answering any question, you are free to skip the question by letting me know as we speak over

the phone. Should any of questions make you uncomfortable and anxious, please let me know at the end of the phone interview so that I can find a way to assist you.

What happens if a participant is hurt taking part in this study?

This research study is covered insurance policy taken out by the University of Cape Town. According to the SA Good Clinical Practice Guidelines 2006, which are based on the Association of the British Pharmaceutical Industry Guidelines, the insurer will pay without you having to prove that the research was responsible for your bodily injury. You may ask study staff for a copy of these guidelines. If you are harmed and the insurer pays for the necessary medical costs, usually you will be asked to accept that insurance payment as full settlement of the claim for medical costs. However, accepting this offer of insurance coverage does not mean you give up your right to make a separate claim for other losses based on negligence, in a South African court. It is important to follow the study instructions and to report straightaway if harm has occurred because of taking part in the study.

If you feel you have been injured because of the participation in this study, it is important that you tell us. We will offer you free care at the study clinic or refer you to a healthcare facility for injuries you feel happened because of participating in the study. This institution does not provide a monetary compensation program. If you need medical care that we cannot provide, we will refer you to the appropriate services or organizations that can provide care for the injury

Where will the study be done?

The group discussions will be conducted at our Desmond Tutu HIV Foundation site at Philippi Village at our youth-friendly and confidential venue.

What are the benefits of being in this study?

There are no direct benefits to you for taking part in the study. However, you may benefit from this study if you agree to test for HIV by being referred to a public clinic. You will, receive treatment for STIs if your STI test results are positive. You may also

benefit from the study by learning how best to protect yourself if all your results are negative. In addition, families and other young people like your daughter may benefit from this study later because the information gathered during this study may help to inform a new strategy for helping young people to make healthy decisions

What are the risks of being in this study?

You may feel uncomfortable or emotional during the group when responding to some of the questions. You may feel uncomfortable or embarrassed by some of the subjects we talk about or activities in the group. In addition, there is a risk that others may know you are participating in this study or that some of your information may be disclosed by members in your group discussion. While we try our best to keep information confidential by using a participant number instead of your name, we have no control over what members of your group decide to share outside of the discussion. We ask that all participants be respectful of the information shared and to not share anything said during the group. In addition, we talk about sensitive topics such as HIV, sex, and STIs. We also test and disclose your test results for HIV and STI to you. We will not share anything we find without your permission.

You may experience side effects from taking the PrEP. The most common risks and side effects from the study drug include dizziness, fatigue, difficulty sleeping, depression, abnormal dreams, diarrhoea, nausea (upset stomach), vomiting, headache, rash and gas. Skin discoloration (small spots or freckles) may also occur.

We will try to minimize any side effects and/or risks to your safety and well-being. Tests will be done to carefully monitor your health, including your kidney and liver functioning. The study doctor or study nurse will ask you about any side-effects you have experienced.

Will what I say be kept confidential?

Many precautions have been taken to protect your information. To safeguard against any loss, your responses to questions will be stored on a safe and secure online facility

called SharePoint that allows access to staff members working on this project. A backup will be stored on computers that are protected by a password. This will be destroyed when the results are published at the end of the research. When the results of this study are presented at scientific meetings or published in scientific journals, no information will be included that could identify you or your answers personally.In addition, if you agree to take part in this study, some of the information you give us including your answers to questions in the survey, and test results will be placed into one or more scientific databases for further research. However, in all the above, your name, your contact details and your address will not be shared with anyone. You will be assigned a unique study number to protect the information you give us so that no one will know that this information was provided by you. Other personal information like your address and date of birth will be stored separately from the answers you provide during the interview. Information from this study may be given to persons or companies, we work with or the sponsor to have access to the research information during and after the study but this will not include your name, address or contact details. The Research Ethics Committee may review the records of your participation in this research to ensure that proper procedures were followed. A representative of the UCT HREC and other regulatory agencies may contact you for information about your experience with this research. This representative will be given your name but will not be given any of your confidential study data, meaning anything you tell us during the interview. You also have a right not to answer any questions this person may ask, and you may stop taking part in this study at any time during the interview.

We also check to make sure that you are not in more than one study by taking your fingerprint on an electronic system. This information is only accessed by a few members of the study team using a secure password. As we conduct months 6 and 12 follow-ups, we would like to collect this information and would like to check your fingerprints to see that you are not taking part in another study at the same time and to make sure that we have your details correctly obtained at each study visit. We call this a biometric system. Only certain site research staff members have access to the system, which stores your fingerprints and details on your name, date of birth, SA

Identity number, address, race, nationality, contact numbers and participant number. There is no study information apart from your visit numbers and dates stored on the system. Your fingerprints cannot be printed, shared or used for any other purpose as they are stored in an encoded form and not as an image (picture). Your details and fingerprints will remain in the system for up to 15 years.

Entering of participants details into the system takes place in person when you are at site. At every visit thereafter, participant's identity and co-Enrollment status will be checked and confirmed using fingerprints. If a participant that has previously presented to site for pre-screening or is enrolled in another study at site attempts to screen for a different study, the system will alert the authorized staff member. In events where participants try to pose as you, their fingerprint will alert the responsible staff member as well.

Do I get paid for taking part in this study?

No, we do not pay you for answering questions in this study. You will, however, receive R130 after completing the group discussion as reimbursement for your time and transport everytime you come to site for a study visit.

Our reimbursement at Months 6 and 12 will remain the same as for the surveys and clinical assessments you completed previously. You will receive R130 after completing the in-person visit, which will take about 3-4 hours, as reimbursement for your time and transport to the site. If we need to complete the survey over the phone, it will take about 1 hour (depending on your responses to the questions) and you will receive R50 as reimbursement for your time. The payment will be done via a secure system like e-wallet that will enable both you and the study team to confirm reciept of payment. We will request that you supply us with an active and private cell number where this payment can be paid and confirmed. You will receive an additional R80 when you come to the site for Month 12 clinical assessments, which will take about 2-3 hours,

as reimbursement for your time and transport to the site. If you prefer, you can decline to receive an electronic transfer and instead receive the full reimbursement amount of R130 when you come to site for clinical assessments

Who should I contact for further information?

If you have questions about the study you can call the site principal investigator, Dr Millicent Atujuna on 021 406 6961.

Who can I call for information about my rights as someone who is helping with research?

There is a group of doctors and researchers whose job it is to help see that research is done carefully and that people in the research are treated fairly and it is made as safe as possible. If you have any questions about these things, or if you have a complaint or complaints about your rights and wellbeing when you choose to take part in this study, please contact the UCT Human Research Ethics Committee: Tel: 021 406 6492 or E-mail: sumaya.ariefdien@uct.ac.za

For the participant

I, _____

(name and surname) have had all of the above information explained and I understand the explanation. I have been given answers to my questions about the study.

- ☐ **I agree to participate in this study and I have received a copy of the information sheet.**
- ☐ **I don't agree to participate in this study.**
- ☐ **I GIVE PERMISSION to be contacted for future studies.**
- ☐ **I DO NOT want to be contacted for future studies.**
- ☐ **I agree to test HIV and STIs and that the samples I provide will be thrown away once the tests have been conducted**
- ☐ **I do not agree to test HIV and STIs and that the samples I provide will be thrown away once the tests have been conducted**
- ☐ **After the explanation you have provided, I now would like to change my mind and test HIV and STIs and that the samples I provide will be thrown away once the tests have been conducted**

Signature: _____

Today's date: _____ (day)/ ____ (month) / _____ (year)

Time: _____

- ☐ **I agree to take PrEP and I am will to provide blood samples for further tests required for one to take PrEP**
- ☐ **I do not agree to take PrEP and I am will to provide blood samples for further tests required for one to take PrEP**
- ☐ **After the explanation you have provided, I now would like to change my mind and agree to take PrEP and I am willing to provide blood samples for further tests required for one to take PrEP**

Signature: _____

Today's date: _____ (day)/ ____ (month) / _____ (year)

Time: _____

For the participant to complete during 6-month in-person survey:

- **I agree to complete additional clinical assessments being offered at 6-month: □ Yes □ No**
- **I agree to participate in the 12-month study follow-up: □ Yes □ No**
- **I have received a copy of this informed consent form: □ Yes □ No**
- **If the 6 and 12-months survey is done via telephone, I agree to receive: □ Electronic and in-person reimbursement □ In-person reimbursement only**

Signature: _____

Today's date: _____ (day)/ ____ (month) / _____ (year)

Time: _____

For witness:

Name and surname of witness: _____

Signature: _____

Today's date: _____ (day)/ ____ (month) / _____ (year)

Time:_____

For researcher to complete:

I _____ *(researcher's name and surname)* declare that I have explained the information given in this document. I provided ample time for questions and answered all questions.

Was a copy of this form given to the participant?

☐ Yes

☐ No: If no, why not: _____

Signature: _____

Today's date: _____ (day)/ ____ (month) / _____ (year)

Time: _____

For researcher to complete electronically, based on participant's response:

Participant name and surname: _____

The participant:

- **Understands and agrees to the changes to the 6-month study follow-up, including completing a telephone survey and clinical assessments on site when possible:**
  □ **Yes** □ **No**
- **Agrees to take part in the 12-month study follow-up:** □ **Yes** □ **No**
- **Agrees to receive:** □ **Electronic and in-person reimbursement**
  □ **In-person reimbursement only**

I _____ *(researcher's name and surname)* declare that I have explained the information given in this document. I answered all questions and have properly recorded the participant's verbal response. Was a copy of this form given to the participant when the participant was seen in person?

☐ Yes