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

Pilot Consent form by Mother/Caregiver for minors between the ages of 15-17 years, Version 5.0

05SEP2020

NCT05504954

APPENDIXB2: 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 for your daughter 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 your daughter, and her right to withdraw from the study at any time. You need to understand what is involved before you agree to allow your daughter 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 allow your daughter to take part, we will ask for your written consent to allow your daughter to participate. With your written consent, we will also,

record our discussions with your daughter. You will receive a copy of these consent forms for your records. This process is called informed consent.

Also, we are asking your daughter to participate with you or female caregiver of your choice. Please let us know if you are happy to take part with your daughter or another Female Caregiver. Should you not want your daughter to participate, she 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 daughter or another female caregiver of your choice. (***Interviewer Note: if the mother/caregiver is not comfortable to take part in the study with her daughter or to allow another caregiver to participant, her daughter will not be able to participate in the study***). While you have given us permission for your daughter to take part in the IMARA study, I would like to ask for your permission for her 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 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 your daughter does not have to participate if you do not want to, however, should you and your daughter be interested to take part, both your daughter and yourself must agree to take part in this study in order for either of you to participate. IMARA is designed 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 allow your daughter to take part in this study that will help us find out more about how people her age make healthy future decisions about their sexual health and best ways to prevent HIV and STIs. We are asking your daughter to help with this research because she is between 15 and 19 years of age and female. We will also be asking other young girls like her to participate.

Does my daughter have to take part?

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

Your daughter cannot be in this study if (1) she does not have permission from your legal guardian (or participating primary female caregiver); (1) she does not want to participate; (2) is not 15-19 years old; (3) she does not understand the steps involved to participate in the study and (4) you the female caregiver refuse to participate in the study, and refuse to allow another caregiver of her choice to participate. This is because it's a mother-daughter program.

What would I have to do if I allow my daughter to take part in the study?

1. First and foremost, you will start by signing a consent form allowing your daughter <18 years to participate in the study.
2. Then your daughter 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, like all participants, she will be asked if she is willing and wants 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 your daughter agrees to test for HIV and STIs, your daughter will provide a finger-prick blood sample and a urine sample. These samples will be used to test for HIV and other sexually transmitted infections (STIs) only. Results for her HIV will be provided at the end of the first session. Your daughter's STI results will be provided at her next meeting. No other tests will be conducted on the samples your daughter provides, and these samples will be discarded after. If your daughter is interested in taking PrEP, we will give your daughter a one month's supply and give your daughter a referral to one of our youth-friendly clinics that are now offering PrEP, where our team will meet your daughter at these clinics for further assistance. In addition, we ask your daughter to provide more blood samples that we will use to conduct further tests to ensure that your daughter is safe to carry on taking PrEP. However, her 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, your daughter cannot change from one to the other.

The program consists of 2 sessions each completed on a different day. We will schedule your daughter on a day she is able to come to our research site where she and her mother or a female caregiver of her 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 adolescent 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 for each family to do.

We will also ask your daughter to answer some of these questions again 6 months. And we will test her urine for STIs again at the 6 month interview. The follow up visit will take about 3-4 hours. We will try to get in touch with her to answer these questions even if she has moved to another area or location.

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

Given the current circumstances with COVID-19, we may need to conduct the survey with your daughter via telephone. If she completes a phone survey, we will ask her each question and record her answers in a tablet computer. She will be free to skip any question that she does not want to answer. There is a risk that others in the home may overhear the conversation or what we are talking about. To minimize these risks, we will recommend that she find a quiet space where she feels comfortable answering the questions.

Because all clinical assessments need to be done in person, we will conduct these tests only when she can come to the research site after the lockdown has been lifted. Just like at the beginning of the study, she 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 her consent form and will remind her of all the clinical procedures and the risks involved before any clinical assessments begin. If your daughter has accepted PrEP from us in the past, we will ask her to provide a blood sample that will be used to test for her

adherence to the PrEP medication. We will contact your daughter 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 for your daughter to complete another follow-up visit at Month 12. We will continue to contact your daughter on a monthly basis to keep in touch between now and then, and we will schedule the visit with her about one month in advance. When she comes for the Month 12 visit, we will ask her to:

i) Complete a survey once again. During the survey, she 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 her relationship and communication with her caregiver around topics like sex, along with questions about her experiences during the COVID-19 lock-down.

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

What if the questions upset my daughter?

Like I indicated earlier, if your daughter feels uncomfortable or does not want to answer any of the questions, this will not affect your daughter's participation in the study. Your daughter can continue with the study and/or withdraw from the study at any time.

What happens if my daughter or 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 your daughter having to prove that the research was responsible for her bodily injury. Your daughter will receive a copy of these guidelines. If she is harmed and the insurer pays for the necessary medical costs, usually she 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 she gives up her 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 your daughter has is injured because of the participation in this study, it is important that she tells us. We will offer her free care at the study clinic or refer her to a healthcare facility for injuries she feels happened because of participating in the study. This institution does not provide a monetary compensation program. If she needs medical care that we cannot provide, we will refer her 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 site at Philippi Village at our youth-friendly and confidential venue.

What are the benefits of being in this study for my daughter?

There are limited benefits from being in this study. Young people, like your daughter, may benefit from finding out about their health including HIV and STI status. Participants may learn new health prevention skills. If your daughter chooses to take part in this study, she will get counseling and testing for HIV, condoms, and information on how to protect herself from HIV. We will offer your daughter free treatment for infections passed during sex should she have one. If your daughter tests positive, we will refer her to a public clinic for further tests, where they will supply your daughter with HIV medication. If she chooses to take PrEP because she is found to be HIV negative, we will do the same as above

What are the risks of being in this study for my daughter?

Your daughter may feel uncomfortable or emotional during group sessions when responding to some of the questions. Your daughter 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 she is participating in this study or that some of her information may be disclosed by members in her group discussion. While we try our best to keep information confidential by using a participant number instead of her name, we have no control over what members of her 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 to her, her test results for HIV and STI to only to her. We will not share anything we find without her permission, however, there are certain events that she may have experienced that we are obligated to report according to South African law. These events include: physical abuse, sexual abuse or neglect perpetrated by a parent or adult. There is also some type of sex considered illegal. For example, any person >16 years who engages in sexual activity with a minor <16 years commits a crime and must be reported. So, if she tells us of such information, we may report it to the authorities such as child welfare or the police. In all of the above situations, we will counsel her, provide appropriate referrals and if she agrees accompany her to the referral services. We will also assist should she wish to involve any trusted adult of her own choice. We advise her to consider these situations which require reporting carefully and what it means for her and her family.

Your daughter may experience side effects from taking PrEP if she chooses to take PrEP. The most common risks and side effects include dizziness, fatigue, difficulty sleeping, depression, abnormal dreams, diarrhea, 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 daughter's safety and well-being. Tests will be done to carefully monitor your daughter's health, including her kidney and liver functioning. The study doctor or study nurse will ask your daughter about any side effects she has experienced.

Will what she says be kept confidential?

Many precautions have been taken to protect your daughter's information. To safeguard against any loss, your daughter's 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 your daughter or her answers. In addition, if your daughter agrees to take part in this study, some of the information she gives us including her answers to questions in the survey, and test results will be placed into one or more scientific databases for further research. On this survey, we will additionally ask your daughter some questions about her experiences during the COVID-19 lock-down. Your daughter's responses will be stored on a secure online database. However, in all the above, your daughter's name, her contact details and her address will not be shared with anyone. She will be assigned a unique study number to protect the information she gives us so that no one will know that this information was provided by your daughter. Other personal information like her address and date of birth will be stored separately from the answers she provides 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 daughter's name, address or contact details. The UCT Research Ethics Committee and other regulatory agencies may review the records of your daughter's participation in this research to ensure that proper procedures were followed. This representative will be given your daughter's name but will not be given any of her confidential study data, meaning

anything your daughter tell us during the interview. Your daughter also has a right not to answer any questions this person may ask, and your daughter may stop taking part in this study at any time during the interview.

We also check to make sure that your daughter is not in more than one study by taking her 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 her fingerprints to see that she is not taking part in another study at the same time and to make sure that we have her 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 her fingerprints and details of her name, date of birth, SA Identity number, address, race, nationality, contact numbers and participant number. There is no study information apart from her visit numbers and dates stored on the system. Your daughter's 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). Her 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 she is at site. At every visit thereafter, participant's identity and co-Enrollment status will be checked and confirmed using fingerprints. If your daughter 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 your daughter, their fingerprint will alert the responsible staff member as well.

Does my daughter get paid for taking part in this study?

No, we do not pay your daughter for answering questions in this study. Your daughter will, however, receive R130 after completing the group discussion as reimbursement for her time and transport every time she comes to site for study visits.

Surveys completed over the phone will take about 1 hour (depending on your daughter's responses to the questions) and your daughter will receive R50 as reimbursement for her time. This payment will be done via a secure system like e-wallet that will enable both her and the study team to confirm receipt of payment. We will request that your daughter supplies us with an active and private cell number where this payment can be paid and confirmed. She will receive an additional R80 when she comes to the site for clinical assessments, which will take about 2-3 hours, as reimbursement for her time and transport to the site. If she prefers, she can decline to receive an electronic transfer and instead receive the full reimbursement amount of R130 when she comes 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 allow my daughter _____ (name and surname) to take part in this study and I have received a copy of the information sheet.**
- ☐ **I don't agree that my daughter takes part in this study.**
- ☐ **I GIVE PERMISSION to my daughter to be contacted for future studies.**
- ☐ **I DO NOT want my daughter to be contacted for future studies.**
- ☐ **I understand the changes made to the study and allow my daughter _____ *(name and surname)* to participate:**
- ☐ **Yes** □ **No**

Signature: _____

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

For witness:

Name and surname of witness: _____

Signature: _____

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

Time: _____

For the researcher to complete if caregiver consent is being requested by phone:

Caregiver name and surname: _____

Participant name and surname: _____

- **The caregiver understands the changes made to the study and agrees for their daughter to participate: □ Yes □ No**

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 caregiver's verbal response.
Was a copy of this form given to the caregiver when the caregiver was seen in person?

☐ Yes
☐ No: If no, why not: _____

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

For researcher to complete if consent is taking place in person:

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: _____