Optimizing PrEP Regimens for Pregnant Women in Sub-Saharan Africa (O-PrEP Study) - Stage 1

Template informed consent form

NCT number NCT06435026
Document Date 12/01/2025

University of North Carolina at Chapel Hill
Consent to Participate in a Research Study
CONSENT FORM—For Pregnant Adult
STAGE 1 SCREENING AND ENROLLMENT

Consent Form Version Date: 08 February 2024
IRB Study # 23/08/4175
Title of Study: Optimizing PrEP Regimens For Pregnant Women In Sub-Saharan Africa (O-PrEP)

Protocol Version 2.0 Dated 20 September 2023

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Funding Source and/or Sponsor: National Institutes of Health (NIH)
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CONCISE SUMMARY

We are doing a research study about "PrEP" for pregnant women that you may qualify to join. "PrEP" stands for "pre-exposure prophylaxis". PrEP is a pill taken once a day to prevent HIV. Not so many women have taken PrEP while they are pregnant and breastfeeding. In a previous study, we found that women who took 1 PrEP pill a day during pregnancy had lower amounts of the PrEP medicine measured in their blood than women who were not pregnant. This study will test different doses of PrEP to identify if a higher dose gives better blood level in pregnancy and check whether there are any bad effects for the mother and the baby.

You need to give permission for you to be in this study. You do not have to be in this study if you don't want to. To join the study is voluntary. You may choose not to participate, or you may withdraw your consent to be in the study, for any reason, without penalty. Details about this study are discussed below. It is important that you understand this information so that you can make an informed choice about being in this research study

If you want to join the study and you qualify, you will take PrEP while you are pregnant and until about 5 months after delivery. You will be placed in a study group by chance to take the regular PrEP dose – that is 1 PrEP pill a day – or 1½ times the regular dose, or 2 times the regular dose. Study staff will contact you every day for the first 2 weeks to watch you swallow the pills at the study clinic, your home or by video call. We call this "DOTs" and it will take about 15 minutes

each day You will come back for medical check-ups at week 1 and week 2 which last 1-2 hours. We will examine you, ask you questions about your health and take your blood, urine and swabs from your vagina and rectum at these study visits to measure PrEP levels and check your health. Then, you will have a "PK visit" on day 15. PK stands for pharmacokinetics. The PK visit will last overnight to measure how much PrEP medicines are in your body at 8 different times during the day and at 1 time on the next day (day 16). Then, you will take PrEP pills by yourself and come back for another medical check-up at week 4. After that, we will contact you from time to time by phone to see if you are alright.

You will repeat all of these visits (DOTS, PK visit and check-ups) later in pregnancy, and again after delivery. When the baby is born, you will come for your study visits with the baby, and we will examine them and take their blood to check how much PrEP is in their body and for bad effects.

You might not benefit directly from being in the study and there are some risks. We don't know if taking higher doses of PrEP pills is safe for you and your baby—that's one of the reasons why we are doing this study, and why it is important that we keep checking that you are feeling well while you are in the study. We also don't know if taking 1 PrEP pill during pregnancy works as well to prevent HIV as it does in women who aren't pregnant. You may have problems with family or friends who disagree with you taking PrEP. If you acquire HIV while taking PrEP, there is a risk that the usual ART won't work as well to treat your infection.

Being in the study is your choice. If you decide you don't want to join the study but still want to take PrEP, we will show you where to go to get PrEP. This consent form gives more detail about being in the study for you to make up your mind. Ask us questions and take as much time as you need to decide.

INTRODUCTION

You are being invited to take part in a research study called "O-PrEP". There are two parts to this study (Stage 1 and Stage 2), and this form is for the first part – "Stage 1". We invite you to join Stage 1 of this study because you are pregnant and are interested in taking PrEP to protect yourself against HIV infection. The person in charge of the study at UNC Project Malawi is Dr Friday Saidi. The United States National Institutes of Health is paying for the study.

This form gives information about both parts of the study. Please read it, or have it read to you, and ask any questions you may have. You can take as much time as you need to fully understand the study. We will ask you questions to see if we have explained the study clearly. You may choose not to participate, or you may withdraw your consent to be in the study, for any reason, without penalty. After you understand the study, if you decide that you will participate, we will ask you to sign or make your mark on this form. You will be offered a copy to keep.

ABOUT THE STUDY

The UNC Project Malawi is doing this study with the University of North Carolina Chapel Hill, USA and University of Zimbabwe Clinical Trials Research Centre (UZ-CTRC) to learn more about a medication called "PrEP." PrEP stands for "pre-exposure prophylaxis." PrEP is a pill taken once a day by people who do not have HIV to help them protect themselves from becoming infected with the HIV virus. Other studies have shown that PrEP works very well in preventing HIV infection. We also know that the level of protection PrEP provides depends on whether someone takes the PrEP pill every day. So far, not many women have taken PrEP while they are pregnant and just after delivery, even though women may be at heightened risk of becoming infected with HIV during this period. We do know, however, that pregnant women who take 1 PrEP pill every day have lower amounts of PrEP medicines in the blood than women who are not pregnant.

The purpose of this study is to identify the best dose of PrEP for young women in sub-Saharan Africa while they are pregnant. In the first part of the study (Stage 1), we will measure the amount of PrEP medicines in the blood of women who take different doses of PrEP to find out if higher doses give better levels in pregnancy. In Stage 2, we will check that women who take the higher dose of PrEP in pregnancy have no bad effects. This study will also check that there are no bad effects for the baby.

1. There are 2 parts to this study. You are being asked to join the first part – Stage 1.

The 2 parts of the study are called Stage 1 and Stage 2. Stage 1 will be done first. This part will include about 54 pregnant women and their babies. When Stage 1 has been completed, Stage 2 will be done. Stage 2 will include about 112 mothers and their babies. If you participate in Stage 1, you may qualify to also participate in Stage 2 if you are pregnant again when that part of the study is done.

2. This study involves pre-exposure prophylaxis, or "PrEP".

The medicine being used for PrEP in this study is a pill that contains two medicines called "emtricitabine" (FTC) and "tenofovir" (TDF) that are commonly used to treat HIV infection and sometimes to treat Hepatitis. We know that FTC/TDF is safe and effective in reducing the risk of HIV infection when taken by people who do not have HIV. But, not many studies about PrEP have involved women while they are pregnant and after delivery, so we need more information during this period. FTC/TDF is approved as PrEP in Malawi and Zimbabwe for people at high risk of acquiring HIV. The Malawi National PrEP Programme offers PrEP to pregnant women and other kinds of people, for example young women, couples where one partner has HIV and the other does not, commercial sex workers and their clients.

3. It's your choice to join the study.

You are free to join or not join. If you join, you can change your mind later and leave the study. Your decision will have no effect on the medical care that you and your baby would normally receive from your usual clinic. Your access to services, and the benefits and rights you normally have, will not be affected. Take your time and consider your decision carefully. If you wish, you can talk to other people about the study. You can also bring other people here to learn about the study with you.

4**. You can get PrEP outside of the study**.

If you want to take PrEP but decide to not join the study, we will show you where the PrEP clinic is. The routine laboratory tests we do in the study to check on your health are also available at the PrEP clinic.

5. Only mothers who qualify can participate in the study.

If you decide to join the study with your baby, we will first do some tests to see if you qualify. More information about the tests is given below. If you do not qualify, you and your baby can't enter the study. If you qualify, you can choose to join the study or not.

6. There are 3 study groups in Stage 1.

Women who join Stage 1 will be randomly assigned (like tossing a coin) to a study group. You can't choose which study group to join. Each group will take a different dose of PrEP.

7. You will have about 19 study visits in the study clinic over the next 8-10 months.

• Screening Visit – We will ask you questions about your health, examine your body and test your blood and urine to check you are healthy and do not have HIV infection. This visit lasts about 4 hours.

• Entry Visit – If you qualify and decide to join the study, you will be told the PrEP dose for your study group.

o Group A will take the regular PrEP dose – 1 pill every day.

o Group B will take 1½ times the regular PrEP dose.

o Group C will take 2 times the regular PrEP dose.

• Middle phase of pregnancy (6 visits) – You will start to swallow PrEP at the Entry Visit. The PrEP dose you take for the first 2 weeks will depend on your study group (A, B or C).

o Study staff will contact you every day for the first 2 weeks to watch you swallow the pills. You should not join the study if it's not okay for study staff to contact you every day for 2 weeks to

watch you swallow your PrEP pills. We call this "directly observed therapy" or "DOTs", and this will take about 15 minutes every day. We will tell you more about DOTs a little later.

o You will come back for medical check-ups at week 1 and week 2, which last 1-2 hours.

o Then, you will have a "PK visit" on day 15. PK stands for pharmacokinetics. PK visits measure how much PrEP medicines are in your body at 8 different times throughout the whole day.

o The PK visit also includes PK measurements at 1 time on the next day (day 16).

o After the PK visit, you will take the regular dose of PrEP by yourself, if you want to continue taking PrEP.

o You will come back for another medical check-up at week 4.

o After that, we will contact you from time to time by phone to see that you are alright and to schedule the next set of study visits.

• Last phase of pregnancy (6 visits) – When you start the last phase of pregnancy (at about 6 months of pregnancy), we will check again that you are healthy and do not have HIV infection. You will swallow the PrEP dose for your study group (A, B or C) for 2 weeks under DOTs again. Then you will complete the same set of study visits as you did in the middle phase of pregnancy – medical check-ups at week 1 and week 2, then a PK visit over 2 days, followed by taking the regular dose of PrEP yourself and another medical check-up at week 4. After that, we will contact you from time to time by phone to check when you deliver, see that you are alright and to schedule the next set of study visits.

• After delivery (6 visits) – About 3 months after delivery, we will check again that you and your baby are healthy and do not have HIV infection. You will swallow the usual PrEP dose for 2 weeks under DOTs again. Then you will complete the same set of study visits as you did before – medical check-ups at week 1 and week 2, then a PK visit over 2 days, followed by taking PrEP yourself and another medical check-up at week 4. After that, you will leave the study.

It is important that you continue going to your usual clinic for the routine antenatal care and baby check-ups as well as attend all of these study visits. If you do not come for a scheduled visit or if you must return to repeat a laboratory test, study staff will contact you or visit you. We will ask you for your address and contact information so that we will be able to contact you and visit you. If at any time you feel sick, you should let the study staff know right away and we may ask you to come back for an extra check-up. You should not join the study if you it's not okay for study staff to contact you or visit you where you live.

8. Different procedures will be done at different study visits.

We will now explain each of the procedures and then show you which ones are done at which visits on the Table of Procedures.

PrEP pills – We'll show you how to take the PrEP pills for the study group you are placed in and tell you about any side effects they may cause.

Directly Observed Therapy ("DOTs") – We will watch you swallow your PrEP pills on the day you enter the study then contact you every day for 2 weeks to watch you swallow your pills. We will do DOTs again for 2 weeks in late pregnancy, and again starting 3 months after delivery. You should not join the study if it's not okay for study staff to watch you swallow the PrEP pills every day for 2 weeks at these 3 different times. Some women may prefer to take their pills in front of a study staff member at the clinic or at home each day. Other women may choose to video record themselves taking their pill or take their pill while on a video call with study staff using a smartphone, tablet or computer to confirm that they have taken their pill. We will talk with you to work out a suitable DOT plan if you decide to join the study. If you want to choose video DOTs, we will explain exactly what you need to do and practice with you before you decide.

Ultrasound scan ("Scan") – We will ask you the date of your last menstrual period and do an ultrasound scan to know how long you have been pregnant and if you are pregnant with more than one baby. Ultrasound scans are commonly done among pregnant women. To do the scan, gel is placed on your belly. Then a small device is moved back and forth on your belly to send and receive sound waves.

The scan will show a picture of your baby and measure the size, which shows how long you have been pregnant. The scan will be done at Bwaila Hospital. We will arrange for you to have the scan at a scheduled time before entering the study. There is no cost for having the scan done.

Laboratory tests for the mother – We will collect blood, swabs, hair and urine. More details are shown below. Some of these tests are done right away and we will tell you the results when they are available. We will write them in your maternity booklet to share with your health care providers at the clinic. Other tests are stored and then done later in a batch. Some tests are done in laboratories in another country, so your samples may be shipped there for testing. The reason for these tests is –

• Blood – To check for infections (HIV, Hepatitis B and Syphilis), your general health and how well your liver and kidneys are working. The volume of blood taken depends on which tests are due at each visit and is between 1 and 4 teaspoons each time (5-20mL).

• Urine – To test if there is sugar or protein in your urine and for sexually transmitted infections.

• Swabs of the vagina and rectum – To look at the normal bacteria that live in the body.

• Hair (for you and your baby) – To measure the concentrate of the study drug in the hair

• Pharmacokinetic ("PK") tests – There are 3 PK visits**. We will bring you to the study clinic very early in the morning so we can collect blood 8 times over 12 hours (1 teaspoon, or 4mL each time).** We will also collect your blood at 1 time the next day (1 teaspoon, or 4ml). We can do this visit here at Bwaila Hospital or the UNC Project Tidziwe Center.

Physical examinations – We will examine your body to check on your health, for example measuring your height, weight, temperature, and blood pressure. At each study visit, we will check on whether the PrEP may be causing side effects.

Questions – We will ask general questions, for example your age, your medical health, and any medications you take. We will also review your medical records. If you get treatment from another clinic or hospital, we will ask to make a copy of those records.

Counselling – We will discuss ways to protect yourself from getting HIV and offer condoms. We do not know for sure if PrEP will protect you from getting infected with HIV. PrEP pills do not protect you against other STIs or pregnancy. Before you leave the study, we will help you find where to continue getting HIV prevention services.

Contraception – After deliver, study staff will discuss with you and help you choose a method of contraception.

TABLE OF PROCEDURES FOR STUDY PARTICIPANTS

Study Visits	Middle Phase of Pregnancy Starting when you have been pregnant for 4-5 months								Late Phase of Pregnancy Starting when you have been pregnant for 6-7 months								After Delivery Starting 3 months after delivery						
	Screen	Entry	Wk1	Wk2	D15	D16	Wk4		Screen	Entry	Wk1	Wk2	D15	D16	Wk4		Screen	Entry	Wk1	Wk2	D15	D16	Wk4/ Exit
Questions	✓	✓	✓	✓	✓		✓		✓	✓	✓	✓	✓		✓		✓	✓	✓	✓	✓		✓
Physical Exam	✓	✓	✓	✓	✓		✓	#	✓	✓	✓	✓	✓		✓	#	✓	✓	✓	✓	✓		✓
Counselling	✓	✓	✓	✓			✓		✓	✓	✓	✓			✓		✓	✓	✓	✓			✓
Scan	✓																						
Put in a study group*		✓																					
PrEP ^		DOTs				By yourself			DOTs					By yourself			DOTs					By yourself	
Collect blood for PK tests					x8	x1							x8	x1							x8	x1	
Collect blood, swabs & urine	✓	✓	✓	✓			✓		✓	✓	✓	✓			✓		✓	✓	✓	✓			✓
HIV test	✓	✓	✓	✓			✓		✓	✓	✓	✓			✓		✓	✓	✓	✓			✓
Teaspoons of blood	4	6	2	2	8	1	2		4	6	2	2	8	1	2		4	6	2	2	8	1	2
Pregnancy test																	✓						✓
Contraception																	✓						✓
Hair sample																	✓				✓		
Study visit will last this long in hours	4	2	1-2	1-2	12~	1	1-2		2	1-2	1-2	1-2	12~	1	1-2		2	1-2	1-2	1-2	12~	1	1-2

* Group A will take the regular PrEP dose -- 1 pill every day. Group B will take 1.5 times the regular PrEP dose. Group C will take 2 times the regular PrEP dose.
^ We will watch you swallow the PrEP pills for the first 2 weeks in each phase. This is called Directly Observed Therapy (DOT)
~ For the PK visits, we will collect you very early in the morning and take blood 8 times over 12 hours in the study clinic. We will also take blood 1 time on the next day.
# In between each phase, we will contact you from time to time to check you are alright. You must contact us if you have problems or don't feel well.

9. We will examine the baby after you deliver.

You should let us know when your labour begins so we can come to examine your baby before you are discharged home. We will do a physical examination, ask questions about your baby's health and feeding method and review your baby's medical records. We will also collect blood from your baby (up to 4 mL or up 1 teaspoon) to measure how much PrEP medicine is in your baby's blood and confirm your baby's kidneys are working well.

10. Your baby will have 2 more study visits when you come to the study clinic.

We will do the same study procedures on the baby that were done at birth. The first visit will be at about 10 weeks old and the second at about 14 weeks.

11. If you become infected with HIV during the study, you and your baby will have extra visits.

We will test you for HIV throughout the study using a rapid test in the clinic and another type of HIV test in the laboratory (RNA PCR) test. If your HIV test results are positive, we will take more blood (15-25 mL or about 3.5 to 5 teaspoons) to:

• Confirm the HIV infection.

• Measure the HIV viral load (how much HIV is in the blood). It usually takes about a week for these results to come back.

• We may check if the HIV in the blood is resistant to the PrEP medicines.

• Save some of the blood for additional tests about the HIV virus.

If you have become HIV infected, we will collect your baby's blood (5 mL or about 1 teaspoon) to test for HIV infection.

These extra visits will take about 1 hour. At these visits, we will collect any remaining PrEP pills from you and refer you for HIV care and treatment.

12. Tests will be done at our laboratory.

We will do most of the tests of you and your baby's specimens right away at our laboratory. We will give you the results of these tests and explain the results to you. However, some specimens will be kept and tested together at the end of the study. If the results show that you or your baby may need medical care or treatment that cannot be provided by the study, we will tell you where you can go for this care. Some tests, such as the PrEP medicine levels, are special and must be sent to specialized laboratories outside the country. If there are any specimens left-over after all the tests for this study have been done for you and your baby, we would like to keep those specimens because they may be useful for studies in the future. We will talk to you about what you want to happen to these left-over specimens in another informed consent form.

13. We may stop your PrEP.

The examinations and laboratory tests we do during the study will help us to tell if the PrEP you are taking is causing any bad effects. If so, the PrEP may be stopped. PrEP may be stopped if you have certain illnesses or need to take other medicines that cannot be taken with PrEP. We will always discuss stopping PrEP with you. Please tell us about any problems you may have with taking PrEP. We may stop the PrEP you are receiving from the study if:

• You are not able to come to study visits.
• You are not able to take PrEP every day.
• Taking PrEP may be harmful to you.
• You ask to stop taking PrEP.

14. We may take you and your baby off the study early.

We expect you to stay in the study for the next 8-10 months. However, we may take you and your baby off the study early if:

• The study is stopped for any reason.
• We determine that you and your baby cannot meet the study requirements (for example, if you move away and cannot come to the clinic).
• We determine that staying in the study might harm you or your baby.

15. Please tell us if you want to leave the study.

You and your baby are free to leave the study at any time for any reason – you just need to tell us. We will ask you and your baby to come to the clinic for one last visit. At this visit, we will do the same types of procedures we do at the week 4 medical check-up visits. We will answer any questions you may have and tell you how to contact us in the future, if you wish. If you withdraw or are withdrawn from this study all data collected up until the point of withdrawal will be retained, however no additional information will be collected unless you provide additional written permission for further data collection at the time of your withdrawal

16. How to stay uninfected after leaving the study.

We cannot give you PrEP after you finish your study visits. Before you leave the study, we will talk again about how to protect yourself against HIV infection and give you information about other clinics that offer PrEP to women. If you want to continue taking PrEP, study staff will provide referral letters for you and a copy of your most recent laboratory test results to take to the non-study PrEP provider so that you get the care that you require.

RISKS OF THE STUDY

17. There may be risks from the study procedures.

Most procedures done in this study are routine medical procedures, with little risk to you and your baby.

Blood Collection: Collecting blood can cause pain, swelling, bruising, or bleeding where the needle is inserted. Rarely, drawing blood can cause fainting or infection where the needle enters the skin. We will ensure that blood collection is done by experienced staff who will use techniques that minimise pain and discomfort to you and your baby.

Urine Collection: There is no risk from collecting urine.

Swab Collection: You may feel slight discomfort when the swab is in your vagina or rectum.

Hair Collection : There is no risk from collecting hair.

Ultrasound scan: There is no risk from ultrasound.

HIV Testing: We will perform an HIV test about 6 times during the study to make sure that you are HIV uninfected before starting or continuing PrEP. You will be counseled before and after the test is done. If you are found to be HIV infected, you will be referred to the local clinic to access ART from the National ART Programme. You can come to the clinic and ask for an HIV test anytime you are worried.

STI Testing: You will be tested for STIs. If you have any of these infections, we will provide you and your partner with treatment.

Acquiring HIV Infection and Drug Resistance: You must understand this information about what PrEP can and cannot do:

• PrEP cannot give you HIV infection.
• Taking PrEP prevents HIV in most people who take it every day, but you still may become infected with HIV while you are taking PrEP.
• PrEP does not prevent pregnancy or STIs.

You still need to use other methods to avoid HIV infection and other STIs while you are taking PrEP, like using condoms every time you have sex and keeping your number of sexual partners low. Study staff will discuss all the different ways you can keep yourself from getting these infections.

If you become infected with HIV while you are taking PrEP, the strain of the HIV virus in your blood might be “resistant” to the medicines in the PrEP pill and some other medications used for HIV treatment (ART). “Resistance” means the virus cannot be killed by that medication, which makes treating the HIV more difficult.

Social harm: Your partner or family members may not agree with you joining a study or taking PrEP. This could lead to arguments and trouble in your relationships. You will be contacted by the study staff every day for 2 weeks at 3 different phases during the study. Because of this, the people you live with may realize that you are involved in a study and could ask you questions about it. You may also experience stigma as a result of being involved in a study about HIV because people may assume that you are HIV-infected. If you have HIV or other infections, knowing this could make you worried. Study staff will discuss this with you before you decide to join the study. They are trained to help you deal with any feelings or questions you have.

Other Risks: Also, there may be uncommon risks or risks we don't know about yet that might occur. You should report any problems to the study staff immediately. There may also be some social risks to participating in this study. You may feel embarrassed or uncomfortable with some of the questions we will ask you, some of the procedures that will be done, or some of the test results that you will receive.

If you have any questions about anything we have said here, please talk to us.

18. There are risks from the PrEP medicines.

There are very few studies that used higher doses of FTC/TDF, so it is unknown if they cause worse side effects than the current dose of PrEP. From what we already know about FTC/TDF levels in women who are pregnant and women who are not pregnant, taking these higher doses of PrEP is not likely to cause very high amounts of FTC/TDF in the body that would be harmful. However, you or your baby may feel sick while participating in the study. These problems may be due to taking PrEP or due to an illness that has no relation to the study, like a cold or flu. You should tell us about any symptoms that you feel while you are participating in the study. You will be given a telephone number to contact the clinic.

You should contact us at any time if you or your baby don't feel well.

In PrEP research studies, nausea and diarrhea were the most common side effects, but happened in only about 10% or one in ten people. Nausea and diarrhea mainly happened in the first month and then went away. A small number (<1% or one in one hundred people) in PrEP studies showed a decrease in how their kidneys work, but this stopped when the people stopped taking the drug.

Other side effects, such as changes in bone mineral density (how much calcium and other minerals are in your bone which keeps them strong) were rare in people taking the drug who did not have HIV and have always gotten better when the drug was stopped.

You could have these side effects or other side effects that we do not know about. Please tell the staff here if you have any side effect that bothers you or does not go away.

Other Medications: Some medications should not be taken while you are taking FTC/TDF. When you visit the study clinic, we will ask you about other medications that you are taking.

Risks to your baby: The medicines in PrEP pills are often used to treat women with HIV infection. Many HIV-infected women have taken these medicines while pregnant and breastfeeding. We know that these medicines pass through to the baby in the womb and are found in breastmilk in small amounts. The information we have so far suggests that these medicines do not cause serious problems in the baby. However, it is still possible that taking PrEP may cause some problems in the baby soon after birth or when they are older. The study staff will check for side effects in babies during study visits and tell you what to do if your baby has any side effects. You should contact the study staff at any time if you are worried about the baby's health.

FTC/TDF PrEP may have side effects that no one knows about yet. We will let you know if we learn anything that might make you change your mind about continuing to participate in the study.

19. There could be risks of disclosure of your or your baby's information.

We will make every effort to keep you and your baby's information private and confidential. Study records and specimens will be kept in secure locations. All specimens and most records will be labelled only with a code number. However, you and your baby's names will be written on some records that are kept in the clinic. Despite our best efforts to keep this information private, it is possible that the information could be obtained by someone who should not have it. If this were to happen, you or your baby could be treated badly or unfairly. You could feel stress or embarrassment.

Benefits of the Study

20. There may be no benefit from being in the study.

We will test you for HIV and other STIs throughout this study. If you take your PrEP pills every day, it may help you to avoid HIV. Participating in this study may give you knowledge and skills that may help you to avoid HIV and other STIs. What we learn about PrEP doses in this study may help women in the future decide if they want to take PrEP while they are pregnant and breastfeeding.

Other information about the study

Even though people outside the research team will not see your name on your research information, our study records will have information that may identify you.

One exception is if you agree that we can give out research information with your name on it. You may give written permission for an insurer (e.g., medical aid), employer, or other person to get copies of your study records. Other exceptions are for information that is required to be reported

under law and for requests for information about your involvement by the United States government agency funding the study. For example, if you become infected with SARS-CoV-2 (the virus that causes 'covid') during the study, we will share that information with the national COVID-19 response team at the local clinic to make sure that you receive appropriate care.

In addition, the laws in Malawi ensures that all institutions conduct themselves in a responsible manner when collecting, processing, storing and sharing your personal information by holding them accountable should they abuse or compromise your personal information in any way.

21. You will not pay to be in the study.

There are no costs to you or your baby for study visits or procedures or the PrEP that is given by the study, and you will not receive payment for participating in the study. You will be reimbursed for the cost of transport to study visits and receive a small amount of cash for the inconvenience of time spent at the clinic. You will be given Malawi Kwacha equivalent of $10 (ten US dollars) for each study visit.

22. Study records may be reviewed by study staff and groups that oversee the study.

Groups that oversee the study include:

- National Health Sciences Research Committee (NHSRC)
- Malawi Ministry of Health
- Pharmacy and Medicines Regulatory Authority (PMRA)
- The University of North Carolina Chapel Hill
- The United States National Institutes of Health and its study monitors
- The United States Food and Drug Administration (FDA)
- The Office for Human Research Protections (OHRP)

The study staff and these groups are required to make every effort to keep study records private and confidential. Your study records may be reviewed by these groups who will use this information only for legitimate business, research, regulatory, and commercial purposes. The study staff will also use your personal information, if needed, to verify that you are not taking part in any other research studies. This includes other studies conducted here at UNC Project Malawi and studies conducted by other researchers that study staff know about.

The results of the study may be presented publicly or published. However, no presentation or publication will use your name or your baby's name or identify you or your baby personally. A description of this study will be available on a website called www.ClinicalTrials.gov . This website will not include information that can identify you or your baby. At most, the website will include a summary of the results of the study. You can search this website at any time.

Your baby's study information may be disclosed to other authorities if required by law.

23. If you or your baby gets sick or injured, contact us immediately.

If you or your baby gets sick during while you are in the study, you should come to the study clinic. If you are not able to come, please contact the clinic manager on the number provided at the end of this form or go to the nearest health care centre for treatment and care and at the next study clinic visit you bring your treatment cards. Your and your baby's health is important to us. We will make every effort to protect your well-being and minimize risks. It is possible, however, that you or your baby could have an illness or injury that is study-related. This means the illness or injury occurred as a direct result of being in the study. If you and/or your baby is injured as a result of being in this study, you and/or your baby will be given immediate treatment for the injuries at the study clinic or we will give you a referral letter and a copy of your most recent laboratory test results to take to the referral institution so that you get the care or treatment that you or your baby requires. You will not pay for that treatment. The cost of this treatment will be paid by the study. The US National Institute of Health (NIH) does not have a mechanism to provide direct compensation for research related injury.

24. Use these contacts at any time if you have questions, concerns, or problems.

• If you have questions about the study, you or your baby have any health or other problems that may be related to study participation or if you want to leave the study, please contact:

Dr. Friday Saidi on +265995403113 or

The UNC Project Malawi Reception on +2651755056.

• If you have questions about your rights or your baby's rights as research participants or concerns about how you or your baby are being treated in the study, please contact:

Dr Evelyn Chitsa Banda
National Health Sciences Research Committee (NHSRC)
+265999936937

SIGNATURE PAGE

IRB # 23/08/4175

Title of Study: Optimizing PrEP Regimens For Pregnant Women In Sub-Saharan Africa (O-PrEP)

SCREENING AND ENROLLMENT- PREGNANT ADULT INFORMED CONSENT FORM STAGE 1

Principal Investigators: Dr. Friday Saidi /Prof. Benjamín H. Chi

Participant's Agreement:

If you agree to participate in this study, **please sign your name or place your thumbprint** in the signature area at the bottom of this page. Before deciding whether to participate in this study, make sure you have read this form, or had it read to you, and that all of your questions have been answered. You should feel that you understand the study, its risks and benefits, and what is expected of you if you decide to join. If you decide to join , we will tell you any new information from this study or other studies that may affect your willingness to stay in the study. You are welcome to ask questions or request more information at any time. You do not give up any rights by signing this form.

PART A: LITERATE PARTICIPANT

Participant is literate: ☐

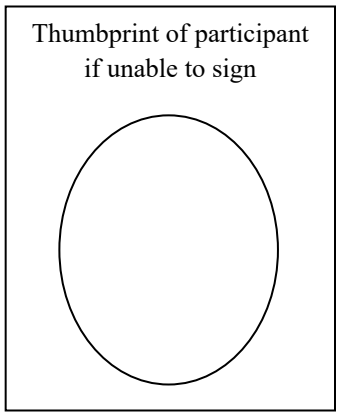
_____	_____	_____
Participant Name (print)	Participant Signature	Date
_____	_____	_____
Study Staff Conducting Consent Discussion (print)	Study Staff Signature	Date

PART B : ILLITERATE PARTICIPANT

Participant is illiterate : ☐

The study staff must complete this section, ONLY if an impartial witness is available.

The **Impartial witness must write participant 's name and date of consent** on the **SHADED AREA.**



Participant Name (print)	Participant Thumbprint	Date

Participant Name and Date Written By…….on…...……

Study Staff Conducting Consent Discussion (print)	Study Staff Signature	Date

Impartial Witness Name (print)	Impartial Witness Signature	Date