Supporting Tailored And Responsive PrEP in Rural North Carolina

Informed Consent Form

October 23rd, 2024

NCT05984030

University of North Carolina at Chapel Hill
Consent to Participate in a Research Study entitled "Meet me where I am: A multilevel strategy to increase PrEP uptake and persistence in rural NC (STARR-NC)"

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IRB Study # 22-3058
Department Study ID: IGHID 12221
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Funding Source and/or Sponsor: National Institutes of Health (NIH)

CONCISE SUMMARY

Things you should know about:

- Taking part in this research study is voluntary (your choice). You do not have to participate, and you can leave the study at any time. No matter what you decide, any other care that you get at your HIV/STI testing location will not change.
- The purpose of the study is to test new ways to increase access to effective HIV prevention medication, called Pre-Exposure Prophylaxis (PrEP).
- If you choose to participate, researchers will ask you to download a digital health app on your personal phone, complete one online study enrollment visit, and additional follow-up study assessments at approximately 3 months. Study activities for each visit will last between 60 - 90 minutes. You will be asked to complete surveys and provide a self-collected blood collection kit, as well as participate in an online interview with a study staff member. You will be in the study for approximately 3 months.
- Common risks from this research include possibly feeling uncomfortable answering questions or others finding out information that you report. While it is helpful if you answer as many questions as you can, you do not have to answer any questions that you do not want to answer. The study staff will make every effort to protect your privacy. There are no anticipated rare or significant risks.
- You may not experience any direct benefit from participating in this study. However, because of this study, you may have the opportunity to be linked to PrEP providers in the area and learn about HIV risk and prevention. Your participation in this study has the potential to make a positive contribution to society by identifying new ways to increase access to PrEP among people for whom access to PrEP has been more limited in the past.

Researchers are asking you to join this study because you are between the ages of 18-39 and meet U.S. Centers for Disease Control and Prevention indications for potentially benefitting from PrEP.

The study staff will offer you a signed copy of this form.

1. What is the key information I should know about this study?

This study involves research. Research is not the same as medical care. Research answers scientific questions. These answers can help find new medicines, treatments, vaccines, and even knowledge on how the human body works. This informed consent form tells you about this study. You can ask questions at any time. You can discuss this study with others before deciding to join.

2. Why are researchers doing this study?

Researchers are doing this study to increase access to Pre-Exposure Prophylaxis (PrEP) across North Carolina. HIV Pre-Exposure Prophylaxis (PrEP) medication has been proven to be effective at preventing HIV infection when taken as prescribed. Even though PrEP has been shown to be effective, not all healthcare settings currently offer PrEP to their patients. Part of the reason for this is that there are not enough healthcare providers who prescribe PrEP, and, some people have difficulty getting the cost of PrEP and PrEP care covered. The purpose of this study is to test new ways to increase access to PrEP for people in North Carolina. The intervention will test whether providing access to resources related to PrEP care at clinics that offer sexually transmitted infection (STI) testing will increase the number of people who start using PrEP.

3. Are there any reasons you should not be in this study?

There are no known medical reasons for not participating in this study.

4. What will I need to do during this study?

During this study, you will be in one of 2 study groups. Researchers will "randomize" you into one of the study groups described here. Randomization means that you are put into a study group by chance. Chance means that, similar to flipping a coin, you will have a 50% chance of being assigned to the standard of care group, and a 50% chance of being assigned to the intervention group. Neither you nor the study staff can choose your study group. The table below indicates what services each group will receive.

Standard of Care Group	Information about HIV prevention, including recommendations and information about PrEP, provided via a digital health app.
Intervention Group	Information about HIV prevention, including recommendations and information about PrEP, provided via a digital health app. Additional activities within the digital health app, access to a remote PrEP navigator, and referral to a telehealth PrEP provider.

This study is using a Standard of Care Group (also known as a “Control Group”) because we do not yet know whether the intervention being tested in this study will be effective. This kind of intervention has not previously been tested in these settings in North Carolina. Using a Standard of Care Group will allow researchers to assess whether providing the additional intervention resources increases PrEP use. That information can be used to make recommendations to health care providers and leaders about what services should be provided in the future. All participants will complete the following procedures regardless of which group they are assigned.

These are approximate dates, depending on the date you are enrolled into the study.

	Screening	*Baseline*	*3-Month Follow up*
Screening Questionnaire	*X*		
Online Survey Assessment		*X*	*X*
Dried Blood Sample			*X*
Qualitative Exit Interview			*X*

In addition, all participants, regardless of which group they are assigned, will be reminded by the study app and study staff to seek standard-of-care HIV and STI testing following the recommended guidelines by the U.S. Centers for Disease Control and Prevention for individuals who are sexually active. The study will not pay for any costs for these tests. These tests are available to you free of charge (or covered by your insurance) at your local health department. You will be asked to allow researchers access to certain medical records, such as results from HIV and STI tests (see Section 17).

5. How long will I be in this study?

If you decide to join, you will be in this study for about 3 months.

6. How many participants will be in this study?

Approximately 336 total participants will be in this study.

7. What possible risks can I expect from participating in this study?

The following is a summary of the known risks of participating. You may experience all, some, or none of these risks. This study is focused on HIV prevention, which may be a difficult or uncomfortable topic at times. There is some risk of feeling uncomfortable, embarrassed, or

upset during your participation in this study. If you are upset by using the app or completing the surveys or the interview, there are trained study staff with whom you can talk, or who can refer you to a health care provider. You do not have to answer any questions that you do not want to answer. It is unlikely you will be at risk of physical harm as a result of study participation.

Though we make every effort to protect your privacy in this study, it is possible that others may learn about the information you report. For instance, if you have family or friends on our study staff, they may learn sensitive information that you report. If you are not “out” to family or friends, there is also the chance that someone may find out about your sexual orientation because you were in this study. You do not have to share any information about yourself that you do not want to share.

The process of HIV and STI testing and learning of a positive HIV or STI test result can involve emotional distress and anxiety. If you experience this, study staff can help refer you to appropriate support services.

You will be asked to complete one mailed blood collection kit. The researchers will use the blood collection kit to measure the amount of PrEP medication in your body, if any. The researchers will not test for any other substances besides PrEP and will not do any other tests on your blood sample. You may potentially experience pain, discomfort, or injury from the self-administered finger stick testing in this kit. The finger prick for self-collected blood draw may hurt for a few seconds right after sticking your finger. The feeling may be like touching a pin or sewing needle.

We make every effort to ensure mailed blood collection kits are packaged subtly. We will confirm your preferred address and request your permission each time before we mail you a kit. However, there is the risk that someone in your home could see the kit.

If you are asked to participate in an interview, your voice will be recorded. Participating in an interview is optional. Your name will not be recorded. The recording will only be used by research team members. The recording is stored on a HIPAA-compliant, secure computer server. It is only available to select study staff. After the study is over, the recording will be destroyed. You may choose to have your interview not recorded.

You will be informed if the study staff learns of any new risks related to participation in the study.

8. What possible benefits can I expect from participating in this study?

Research is designed to benefit society by gaining new knowledge. You may not experience any direct benefit from participating in this study. However, because of this study, you may have the opportunity to learn about HIV risk and prevention and be linked to PrEP services. Your participation in this study has the potential to make a positive contribution to society by identifying new ways to increase access to PrEP among people for whom access to PrEP has been more limited in the past.

9. What other choices do I have?

If you choose not to participate in this study:

- You may choose to do nothing
- You may choose to join a different research study
- You may choose to get HIV information and counseling (have someone talk to you about HIV and testing) outside of the context of this study
- You may choose to get HIV PrEP services available in the community outside of the context of this study

If you would like more information about the risks and benefits of each one of these choices, talk to the study staff. You can also discuss these options with your doctor. Regardless of your choice, any other care that you get at your HIV/STI testing location will not change. Your decision not to participate will not lead to any penalty, or loss of benefits or rights that you would normally have otherwise.

10. What if we learn about new findings or information during this study?

New information learned through this study will be shared with you once the study is complete.

11. Will I receive any other clinical results?

You will not receive clinical test results through the study.

12. Can I change my mind about participating in this study?

Yes, you can change your mind at any time. Your participation in this study is completely up to you (voluntary). Tell the study staff if you are thinking about leaving this study. Again, any other care that you get now or in the future at your HIV/STI testing location will not change. Your decision to leave the study will not lead to any penalty or loss of benefits or rights that you would normally have otherwise.

13. Can researchers take me off this study early?

Yes, researchers can take you off this study at any time:

- If researchers believe that your continued participation in the study would not be in your best interest due to a laboratory abnormality, medical condition or other situation.
- If you do not follow the study requirements. This includes but is not limited to presenting a safety risk to research staff, interfering with study conduct, or fraudulent engagement with study activities.
- If the study is stopped or cancelled for any reason.
- If you test positive for HIV (see section 14).

14. What happens if I get HIV during this study?

If you test positive for HIV or other STIs at any point during study follow-up you will be appropriately connected to care through the North Carolina State Health Department's standard linkage to care procedures. If you test positive for HIV during study follow-up, your participation in the study will end. Prior to your participation ending, you will be asked to complete a brief end-of-study survey.

If you test positive for other STIs during study follow-up your participation will continue as planned.

15. What happens at the end of this study?

Your participation in the study will end after approximately 3 months. There are no plans for longer-term follow-up related to this study or any of its procedures. At the end of the study, you may choose to keep the digital health application installed on your phone, or you may choose to uninstall the app. The app will continue to work on your phone for as long as the study remains open (estimated through June of 2025). Once the study ends, the app may no longer work correctly as it may not continue to be updated.

If the intervention is found to be effective, and funding is available, the study team plans to work with each of the participating HIV/STI testing locations to expand the intervention to all eligible future clients. The study team will also share the results from the study with all study participants and leaders in the North Carolina Department of Health.

16. Will my samples and personal (private) information be used, stored, or shared after this study is over?

There are no plans for the NIH – or any other group affiliated with the study - to sell your samples for commercial profit (to make money), even if information that could identify you is removed. All samples will be destroyed at the end of the study. Your personal private information will be destroyed/deleted at the end of the study. At the end of the study, you may be asked if you would like to be contacted for future research opportunities. If you give your permission at that time, the form of contact information you provide will be stored securely in a password protected file, on a HIPAA-compliant computer server for communications about future research. If you choose to provide contact information at the end of the study, your information will not be affiliated in any way with any information or data you provided as part of this study.

17. How will researchers protect my samples and personal (private) information (information collected about me for the study)?

Your participation in this study will be kept confidential and private as permitted by law. This includes the information you provide in the surveys and interview, self-collected blood sample, lab results, medical records, and any data collected from the digital health phone app.

Researchers have plans and procedures in place to protect your samples and your personal (private) information. They keep your study records in a secure place. They do not use your name in publications, meetings, or on your samples. Instead, they use a code to link your personal (private) information and your samples to you. The key to the code will be kept separate from your samples and information. Only the researchers can match your name to the code if needed. Any information collected about you for the study will be kept confidential and will be shared only with your permission, or as required by law. The results of this research may be published in a medical book or journal or be used for teaching purposes. However, your name or identifying information will not be used.

Self-collection biospecimen kits will be mailed from a CLIA-certified, HIPAA-compliant testing laboratory and fulfillment center. Your name and mailing address will be entered by study staff into a password-protected, encrypted, secure online ordering portal to process and track the shipment. None of the information you share in the surveys you take as part of your study visits will be shared with the lab. Test kits will be mailed in a generic mailing envelope or box so that the contents will not be visible to anyone unless the mailer is opened.

There are some groups watching over this study. They want to make sure that researchers and their staff are protecting your rights and keeping you safe. They also want to see if researchers are following the approved study plan. People from these groups may review your study-related health records. Researchers may also share any information collected for this study ("personal/private information") with the groups that are listed below. These groups will only use your personal (private) information for legitimate business, public health, research, regulatory, and commercial purposes. For example, this information may include any unexpected problems or harms related to study participation. It is important for researchers and the other groups to also share this type of information with regulatory authorities (RAs)/entities (REs) so that they can decide if this new intervention is safe and works the way it is supposed to.

These groups watching over this study and the groups your information is shared with, have a duty to keep your information confidential. Some of these groups are:

- The Institutional Review Board (IRB) of UNC-Chapel Hill
- The U.S. National Institutes of Health (NIH)
- The U.S. Office for Human Research Protections (OHRP)
- External study monitors

U.S. Federal laws protect the privacy of your protected health information ("personal/private information"). However, there are exceptions to these laws. The Researchers will ask you to sign a form ("HIPAA Authorization") to give your permission for certain uses and sharing of your personal (private) information for the study. **Specifically, the researchers will ask you to grant permission for them to review certain medical records. Reviewed medical records will include HIV and STI testing done at your local HIV/STI testing location, and**

records related to PrEP use, should you choose to start PrEP, such as PrEP provider notes and blood test results. That form provides more details about the types of information that may be used and shared, and how it will be protected. There is a chance that clinicians and staff at your local HIV/STI testing location may become aware of your participation in this study. Staff and clinicians at your local HIV/STI testing location will not have access to any of your personal information they have not previously been granted access to.

18. What is a Certificate of Confidentiality?

Researchers have a Certificate of Confidentiality from the U.S. National Institutes of Health. This certificate is a tool to help protect your personal (private) information (information collected about you for the study) and your samples. Researchers can use this tool to legally refuse to give your information or samples to others. For example, researchers can say “No” to a court that is trying to get information about you. The court system cannot force researchers to talk about you being in the study.

But the courts can make researchers give personal (private) information about you to prevent serious harm to you or others. And researchers have to give your information to people who work at the organizations who are paying for this study or the U.S. FDA when asked. In this case, the information will be used to check or evaluate the study.

Researchers can release personal (private) information about you when you say it is okay. You can tell others about your being in the study. For example, you can allow your boss, insurer, doctor, or others to get study information. Then researchers cannot use the Certificate of Confidentiality to withhold the information from you; this tool does not prevent you from having access to your own study information.

A description of this clinical trial will be available on https://clinicaltrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

19. Will I have to pay anything to participate in this study?

You will not be charged for anything that is done for this study. This includes the download and use of the phone application, as well as the online screener. You or your health insurance company will have to pay for any medical care that is not part of this study, as you would usually do.

Using the mobile app or completing the online surveys on your personal phone may also use part of your data plan and may cost you money. Please review your data use plan to estimate what, if any, additional charges you may be billed for.

20. Will I receive any payment for my participation in this study?

You may receive up to $200 for your participation in the study, as follows:

- Enrollment activities: $60
- Follow-up 3-month survey: $40
- Return of 3-month whole blood self-collection kit: $50
- Optional qualitative exit interview: $50

21. Who should I contact if I think that I am hurt because of my participation in this study?

All research involves a chance that something bad might happen to you. If you think you are hurt because of your participation in this study or have questions about an injury, please tell Dr. Sarah Rutstein. You can do it in person at 2156 Bioinformatics, 130 Mason Farm Road, Chapel Hill NC 27599 or, call 919-843-5859. We can help link you to necessary medical care, if needed. If you become ill or are physically injured during the study, you should seek medical care.

Care for such injuries will be billed in the ordinary manner to you or your insurance company. Since this is a research study, payment for any injury resulting from your participation in this study may not be covered by some health insurance plans. Neither the U.S. NIH nor the University of North Carolina at Chapel Hill will be able to reimburse you (pay you back) for treatment expenses. There is no option for money or other forms of compensation through NIH or the University of North Carolina at Chapel Hill. You do not give up any of your legal rights by signing this consent form.

22. Who is sponsoring this study?

This research is funded by the US National Institutes of Health (NIH). This means that the research team is being paid by the sponsor for doing the study. The researchers do not, however, have a direct financial interest with the sponsor or in the final results of the study.

23. What are my rights and who should I contact if I have questions?

You have the right to leave this study at any time and for any reason. Any other care that you get now or in the future at this site will not change. You will not give up your legal rights by signing this informed consent form. You also have the right to know about any new information from this study or other related studies. This information may affect your health, well-being (welfare), or decision to stay in this study.

If you have questions or concerns about your rights as a research subject, or if you would like to obtain information or offer input, you may contact, anonymously if you wish, UNC Institutional Review Board (IRB) at 919-966-3113 or by email to IRB_subjects@unc.edu.

24. Do I give researchers permission to contact me?

Sometimes researchers may want to contact you to get more information or to clarify information about you for this study. They may also want to contact you to see if you are interested in joining future studies. The researchers will only call you for current or future research related information.

____ (Initials) Yes, researchers may contact me.	____ (Initials) No, researchers may not contact me.

Additionally, the study team would like to contact you by text messaging or e-mail, however you may say "no" to receiving these messages and still participate in this study. If you say "yes", messages may contain personal information about you and may be sent or received by the study team's personal electronic devices or in a method that is not able to be encrypted (protected) and there is the risk your information could be shared beyond you and the study team. This information may include information such as reminders and notifications to contact the study team.

If you wish to stop receiving unprotected communication from the study team or have lost access to your device, please notify the study team using the study contact information at the beginning of this consent form. After the study is complete and all research activities finished, or you withdraw from the study or request to stop receiving unprotected communication, you will no longer receive un-encrypted (un-protected) messages specific to this study.

_____ Yes, I consent to the study team utilizing the following (cell phone number, email) to send communication:

E-mail: _____

Cell-phone #_____

_____ No, I do not consent to receive un-protected communication from the study team.

25. How do I confirm my decision to be in this study?

My signature below confirms that the study and this form was explained to me and:

- I had the opportunity to read this form or that it was read to me
- I had the opportunity to ask questions
- I had the opportunity to discuss my study participation with others
- I voluntarily decided to participate in this study

Participant's Name (print)	Participant's Signature and Date

26. If you are invited to participate in an interview and agree to participate, please indicate if you consent to be audio recorded during the interview.

Please **add your initials** the line that best matches your choice:

_____ OK to record me during the interview.

_____ Not OK to record me during the interview.