CONSENT FORM TO BE PART OF A RESEARCH STUDY

Title of Research: PrEP Pro: Adapting a Multi-component Intervention to Train and Support Providers to Promote PrEP for Adolescent Girls and Young Women in the Deep South

UAB IRB Protocol #: IRB-300008567

Principal Investigator: Latesha Elopre, MD, MSPH and Lynn Matthews, MD, MPH

Sponsor: National Institutes of Health

General Information	You are being asked to take part in a research study. This research study is voluntary, meaning you do not have to take part in it. The procedures, risks, and benefits are fully described further in the consent form.
Purpose	The purpose of the study is to train family medicine providers on how to take a sexual history and provide pre-exposure prophylaxis (PrEP) care for Adolescents and Young Adults ages 14-24 in the South.
Duration & Visits	You will be in this study for about 3 months.
Overview of Procedures	As a PrEP Champion in this pre-test phase of the PrEP Pro study, you will do the following: 1. Participate in a demographic and pre-training questionnaire 2. Complete about 4 hours of PrEP Champion training with investigators 3. Participate in a post-training questionnaire 4. Deliver training to a group of family medicine residents at your clinical site 5. Serve as a resource and leader for PrEP provision and care in your clinical setting 6. Keep notes of your interactions with the clinic team and record the number of hours you spend on PrEP Champion activities 7. Communicate with other PrEP Champions at different clinical sites to discuss and troubleshoot barriers to PrEP provision and care
Risks	At present, we do not see any major risk of harm from your participation. There is a risk that you may feel uncomfortable discussing some of the topics. Otherwise, the risks associated with participation in this study are no greater than those encountered in your routine work as a Family Medicine provider in a training program.
Benefits	There is a possibility that the final tools and products we develop can help you and other family medicine providers to more effectively take a sexual history and provide pre-exposure prophylaxis (PrEP) care for Adolescents and Young Adults ages 14-24 in the South.
Alternatives	One alternative may be not to participate in the study.

Purpose of the Research Study

We are asking you to take part in a research study. The purpose of this research study is to adapt and evaluate an intervention to train family medicine providers on how to take a sexual history and provide pre-exposure prophylaxis (PrEP) care for Adolescents and Young Adults ages 14-24 in the South. Research shows us that

there are many opportunities to improve sexual health services and pre-exposure prophylaxis (PrEP) care for Adolescents and Young Adults ages 14-24 in the U.S. South.

Over the past two years, a group of investigators from UAB worked with a scientific team and community advisory boards comprising family medicine providers and administrators to develop some tools and products that will be used to train family medicine providers on how to take a sexual history and provide PrEP to Adolescents and Young Adults. We conducted a pre-test of this intervention to gather feedback from two sites with three PrEP Champions and seven residents from May thought July 2023.

We will now be conducting a larger-scale pilot test of the intervention. This part of the study will include up to 6 clinical sites, who have agreed to implement this training program for their family medicine residents. Each site will have one to two enrolled PrEP Champions and up to ten enrolled family medicine resident trainees (FMRTs) who will be mentored by the PrEP Champion(s). These residency program sites may choose to provide training using PrEP Pro tools to more resident trainees than those who participate in the study. By receiving training, you are not committing to participating in the PrEP Pro study.

Study Participation & Procedures

If you agree to join the study, you will be a "PrEP Champion," who is an agent of change, empowering their peer providers within a clinical practice or "site" to engage in innovations, practice new skills, and implement new care strategies through communication, marketing, education, skill-building, and assessment. As a PrEP Champion in this pilot-test phase of the PrEP Pro study:

- You will complete a baseline questionnaire to capture sociodemographics (age, race, gender, years of practice, client volume) and experiences with PrEP provision.
- You will complete an estimated 4 hours of training over 3 sessions with study team members. These sessions will consist of lectures, discussions, and practice using the PrEP Champion-specific and base curriculum evidence-based training tools adapted from and informed by existing tools. You will also be trained in effective curriculum delivery.
- You will complete a post-training questionnaire within 30 days after the end of the 6-month pilot-test period. This questionnaire will evaluate acceptability and feasibility of the intervention.
- You will schedule at least two 1-hour sessions with resident trainees at your clinical site. The administration of this clinical site has agreed to implement this evidence-based training program for its residents. Residents may choose whether or not to participate in the PrEP Pro study by deciding to complete or not complete the study pre- and post-training questionnaires. Residents who choose not to participate in the study may still receive the PrEP Pro training, as the program administration sees fit.
- You will administer the same PrEP Pro training you received from our team, using the tools we provide (PowerPoints, recorded presentations, physical reference tools, patient-facing materials, and access to the PrEP Pro website with all of our content), to the group of family medicine resident trainees at the clinical site. A member of our team will attend and/or record these training sessions to monitor quality control, consistent content delivery, and support you, as needed.
- After training the residents, you will be available to support these residents as a PrEP Champion for six months, whom they can come to with questions, concerns, and needs regarding PrEP provision and care in a clinical setting.
- You are encouraged to meet regularly with your clinic administrator or social worker who would be responsible for entering insurance claims for PrEP services to discuss barriers that may arise.

- You will keep notes of all PrEP-related interactions and duties in the clinic setting (supporting residents, discussing with administrator, providing additional resources), record the number of residents that contact you regarding PrEP provision and care, and record the amount of time (hours) you spend on these activities in the PrEP Champion Time Log that you will be provided with at the time of your training. You will be paid $50 per hour that you spend on these activities during the six-month period after your initial training, as a consulting fee.
- You will be connected with the other PrEP Champion(s) who are enrolled in this study to form a community of practice, which will give you the opportunity to discuss, learn, and troubleshoot barriers to PrEP provision and care with your peers. You may choose to meet with this group in person, virtually, or communicate in another manner of your choosing.
- You will be given tools called pocket reference cards to distribute to your resident group. These are informational cards that provide quick-access information and can be maintained on the person in a clinical setting for referencing before, during, or after patient appointments.
- You will have access to the manual (Google Sites webpage accessible by web link) of resources and training materials to troubleshoot challenges that may arise, and the study team will be available as needed.

Risks and Discomforts

At present, we do not see any major risk of harm from your participation.

- There is a risk that you may feel uncomfortable discussing some of the topics. Otherwise, the risks associated with participation in this study are no greater than those encountered in daily life.

Benefits

There is a possibility that the final tools and trainings we develop can help you and other family medicine providers to take a sexual history and provide pre-exposure prophylaxis (PrEP) care for Adolescents and Young Adults ages 14-24 in the South.

Alternatives

One alternative may be not to participate in the study.

Confidentiality and Authorization to Use and Disclose Information for Research Purposes

Your name will not be linked to your pre-training or post-training questionnaire. Your answers will be stored electronically in a secure environment and used for research or academic purposes now or later in ways that will not reveal who you are. Your answers will be linked to the participant number we give to you, and we will refer to you in this way in the data, any publication, report, or other research output.

As this is a small study, there is a possibility that investigators or others will know that you participated at a PrEP Champion. We will make every effort to keep your identity confidential.

Who may use and give out this information?

The information, including demographics, audio recordings of training sessions, pre- and post-training questionnaire data, and PrEP Champion notes and Time Logs, you give us during the study may be used and

given to others by the staff. They might see the research information during and after the study. However, your identity will not be given to others outside of the study team and the clinical site which has agreed to participate in this program.

Who might get this information?

All individuals/entities listed in the informed consent document(s), including but not limited to the principal investigators leading this project, other investigators and research staff, and others performing services related to the research (whether at UAB or elsewhere).

Information obtained about you for this study will be kept confidential to the extent allowed by law. However, research information that identifies you may be shared with people or organizations for quality assurance or data analysis, or with those responsible for ensuring compliance with laws and regulations related to research. They include:

- the UAB Institutional Review Board (IRB). An IRB is a group that reviews the study to protect the rights and welfare of research participants.
- the Office for Human Research Protections (OHRP)
- the National Institutes of Mental Health (NIMH)
- UAB Center for AIDS Research (UAB CFAR)

The information from the research may be published for scientific purposes; however, your identity will not be given out in those publications.

Why will this information be used and/or given to others?

Information about you and your practice that might identify you may be given to others to carry out the research study. We will make every effort to keep your identity confidential.

Voluntary Participation and Withdrawal

Whether or not you take part in this study is your choice. There will be no penalty if you decide not to be in it. If you decide not to be in the study, you will not lose any benefits you are otherwise owed.

You are free to withdraw from this study at any time. Your choice to leave the study will not affect your relationship with this institution.

If you are a UAB employee, taking part in this research is not a part of your UAB duties. You can refuse to enroll or withdraw after enrolling at any time before the study is over, with no effect on your job at UAB. You will not be offered or receive any special consideration if you take part in this research.

Cost of Participation

There will be no cost to you for taking part in this study.

Payment for Participation

You will be reimbursed $50/hour for your participation in the study, which will be given to you in the form of a Greenphire ClinCard debit card.

Based on conversations with current PrEP Champions who take on this role informally and based on what residents are paid to moonlight, PrEP Champions will be paid a consulting fee of $50/hour for their time spent supporting HCPs. We believe that trainees who elect to become PrEP Champions will be primarily motivated by personal and professional interest and the rewards of becoming recognized clinical experts, which can support scalability; we will provide financial incentives during this formative work given the additional demands of frequent interactions with the study team and requests to log time and interactions.

Questions

If you have any questions, concerns, or complaints about the research, please contact the Principal Investigators. You may contact Dr. Latesha Elopre at lelopre@uabmc.edu or Dr. Lynn T. Matthews at lynnmatthews@uabmc.edu.

If you have questions about your rights as a research participant, or concerns or complaints about the research, you may contact the UAB Office of the IRB (OIRB) at (205) 934-3789 or toll-free at 1-855-860-3789. Regular hours for the OIRB are 8:00 a.m. to 5:00 p.m. CT, Monday through Friday.

Legal Rights

You are not waiving any of your legal rights by signing this consent form.

Signatures

Your signature below indicates that you have read (or been read) the information provided above and agree to participate in this study. You will receive a copy of this signed consent form.

Printed Name of Participant	Signature of Participant	Date
Name of Person Obtaining Consent	Signature of Person Obtaining Consent	Date