Permission to Take Part in a Human Research Study

Title of Research Study: Adaptation and Pilot Test of an Electronic Health Record-based Approach to Increase PrEP Knowledge and Uptake: the EMC^2 PrEP Strategy

Principal Investigator: Allison Pack, PhD, MPH

Supported By: This research is supported by Merck.

Financial Interest Disclosure: The following disclosure is made to give you an opportunity to decide if this relationship will affect your willingness to participate in this research study:

In addition to the grant Dr. Pack received from Merck to conduct this research, she also has received grants through Northwestern University from, Pfizer, the Gordon and Betty Moore Foundation, the RRF Foundation for Aging, Lundbeck, and Eli Lilly.

Key Information:
The first few pages of this document include a summary of this study to help you decide whether or not to participate. Detailed information is provided after the summary.

Why am I being asked to take part in this research study?
We are asking you to take part in this research study because you are an English speaking adult woman in primary care who could help us understand the impact of some educational materials about women's health.

What should I know about a research study?
- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Why is this research being done?
- The purpose of this study is to evaluate the impact of educational materials that help women learn about new options to promote women's health. You may or may not have received these materials.
- The main benefits of being in this study include learning about the new options and helping improve ways that we can inform other women.

How long will the research last and what will I need to do?
We expect that you will be in this research study for a one-time interview lasting approximately 45 minutes to an hour.

You will be asked to complete a survey and, possibly, answer several open-ended questions.

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Is there any way being in this study could be bad for me?
There always exits the potential for loss of private information; however, there are procedures in place to minimize this risk. You may also stop participation at any time or skip any question if you feel uncomfortable.

Will being in this study help me any way?
We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include a better understanding of HIV prevention options.

What happens if I do not want to be in this research?
Participation in research is completely voluntary. You decide whether or not to participate. If you choose to not participate, there will be no penalty to you or loss of benefit to which you are entitled. Your alternative to participating in this research study is to not participate.

Detailed Information:
The rest of this document includes detailed information about this study (in addition to the information listed above).

Whom can I talk to?
If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at 312-503-2685.

This research has been reviewed and approved by an Institutional Review Board (IRB). You may talk to them at (312) 503-9338 or irbcompliance@northwestern.edu if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

How many people will be studied?
We expect about 200 people will be in this research study.

What happens if I say "Yes, I want to be in this research"?
If you participate in this research you will be asked to participate in 1 interview, either in-person at Northwestern University, over the telephone or over a secure webconferencing platform like Zoom or Teams. The interview will take place soon and will take about 45 minutes to an hour to complete. At this interview, you will first be asked some general questions about your background and how you understand health information. Next, you will also be asked some questions about HIV. We will then give you some information about a new way to prevent HIV and ask what you think about it. If you already received the educational program, you will be asked a few more questions so we can better undertand what you thought of the program.

What are my responsibilities if I take part in this research?
If you take part in this research, you will be responsible to complete only this 1 interview.

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What happens if I say "Yes", but I change my mind later?

You can leave the interview at any time; it will not be held against you.

Choosing not to be in this study or to stop being in this study will not result in any penalty to you or loss of benefit to which you are entitled. Specifically, your choice not to be in this study will not negatively affect your right to any present or future medical treatment at Northwestern University/Northwestern Memorial Healthcare.

If you agree, this data will be handled the same as research data.

Detained Risks: Is there any way being in this study could be bad for me?

This study involves the use of your identifiable, personal information and there is a chance that a loss of confidentiality could occur. The researchers have procedures in place to lessen the possibility of this happening. If part of your interview is audio-recorded, the recordings will be deleted at the of this study.

Will it cost me anything to participate in this research study?

Taking part in this research study will not lead to any costs to you.

Will being in this study help me in any way?

We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include learning about a new HIV prevention option and helping improve ways that we can inform other women about this new option.

What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of this institution.

The sponsor, monitors, auditors, the IRB, the Northwestern University Office for Research Integrity, the US Office of Research Integrity (ORI), the US Office for Human Research Protections (OHRP), and the US Food and Drug Administration (FDA) may be granted direct access to your medical records to conduct and oversee the research. By signing this document, you are authorizing this access. We may publish the results of this research. However, we will keep your name and other identifying information confidential.

A description of this clinical trial may be available on http://www.ClinicalTrials.gov, if required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Data Sharing

De-identified data from this study may be shared with the research community at large to advance science and health. We will remove or code any personal information that could identify you before files are shared with other researchers to ensure that, by current scientific standards and known methods, no one will be able to identify you from the information we share. Despite these measures, we cannot guarantee anonymity of your personal data.

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What else do I need to know?

If you agree to take part in this research study, You will receive a $45 physical or virtual gift card for your participation in this study within a few weeks of when you complete your interview.

Please note there are additional instructions should you wish to use the gift card to withdraw cash from an ATM, at a restaurant or a gas station. These instructions will be mailed to you with the gift card. You will incur fees if the card is not used in 12 months or more.

HIPAA Authorization

We are committed to respect your privacy and to keep your personal information confidential. When choosing to take part in this study, you are giving us the permission to use your personal health information that includes health information in your medical records and information that can identify you. For example, personal health information may include your name, address, phone number or social security number. Your health information we may collect and use for this research includes:

- Medical history
- Lab tests, or certain health information indicating or relating to a particular condition as well diaries and questionnaires
- Records about study medication or drugs
- Records about study devices
- HIV testing results
- Sexually transmitted illnesses

The following clinical providers may give the researchers information about you: all current and previous health care providers, including but not limited to the Shirley Ryan AbilityLab (SRALAB) and Northwestern Memorial HealthCare/Northwestern Medicine entities and its current and future affiliates.

Once we have the health information listed above, we may share some of this information with the following offices or entities outside of Northwestern University and its clinical partners (or affiliates): the Northwestern University Institutional Review Board Office and Office for Research Integrity; the US Office of Research Integrity; the US Office for Human Research Protections; the US Food and Drug Administration.

Any research information shared with outside entities will not contain your name, address, telephone or social security number or any other personal identifier unless disclosure of the identifier is necessary for review by such parties or is required by law or University policy [except that such information may be viewed by the Study sponsor and its partners or contractors at the Principal Investigator's office].

The following entities may receive your health information:

- Authorized members of the Northwestern University, who may need to see your information, such as administrative staff members from the Office for Research, Office for Research Integrity and members of the Institutional Review Board.
- Clinical affiliates, including but not limited to the Shirley Ryan AbilityLab (SRALAB), Northwestern Memorial HealthCare, and the Ann & Robert H. Lurie Children's Hospital of Chicago (Lurie Children's). Your participation in this clinical trial may be

tracked in an electronic database and may be seen by investigators running other trials that you are enrolled in and by your healthcare providers
- Clinical affiliates, including but not limited to Northwestern Memorial HealthCare, for purposes including, but not limited to, the affiliate's provision of care to you and/or the affiliate's scheduling of appointments and/or billing activities.
- Other University research centers and University contractors who are also working on the study,
- Study monitors and auditors who make sure that the study is being done properly,
- Merck, who is sponsoring the study, and that company's contractors and partners.

Those persons who get your health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it. Some of those persons may be able to share your information with others without your separate permission.

The results of this study may also be used for teaching, publications, or for presentation at scientific meetings.

Unless you revoke your consent, it will expire at the end of the research study.

Although you may revoke consent to participation in this research at any time and in any format, you must revoke authorization for use or disclosure of your health information in writing.

To revoke your authorization, write to:

Allison Pack, PhD, MPH
Northwestern University
Department of General Internal Medicine
750 N Lake Shore Dr, 10th Floor
Chicago, IL 60611

You do not have to authorize the use or disclosure of your health information; however, you will not be allowed to take part in this research study. If you do not authorize the use or disclosure of your health information, it will not affect your treatment by health care providers, or the payment or enrollment in any health plans, or affect your eligibility for benefits.

Optional Elements:

The following research activities are optional, meaning that you do not have to agree to them in order to participate in the research study. Please indicate your willingness to participate in these optional activities by placing your initials next to each activity.

I agree	I disagree	
_____	_____	The researcher may keep my contact information in order to contact me in the future to see if I am interested in participating in other research studies by the Principal Investigator or researchers in the Center for Applied Health Research on Aging.

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Consent

Once completed, you will get an automatic email with the signed version of this consent. If you want a paper copy of this consent for your records, you can print it from the screen.

Your signature documents your permission to take part in this research and for disclosure and use of personal health information from your medical record for purposes of this study.

_____ _____

Electronic Signature of participant Date

_____ _____

First Name Last Name

_____ _____

Electronic Signature of person obtaining consent Date

_____

_____

First name of person obtaining consent Last name of person obtaining consent