

**In-the-kNOW (Novel Approaches to Optimizing Women's Health): A
Mobile Application to Optimize HIV Prevention and
Sexual/Reproductive Health Communication Among Black Women in
the Southern U.S.**

NCT05080972

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You Are Being Asked to Be in a Research Study

You are being asked to be in a research study. A research study is designed to answer a scientific question. If you agree to be in the study you will be one of 60 people who are being studied, at Emory.

Why is this study being done?

This study is being done to answer the question: How can a mobile phone application that is developed and designed for Black women improve HIV knowledge and the acceptability of pre-exposure prophylaxis (PrEP)? You are being asked to be in this research study because your participation will allow the research team to assess the feasibility, acceptability, and usability of a mobile phone app entitled “Savvy HER” that is developed for Black women.

Do you have to be in the study?

It is your choice to join this research study. You do not have to be in it. Before you choose, take time to learn about the study.

What do you have to do if you choose to join this study?

If you qualify and choose to join the study, you will participate for 4 months. During this time, you will be asked to complete an online survey and will be given 4 months to use the Savvy HER mobile app (only if you are part of the group using the Savvy HER mobile app). After using the app, you will be asked to participate in interviews where you will provide feedback on your experiences using the app.

How is this study going to help you?

If you are in the study, you will be helping the researchers answer the study question: How can a mobile phone app developed for Black women be used to help Black women increase their knowledge about HIV prevention and acceptability towards PrEP?

What are the risks or discomforts you should know about before deciding?

The study will take time. All studies have some risks. Some risks are relatively small, like being bored or losing time. Some are more serious – for this study, these include, loss of privacy, and breach of confidentiality. A full list of expected risks, their frequency, and severity are in the “What are the possible risks and discomforts?” section of this document.

Alternatives to Joining This Study

Since this is not a treatment study, the alternative is not to participate.

Costs

There will be no costs to you for participating in this study. You will not be charged for any of the research activities.

What Should You Do Next?

Read this form, or have it read to you. Make sure the study doctor or study staff explains the study to you. Ask questions such as how much time you will have to spend on the study, any words you do not understand, and more details about study procedures. Make sure you understand which parts of the study are research and which are standard care that you would have even if you did not join the study. Take time to think about this and talk about it with your family and friends.



Emory University Consent to be a Research Subject

Title: In-the-kNOW (Novel approaches to Optimizing Women's Health): A mobile application to optimize HIV prevention and sexual/reproductive health communication among Black women in the Southern U.S.

Mobile HIV Prevention App for Black Women

IRB #: 00177075

Principal Investigator: [REDACTED], PhD; Nell Hodgson School of Nursing, Emory University

Funding Source: National Institutes of Health (NIH)

Introduction

You are being asked to be in a research study. This form is designed to tell you everything you need to think about before you decide to consent (agree) to be in the study or not to be in the study. **It is entirely your choice. If you decide to take part, you can change your mind later on and withdraw from the research study. You can skip any questions that you do not wish to answer.**

Before making your decision:

- Please carefully read this form or have it read to you
- Please ask questions about anything that is not clear

You can take a copy of this consent form, to keep. Feel free to take your time thinking about whether you would like to participate. By signing this form you will not give up any legal rights.

This trial will be registered and may report results on www.ClinicalTrials.gov, a publicly available registry of clinical trials.

What is the purpose of this study?

The purpose of this study is to get information from you to determine what Black women want to know about Human Immunodeficiency Virus/Sexually Transmitted Infections/ and any other women's health topics, and how we can keep you accessing the information on a regular basis using technology.

What will you be asked to do?

A total of 60 PrEP-eligible Black women will be randomized (i.e., like drawing straws) into the Savvy HER study; control and intervention groups where the intervention arm (n = 30) and the control arm (n = 30) and complete baseline and 4-month follow-up assessments.

Savvy HER (intervention) participant

You will be asked to take a survey, use the Savvy HER mobile app for 4 months, take another survey, and be interviewed. At the interview, you will be asked to answer questions in a 30-minute discussion with a research study staff.

Control participant

You will be asked to take a survey, access at your discretion online resources for 4 months, take another survey, and be interviewed. At the interview, you will be asked to answer questions in a 30-minute discussion with a research study staff.

Who owns your study data and samples?

If you join this study, you will be donating your samples and data. You will not be paid if your samples or data are used to make a new product. If you leave the study, the data and samples that were already collected may still be used for this study (**See: Privacy Protection**).

What are the possible risks and discomforts?

There may be side effects from the study procedures that are not known at this time.

The most common risks and discomforts expected in this study are:

For the virtual groups, participants' privacy is not guaranteed. There is a potential risk that information shared by a participant could be discussed by another participant outside the group. The consent form and Terms of mobile app use will strongly state that information about other participants should not be shared outside of the research, and research staff will highlight this point during the informed consent process both at the beginning and end of online group forums. CAB members are at no risk as they are not participants but collaborators in the study, and they are permitted to disengage from the monthly meetings at any time.

The less common risks and discomforts expected in this study are:

Personal information may accidentally be revealed. To protect you from the risk of your private information being revealed, each participant will be assigned a unique alphanumeric ID which will be used on all documents and research materials instead of names, except for the consent form, which will include participant names, not the unique ID. Interview and focus groups, following transcription, will be anonymized. Field notes will not include the real names of participants or persons they mention. All observations, whether relating to people, interactions, or things, will be treated as confidential information and handled applicably.

Researchers may learn something new during the study that may affect your choice to be in the study. If this happens, they will tell you about it. Then you can choose if you want to stay in this study. You may be asked to sign a new form if you choose to stay in the study

Will you benefit from the study?

Participants may potentially benefit through an improved ability to engage with trusted HIV prevention content (including HIV testing, initiation of PrEP, condom use, and improved communication with their HCP). Participants may also benefit from access to various resources and online social network engagement. Improving engagement in care could lead to improved quality of life and reduced HIV acquisition.

Will you be paid for your time and effort?

You will get **\$50** for completing the first survey and **\$80** for completing the final survey and interview. If you do not finish the study, you will be paid for the surveys you have completed. You will receive \$__130__ total if you complete all study activities.

How will your private information be protected?

Whenever possible, a study number, rather than your name, will be used on study records. Your name and other identifying information will not appear when we present or publish the study results.

Privacy Protection. Protecting the privacy of participants in research is very important. We will protect privacy in several ways: (See **Authorization to Use and Disclose Protected Health Information** below).

1. Research staff will get your contact information and informed consent digitally/virtually (e.g., using REDCap, DocuSign, and Zoom).
2. Data will never be communicated together with names in any written materials. This information will be attached only to a number, and all study information in paper form will be kept in locked file cabinets, at Emory University. Contact information for participants (i.e., name, address, and telephone number) will be entered into a secure study computer.
3. All study staff will be trained in security and confidentiality procedures and will sign a confidentiality agreement before data collection begins. After interview recordings have been transcribed and compared to the transcript for accuracy, they will be deleted. Online material will be stored on an encrypted institutional (Emory University) server. Advisory board members, Participants, and research study staff will have login/password-protected access to the prototype version of the app to exclude public use of the mobile app.
4. **TBD Health** is a vendor partner with the Savvy HER study providing convenient at-home HIV/STI test kits and results for participants. **TBD Health** will have access to the protected health information of participants, similar to visiting a healthcare facility or healthcare provider for personal healthcare service(s). While noting HIPAA regulations, **TBD Health** is authorized to share the test results with the Savvy HER research study team.

Certificate of Confidentiality

There is a Certificate of Confidentiality from the National Institutes of Health for this Study. The Certificate of Confidentiality helps us to keep others from learning that you participated in this study. Emory will rely on the Certificate of Confidentiality to refuse to give out study information that identifies you. For example, if Emory received a subpoena for study records, it would not give out information that identifies you.

The Certificate of Confidentiality does not stop you or someone else, like a member of your family, from giving out information about your participation in this study. For example, if you let your insurance company know that you are in this study, and you agree to give the insurance company research information, then the investigator cannot use the Certificate to withhold this information. This means you and your family also need to protect your own privacy.

The Certificate does not stop Emory from making the following disclosures about you:

- Giving state public health officials information about certain infectious diseases,
- Giving law officials information about abuse of a child, elderly person or disabled person.
- Giving out information to prevent harm to you or others.

Giving the study sponsor or funders information about the study, including information for an audit or evaluation.

Withdrawal from the Study

You have the right to leave a study at any time without penalty. You may refuse to do any procedures you do not feel comfortable with, or answer any questions that you do not wish to answer. If you withdraw from the study, we will use the information that you provided during the time that participated in the study.

The researchers and funder also have the right to stop your participation in this study without your consent if:

- They believe it is in your best interest,
- You do not agree to changes that may be made in the study plan,

INSERT APPROPRIATE HIPAA OR CONFIDENTIALITY LANGUAGE HERE

Authorization to Use and Disclose Protected Health Information

The privacy of your health information is important to us. As part of this study, we will get your protected health information (PHI) from health care entities who are covered by the Health Insurance Portability and Accountability Act and regulations (HIPAA). Because the health care entities are covered by HIPAA, we must have your authorization to get your PHI from them. However, once we get your PHI from the health care entities, it changes from PHI to individually identifiable information (IIHI) and is no longer covered by HIPAA. We will put your IIHI in a separate research record that is not a part of your medical record. IIHI placed in the separate research record is not covered by HIPAA.

Purpose of this Authorization:

By signing this form, you give us permission to get your PHI from health care entities and to use and disclose your IIHI as described in this document. You do not have to sign this form. If you do not sign this form, then you may not participate in the research study.

No Provision of Treatment

There is no research-related treatment involved in this study. You may receive any non-research related treatment whether or not you sign this form.

IIHI that Will be Used/Disclosed:

The IIHI that we will use or disclosed for the research study includes:

- Laboratory test results.

Use and Disclosure of Your IIHI That is Required by Law:

We will use and disclose your IIHI when we are required to do so by law. This includes laws that require us to report child abuse or abuse of elderly or disabled adults.

People Who will Use/Disclose Your IIHI:

The following people and groups will use and disclose your IIHI in connection with the research study:

- The Principal Investigator and the research staff will use and disclose your IIHI to conduct the study.
- **TBD Health** will use your IIHI to make sure the research is done correctly and safely.
- Emory offices that are part of the Human Research Participant Protection Program and those that are involved in study administration. These include the Emory IRB, the Emory University and Healthcare Compliance Offices, and the Emory Office for Clinical Research.



Contact Information

Contact [REDACTED] at [REDACTED]:

- if you have any questions about this study or your part in it, or
- if you have questions, concerns, or complaints about the research

This study has been reviewed by an ethics committee to ensure the protection of research participants. If you have questions about your **rights as a research participant**, or if you have **complaints** about the research or an issue you would rather discuss with someone outside the research team, contact the Emory Institutional Review Board at [REDACTED] or [REDACTED]

To tell the IRB about your experience as a research participant, fill out the Research Participant Survey at



<https://tinyurl.com/ycewgkke>.

Consent and Authorization

TO BE FILLED OUT BY SUBJECT ONLY

Print your name, **sign**, and **date** below if you choose to be in this research study. You will not give up any of your legal rights by signing this form. We will give you a copy of the signed form to keep.

Name of Subject

Signature of Subject (18 or older and able to consent)

Date

Time

Signature of Legally Authorized Representative

Date

Time

Authority of Legally Authorized Representative or Relationship to Subject

TO BE FILLED OUT BY STUDY TEAM ONLY

Name of Person Conducting Informed Consent Discussion

Signature of Person Conducting Informed Consent Discussion

Date

Time