# You Are Being Asked to Be in a Research Study

**Concise presentation of key concepts**

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 70 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" which is developed for Black women.

**Do you have to be in the study?**

It is your decision to be part of this research study. You do not have to be in it. Before you make your decision, you should take time to learn about the study.

**What do I have to do if I choose to participate in this study?**

If you are eligible and want to be part of the study, you will participate for 6 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. 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 I should know about before making a decision?**

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.

# Emory University
# Consent to be a Research Subject

**Title**: Mobile HIV Prevention App for Black Women

**Principal Investigator:** Rasheeta Chandler, 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.

## Study Overview

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.

## Procedures

App Usability Pretest participant

You will be asked to take a survey, use the SaVVY HER mobile app for 4 weeks, take another survey, and be interviewed. At the interview, you will be asked to answer questions in a 60-minute discussion with the research study staff.

SaVVY HER participant

You will be asked to take a survey, use the SaVVY HER mobile app for 4 weeks, 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.

**Privacy Protection.** Protecting the privacy of participants in research is very important. We will protect privacy in several ways:

1. First, research staff will get your contact information and informed consent digitally/virtually (e.g. using 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 a 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 focus group 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.

**Risks and Discomforts**

For the virtual groups, participant's 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 are permitted to disengage from the monthly meetings at any time.

**New Information**

It is possible that the researchers will learn something new during the study about the risks of being in it. If this happens, they will tell you about it. Then you can decide if you want to continue to be in this study or not. You may be asked to sign a new consent form that includes the new information if you decide to stay in the study.

**Benefits**

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.

**Compensation**

*Participants*: 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.

**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.

**Voluntary Participation and 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 were to object to any future changes that may be made in the study plan;
- for any other reason.

**Contact Information**

Contact Rasheeta Chandler, PhD at 404-727-8164:

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

Contact the Emory Institutional Review Board at 404-712-0720 or 877-503-9797 or irb@emory.edu:

- if you have questions about your rights as a research participant.
- if you have questions, concerns or complaints about the research.
- You may also let the IRB know about your experience as a research participant through our Research Participant Survey at http://www.surveymonkey.com/s/6ZDMW75.

**Consent**

Please, print your name and sign below if you agree to be in this study. By signing this consent form, you will not give up any of your legal rights. We will give you a copy of the signed consent, to keep.

_____

Name of Subject

_____ _____

Signature of Subject Date Time

_____ _____

Signature of Person Conducting Informed Consent Discussion Date Time