Title: Sistas Informing Sistas on Topics about AIDS and PrEP (SISTA-P)

NCT06307028

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Informed Consent Form

RUTGERS
UNIVERSITY | NEW BRUNSWICK

# CONSENT TO TAKE PART IN A RESEARCH STUDY

**TITLE OF STUDY:** Sistas Informing Sistas on Topics about AIDS and PrEP (SISTA-P)

**Principal Investigator:** Shawnika Hull, PhD

This consent form is part of an informed consent process for a research study and it will provide information that will help you decide whether you want to take part in this study. It is your choice to take part or not. After all of your questions have been answered and you wish to take part in the research study, you will be asked whether you agree to continue. Your alternative to taking part in the research is not to take part in it.

**Who is conducting this research study and what is it about?**

You are being asked to take part in research being conducted by Shawnika Hull who is a professor in the Department of Communication at Rutgers University. The purpose of this study is to better understand women's perspectives about an HIV prevention tool, which will be described to you in detail.

**What will I be asked to do if I take part?**

You will be asked to take part in six group sessions discussing HIV prevention and empowerment. These sessions will take up to three hours to complete. Transportation will be provided at no cost. The first four sessions will take place in the same week. The fifth sessions will take place four weeks and the last session will take place two weeks later. During the sessions, we will provide you with information about, and a new HIV prevention tool. We anticipate that 20 women will participate in total. There will be up to 12 women in your group. We will ask you questions about yourself, your behavior, and your experiences during the session. After the last session, we will ask you to complete a survey. When each sessions are over, you will receive a $50 gift card per session for your time. If you complete the surveys, you will receive $50 each.

**What are the risks and/or discomforts I might experience if I take part in the study?**

There is a chance that you will experience emotional discomfort as a result of the discussion. If you do, we will provide you contact information for a staff member who can help you find appropriate services. Breach of confidentiality is a risk of harm, but a data security plan is in place to minimize such a risk. You will be asked to sign at the start of each session to keep group discussions confidential. Also, some questions may make you feel uncomfortable. If that happens, you can skip those questions or withdraw from the study altogether..

**Are there any benefits to me if I choose to take part in this study?**

There are no direct benefits to you for taking part in this research. You will be contributing to knowledge about HIV prevention in your community.

**Will I be paid to take part in this study?**

You will receive a $50 gift card after completing each session. You will receive a $50 gift card after completing the pre-test and follow up. You will also receive transportation to and from the study location at no cost to you. In total, you will receive (in gift cards):

- $50 after the Pre-Intervention Survey
- $50 after Session 1
- $50 after Session 2
- $50 after Session 3
- $50 after Session 4
- $50 after Session 5 (4 weeks after Session 4)
- $50 after Session 6 (6 weeks after session 4)
- $50 after completing the follow-up (6-weeks after session 4)

**How will information about me be kept private or confidential?**
All efforts will be made to keep your responses confidential, but total confidentiality cannot be guaranteed. We will ask you to provide contact information for scheduling purposes. The identifiable information *will not* be stored with your responses. Your responses will be assigned a unique number, which will be stored separately from your identifiable information so others will not know which responses are yours. We will securely store the key code linking your responses to your identifiable information in a separate password-protected file which will be destroyed after data analysis is complete and study findings are professionally presented or published. No information that can identify you will appear in any professional presentation or publication.

**What will happen to information I provide in the research after the study is over?**
After information that could identify you has been removed, de-identified responses may be used by or distributed to investigators for other research without obtaining additional informed consent from you.

**What will happen if I do not want to take part or decide later not to stay in the study?**
Your participation is voluntary. If you choose to take part now, you may change your mind and withdraw later. In addition, you can choose to skip discussion questions that you are not comfortable answering or leave the session at any time. You may also withdraw your consent for use of responses you provided during the session, but you must do this in writing to the PI, Shawnika Hull.

**Who can I call if I have questions?**
If you have questions about taking part in this study, you can contact the Principal Investigator: Shawnika Hull, Department of Communication, Shawnika.hull@rutgers or the Study Manager (sista@comminfo.rutgers.edu).
If you have questions about your rights as a research subject, you can contact the IRB Director at: (732) 235-2866 or the Rutgers Human Subjects Protection Program at (973) 972-1149 or email us at humansubjects@ored.rutgers.edu.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state, or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

## PERMISSION (AUTHORIZATION) TO USE OR SHARE HEALTH INFORMATION THAT IDENTIFIES YOU FOR A RESEARCH STUDY

The next few paragraphs tell you about how investigators want to use and share identifiable health information from your medical record in this research. Your information will only be used as described

here or as allowed or required by law. If you sign this consent form, you agree to let the investigators use your identifiable health information in the research and share it with others as described below. Ask questions if there is something you do not understand.

**What Is The Purpose Of The Research And How Will My Information Be Used?**
You are being invited to take part in this research study which is described at the beginning of this form. The purpose of collecting and using your health information for this study is to help investigators answer the questions that are being asked in the research.

**What Information About Me Will Be Used?**

- Medications
    - After the final survey, we may ask you to provide a photograph of relevant prescriptions or medications. This is voluntary and confidential. We will protect your privacy by using a Box.com folder labelled with your unique study ID number. We will delete any photographs immediately after they are received and recorded.

**Who May Use, Share or Receive My Information?**
The research team may use or share your information collected or created for this study with the following people and institutions:

- Rutgers University Investigators Involved In The Study
- The Rutgers University Institutional Review Board and Compliance Boards
- The Office for Human Research Protections in the U.S. Dept. of Health and Human Services
- Medical Personnel as Necessary For Clinical Care:
    - The Women's Collective
    - Positive Impact Health Centers
- **List every other class of persons or organizations not affiliated with Rutgers University**
    - The National Institutes of Health

Those persons or organizations that receive your information may not be required by Federal privacy laws to protect it and may share your information with others without your permission, if permitted by the laws governing them.

**Will I Be Able To Review My Research Record While The Research Is Ongoing?**
No. We are not able to share information in the research records with you until the study is over. To ask for this information, please contact the Principal Investigator, the person in charge of this research study.

**Do I Have To Give My Permission?**
No. You do not have to permit use of your information. But, if you do not give permission, you cannot take part in this study. (Saying no does not stop you from getting medical care or other benefits you are eligible for outside of this study.)

**If I Say Yes Now, Can I Change My Mind And Take Away My Permission Later?**
Yes. You may change your mind and not allow the continued use of your information (and to stop taking part in the study) at any time. If you take away permission, your information will no longer be used or shared in the study, but we will not be able to take back information that has already been used or shared with others. If you say yes now but change your mind later for use of your information in the research, you must write to the researcher and tell them of your decision: Shawnika Hull, PhD.

**How Long Will My Permission Last?**
There is no set date when your permission will end. Your health information may be studied for many years. By beginning the session, you acknowledge that you are 18 years of age or older, have read the information and agree to take part in the research, with the knowledge that you are free to withdraw your participation without penalty.