UNIVERSITY of MARYLAND
THE FOUNDING CAMPUS

PHASE 1: RESEARCH INFORMATION SHEET

Protocol Title: Phase 1: The Development of a mHealth-Based Intervention for Young Black Adults

Study No.: HP-00093564

Principal Investigator: Jaih Craddock, PhD, MSW

Sponsor: The University of Maryland, Baltimore, Institute for Clinical & Translational Research (ICTR) and Clinical Translational Science Award (CTSA) grant number 1UL1TR003098.

This is a research study, participation is voluntary, and you can ask questions at any time.
The Principal Investigator can be reached at mhi4yba@ssw.umaryland.edu or (443) 990-1671.

PURPOSE OF STUDY

This study will take place in two phases. **This is Phase 1.** In this phase (Phase 1), one-on-one qualitative interviews with 20 young Black women and men aged 18 to 24 from the Baltimore area will be held, via zoom or another virtual meeting space, to discuss sexual health communication, relationship dynamics, and influences of these factors on sexual health and HIV risk and prevention behaviors, as well as needs, wants and expectations for technology-based HIV intervention geared towards young Black adults. Based on findings from interviews conducted in this study, a culturally-tailored HIV preventive intervention will be selected and adapted to include those factors found to be important to you and other young Black adults.

A technology-based sexual health promotion and HIV preventive intervention will be developed in Phase 2 of this study, we will be conducting focus groups with 24 young Black adults to provide feedback on how we have incorporated HIV intervention-related content and factors that you and other young Black adults identified as important to your sexual relationships, sexual health and HIV prevention efforts into the technology-based product. As a Phase 1 participant, you may be eligible to participate in Phase 2.

PROCEDURES

If you agree to participate in Phase 1 of this research study, you will be asked to do the following:

You will be asked to complete a one-on-one qualitative interview on zoom or another virtual meeting space and a brief social network survey. Procedures of the study will include the following:

a) You will be sent a link to the study's website which will include information about the study, its procedures, and a copy of the consent form. To qualify to be a participant, you must (a) fall in the age range of 18 to 24, (b) identify as a Black or African American, (c) be sexually active, (d) have ever had "heterosexual" sex, and (e) live in the Baltimore Area.

b) Once it has been determined that you are eligible to participate in the study, you will be sent an online consent form via email or text message-link (based on your preference) to read and provide consent before participation in the interview.

c) Once you have received and read the online consent form and confirmed your interest in the study via the online consent form, you will be eligible to participate in the study and the interview will be scheduled via zoom, facetime, google meets or another virtual platform, based on your preference. The consent form and the study information will also be available on the studies website hosted by the School of Social Work, for review at any time.

d) Before the scheduled interview begins, the interviewer will review the consent form with you, explaining all of the study's procedures, provide time and space for you to ask questions and address any concerns, and then the interviewer will request verbal consent from you to participate in the study (e.g., Based on what we discussed regarding the study and its procedures, would you like to continue as a participant in this study?)

e) If you agree to continue in the study you will then complete one-on-one semi-structured qualitative interviews with a research staff, which will be followed by a brief social network data survey.

a. One-on-one semi-structured qualitative interview will take about 45 minutes to complete and will be audio-recorded with your permission. Interview topics will include individual characteristics (e.g., education, partner status, condom use self-efficacy, experiences with STIs and HIV, access to services and HIV-related behaviors), social network member (SNM) relationships (e.g., friend, family, sexual partner, romantic partner, etc.), sexual health communication, social media use, and needs, wants and expectations for mHealth-based HIV intervention geared towards YBA.

b. Once interviews are conducted, audio-records of all interviews will be transcribed and deleted. Any identifiable information (e.g., names and locations) will be

removed during transcription and cleaning of the transcripts. For completing the interview, you will receive a $40 Tango e-gift card for their time.

c. Social network survey will be sent to you after completion of the interview and take approximately 20 minutes to complete. You will be given a participant identification numbers (PIDs) to enter into the survey when prompted. PIDs given to you will be given at random and kept separate from all other information in an encrypted document on a password secured computer. After the completion of the study, PIDs will be retained but will no longer be able to be linked to identifying information (e.g., participant information). For the social network data, social network member's names will be removed and separate social network member or SNM IDs will be used. For completing the social network survey, you will be given a $15 Tango e-gift card for your time.

POTENTIAL RISKS/DISCOMFORTS:
Although your participation in the study may not be fully anonymous due to the qualitative interview, your information, survey and interview details will remain confidential as a participant identification number will be given to you and will be kept separate from all other participant information in an encrypted document on a password secured computer and will not be shared with others. The researchers will take measures to maintain the confidentiality of your data to the best of their abilities (see confidentiality section of this document).

POTENTIAL BENEFITS
There are no potential benefits for participating in the study. However, the results of this study may help in the development of a culturally-tailored, mHealth (i.e., text-message or social app) HIV preventive intervention that will be implemented within social and sexual networks of young Black adults.

ALTERNATIVES TO PARTICIPATION
This is not a treatment study. Your alternative is to not take part. If you choose not to take part, your healthcare at University of Maryland, Baltimore will not be affected.

COSTS TO PARTICIPANTS
It will not cost you anything to partake in this study.

PAYMENT TO PARTICIPANTS
You will receive a $40 Tango e-gift card for completing the interview. There will be an additional $15 Tango e-gift card given to you for completing the social network survey.

CONFIDENTIALITY AND ACCESS TO RECORDS
Interviews will be audio-recorded with your permission. Once interviews are conducted, audio-records of all interviews will be transcribed and deleted. Any identifiable information (e.g., names and locations) will be removed during transcription and cleaning of the transcripts. Both qualitative and network data will be kept in an encrypted document on a password-protected

computer in a locked cabinet in a locked office at the University of Maryland School of Social Work. You will be given participant identification numbers (PIDs). PIDs given to you will be kept separate from all other participant information in an encrypted document on a password secured computer. After the completion of the study, all forms except the future contact form will be destroyed, and PIDs will be retained but will no longer be able to be linked to identifying information. For the social network data, social network member's names will be removed and separate SNM IDs will be used.
Efforts will be made to limit 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 organization.

RIGHT TO WITHDRAW
Your participation is voluntary. Your decision whether or not to participate will involve no penalty or loss of benefit to which you are otherwise entitled. You may withdraw consent at any time and stop participating without penalty. You are not waiving any legal claims, rights, or remedies because of your participation.

CAN I BE REMOVED FROM THE RESEARCH?
The person in charge of the research study or the sponsor can remove you from the research study without your approval. Possible reasons for removal include, you being visibly intoxicated or incapacitated. The sponsor can also end the research study early.

UNIVERSITY STATEMENT CONCERNING RESEARCH RISKS
The University is committed to providing participants in its research all rights due them under State and federal law. You give up none of your legal rights by signing this consent form or by participating in the research project. This research has been reviewed and approved by the Institutional Review Board (IRB). Please call the Institutional Review Board (IRB) if you have questions about your rights as a research participant.

The research described in this consent form has been classified as minimal risk by the IRB of the University of Maryland, Baltimore (UMB). The IRB is a group of scientists, physicians, experts, and other persons. The IRB's membership includes persons who are not affiliated with UMB and persons who do not conduct research projects. The IRB's decision that the research is minimal risk does not mean that the research is risk-free. You are assuming risks of injury as a result of research participation, as discussed in the consent form.

If you are harmed as a result of the negligence of a researcher, you can make a claim for compensation. If you have questions, concerns, complaints, or believe you have been harmed through participation in this research study as a result of researcher negligence, you can contact members of the IRB or the staff of the Human Research Protections Office (HRPO) to ask questions, discuss problems or concerns, obtain information, or offer input about your rights as a research participant. The contact information for the IRB and the HRPO is:

University of Maryland Baltimore
Human Research Protections Office
620 W. Lexington Street, Second Floor
Baltimore, MD 21201
410-706-5037