Form Approved
OMB No. 0920-0840
Expiration Date 02/29/2016

"Informing the Development of Mobile Apps for HIV Prevention, Treatment, & Care"

Attachment 3a. Consent form for PLWH and high-risk MSM focus group

Columbia University Medical Center Consent Form

Medical Center Institutional Review Board: 212-305-5883
Consent Form #: CF-AAAL6604 Copied From: CF-AAAL2737

Attached to Protocol: IRB-AAAK3559
Principal Investigator: Rebecca Schnall (rb897)

IRB Protocol Title: Informing the Development of Mobile Apps for HIV Prevention, Treatment and Care

Consent Number: CF-AAAL6604
Participation Duration: 1.5 hours
Anticipated Number of Subjects: 50

Consent - Mobile App Development - Design Sessions and Focus Groups
(Reading Flesch-Kincaid Grade Level 7.7)

Contact

Contact Numbers	Title	Contact Type
Rebecca Schnall Telephone: 212-342-6886	Assistant Professor Nursing	Principal Investigator

Research Purpose
This is a research study, which is funded by the Centers for Disease Control and Prevention (CDC) is intended to identify features for a mobile app for meeting the healthcare needs of Persons Living with HIV (PLWH) or those at risk for HIV.

Information on Research
You are being asked to participate in this research study because you are living with HIV or are at high-risk for HIV.

INTRODUCTION
You are being asked to participate in this research study because you are living with HIV or are at high-risk for HIV.

The purpose of this form is to give you information to help you decide if you want to take part in a research study. This consent form includes information about:

- Why the study is being done;
- The things that you will be asked to do if you are in the study;
- Any known risks involved;
- Any potential benefit; and
- Options, other than taking part in this study, that you have.

A member of the research team for this project will discuss the study with you. If at any time you have questions about the study, please ask a member of the study team. Take all the time you need to decide whether you want to take part in this research study.

The purpose of this research is described below in the 'What is Involved in This Study?' section of this consent form.

This consent form is written to address a research subject.

WHAT IS INVOLVED IN THIS STUDY?
You will be asked to complete a survey and participate in a focus group, or design session about using a mobile app for HIV prevention and testing. All study activities should take about 2 hours. We will record and transcribe the discussion and use this information to design a mobile app for a person living with or at high-risk for HIV.

PERMISSION FOR FUTURE CONTACT
The researchers may want to contact you in the future. This study has the potential for revealing information about mobile app for HIV prevention and treatment.
We would contact you only once to solicit your participation in any research associated with the current study.

Please initial below to show whether or not you give permission for future contact.
_____ (initial) I give permission to be contacted in the future for research purposes.
_____ (initial) I give permission to be contacted in the future for information relating to this study.

Risks
A potential risk is loss of privacy regarding your decision to participate or not participate in the focus group. To protect against this risk, neither Columbia University/NY Presbyterian Hospital nor your care providers will know whether or not you have agreed to participate in the focus group. Another privacy risk is that other adolescents who are participating in the focus group may not keep what is discussed in the focus group session private. We will ask everyone to keep private what was discussed in the group. To further protect your privacy we will store the recording in a locked office and the transcription will be de-identified and stored on a password protected computer in a secure area. Moreover, the opinions that you share will not be linked with your name in any reports of study findings.

Benefits
There are no direct benefits to study participants. Your participation will assist the study team in improving HIV care for PLWH.

Alternative Procedures
The alternative is to not to participate in the focus group or complete the survey.

Privacy
Columbia University is conducting this study. The study is funded by the Centers for Disease Control and Prevention (CDC).

Every effort will be taken to protect your identity as a participant in this study. You will not be identified in any report or publication of this study or its results. Your computer and audio recordings will be assigned a unique identification number, and separated from your name or any other information that could identify you. The research file that links your name to the code number will be kept in a locked file cabinet and only the investigator and study staff will have access to the file.

Any information collected during this study that can identify you by name will be kept private. We will do everything we can to keep your data secure, however, complete privacy cannot be promised. Despite all of our efforts, unanticipated problems, such as a stolen computer may occur, although it is highly unlikely.

By participating in the focus group and completing the survey you grant permission for the data to be made available to:

- The investigator and study staff who may be evaluating the study;
- Columbia University; and
- Applicable Institutional Review Boards ("IRBs") that independently review the study to assure adequate protection of research participants, as required by federal regulations.

Data will be transferred to CDC but will not include any information that will identify you directly.
The recordings will be destroyed after analysis is completed. If the results of the study are published or presented at a medical or scientific meeting you will not be identified.

Token of Appreciation

You will receive $25 as a token of appreciation.

Voluntary Participation

Your participation in the study is voluntary. You may decide not to participate in the study. If you decide to participate, you are free to withdraw from the study at any time. Your refusal to participate, or your early withdrawal, will not affect any benefits to which you are otherwise entitled from Columbia University, New York Presbyterian Hospital nor will it affect the care provided by the members of your care team.

Additional Information

If you have any questions or concerns about the study, you may contact Rebecca Schnall (rb897@columbia.edu) or (212) 342-6886.

If you have any questions about your rights as a study subject, you may contact:
Institutional Review Board
Columbia University Medical Center
622 W. 168th Street, 4th Floor

New York, NY 10032
Telephone: (212) 3055883

Audio Recording
We are asking for your permission to allow us to audiotape part of the research study.

The recording(s) will be used for analysis by the research team.

The recording(s) will include your voice and your name or any other identifier will not be associated with the audio recordings.

The recording(s) will be stored on a password protected computer in a locked office in the Columbia University School of Nursing and will be destroyed upon publication of the results.

Your signature on this form grants the investigator named above permission to record you as described above during participation in the above referenced study. The investigator will not use the recording(s) for any other reason than that/those stated in the consent form without your written permission.

Statement of Consent
I have read the consent form and talked about this research study, including the purpose, procedures, risks, benefits and alternatives with the researcher. Any questions I had were answered to my satisfaction. I am aware that by signing below, I am agreeing to take part in this research study and that I can stop being in the study at any time. I am not waiving (giving up) any of my legal rights by signing this consent form. I will be given a copy of this consent form to keep for my records.

Signature
Study Participant
Print Name_____Signature_____Date_____

Person Obtaining Consent
Print Name_____Signature_____Date_____