

Form Approved
OMB No. 0920-0840

Expiration Date 02/29/2016

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

Attachment 3f. Assent form for Usability Design Sessions

Public reporting burden of this collection of information is estimated to average 5 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC/ATSDR Reports Clearance Officer; 1600 Clifton Road NE, MS D-74, Atlanta, Georgia 30333; Attn: OMB-PRA (0920-0840)

Columbia University Medical Center Assent Form

Medical Center Institutional Review Board: 212-305-5883
Consent Form #: CF-AAAL6603 Copied From: CF-AAAL2736

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-AAAL6603
Participation Duration: 1.5 hours
Anticipated Number of Subjects: 8

Assent -Usability - Informing the Development of a mobile app (Reading Flesch-Kincaid Grade Level 7.7)

Contact

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

Research Purpose

This is a research study to assess the usability of a mobile app for HIV prevention and care. This study is funded by the Centers for Disease Control and Prevention (CDC). We will use feedback from participants to refine the current mobile app design.

Information on Research

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?

The usability testing will take place in a laboratory setting; you and the researcher will be in a room with a computer. This computer will have a recording device connected to the computer screen. You will not be video recorded; only the computer screen and your voice will be recorded.

You will begin by filling out a brief background and computer usage survey. Next, instructions about the functions of the mobile app for HIV prevention, testing and care will be provided. You will then be provided with scenarios, which are consistent with individuals who may use the mobile app. These scenarios are designed to walk you through all of the functions of the computer-based system. During each task we will be asking you to think aloud about your expectations and reactions to the application as you work with the system. After each scenario you will be asked to provide comments about your reactions as a user of the computer-based system.

Throughout your interaction with the system we will be collecting several pieces of information. We will be recording your interaction with the system via recorder that is connected to the computer that you are using. The researcher will be at your side taking notes about the system's performance as well as measuring the start and stop times of each task. At times, we may prompt you to tell us what you are thinking. We realize that providing commentary may be distracting, but it is important for us to know what you are thinking as you carry out the tasks.

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

You may feel some discomfort during the research by being asked to think aloud while you are using the computer, if you are unfamiliar with some of the computer skills that are required to use the system, or if you feel self-conscious by being observed. If you are uncomfortable for any reason, you may discontinue the research session at any time.

Benefits

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

Alternative Procedures

The alternative is to not to participate in the study.

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 usability testing you grant permission for usability 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 Schnell (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
722 W. 168th Street, 4th Floor
New York, NY 10032
Telephone: (212) 305-5883

Audio/ Video Recording

We are asking for your permission to allow us to both audio and videotape as part of that research study. The recording(s) will be used for analysis by the research team.

The recording(s) will include screen shots of the computer and your words and your face will be blocked out.

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 assent 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 assent form. I will be given a copy of this assent form to keep for my records.

Signature

Assent

Print Name _____ Signature _____ Date _____

Person Obtaining Assent

Print Name _____ Signature _____ Date _____