Attachment #9:
Part 5: Android Usability Testing

Consent Form
Procedures
Recruitment/Advertisement

APPROVED
Oct 17, 2011
WIRB®

National Cancer Institute (NCI), Bethesda, Maryland, United States
20111501

RESEARCH SUBJECT INFORMATION AND CONSENT FORM	
TITLE:	Solar Cell: A Mobile UV Manager for Smart Phones Android Usability Testing

This consent form contains important information to help you decide whether to participate in a research study.

The study staff will explain this study to you. Ask questions about anything that is not clear at any time. You may take home an unsigned copy of this consent form to think about and discuss with family or friends.

- **Being in a study is voluntary – <u>your choice</u>.**
- **If you join this study, you can still <u>stop at any time</u>.**
- **<u>No</u> one can <u>promise</u> that a study will help you.**
- **Do not join this study unless all of your <u>questions</u> are <u>answered</u>.**

After reading and discussing the information in this consent form you should know:

- Why this research study is being done;
- What will happen during the study;
- Any possible benefits to you;
- The possible risks to you;
- Other options you could choose instead of being in this study;
- How your research information will be treated during the study and after the study is over;
- Whether being in this study could involve any cost to you; and
- What to do if you have problems or questions about this study.

<u>Please read this consent form carefully.</u>

RESEARCH SUBJECT INFORMATION AND CONSENT FORM
Android Usability Testing

TITLE:	Solar Cell: A Mobile UV Manager for Smart Phones
PROTOCOL NO.:	None WIRB® Protocol #20111501
SPONSOR:	National Cancer Institute (NCI) Bethesda, Maryland United States
INVESTIGATOR:	David Buller, Ph.D. Suite 225 1667 Cole Blvd Golden, Colorado 80401 United States
SITE(S):	Klein Buendel, Inc. Suite 225 1667 Cole Blvd Golden, Colorado 80401 United States
STUDY-RELATED PHONE NUMBER(S):	David Buller, Ph.D. 303-565-4340

This consent form may contain words that you do not understand. Please ask the principal investigator or the study staff to explain any words or information that you do not clearly understand. You will have time to ask questions and if you agree will be asked to sign this consent form.

SUMMARY

You are being asked to be in a research study. The purpose of this consent form is to help you decide if you want to be in the research study. Please read this form carefully. To be in a research study you must give your informed consent. "Informed consent" includes:

- Reading this consent form,
- Having the principal investigator or staff explain the research study to you, and
- Asking questions about anything that is not clear.

You should not join this research study until all of your questions are answered. If you take part in this research study, you will be given a copy of this signed and dated consent form.

PURPOSE OF THE STUDY

The overall goal of the study is to design a smart phone application, *Solar Cell*, which uses smart phone technology to aid users in protecting their skin from damaging ultraviolet radiation (UV) in sunlight, a primary cause of skin cancer. The goal of this part of the study is to test the application outside to see how usable it is there, including seeing if the application is viewable in sunlight.

PROCEDURES

The usability testing will take about 90 – 120 minutes. If testing outdoors, testing sessions will occur on days with clear or partly cloudy skies and in locations with full sunlight and in shade. An iPhone or Android handset with the *Solar Cell* mobile application will be provided for you to use during the usability testing session.

You will be given a scenario and set of tasks to mimic real-world use of *Solar Cell*. These may include:

(1) starting the mobile application and setting up a person,
(2) interpreting the information on the sun exposure screen,
(3) changing the alert settings and applying more sun protection,
(4) adding sunscreen and clothing details,
(5) viewing vitamin D information,
(6) inputting a medication that causes sun sensitivity,
(7) creating a second person, and
(8) locating the planning function.

While working independently, you will talk aloud while performing the tasks, indicating your reactions to *Solar Cell*, difficulties encountered, and solutions tried. If testing outdoors, we will also ask you to state whether you can read the screen during each task to determine if sunlight interferes with use of *Solar Cell*.

Next, you will complete a brief survey on the usability of *Solar Cell* (i.e., ease of use, attractiveness of graphics and screen design) and, if testing outdoors, on ability to read the screen in sunlight. After the questionnaire, you will participate in a short interview where you describe your reactions to *Solar Cell*, discuss how you could use it, and identify barriers to use.

Research staff will take notes as you perform the tasks.

RISKS AND DISCOMFORTS
There are no known risks for participating in this research.

BENEFITS
There are no direct benefits to you for participating in this study. However, you may benefit from the knowledge that you have helped evaluate the effectiveness of a state-of-the-art mobile software application, *Solar Cell*, to support decision-making related to sun protection and exposure by Americans to reduce the risk of developing skin cancer attributable to chronic and severe UV exposure and developing other cancers attributable to vitamin D deficiency.

COSTS
There are no costs associated with this study, except for your time.

INCENTIVE FOR PARTICIPATION
Subjects who participate in the usability testing session will receive $40 as a token of appreciation for your time and input.

ALTERNATIVES TREATMENT
Your alternative is not to participate in this study.

CONFIDENTIALITY
Study information collected about you will be given to the sponsor. "Sponsor" means any persons or companies that are working for or with the sponsor, or owned by the sponsor.

The consent form signed by you will be looked at and/or copied for research or regulatory purposes by:

- Department of Health and Human Services (DHHS) agencies,
- the sponsor;
- Western Institutional Review Board® (WIRB®).

Total confidentiality cannot be guaranteed because of the need to give information to these parties. The results of this research study may be presented at meetings or in publications. Your identity will not be given out during those presentations. The information you provide us will be kept private under the Privacy Act.

VOLUNTARY PARTICIPATION AND WITHDRAWAL
Your participation in this study is voluntary. You may decide not to participate or you may leave the study at any time. Your decision will not result in any penalty or loss of benefits to which you are entitled.

Your participation in this study may be stopped at any time by the study investigator or the sponsor without your consent for any reason.

SOURCE OF FUNDING FOR THE STUDY
Funding for this research study is provided by the National Center on Minority Health and Health Disparities at the National Institutes of Health.

QUESTIONS
Contact David Buller, Ph.D. at 303-565-4340 for any of the following reasons:

- if you have any questions about this study or your part in it,
- if you feel you have had a research-related problems, or
- if you have questions, concerns or complaints about the research.

If you have questions about your rights as a research subject or if you have questions, concerns or complaints about the research, you may contact:

Western Institutional Review Board® (WIRB®)
3535 Seventh Avenue, SW
Olympia, Washington 98502
Telephone: 1-800-562-4789 or 360-252-2500
E-mail: Help@wirb.com.

WIRB is a group of people who independently review research.

WIRB will not be able to answer some study-specific questions, such as questions about appointment times. However, you may contact WIRB if the research staff cannot be reached or if you wish to talk to someone other than the research staff.

Do not sign this consent form unless you have had a chance to ask questions and have gotten satisfactory answers.

If you agree to be in this study, you will receive a signed and dated copy of this consent form for your records.

CONSENT
I have read this consent form. All my questions about the study and my part in it have been answered. I freely consent to be in this research study.

By signing this consent form, I have not given up any of my legal rights.

I authorize the release of my research records for research or regulatory purposes to the sponsor, DHHS agencies, and WIRB®.

_____
Subject Name (printed)

CONSENT SIGNATURE:

_____ _____
Signature of Subject (18 years and older) Date

I confirm that the research study was thoroughly explained to the subject. I reviewed the consent form with the subject and answered the subject's questions. The subject appeared to have understood the information and was able to answer the following questions correctly:

1. What is the purpose of this study?
2. If you decide to be in the study, what will you be asked to do?
3. What is the possible benefit of participating in this study?
4. What are the possible risks of participating in this study?
5. If you decide not to participate in this study, what options do you have?
6. Will participating in this study cost you anything? If so, what will you have to pay for?
7. Do you have to be in this study?
8. If you decide to be in the study, can you leave the study when you want to?

_____ _____
Printed Name of Person Conducting the Informed Consent Discussion Position

_____ _____
Signature of Person Conducting the Informed Consent Discussion Date

OMB No.: 0925-0642-04
Expiration Date: 9/30/2014

PRIVACY ACT NOTIFICATION STATEMENT

Collection of this information is authorized by The Public Health Service Act, Section 412 (42 USC 285 a-1). Rights of study participants are protected by The Privacy Act of 1974. Participation is voluntary, and there are no penalties for not participating or withdrawing from the study at any time. Refusal to participate will not affect your benefits in any way. The information collected in this study will be kept private under the Privacy Act. Names and other identifiers will be separated from information provided and will not appear in any report of the study. Information provided will be combined for all study participants and report as summaries.

NOTIFICATION TO RESPONDENT OF ESTIMATED BURDEN

Public reporting burden for this collection of information is estimated to average 120 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: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0642). Do not return the completed form to this address.

Android Usability Testing Procedures

This cohort will consist of 10 individuals who are 18 or older, proficient in English, and who have a smart phone with Android operating system.

The Android version of *Solar Cell* will be tested for usability in outdoor environments. We will ensure that the mobile smart phone application will be viewable in sunlight, as many users will undoubtedly use it outdoors. Ms. Cloyd, Klein Buendel's usability consultant will conduct all usability tests. Usability will be conducted in a series of tests with different user groups. Findings will be used to improve the application between usability tests. This approach is called Rapid Iterative Testing and Evaluation (RITE) and is commonly used in application development.

Three groups of adults will participate – adults under 40 (who may be more experienced using mobile applications); adults 40 and older (who may be less experienced using mobile applications) and adults with children under age 18 (who may be interested in using the People and Profiles feature to obtain sun protection advice for their children). Results will be used to refine the Android version for the randomized trial.

Procedures for Conducting the Android Usability Testing

Welcome & Consenting

If the usability test is after office hours, one staff person should wait outside or in the lobby to make sure participant can get into the building. When the participant arrives, the staff person will welcome the participant and ask them to take a seat and enjoy refreshments. If the scheduled participant has not arrived 10 minutes after the scheduled time, the test moderator will call them to see if they are coming or need additional directions.

Once the participant is settled, the test moderator will go over the consent form (see Attachment #6) and ask if the participant has any questions, making sure to let him/her know that they are happy to answer questions. The test moderator will check to make sure the participant has completely read the consent form and fully

understands it, then ask the participant to sign the consent form. Once the consent form is signed, the test moderator will also sign it as the person conducting the consenting process, make copies and provide the participant with a copy of their consent form (keeping the original for Klein Buendel's records).

The test moderator will explain to the participant that they will be using a smart phone to test a smart phone application that Klein Buendel is developing. The test moderator will show them the smart phone and ask them if they are comfortable using the phone and if they have any questions about how the phone works. If the participant is not familiar with the smart phone, the test moderator will locate an application on the phone they are familiar with (such as Shazam or Facebook or a common website on the browser) and show them how the application or browser works on the phone they will be using. Once the participant is comfortable with the phone, the test moderator will begin the discussion.

Discussion

Once the consenting process is complete and participant is comfortable with the phone, the test moderator will explain that the session is intended to help Klein Buendel learn how user-friendly the application is and how to make it better. The test moderator will explain to participant that his/her opinions are valuable and that the more honest he/she is, the more Klein Buendel will learn about the mobile application. The test moderator will let participant know that if he/she has troubles using the application, he/she should describe the difficulties out loud so that the test moderator can learn how to make the application better. The test moderator will remind participant that Klein Buendel has some specific goals, so the test moderator may redirect the conversation at times, but that he/she will always value the participant's input.

The participant will be encouraged to speak freely and any difficult participants will be managed appropriately. If a participant cannot be managed and is completely uncooperative, the test moderator will politely offer them their payment and thank them for their time.

Wrap-up & Incentive

At the end of the session, the participant will be asked if they have any questions and reminded that they can always contact study staff or the Western Institutional Review Board (WIRB) with any questions or concerns they might have about their participation in the study.

Android Usability Testing Recruitment

The Android Usability Testing participants will be recruited in Colorado via advertisements on Craigslist, advertisements in campus newsletters (University of Colorado Boulder), and contacts with community organizations.

Usability testing participants will be recruited in the Washington, DC area through a recruitment firm recommended by the NCI Evaluation Lab.

Advertising

Approximately three weeks prior to the first usability testing session, research staff will place IRB-approved advertisements (see below) on Craigslist and in CU campus newsletters. The advertisements will also be distributed among existing Klein Buendel (KB) and the University of Colorado (CU) networks. The advertisements will direct potential participants to contact study staff via telephone or email.

TEXT FOR ADVERTISEMENT:

Have an Android or iPhone? Receive $40! (Lakewood, CO)

We are currently recruiting participants to test a prototype application for smart phones related to sun safety.

In order to qualify for this study you need to have a smart phone that runs the Android operating system.

THIS WILL REQUIRE IN-PERSON PARTICIPATION IN LAKEWOOD, CO.

Contact <<Name>> at 303-565-xxxx if you're interested. You will receive $40 for your time and input.