Attachment #3:
Part 2: Cognitive Interview

Consent Form

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 Cognitive Interview

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
Cognitive Interview

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.
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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 may take home an unsigned copy of this consent form to think about or discuss with family or friends before making your decision.

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 purpose of this part of the study is to evaluate the questions to be used for this study to see if they will be effective to gather the information needed.

PROCEDURES

This interview will take place at Klein Buendel's offices located in Lakewood, CO. It will take about one hour. We would like your opinion to help determine whether the questions in a survey are understandable or not. The questions ask about sunburn prevalence, frequency of sun protection behavior, personal sun protection (outcome expectations, self-efficacy, and intentions for sun safety), and potential moderators (demographics, skin type, skin cancer history, norms for sun safety and tanning image).

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 interview will receive $40 as a thank you for your time and input.

ALTERNATIVES
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 doctor 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 Cancer Institute (NCI) 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 problem, 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®.

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

_____
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