Appendix G:

IRB Approval

Western Institutional Review Board®
3535 7th Avenue SW | Olympia, WA 98502-5010
PO Box 12029 | Olympia, WA 98508-2029
Office: (360) 252-2500 | Toll Free: (800) 562-4789
www.wirb.com

Certificate of Approval

THE FOLLOWING WERE APPROVED

INVESTIGATOR: David Buller Ph.D.
Suite 225
1667 Cole Blvd
Golden, Colorado 80401

BOARD ACTION DATE: 10/17/2011
PANEL: 7
STUDY APPROVAL EXPIRES: 10/17/2012
STUDY NUM: 1127665
WIRB PRO NUM: 20111501
INVEST NUM: 112561
WO NUM: 1-686447-1
CONTINUING REVIEW: Annually
SITE STATUS REPORTING: Annually

SPONSOR: National Cancer Institute (NCI)
PROTOCOL NUM: None
AMD. PRO. NUM:
TITLE:
Solar Cell: A Mobile UV Manager for Smart Phones Phase II

APPROVAL INCLUDES:
Investigator
Beta Test Screening Script #9264739.0 - As Submitted
Cognitive Interview Screening Script #9264737.0 - As Submitted
Cohort 2 Procedures - Beta Testing
Cohort 3 - Procedures (Usability Testing)
Cohort 3 - Questions and Discussion Guide (Usability Testing) #9336484.0 - As Submitted
Cohort 3 Recruitment (Usability Testing)
Cohort 5 - Recruiting and Consenting Adult Participants
Demographic Survey #9264734.0 - As Submitted
Recruitment of Subjects Under the Grant Solar Cell - A Mobile UV Manager for Smart Phones
Usability Test - iPhone and Android Screening Script #9264735.0 - As Submitted
Consent Form - Beta Testing [S0]
Consent Form - Cognitive Interview [S0]
Consent Form - Dermatologist and Primary Care Physician Interviews [S0] -
Consent Form - Usability Testing [S0]
Research Subject Information Sheet #9302487.0 - As Modified

WIRB APPROVAL IS GRANTED SUBJECT TO:
The Board requires that all subjects must be able to consent for themselves to be enrolled in this study. This means that you cannot enroll incapable subjects who require enrollment by consent of a legally authorized representative.

The Board directed that persons who are unable to read are not allowed to consent for themselves or others to participate in this study.

Theodore D. Schultz, J.D., Chairman

10/18/2011
(Date)

This document electronically reviewed and approved by Schultz, Ted on 10/18/2011 9:55:03 AM PST. For more information call Client Services at 1-360-252-2500.

The Board found that this research meets the requirements for a waiver of documentation of consent for Cohort 5 under 45 CFR 46.117(c)(2)

The Board determined that the device as used in this research study is a non-significant risk device.

WIRB HAS APPROVED THE FOLLOWING LOCATIONS TO BE USED IN THE RESEARCH:

Klein Buendel, Inc, Suite 225, 1667 Cole Blvd, Golden, Colorado 80401

If the PI has an obligation to use another IRB for any site listed above and has not submitted a written statement from the other IRB acknowledging WIRB's review of this research, please contact WIRB's Client Services department.

ALL WIRB APPROVED INVESTIGATORS MUST COMPLY WITH THE FOLLOWING:

1. Conduct the research in accordance with the protocol, applicable laws and regulations, and the principles of research ethics as set forth in the Belmont Report.

2. Although a participant is not obliged to give his or her reasons for withdrawing prematurely from the clinical trial, the investigator should make a reasonable effort to ascertain the reason, while fully respecting the participant's rights.

3. Unless consent has been waived, conduct the informed consent process without coercion or undue influence, and provide the potential subject sufficient opportunity to consider whether or not to participate. (Due to the unique circumstances of research conducted at international sites outside the United States and Canada where WIRB approved materials are translated into the local language, the following requirements regarding consent forms bearing the WIRB approval stamp and regarding certification of translations are not applicable.)
    a. Use only the most current consent form bearing the WIRB "APPROVED" stamp.
    b. Provide non-English speaking subjects with a certified translation of the approved consent form in the subject's first language. The translation must be approved by WIRB.
    c. Obtain pre-approval from WIRB for use of recruitment materials and other materials provided to subjects.

4. Obtain pre-approval from WIRB for changes in research.

5. Obtain pre-approval from WIRB for planned deviations and changes in research activity as follows:

    If this research is federally funded or conducted under an FWA, obtain pre-approval from WIRB for all planned deviations and changes in research activity, except where necessary to eliminate apparent immediate hazards to the human subjects. OHRP considers all planned protocol deviations to be changes in research that need prior IRB review and approval.

    If this research is **not** federally funded and **not** conducted under an FWA, obtain pre-approval from WIRB for any planned deviations that could adversely affect the rights, safety or welfare of subjects, or the integrity of the research data and any changes in the research activity, except where necessary to eliminate apparent immediate hazards to the human subjects. FDA has not adopted the policy that all planned protocol deviations are changes in research that need prior IRB review and approval.

    Deviations necessary to eliminate apparent immediate hazards to the human subjects should be reported within 10 days.

6. Promptly report to WIRB all unanticipated problems (adverse events, protocol deviations and violations and other problems) that meet all of the following criteria:
    a. Unexpected (in terms of nature, severity or frequency);
    b. Related or possibly related to participation in the research; and
    c. Suggests that the research places subjects or others at a greater risk of harm than was previously known or recognized.

    Please go to www.wirb.com for complete definitions and forms for reporting.

7. Provide reports to WIRB concerning the progress of the research, when requested.

8. Ensure that prior to performing study-related duties, each member of the research study team has had training in the protection of human subjects appropriate to the processes required in the approved protocol.

Federal regulations require that WIRB conduct continuing review of approved research. You will receive Continuing Review Report forms from WIRB. These reports must be returned even though your study may not have started.

DISTRIBUTION OF COPIES:
Contact, Company
David Buller Ph.D., Klein Buendel, Inc.

