

Attachment 16: IRB CERTIFICATE OF APPROVAL
Web-based Skills Training for SBIRT (Screening, Brief Intervention, and Referral to Treatment)
August 2011

THE FOLLOWING WERE APPROVED:**INVESTIGATOR:** Kelly Carpenter MA, Ph.D.
1121 34th Avenue
Seattle, Washington 98122**BOARD ACTION DATE:** 1/26/2011**PANEL:** 3**STUDY APPROVAL EXPIRES:** 1/26/2012**STUDY NUM:** 1122531**WIRB PRO NUM:** 20102107**INVEST NUM:** 69105**WO NUM:** 1-646958-1**CONTINUING REVIEW:** Annually**SITE STATUS REPORTING:** Annually**SPONSOR:** National Institute on Drug Abuse (NIDA)**PROTOCOL NUM:** None**AMD. PRO. NUM:****TITLE:**

Web-based Skills Training for SBIRT -- SBIRT-PC: Screening, Brief Intervention and Referral to Treatment for Tobacco, Alcohol, and Other Drugs in Primary Care

APPROVAL INCLUDES:

Investigator

Advertisement - Letter - Helping patients quit tobacco and #8524322.0 - As Submitted

Advertisement - Website - Welcome to the SBIRT in #8524326.0 - As Submitted

Core Curriculum and Basics of Motivational Counseling #8524336.0 - As Submitted

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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.

Federal Regulations do not recognize Co-Principal Investigators. Therefore, the Board has approved the two investigators for this study as if each is THE Investigator and holds each individually responsible for the conduct of the entire study.

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

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

IF YOU HAVE ANY QUESTIONS, CONTACT WIRB AT 1-800-562-4789

This is to certify that the information contained herein is true and correct as reflected in the records of the Western Institutional Review Board (WIRB), OHRP/FDA parent organization number IORG 0000432, IRB registration number IRB00000533. WE CERTIFY THAT WIRB IS IN FULL COMPLIANCE WITH GOOD CLINICAL PRACTICES AS DEFINED UNDER THE U.S. FOOD AND DRUG ADMINISTRATION (FDA) REGULATIONS, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) REGULATIONS, AND THE INTERNATIONAL CONFERENCE ON HARMONISATION (ICH) GUIDELINES.



Theodore D. Schultz, J.D., Chairman

1/29/2011

(Date)

This document electronically reviewed and approved by Ennever, John on 1/29/2011 11:22:59 AM PST. For more information call Client Services at 1-360-252-2500

APPROVAL INCLUDES, Continued From Previous Page:

Core Curriculum Knowledge Test #8524330.0 - As Submitted

Demographic Questions #8524329.0 - As Submitted

Eligibility Screening #8524327.0 - As Submitted

Perceived Barriers to SBIRT Questionnaire #8524334.0 - As Submitted

Protocol (12-20-2010)

Recruitment of Subjects Under the Grant N44DA-9-2216 (Web-based Skills Training for SBIRT)

Reminder Emails #8524328.0 - As Submitted

SBIRT Attitudes #8524332.0 - As Submitted

SBIRT Clinical Practices Questionnaire #8524335.0 - As Submitted

SBIRT Self-Efficacy #8524333.0 - As Submitted

Standardized Patient Case for Role-Play #8524337.0 - As Submitted

Virtual Standardized Patient Evaluations #8524331.0 - As Submitted

Consent Form [S0]

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

- Talaria, Inc., 1121 34th Avenue, Seattle, Washington 98122

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

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Tasha Mikko
Susan Stoner Ph.D.

Company Name

Talaria, Inc.
Talaria, Inc.
Talaria, Inc.