Attachment 4: RESEARCH SUBJECT INFORMATION AND CONSENT FORM
Web-based Skills Training for SBIRT (Screening Brief Intervention and Referral to Treatment)
November 2011

RESEARCH SUBJECT INFORMATION AND CONSENT FORM

TITLE: Substance Use Screening and Intervention for Primary Care

PROTOCOL NO:

SPONSOR AND SOURCE OF FUNDING: National Institute on Drug Abuse (NIDA)
Bethesda, Maryland
United States

INVESTIGATORS: Susan Stoner, PhD
Talaria, Inc
1121 34th Avenue
Seattle, Washington 98122
United States

SITE(S): This is an online study conducted by Talaria, Inc.
Our offices and servers are located at:
1121 34th Avenue
Seattle, Washington 98122
United States

STUDY-RELATED PHONE NUMBER(S): **Susan Stoner, PhD**
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Tasha Mikko, MSW, Study Coordinator
(206) 748-0443, extension 19

SUB-INVESTIGATORS:
John Baer, PhD
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SUMMARY

We are asking you to be in a research study. For detailed information on the study, please read this consent form carefully. If you have any questions, please call the study coordinator. When all your questions have been answered you can decide if you want to be in the study. This process is called "informed consent."

PURPOSE

The purpose of this study is to evaluate two new online CME training programs for primary care providers to enhance their skills related to substance abuse screening, brief intervention and referral to specialty care. Your participation will help us to determine how well the training

programs perform and how to improve them for future users. We expect that about 94 subjects will participate.

PROCEDURES

If you choose to participate in this study, you will be asked to provide your contact information so that we can email you study related information, call you to conduct a telephone standardized patient interaction, and mail your study payment.

Initial Assessment. After completing this consent form, you will fill out a set of questionnaires on the computer. These questions will be about your knowledge, attitudes, and practices related to conducting substance abuse interventions in your primary care practice. Some questions are case-based and require you to imagine that you are seeing a patient and to type what you would say to him or her. These questionnaires will take about 30 minutes to complete.

Training. You will be randomly assigned to one of two online training programs. Either one takes about 2.5 hours to complete and must be completed within one week. Each is training accredited for 2.5 prescribed CME credits by the American Academy of Family Physicians (AAFP), pending your successful completion of a brief CME knowledge test. A minimum score of 75% is required to pass, but you may re-take the CME knowledge test if you do not pass on your first attempt.

Second Assessment and Telephone Standardized Patient Interaction. After completing the training, you will fill out another set of questionnaires on the computer, which will take about 40 minutes. These questionnaires are similar to those in the initial assessment. You will also be asked about your opinions of the training program. At the end of the second assessment you will receive your CME completion certificate. Next, you will be asked fill out an online form giving study coordinator several time(s) when you will be available for a 10-minute telephone interaction with a standardized patient (SP), portrayed by a professional actor. The study coordinator will contact you to finalize scheduling the SP call. Prior to the SP call, you will be provided medical background, screening results and clinical objectives for the telephone interaction. The actor will call you at the phone number you provide. The call will be audio-recorded. During the 10 minute consult with the "patient," we ask that you behave as though the patient were someone you see in your practice. After completing your standardized patient interaction, you will be mailed a check for $250.

Three Month Follow-up Assessment. Three months after you complete the other study procedures, you will be emailed a link to a final set of questionnaires. This assessment will take about 10 minutes and will include questions about your clinical practices. You will be mailed a check for $50 for completing this final assessment.

RISKS, STRESS, OR DISCOMFORT

There are no known risks of using the training or answering the questions contained in the assessment, other than the risk of breach of confidentiality, which is low (see confidentiality section below for details). It is possible that interacting with the standardized patient may make you uncomfortable. You are free to stop participating in the study at any time.

BENEFITS
You may or may not benefit directly from participating from this study. The goal of the training is to increase treatment of substance abuse in primary care settings, and your knowledge of this topic may improve. Because the results of this study will be used to improve the training, your participation is likely to contribute to the future quality of the training.

COSTS
You will not be charged for receiving CME credits or otherwise participating in this study.

PAYMENT FOR PARTICIPATION
If you successfully complete the training, you will earn 2.5 prescribed CME credits. In addition, if you complete the initial assessment, the second assessment, and the standardized patient telephone call, you will be paid $250; payment will be mailed within two weeks. If you complete the three month follow-up assessment, you will be paid an additional $50; payment will be mailed within two weeks. Checks will be disbursed by Talaria, Inc., and sent through the mail to the address that you provide.

ALTERNATIVES
This is not a treatment study. Your alternative is not to participate in this study.

VOLUNTARY PARTICIPATION/WITHDRAWAL
Taking part 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. You may request that your information be withdrawn up to three months after the study is complete.

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

CONFIDENTIALITY
Information from this study will be given to the sponsor. "Sponsor" includes any persons or companies which are contracted by the sponsor to have access to the research information during and after the study. The information that you give may be examined by the sponsor and Talaria Inc. It may be looked at and/or copied for research or regulatory purposes by the U.S. Department of Health and Human Services (DHHS) agencies or by the Western Institutional Review Board.

Absolute confidentiality cannot be guaranteed because of the need to give information to these parties. However, the online forms that you fill out and your audio-recorded standardized patient interaction will be identified only by an ID code. There will be a link between your name and your ID code until the follow-up assessment is complete and your payment is issued, at which time the link will be destroyed. If you inform us that you choose to withdraw from the study before the follow-up, the link will be destroyed at that time. Once the link is destroyed, no one will be able to match your name to the answers that you have given. Until the link is destroyed, it will be stored in a password-protected database at Talaria, Inc., accessible to study personnel

only. If we publish or otherwise disseminate results of this study, we will not use your name. Audio-recordings will be destroyed once data analysis is complete, no later than 12/31/13.

QUESTIONS
If you have any questions concerning your participation in this study, if at any time you feel you have experienced a research-related problem, or if you have questions, concerns or complaints about the research, please contact:

Tasha Mikko, MSW, Study Coordinator at 206-748-0443 ext. 19

If you have questions about your rights as a research subject or if you wish to talk to someone other than the research staff, you may contact the agency providing independent review of this research:

Western Institutional Review Board® (WIRB®)
3535 Seventh Avenue, SW
Olympia, Washingtan98502
Telephone: 1 -800-562-4789 or 360-252-2500
E-mail: Help@wirb.com.

WIRB is a group of people who perform independent review of 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 accept this consent statement unless you have had a chance to ask questions and have satisfactory answers to all of your questions.

CONSENT
I have read the description of the study above and consent to take part in this research study. If I have questions about the research, I can contact one of the researchers listed above. I voluntarily consent to take part in this study.

By choosing "Accept", I have not waived any of the legal rights which I otherwise would have as a participant in a research study.

If you agree with consent statement above, please click the "Accept" box below, and then click the Next button.

If you do not agree, and do not want to participate in the study, please close this window.

( ) Accept

Close Window

To print a copy of this consent statement for your records, please click here.