Supporting Statement A for

Web-based Skills Training for SBIRT (Screening Brief Intervention and Referral to Treatment), NIDA

November 2011

Talaria Inc., with funding from the National Institute on Drug Abuse (NIDA)
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A.1 Circumstances Making the Collection of Information Necessary

This OMB Clearance request is for a project resulting from a Small Business Innovation and Research (SBIR) Contract solicitation from the National Institute on Drug Abuse (NIDA).

(a) Authority

Authorization making the collection of this data necessary is found in U.S.C. Title 42, Chapter 6A, Subchapter III, Part C, Subpart 15-National Institute on Drug Abuse:

(b) In general

The general purpose of the National Institute on Drug Abuse (hereafter in this subpart referred to as the "Institute") is the conduct and support of biomedical and behavioral research, health services research, research training, and health information dissemination with respect to the prevention of drug abuse and the treatment of drug abusers.

(c) Research program

The research program established under this subpart shall encompass the social, behavioral, and biomedical etiology, mental and physical health consequences, and social and economic consequences of drug abuse. In carrying out the program, the Director of the Institute shall give special consideration to projects relating to drug abuse among women (particularly with respect to pregnant women).

(d) Collaboration

The Director of the Institute shall collaborate with the Substance Abuse and Mental Health Services Administration in focusing the services research activities of the Institute and in disseminating the results of such research to health professionals and the general public.

Justification

The purpose of the proposed SBIR data collection is to evaluate a web-based training program for primary care providers. This web-based training program teaches providers to screen, provide brief interventions and provide appropriate referrals for substance use disorders in primary care patients. Abuse of tobacco, alcohol and other drugs has high costs in both human and economic terms. Since most Americans will see a primary care provider within any two year time period, these providers have the opportunity to identify and intervene with substance abusers and risky users at an early stage, preventing many negative health and societal consequences. Screening and brief intervention (SBI), similarly called SBIRT (screening, brief intervention, referral to specialty treatment), for substance use problems has been shown to be effective in primary care settings. Nonetheless, despite effectiveness

studies, calls for routine adoption of screening and intervention from such national bodies as the US Preventive Services Task Force (2004) and publication of national treatment guidelines (e.g., Fiore et al., 2008), adoption of screening and brief intervention by primary care providers is minimal. Data collection for the present project will evaluate the effectiveness of a web-based training program designed to increase the provision of screening and intervention for substance use in primary care.

Estimated prevalence rates of tobacco dependence and substance abuse disorders in primary care patients are high. Twenty-one percent of Americans remain dependent on tobacco and tobacco use is the leading preventable cause of morbidity and mortality (CDC, 2006). Lifetime rates of alcohol abuse and dependence are 17% and 12% respectively (Hasin, Stinson, Ogburn & Grant, 2007). National health surveys in the 1990s found prevalence of all alcohol use disorders (including hazardous and heavy drinking) to range from 14 to 24% of the population (Archer & Grant, 1995; Dawson et al., 1995; Grant, 1993). Importantly, similar rates have been found in studies of prevalence of alcohol use disorders in primary care patients (Adams et al., 1996; Piccinelli et al., 1997; Volk, Steinbauer, & Cantor, 1996). In a more recent study, Carballo (2006) found that 30% of adolescents presenting at primary care answered “yes” to at least one of the questions a commonly used screening instrument, indicating some level of problematic drinking. There is less information about prevalence of illicit drug use, but a recent study found monthly use of marijuana to be 8.4% in women 18 to 24 years of age presenting in primary care (Rose et al., 2007). In 2009 the NSDUH (SAMSHA, 2010) estimated that 8.7% of Americans aged 12 and older used illicit drugs (marijuana: 6.6%; non-medical prescription use: 2.8%; cocaine: .7%; methamphetamine: .2%). These rates may seem low in comparison to alcohol and tobacco, but the numbers are significant, and illicit drug use has particularly high societal costs due to extreme health risks and associated criminal behavior.

Screening and brief intervention for substance use disorders in primary care has been shown to be generally efficacious for substance use problems. Alcohol-related screening and brief interventions delivered in primary care has been shown to decrease alcohol consumption, alcohol-related outcomes such as emergency room visits and alcohol-related motor vehicle accidents, and associated medical costs (e.g., Babor et al., 2006; Mundt, 2006). A World Health Organization (WHO) study conducted in eight countries involving over 1600 participants found that brief interventions reduced daily alcohol consumption on average by 17% and intensity of drinking by 10% (WHO Brief Intervention Study Group, 1996). Babor et al. (2007) summarized 25 years of research on the components of screening and brief intervention, the available screening instruments, and the overall results of more than 100 clinical trials of screening, brief intervention, referral to treatment (SBIRT) for alcohol use. Screening and brief intervention continues to provide exceptionally strong data on the short term positive impact on individual health and is supported for use in a variety of settings. Evidence for the validity of brief interventions for alcohol is sufficient to convince the U.S. Preventive Services Task Force (2004) to

recommend that it be included in routine medical practice. Strong evidence is also available to support tobacco-related brief interventions. Primary care providers who deliver tobacco cessation interventions can as much as double the chance of their patients quitting smoking and these interventions are even more powerful when combined with pharmacotherapies, such as nicotine replacement or bupropion (e.g., Litt, 2002). The evidence base for screening and brief intervention has recently expanded to include data on the effectiveness with drug use problems. A WHO study (Humenuik et al., 2008) examined the use of screening and brief intervention with a drug using population in a variety of public health clinic types in the U.S., Australia, Brazil and India. While the methodology varied across sites, and the results therefore have uncertain clinical significance, the study does demonstrate the feasibility of using both the screening and brief intervention across a broad population with a varied drug use history, and within several different cultural environments. Similarly, Madras et al. (2009) conducted a secondary analysis on a SAMHSA-funded screening and brief intervention service program with nearly a half million persons visiting a variety of clinics and found consistent evidence for screening and brief intervention reducing alcohol and drug use over a six month period.

Unfortunately, despite the evidence base, most medical providers do not routinely conduct alcohol or drug related screening or interventions with their patients (e.g., Friedmann, McCullough, Chin, & Saitz, 2000). Barriers to intervening include time constraints (both training time and intervention time), perceived inadequate preparation to deliver substance abuse interventions, skepticism about the effectiveness of treatment and the perception that substance abuse is a “difficult” topic to discuss and that substance abusers are a “difficult” population with which to work (Farmer & Greenwood, 2001; Johnson, Booth & Johnson, 2005). Given that training can address these concerns, there is a clear need to develop effective and accessible training programs for primary care providers in screening and brief intervention for substance use disorders.

The web-based training program developed by Talaria, Inc. as part of NIDA’s SBIR contract N44DA-9-2216 has been designed to overcome the specific barriers cited above. Lack of training time is addressed by offering short modules conveniently available on demand via the internet. Low levels of confidence in ability are overcome by offering education and skills training in screening, targeted brief intervention and referral for tobacco, alcohol, and drug abuse and dependence with direct instruction supplemented by best practice case demonstrations. A website, or “performance support system” (Weindgardt, 2004) makes the training modules and supplemental materials available as a long-term resource and skills refresher. To increase practitioner awareness of, and belief in, the efficacy of substance abuse interventions, the program emphasizes the effectiveness of screening and brief intervention across substances and offers access to validated screening measures, including a computerized version of the NIDA adapted version of the ASSIST (Alcohol, Smoking and Substance Involvement Screening Test) supplemented with the AUDIT-C (Alcohol Use Disorders Identification

Test). Providers' negative beliefs about substance abuse and abusers will be addressed with education regarding commonly held myths about substance abuse and substance abusers. Finally, concerns about intervention time are addressed by teaching intervention techniques that are brief and including video and audio-based examples. The computerized ASSIST plus AUDIT-C is automatically scored and provides both a printable Patient Feedback Form and a Provider Report which gives a risk level and includes general treatment recommendations.

Although screening and brief intervention is an evidence-based procedure, there is no evidence that the new web-based training program increases provider knowledge, improves provider attitudes towards substance use interventions or substance abusers or improves provider skills in delivering interventions for substance use problems. Therefore, it is necessary to conduct a randomized trial to show the effectiveness of the new training program. This evaluation will include collecting data from 94 primary care providers both before and after they complete the training program. In Phase I of the training program usability data was collected from 9 primary care providers to evaluate their initial responses to a prototype of the web-based training. Results from this usability test were used to inform development of the training program, but no data was collected on knowledge, attitudes or skills of the providers in the Phase I study. It is necessary to collect this information in the proposed Phase II data collection as NIDA requires evidence that training programs are effective.

A.2 Purpose and Use of the Information Collection

Purpose of data collection

The proposed data collection will provide evidence that providers who use the web-based training program increase their knowledge, improve their attitudes towards substance use interventions and substance abusers and improve their skills in delivering interventions for substance use problems. In addition the knowledge, attitude and skills of the providers who use the web-based training will be compared to providers who use a traditional reading materials training, providing evidence that the newly created web-based training is superior to reading existing materials that cover the same content. Furthermore, data will be collected regarding the usability and satisfaction with the training program (i.e., Did the program work? Was it easy to use? Did they like it?) in order to provide information that will inform further development of the training. Finally, data will be collected regarding provider's actual use of screening and brief intervention in the three months following the training in order to determine if the training has any effect on provider's actual clinical behavior.

Summary of data collection plan

This data collection will include 94 primary care providers who will be assessed both before and after they complete one of two training programs. The providers in the study will be randomly assigned to use

the new web-based training, or to read a series of articles regarding providing screening and brief intervention in primary care. Both the training programs have been approved for continuing medical education credits by the American Association of Family Practitioners. In Phase I of the training program usability data was collected from 9 primary care providers to evaluate their initial responses to a prototype of the web-based training. Results from this usability test were used to inform development of the training program, but no data were collected on knowledge, attitudes or skills of the providers in the Phase I study. It is necessary to collect this information in the proposed Phase II data collection as NIDA requires evidence that training programs are effective.

Information to be collected.

Information will be collected at 3 time points: 1) the baseline assessment before training occurs, 2) the post-test assessment immediately after training and 3) the follow-up assessment 3 months after training.

Baseline assessment: Participants will complete the baseline assessment, consisting of a demographics form, a knowledge pre-test, a video-based skills assessment, an attitudes, self-efficacy and barriers to delivering substance abuse treatment questionnaire, and a clinical practices questionnaire asking about substance abuse assessment and treatment provided in the past three months. See Attachments: 1-8, 11-13

Post-test Assessment: The knowledge test, the video-based skills assessment, and the attitudes, self-efficacy and barriers questionnaire will be repeated after training is completed. In addition, a Clinical Practice Intentions Questionnaire will be given at post-test, along with satisfaction questionnaires customized for each training program. Following the post-test, participants will conduct a brief standardized patient interaction on the telephone. Two experienced actors trained and supervised by study personnel will serve as standardized patients for the study. Standardized patient (SP) interviews will take approximately 10 minutes and will be scheduled at the participant's convenience. SP interviews will be digitally recorded. Audio files will be stored on Talaria's secure server identified only by a participant ID code. See Attachments, 7-9, 10-12, 14-15

3 Month Follow-Up. Three months after completing the standardized patient interview, participants will be emailed a link to a brief follow-up assessment, including the Clinical Practices Questionnaire and the attitudes, self-efficacy and barriers questionnaire. See Attachments 8, 11-13

Data collection hypotheses

1. As compared to those who complete the reading materials control training and controlling for pre-test scores, providers who use the web-based training will have:
    a. higher scores on the Knowledge Test (Attachment 7:Knowledge Tests),

b. higher scores on tests of substance use screening and intervention skills, as measured by the Video Standardized Patient Evaluation (Attachment 10: Video Standardized Patient Evaluations), and

c. more positive attitudes towards patients with substance use problems and higher self-efficacy for providing substance abuse services, as measured by the SBIRT Attitudes Questionnaire (Attachment 11: SBIRT Attitudes Questionnaire).

2. Providers who use the web-based training will have higher scores on the Standardized Patient Telephone Interaction – Patient Profile (Attachment 15: Standardized Patient Telephone Interaction – Patient Profile) than those who use the reading materials training.
3. The scores on the Video Standardized Patient Evaluation (Attachment 10) will be positively correlated with the scores on the Standardized Patient Telephone Interaction – Patient Profile (Attachment 15).
4. Providers who use the web-based training will have higher scores on the Satisfaction Questionnaire (Attachment 14:Satisfaction Questionnaire) than those who complete the written materials training.

Data analysis plan.

Preliminary analyses will be conducted to ensure the quality of the data. Frequency distributions and descriptive statistics will be examined to identify data input errors, outliers, and other threats to the integrity of subsequent analyses. Demographics and pretest variables will be examined to determine whether randomization effectively produced equivalent groups. Any demographic variable that is not equivalent between groups at pre-test will be used as a covariate in subsequent analyses.

To test Hypotheses 1a, b, and c, pertaining to knowledge and skills acquisition and attitude change, multivariate analysis of covariance (MANCOVA) will be conducted. The independent variable will be group (Intervention vs. Control), and the dependent measures will be posttest scores on the measures; pretest scores will be entered as covariates. Planned contrasts will be used to evaluate specific hypotheses.

To test Hypothesis 2, pertaining to scores on the telephone-based Standardized Patient Telephone Interaction – Patient Profile (Attachment 15), an independent group t-test will be conducted. The dependent measure will be mean scores. The hypothesis will be supported if the participants who went through the web-based training have mean scores that are significantly higher than the written materials control group.

To test Hypothesis 3, pertaining to correlating the Video Standardized Patient Evaluation (Attachment 10) and the Standardized Patient Telephone Interaction – Patient Profile (Attachment 15), preliminary

criterion validity of the video assessment will be evaluated by correlating video assessment scores with scores on the standardized patient interviews using Pearson's r.

To test Hypothesis 4, regarding satisfaction with training, scores on the likert scale questions on the Satisfaction Questionnaire (Attachment 14) will be averaged and group means compared via an independent groups t-test. Answers to open-ended questions will be summarized and described.

How will data be used?

The data will be analyzed and the results and implications of the results will be documented in a manuscript submitted to a peer-reviewed journal. Findings illustrating the superior knowledge and skills gain in providers using the web-based training will serve to encourage providers to use such trainings and for federal agencies and institutes to fund the development of such trainings. Without the collection of this data, there would be no evidence that the web-based training was effective at increasing provider knowledge and skills.

Who will collect the information?

Talaria, Inc., recipients of the NIDA contract will collect and analyze the data.

A.3 Use of Information Technology and Burden Reduction

Whenever possible, advanced technology will be used to collect and process data to reduce respondent burden and make data processing reporting more timely and efficient. The majority of data collections will take place online using automated survey forms. In all data collections, the number of questions will be held to the absolute minimum required for the intended use of the data. Data will be collected as part of the screening and completion of surveys. A Privacy Impact Assessment (PIA) will be conducted for the study (Attachment 18).

Information technology to be used.

1. Web-based data collection. All information (except the standardized patient interview) will be collected over the Internet, thus making participation more convenient and faster. Information will be stored on Talaria's secure server.

2. Web-based screening. Screening for inclusion in the study will be conducted on the web. Potential participants will answer a few questions about their eligibility and computer algorithms will determine if the study is a good fit. This saves participant time when compared to a traditional telephone or in-person screening interview. Participants will know if they are a good fit in about 2 minutes.

3. Telephone standardized patient interview. Traditionally standardized patient interviews are conducted face-to-face. In order to make data collection easier, standardized patient interviews will be conducted over the telephone.

4. Training conducted via Internet. All training conditions will be conducted over the internet. Dependent on condition, the training will be online or PDF, and the assessments will be online. This saves considerable participant travel time as they can complete the training at their convenience and in their own homes or offices.

A.4 Efforts to Identify Duplication and Use of Similar Information

There is no similar information to the data being collected available in any other database. This is a unique training protocol.

A.5 Impact on Small Businesses or Other Small Entities

The burden on small businesses or other small entities will be reduced by the voluntary nature of the data collections. This is a continuing education that will contribute to the professional development of the participant and a positive impact on their profession at large.

A.6 Consequences of Collecting the Information Less Frequently

A single set of questionnaires will be administered once per evaluation per specific respondent group. Any less frequent response would not yield useful data for program planning and management improvements.

A.7 Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

The request fully complies with regulation 5 CFR 1320.5.

A.8 Comments in Response to the Federal Register Notice and Efforts to Consult Outside Agency

The 60-day Federal Register Notice of the proposed research was published on May 24, 2011, in Volume 76, #100, pp 30177-30178, on 05/24/2011. No comments have been received to date. The 30-day Federal Register Notice was published on August 12, 2011 in Volume 76, #156, pp 50233-50234, on 08/12/2011.

Outside consultation was conducted with the University of Washington, Swedish Medical Center, and Free and Clear. These organizations are representative of the diverse groups of Talaria research partners. We contacted the following individuals who provided us with comments and suggestions and participated in the development of the program.

Name	Qualifications	Title	Dept/Org	Role in the Project
Kelly Carpenter	PhD	Sr. Research Scientist	Talaria, Inc	Co-Principal Investigator
Susan Stoner	PhD	Research Scientist	Talaria, Inc	Co-Principal Investigator
Glenda Polwarth	BS	Chief Technology Officer	Talaria, Inc	Chief Technology Officer, will manage technology development.
John Baer	PhD	Research Professor	Univ of Washington, Dept of Psychology	Co-Investigator, will assist in the development of clinical cases, assessment instruments, coding schemes, training, data analysis and preparation of manuscripts.
Beatriz Carlini	PhD, MPH	Research Scientist	Free & Clear, Inc	Co-Investigator, will assist in the development of training modules, recruitment of study participants and data analysis.
Paul Gianutsos	MD, MPH	Associate Director	Swedish Medical Center, Family Medicine Residency	Co-Investigator, will assist in content development, subject recruitment and CME accreditation.
Mark	MD	Professor	Univ of	Consultant, will contribute

Sullivan			Washington, Dept. Psychiatry & Behavioral Science	expertise in prescription opiates, and assist in content development and reviews.
Joseph Merrill	MD	Clinical Assistant Professor	Univ. Washington, Dept of Medicine	Consultant, will contribute expertise in heroin, cocaine and other street drugs, and assist in content development and reviews.
Christopher Dunn	PhD	Associate Professor	Univ of Washington, Dept. Psychiatry & Behavioral Science	Consultant, will contribute expertise in SBIRT, MI, and assist in content development and reviews.
Denise Walker	PhD	Research Assistant Professor	Univ. of Washington, Addictive Behaviors Resarch Center	Consultant, will contribute expertise in marijuana use, adolescents and assist in content development and reviews
Cheryl Slean	MFA	Writer/ Director/ Producer	Fin Films, llc	Consultant, will provide script writing, directing and production management for media development.

A.9 Explanation of Any Payment of Gift to Respondents

Primary Care Providers (PCPs) are generally very busy and highly compensated individuals. The total time they are anticipated to be engaged in the study is 4.67 hours. This includes 2.5 hours responding to study measures (see table on page 15), 2.0 hours for viewing the Continuing Medical Education (CME) course material, and 0.17 hours for other study procedures (e.g., reading the consent statement). To show appreciation for their time and efforts in evaluating the Web-based Skills Training for SBIRT program the following incentives will be paid. The respondents who complete the pre and post test assessments and a 10 minute standardized patient evaluation via telephone will receive an honorarium of $250 and 2.5 CME credits. Respondents who complete the 3 month follow up assessments will receive an additional honorarium of $50; *the hourly average cost for online CME course is $25/hr, the $50/hr rate calculation is based on a $75 hourly rate for internal medicine physicians from Payscale.com, the participant is receiving the CME credit therefore it is not calculated in the cost to the respondent.

This payment is necessary to adequately compensate the participants, who will be health care providers. The average salary for a primary care physician in the United States **ranges from 104,000 to 180,000.** http://www.payscale.com/research/US/Certification=Board_Certified_Primary_Care/Salary

There is also the Standardized Patient interview. This is in addition to the questionnaires and has to be scheduled. Incentives for this extra effort from the providers are used to recruit participants. We have compensated physicians and nurses on previous projects, for example, the Phase I portion of this project N43 DA-08-2216 "Web-based Skills Training for SBIRT". Other projects include: 5R44NR008839 - Phase II- Participants were physicians. They were paid $250 for 1.5 hours of their time, plus 2.5 CME credits; 1R42CA141875 - Phase I- Participants were registered nurses. They were paid $150 for 1 hour of their time; and 1R43DA026659 - Phase I- Participants were registered nurses. They were paid $100 for 1 hour of their time. Participant incentives will be essential to recruit sufficient numbers of participants and to have the desired response rates.

Other, similar projects also compensate primary care providers at similar rates. For example, Short et al (2006) compensated physicians $150 for taking three assessments and completing at least 4 hours of CME (Small Business Innovation and Research grant, National Institute of Mental Health (R44-MH62233). While they did not report the time involved in their published results, their assessment involved only paper surveys. Research has shown that physicians are resistant to participation without financial reimbursement (Herber, et al, 2009), and that offering incentives to participants greatly increases response rates as well as speed of response (Dillman, 1978; 2000).

A.10 Assurance of Confidentiality Provided to Respondents

The respondent questionnaires surveys will not collect individually identifiable information. Personally identifiable data will be collected only for incentive payments and will be stored in a separate, secure database. The data will be stored for 3 years in keeping with the NIH requirement and then purged, unless directed otherwise by NIDA. Standard Human Subjects' Guidelines will be followed, the data collection has been approved by WIRB's Human Subjects Review. (See Attachment 16: IRB Approval).

Security of electronic data—The database is protected with a Secure Socket Layer certificate from VeriSign to ensure that data collected over the Internet is secure. Each participant will be automatically assigned an ID number to be used in the study in lieu of personal identifiers; there will be no links between participants' names and their data. Email addresses will be collected, but will not be connected to study data. Names and addresses will be collected for the purposes of paying the participants, and awarding CME, but this information will not be linked to other study data. This information will be kept in a locked digital file and locked filing cabinet that is only accessible to the PI and research assistants involved in the study. Digital data will be stored on secured databases accessible only through password-

protected computers that are only accessible to trained research staff, any reports or publications will be of aggregated data so no personally identifiable data can be obtained. Audio recordings will be deleted by 12/31/2013. NIDA will conduct a Privacy Impact Assessment annually. All participants will complete informed consent documents that will explain Talaria's confidentially procedures and how they can opt out of the study at any point.

A.11 Justification for Sensitive Questions

The questions asked will not be of a sensitive nature. To avoid fear of disclosure of perceived sensitive information, participants will be told that their responses will be treated in a confidential manner, and will be reported in terms of aggregate numbers or summary statistics. Standardized Patient Interviewers administering telephone surveys will be specially trained to ask questions in a sensitive manner and to handle any subsequent discussion skillfully so as not to include sensitive information.

A.12 Estimates of Hour Burden Including Annualized Hourly Costs

Participants will complete each measure 1-3 times, according to the following schedule:

		Times Administered			
	Time (min)	Pretest	Posttest	Follow-Up	Total
Demographics	5	1			5
Knowledge Test	15	1	1		30
Clinical Practices Questionnaire	5	1		1	10
Clinical Practice Intentions Questionnaire	5		1		5
Video Standardized Patient Evaluation	35	1	1		70
SBIRT Attitudes Questionnaire	2	1	1		4
SBIRT Self-Efficacy Questionnaire	1	1	1	1	3
Perceived Barriers to SBIRT Questionnaire	3	1		1	6
Satisfaction Questionnaire	4		1		4
Standardized Patient Telephone Interaction	15		1		15
Grand Total for study measures					152

The annual reporting burden is based on the average time taken by testers and sample users who tested the online components. As shown above, the total time estimated per respondent to complete the study measures is 152 minutes, or approximately 2.5 hours. The total time anticipated for respondents to be engaged in the entire study is 4.67 hours (2.5 for study measures above, 2.0 hours for viewing CME course material, and 0.17 hours for other study procedures)

Therefore, the estimated total annual burden hours requested is as follows:

Table 12-1

Type of Respondents	Estimated Number of Respondents	Estimated Number of Responses per Respondent	Average Burden Hours per Set of Responses	Estimated Total Annual Burden Hours Requested
Primary Care Providers	94	1	4.67	439

A.12 - 2 Annualized Cost To Respondents

The annual cost to respondents is as follows:

Type of Respondents	Estimated Number of Respondents	Estimated Number of Responses per Respondent	Average Burden Hours Per Response	Wage Rate /hr	Cost
Primary Care Providers	94	1	2.0	$50.00	$7,050.00

*the hourly average cost for online CME course is $25/hr, the $50/hr rate calculation is based on a $75 hourly rate for internal medicine physicians from Payscale.com, the participant is receiving the CME credit therefore it is not calculated in the cost to the respondent

A.13 Estimate of Other Total Annual Cost Burden to Respondents or Record Keepers

There will be no capital, operating, start-up or maintenance costs to the respondent.

A.14 Annualized Cost to the Federal Government

All costs are covered by the SBIR Phase II Contract. The total cost for the two-year Phase II NIDA SBIR contract to Talaria is $739,862. Total government personnel costs are of 10 percent of the NIDA Project Officer time (10% of annual salary) and is $10,600, assuming a median annual salary of $106,000 for an NIH evaluation professional to govern and guide the evaluation effort. Salary is based on the 2011 Federal General Schedule (http://www.opm.gov/oca/03tables/html/dcb.asp). Details are provided in the table below.

Salary/Item	Annual Cost
Talaria SBIR Phase II (one year total)	$369,931
NIH/NIDA evaluation professional	$10,600
Total Average Annual Cost	$380,531

A.15 Explanation for Program Changes or Adjustments

This is a new data collection.

A.16 Plans for Tabulation and Publication and Project Time Schedule

For Data Analysis description please see section A.2.

A.16 - 1 Project Time Schedule

Activity	Time Schedule
Participants are recruited	1 – 2 months after OMB approval
Online study, participants complete initial CME and online questionnaires	2 - 6 months after OMB approval
Participants schedule and complete a 10 minute standardized patient evaluation via telephone	3 - 8 months after OMB approval
Participants complete follow-up online assessments	6 - 10 months after OMB approval
Analyses	8 - 12 months after OMB approval
Publication	16+ months after OMB approval

A.17 Reason(s) Display of OMB Expiration Date is Inappropriate

No exception is requested. The OMB expiration date will be displayed.

A.18 Exceptions to Certification for Paperwork Reduction Act Submissions

No exceptions to the certification statement identified in OMB Form 83-I, item 19, “Certification for Paperwork Reduction Act Submissions” are requested.