Supporting Statement B for

Web-Based Training for Pain Management Providers (NIDA)

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Clinical Tools, Inc., with funding from the National Institute on Drug Abuse (NIDA)
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B. Collections of Information Employing Statistical Methods

B.1. RESPONDENT UNIVERSE AND SAMPLING METHODS

Samples for all research will be drawn from health care providers living in the United States, who are fluent in English, and have Internet access. In accordance with the Draft Provisional Guidance on the implementation of the 1997 Standards for Federal Data on Race and Ethnicity, final samples for all proposed studies will be generally representative of the US population in terms of gender, race, and ethnicity. In order to ensure a representative sample is obtained, minorities will be slightly oversampled. Female participants will likely be oversampled due to their over representation in the fields of nursing and physician assisting. Target enrollment for each study proposed in this application is provided in the following table:

Table B.1-1: Target Enrollment

Target Enrollment, Pain Management Providers		
	US Population*	**Evaluation**
Ethnic Category		
Hispanic or Latino	15.4%	12-13 (15-16%)
Not Hispanic or Latino	84.6%	67-68 (84-85%)
Ethnic Category: Total of All Subjects	**100%**	**80** (100%)
Racial Category		
American Indian/Alaskan Native	1.6%	0-2 (1-2%)
Asian-American	3.6%	4 (5%)
Native Hawaiian or Other Pacific Islander	0.1%	0-1 (0-1%)
Black or African-American	13.3%	10-12 (13-14%)
White	80%	64 (80%)
Racial Category: Total of All Subjects		**80 (100%)**

*Based on 2008 estimates obtained 12/14/09 from http://www.factfinder.census.gov.

The expected response rate for the evaluation (complete responses and/or enrollees) is approximately 80% to 85%. These rates are based on previous experience of CTI researchers and consultants.

Participants will be recruited through print media and nonprofit organizations with related goals. All potential participants will e-mail the study coordinator; based on specific screening forms, eligible participants will be identified. A stratified sample of respondents (based upon

the research's target enrollment of racial, ethnic, and gender subgroups) will be asked to participate by the Principal Investigator or a designee.

B.2. PROCEDURES FOR THE COLLECTION OF INFORMATION

For the purposes of the proposed studies a response rate of 80% to 85% for the evaluation should be sufficient. Specialized sampling procedures are not required.

Participants who are invited to participate in the research will be emailed information packets. Once participants indicate that they have reviewed the information packets, they will be assigned an ID number and password and directed to the website. Only users who have been provided with an ID number and password will have access to the online research instruments. Quality control measures will include data logging checks prior to and during the studies and weekly e-mail reminders to participants in the evaluation.

B.3. EFFORTS TO IDENTIFY DUPLICATION AND USE OF SIMILAR INFORMATION

Response rates for the study will be calculated by dividing the number of participants who provide full data sets for each study by the total number of subjects enrolled for each study.

For the evaluation, 80 participants will be enrolled, with the expectation that 68 of those will yield full data sets (completion rate of 80%-85%). A review of the relevant literature indicates that for this study a small- to medium-effect size should be expected for the attitude measure, and a large-effect size should be expected for the knowledge measure. According to Cohen (1988), for a study of this type, with a power of .80 and one-sided alpha of .05, at least 400 participants would be needed to detect a small-effect size (200 per group), and 66 participants would be needed to detect a medium-effect size (33 per group).[5] Due to logistics and resources, it is not possible to include 400 participants in the proposed study. However, 80 complete data sets

should be more than adequate to detect gains in knowledge and to detect a change in attitudes should the effect size be slightly smaller than medium.

Response rates for the evaluation will be maximized by remunerating participants for their time (see section A.9.) and by sending e-mailed reminders to participants once a week. The response rate for the evaluation will also be enhanced by the fact that participants will be receiving free training and education related to their profession. Participants who drop out prior to completion will be compensated for the portion of the study completed, as listed in section A.9.

If, after two weeks, respondents have offered no data at all, they will be e-mailed and asked whether or not they are still interested in participating in the study. Nonrespondents and dropouts will be asked to describe their reasons for not responding or not completing the study. Potential participants who refuse to participate or who leave the study at any point will be allowed to do so without penalty or jeopardy.

B.4. TEST OF PROCEDURES OF METHODS TO BE UNDERTAKEN

In the proposed evaluation, participants will complete an assessment three times: 1) "Pre-" which will be before exposure to the education/training materials; 2) "Post-" which will be immediately after using the training materials, and 3) "Follow-up" which will be six weeks after using the training materials. The assessment will include the following measures: Medical Record Patient Encounter, Learner Self-Assessment Modified Interpersonal Skills Inventory/, Knowledge and Competency Measure, and Participant Attitude Measure. The measures used in the evaluation will first be pilot tested with a small sample of the population ($n \leq 9$). The data from this pilot test will be analyzed for internal reliability and to eliminate knowledge questions that a high percentage (85%) can answer correctly without being exposed to the program.

B.5. INDIVIDUALS CONSULTED ON STATISTICAL ASPECTS AND INDIVIDUALS COLLECTING AND/OR ANALYZING DATA

The NIDA Project Officer is Quandra Scudder. Ms. Scudder will review the final report, including data analysis. Table B.5-1 below shows the individuals who will be consulted on data analysis or will collect and analyze data:

Table B.5-1: Data Collection and Analysis

Name	Title	Affiliation	Statistical Role	Phone Number
T. Bradley Tanner, MD	Primary Investigator	Clinical Tools, Inc.	Data Collection and Analysis	919-960-8118
Mary P. Met-calf, PhD, CHES	Research Scientist	Clinical Tools, Inc.	Data Analysis	919-960-8118
Karen Rossie, DMD, PhD	Research Scientist	Clinical Tools, Inc.	Data Collection and Analysis	919-960-8118
Tracy Shaw, MA	Evaluation/Assessment Consultant	Independent Consultant	Consulting on Data Collection and Analysis	541-285-7945

In addition, research assistants at CTI will also assist with data collection and analysis.