Supporting Statement A for

Web-based Media Literacy Parent Training for Substance Use Prevention in Rural Locations (NIDA)

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**** NOTE – SUPPORTING STATEMENT B SHOULD BE COMPLETED WHEN THE DATA COLLECTION EMPLOYS STATISTICAL METHODS. SUPPORTING STATEMENT B IS A SEPARATE FILE, TITLED, "SSB", WITH SAME TITLE PAGE, BUT WITH A DIFFERENT TABLE OF CONTENTS SEE ATTACHMENT, "SAMPLE SSB", FOR MORE INFORMATION ON WRITING SSB.**

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A.1 Circumstances Making the Collection of Information Necessary

The project is an evaluation of a substance use prevention intervention designed to overcome barriers to prevention efforts in rural communities using a computer program, Media Detective Family (MDF). It reaches parents and their elementary school-aged children with an interactive curriculum through a website or on a mobile or wireless device (i.e., tablet computer or smartphone). The MDF program focuses on improvements in children's knowledge and behavioral intention in the areas of alcohol and tobacco use and increased knowledge and skills for both adults and children in the area of media literacy. A web-only version of MDF was initially developed as part of a NIDA SBIR Phase I contract, and its feasibility, attractiveness, usability, and commercial viability were established. In the current NIDA SBIR Phase II contract, the MDF program will be evaluated in a randomized controlled trial to establish the effectiveness of the program for positively impacting family members. Data will be collected from approximately 200 parent-child pairs (total n=400) living in six rural counties in North Carolina and Texas.

The randomized controlled trial will collect information on the knowledge, norms, skills, behavior, behavioral intentions, and demographic characteristics of volunteer participants (children and adults) before and after they are exposed to the MDF computer program or a control computer program. It is in the interest of NIDA to determine if children and adults in rural communities benefit from MDF. The findings will provide valuable information to establish MDF as an evidence-based substance use prevention intervention. Further, there is a need for these evaluation results to: (1) enhance the quality of substance use prevention services, and (2) to reduce the risk of the target population of rural youth engaging in substance use behaviors. To ensure a benefit of this funded study to the general public, the resulting MDF program, if shown to be effective, will be broadly marketed and disseminated for use by interested families. In addition, it will be important to disseminate the evaluation results to the scientific community, which will occur via presentations at professional conferences and publications in peer-reviewed journals.

These benefits are congruent with NIDA's research goals. NIDA has the legislative authority to conduct this research through 42 U.S. Code § 6A(III)(15): National Institute on Drug Abuse (§§ 285o: Purpose of Institute).

A.2 Purpose and Use of the Information Collection

A research team at innovation Research and Training (iRT; a small business based in Durham, NC) will conduct the proposed evaluation research. Using a randomized controlled trial study design, information will be collected on the characteristics of children and adults participating in the MDF computer program or a control computer program. The main mode of data collection will use audio computer-assisted self interviewing (ACASI) technology to administer questionnaires and will occur at three time points: at pretest, after using the MDF computer program or a control computer program for one month, and at 3-month follow-up. The questions included in the questionnaires for both adults and children will cover topics including knowledge, norms, skills, behavior, behavioral intentions, and demographic characteristics (see Attachments 1-6 for adult questionnaires and Attachments 7-12 for child questionnaires). These data collection instruments were compiled for the proposed research. Most of the questions in both the adult and child questionnaires have been used in previous research and have established reliability and validity with similar study populations (See Attachment 17: Certification of the Institutional Review Board, Measures section for an outline of psychometric properties and references). Most of the child measures have been used in previous research with this age group, and knowledgeable experts (Tracy Scull, PhD [Principal Investigator], Janis Kupersmidt, PhD [Co-Investigator], and the consultants listed in A.8) have endorsed their appropriateness for 3rd, 4th, and 5th grade children. The use of ACASI technology for data collection assures participant privacy, improves participants' understanding of questions and response choices, reduces errors in data entry and coding, and improves efficiency of data collection.

In addition to the questionnaires, adult participants in both the intervention and control groups will fill out program usage logs for two time periods: the initial 1 month of use of their assigned computer program and the 3-month follow-up period. These logs are simple notations of date, time, and type of persons (e.g., study

parent, study child, other adults, and/or other children) who used the computer program, and are a minimal data collection burden for the participants (see Attachment 16).

For all data collected, the research staff will use unique, randomly-selected identification numbers in place of names and email addresses to provide confidentiality to participants.

The data collected will allow the assessment of several important points. First, the immediate and short-term efficacy of the MDF computer program will be evaluated, determining whether participation in the intervention group results in improvements in desired outcomes relative to the control group. Outcomes of interest include children's intentions to use alcohol or tobacco products, media interpretation, and media deconstruction skills, as well as adults' media deconstruction skills, media literacy knowledge, media mediation behaviors, and skills continuation. Second, we plan to examine potential moderators of program effectiveness including location, grade, child's sex, and prior substance use experimentation. Third, we plan to investigate the role of program dosage on the effectiveness of the MDF computer program. Fourth, we plan to examine whether media interpretation cognitions mediate the program effectiveness for producing positive outcomes. Finally, consumer satisfaction with the MDF computer program will be evaluated.

Use of results: The findings will provide valuable information to establish MDFprogram as an evidence-based substance use prevention intervention. The study design (randomized controlled trial) and inclusion of data collection at 3-month follow-up are appropriate for inferring causality and determining whether any changes observed last beyond the initial period of program use. The findings will be disseminated to the scientific community and to the public through press releases, presentations at professional conferences, and publications in peer-reviewed journals. In addition, if the MDF intervention is found to be successful in changing attitudes, skills, and behaviors related to substance use, MDF will be marketed and made available to families that can benefit.

A.3 Use of Information Technology and Burden Reduction

All data will be collected electronically, using audio computer-assisted self interviewing (ACASI) technology. Both adult and child participants will fill out all questionnaires on computers with headphones using ACASI, with a trained staff data collector present to assist with the technology. This method permits the adult and child in each participant pair to fill out questionnaires simultaneously and privately. As part of their data collection at posttest and 3-month follow-up, adults will input the information from their pen-and-paper usage logs, thereby eliminating the need for the research staff to input this information. Overall, the use of ACASI technology for data collection assures participant privacy, reduces errors in data entry and coding, and improves efficiency of data collection, minimizing the burden on study participants.

Enrolled families meeting project staff at a location in the community for administering of questionnaires requires families to make time for travel and possibly child care for siblings. Project staff can also meet families (adult and child) in their homes to administer questionnaires if families prefer this location, as this strategy reduces the amount of time families need to participate in the study. Adult participants may also choose to complete their questionnaires apart from the child's data collection with the trained data collector by using a web link at their own convenience, and a trained data collector will be available by phone or email to provide assistance with the adults' questionnaire completion. This would give parents the opportunity to not be present for the child's completion of questionnaires. This would make participation in the study more convenient for families. For example, parents can be given an online link to complete the questionnaire at their leisure. Once completed, project staff may administer questionnaires to the child while they are at an afterschool program or other similar location.

The NIH Privacy Impact Assessment (PIA) Officer has determined that the PIA for the database being used to collect the information in this Data Collection Request is unnecessary. The proposed data collection will collect both identifiable and non-identifiable information. For the pretest, posttest, and follow-up questionnaire data, participants' de-identified responses will be stored separately from their contact information and consent forms. Consent forms will be signed at the local data collection site and will be mailed periodically to the iRT office. Consent forms can also be signed at the participants' homes and mailed back to the iRT office. Allowing participants to return signed consent forms through mail gives family participants more flexibility and

allows for the adult participants to complete their questionnaires at home without having to see a data collector in person. At the iRT office, consent forms will be kept in a locked file cabinet that can only be accessed by project staff. Participants use a unique identification number when completing questionnaires in place of their name. There will be a list of names and unique identifiers kept at iRT between the pretest and 3-month follow-up. This linking list will allow us to match questionnaire responses from the same participant across the three time points, and to match program usage data to the appropriate participant. This document will be kept in a locked file cabinet at iRT. No one other than project staff members will have access to the data and ID list. After the all data is collected at the 3-month follow-up and checked for errors, the list of names and identifiers will be destroyed, making the resulting dataset anonymous.

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

Based on an in-depth review of the peer-reviewed literature and ongoing professional-to-professional discussions with media literacy and substance use prevention experts, there are no known family-based substance use prevention programs that focus on media literacy and address the prevention needs of rural families. The MDF computer program was developed based on an established theory for media literacy (i.e., the Media Interpretation Process model) as well as prior evidence-based interventions for youth (i.e., Media Detective and Media Ready). MDF was initially developed as a web-only intervention through a NIDA SBIR Phase I contract, and its feasibility, attractiveness, usability, and commercial viability were established. In the current NIDA SBIR Phase II contract, the MDF will be evaluated to establish its effectiveness in positively impacting family members for substance use prevention in rural areas. Because MDF is a new substance use prevention intervention, there are no existing data that could serve the purpose of evaluating the efficacy of this program.

A.5 Impact on Small Businesses or Other Small Entities

No small businesses will be involved in this study.

A.6 Consequences of Collecting the Information Less Frequently

This is a single-time research study in which participants complete questionnaires three times over a four-month research period: at pretest, at posttest after using the MDF computer program or a control computer program for one month, and at 3-month follow-up. This design minimizes burden on participants and reduces the likelihood of attrition (compared with longer respondent re-contact intervals), while also allowing the research study to assess both immediate and short-term outcomes of exposure to the MDF computer program.

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

As explained in A.6, the proposed data collection is a single-time research study in which 400 adult and child participants complete questionnaires three times over a four-month research period. Respondents' participation in the data collection is limited to this four-month period. Response times for each of the 3 questionnaires will be less than 1 hour, based on consultation with a total of 8 potential respondents (4 adult-child pairs).

This data collection fully complies with 5 C.F.R. 1320.5.

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

Statistical consultation for this information collection was received from Antonio Morgan-Lopez, PhD, Senior Research Quantitative Psychologist, RTI International, amorganlopez@rti.org, (919) 316-3436.

Additional consultation on the content and design of the intervention program and the data collection instrument was received from (1) Mahnaz Moallem, PhD, Professor of Instructional Technology & Research and Program Coordinator for Instructional Technology Program, University of North Carolina at Wilmington, moallemm@uncw.edu, (910) 962-4183; and (2) Barbara Davis Goldman, PhD, Research Associate Professor in the Department of Psychology and Scientist in the FPG Child Development Institute, University of North Carolina at Chapel Hill, barbara_goldman@unc.edu, (919) 966-7169.

The 60-day Notice was published in the Federal Register on 03/27/2013, Vol. 78, No. 59, pp. 18612-18613. No comments were received.

A.9 Explanation of Any Payment of Gift to Respondents

Remuneration will be provided in exchange for participation in the randomized controlled trial to assist with the impact of study participation on productive time for the rural participants. It is important that we reach a wide sample of rural families, and that those initially recruited into the study remain in the study for all data collection time points over a four-month period. The total time commitment this study asks of each participant is 6 hours. About half (roughly 3 hours) of this time burden is for data collection, as detailed in A.12, below. Participants will spend an additional 3 hours on completion of the intervention or control computer program to which they are assigned. In light of these time demands, parent-child pairs in both the intervention and control conditions will receive a total of $95 in incentives ($20 for completing the pretest, $5 for completing the assigned computer program, $30 for completing the posttest, and $40 for completing the 3-month follow-up). The amount of the incentive is in line with that given to participants in other research studies conducted by Innovation Research and Training, Inc. In addition, parent-child pairs in the control condition will be offered four-month access to the MDF computer program following the completion of data collection. Participants will also be reimbursed for mileage incurred to and from the data collection site for all appointments.

The choice to use the proposed incentives was made with the following considerations:

Data Quality: Collecting data in rural areas is a challenge because of the voluntary nature of participation and typical long driving distances between potential participants' residences, workplaces, schools, and community-based data collection sites (e.g., public libraries, community colleges, community centers). Therefore, participant attrition is more likely. Incentives may improve the overall response rates for participants.

Burden on the respondent: Because the data collection is voluntary and administered in an informal setting, participating in the data collection may be perceived as an atypical activity for rural families, thus placing undue burden on the respondents.

Past experience: In the Phase I study of MDF, the data collectors determined that the adults and children appreciated the remuneration and the incentives helped to keep them focused during data collection and responsive when data collection times were being scheduled.

Improved coverage of specialized respondents, rare groups, or minority populations: In this study, a key matching variable in the study design is child gender. We also have a study design balanced by geographic location. Therefore, it is important that a balance be maintained between the intervention and control groups and across the 6 study counties, with minimal loss of participants in any of the groups.

A.10 Assurance of Confidentiality Provided to Respondents

Care was taken to avoid the use of the word 'confidential' in the absence of a legal basis for its use. Every effort will be made to protect participants' privacy, and the consent, permission, and assent forms indicate this to participants. Participants will be fairly advised of the data disclosure possibilities and of the procedures in place to maintain their privacy. Participants will be told that their answers will be kept private, securely stored in locked file cabinets and/or on password protected servers, only accessible to research staff members who work on this project (see Attachments 8 and 9). They will also be told that once the study concludes, the linking list that contains both names and secret numbers will be destroyed, making the data set anonymous. This study has been reviewed by the NIH Privacy Act Office. A Privacy Impact Assessment will be conducted.

The research design and protocol have been approved by the iRT Institutional Review Board (see Attachment 17).

A.11 Justification for Sensitive Questions

Sensitive Questions

The project is a family-based intervention that aims to aid in the primary and secondary prevention of substance use among youth. The RCT of this project requires the collection of potentially sensitive data on alcohol and tobacco attitudes and behaviors from adult and child participants (see questionnaire items in Attachments 1 through 12). The pretest, posttest, and 3-month follow-up questionnaires for both adults and children will collect data on topics including media literacy knowledge and skills, media interpretations, substance use norms, substance use behavior and behavioral intentions, and demographic characteristics (including household size and annual household income).

Key outcomes of this evaluation research study of MDF are children's attitudes, intentions, and behaviors related to alcohol and tobacco. We are also interested in factors that may moderate the effectiveness of the MDF computer program. Based on existing literature, we will examine the role of prior child substance use experimentation and parent substance use (as well as other factors, such as location and child gender) as moderators of program effectiveness. In other words, we will determine whether MDF was more or less effective for participants in certain groups: e.g., children who have already experimented with alcohol or tobacco, or children whose parents are regular smokers.

It is necessary to discover whether MDF computer program use is associated with improvements in substance use outcomes, and whether effectiveness varies by participant/family characteristics. The data collected will provide valuable information to establish the program as an evidence-based substance use prevention intervention.

Personally Identifiable Information

This project uses unique identification numbers to maximize protections to respondents' privacy. For all data collected and analyzed as part of the RCT, unique, randomly-selected identification numbers will be used in place of names and email addresses to provide confidentiality to participants. Participants' contact information will be collected with the sole purpose of providing families with the incentives for study participation, will be kept separate from the study data, and will be destroyed at the completion of the study. No other personally identifiable information will be collected as part of this study. Participants' de-identified responses will be stored separately from their contact information and consent forms. Consent forms will be signed at the local data collection site and will be mailed periodically to the iRT office. Consent forms can also be signed at the participants' homes and mailed back to the iRT office. At the iRT office, consent forms will be kept in a locked file cabinet that can only be accessed by project staff. There will be a list of names and unique identifiers kept at iRT between the pretest and 3-month follow-up. This linking list will allow research staff to match questionnaire responses from the same participant across the three time points, and to link adult and child participant pairs. This document will be kept in a locked file cabinet, and only research staff members will have access to the data and ID list. After all data is collected at the 3-month follow-up and checked for errors, the list of names and identifiers will be destroyed, thus rendering the dataset anonymous.

Consent Process and Privacy of Data

All participants will undergo informed consent procedures prior to data collection (see Attachments 14 and 15). Adults will provide written consent for their own participation and their child's participation. Children will provide written assent. Through the consent and assent process, all participants will be informed about the nature of the study and reminded that their participation is entirely voluntary. They will be informed about the possible benefits and consequences of participation. They will also be reminded that during data collection, they can skip any question they do not wish to answer for any reason and without consequences. Participants will be told that their answers will be kept private, securely stored in locked file cabinets and/or on password protected servers, only accessible to research staff members who work on this project. They also will be told that once the study concludes, the linking list that contains both names and secret numbers will be destroyed, making the data set anonymous.

A.12 Estimates of Hour Burden Including Annualized Hourly Costs

A12 – 1 Estimates of Hour Burden

Type of Respondents	Number of Respondents	Frequency of Response	Average Time per Response	Annual Hour Burden
Adults,				
Permission & Consent		1	10/60	33.33
Pretest		1	50/60	166.67
Posttest	200	1	45/60	150.00
Follow-up		1	45/60	150.00
Usage Log		2	10/60	67.00
Children				
Assent		1	10/60	33.33
Pretest		1	50/60	166.67
Posttest	200	1	45/60	150.00
Follow-up		1	45/60	150.00
Totals	**400 unique respondents**			**1067.00**

Participants are adult-child pairs (one adult and his or her child in the third, fourth, or fifth grade; n=400: 200 adults and 200 children) who volunteer for the study. Adult-child pairs will be randomly assigned to either the intervention or control group. All adult and child participants in both groups will fill out questionnaires three times (at pretest, posttest, and 3-month follow-up) using audio computer-assisted self-interviewing (ACASI) technology to facilitate data collection, assure privacy, reduce errors in data entry and coding, and improve efficiency of data collection. As part of the informed consent process, there will be a permission and consent form for parents to fill out (estimated to take 10 minutes) and an assent form for children to fill out (estimated to take 10 minutes). The pretest data collection is expected to take slightly longer (50 minutes versus 45 minutes for posttest and follow-up) because of the additional questionnaire items on demographic characteristics and media use.

In addition to the questionnaires, adult participants in both the intervention and control groups will fill out program usage logs for two time periods: the initial 1 month of use of their assigned computer program, and the 3-month follow-up period. These logs are simple notations of date, time, and people who used the computer program, and are a minimal data collection burden for the participants (estimated to take 10 minutes, as shown in Table A12-1).

The total projected hour burden for the MDF evaluation study is 1067 hours of participant time, with each participant's involvement limited to 4 months. Divided among 400 participants, the 1067 hours break down to about 2.67 hours per participant.

A12 – 2 Annualized Cost to Respondents

Type of Respondents	Number of Respondents	Frequency of Response	Average Time per Response	Hourly Wage Rate	Respondent Cost	Compensation per Response	Total Compensation
Families, Permission/Consent (parents), Assent (children), and Pretest	200	1	120/60	$0.00	$0.00	$20.00	$4,000.00
Families, Posttest	200	1	90/60	$0.00	$0.00	$30.00	$6,000.00
Families, Follow-up	200	1	90/60	$0.00	$0.00	$40.00	$8,000.00
Families, Usage Log	200	2	10/60	$0.00	$0.00	$2.50	$1,000.00
Totals	**200 unique respondent families**						**$19,000.00**

Note that in the table above, families (adult-child pairs) are listed as the respondent type because the incentives are provided to families rather than individuals. Hourly wage rates for participants were calculated at zero due to the fact that participants will be compensated for their time at a rate of $20.00 for pretest, $30.00 for posttest, $5.00 for program completion (as measured through completed usage logs) and $40.00 for 3-month follow-up. The data collection appointment times will be flexible so that adults can choose times outside of their working hours (e,g, in the afternoons, evenings, and weekends), so there will be no loss of wages for the respondents. Respondents will receive their incentives via check, mailed to them after the data collection appointment. This method was chosen because of administrative policies at iRT, which is doing the data collection. This method avoids the potential safety risk of having data collectors handle cash or checks directly.

Total projected cost to respondents is $0.00.

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

There are no capital, start-up, operational, or maintenance costs to the respondents in providing the information required by this research.

A.14 Annualized Cost to the Federal Government

The annual cost to the Federal Government is $507,808.00. This includes 5% of the annual full-time effort of a NIDA project officer (estimated at $8,000.00). This also includes a total of $499,808.00 as a SBIR Phase II contract between NIDA and innovation Research and Training for the development and evaluation study of the Media Detective Family intervention [a two-year contract from September 15, 2012 to September 14, 2014]. The SBIR Phase II contract includes $19,000.00 for participant incentives (see A.12).

A.15 Explanation for Program Changes or Adjustments

This is a new collection of information.

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

A16 – 1 Project Time Schedule

Activity	Time Schedule
Local data collectors hired and trained	1-2 months after OMB approval
Begin participant recruitment	3-4 months after OMB approval
Enroll study participants	3-7 months after OMB approval
Complete data collection	8-9 months after OMB approval
Analyses	9-12 months after OMB approval
Publication	12-15 months after OMB approval

Preliminary Analyses. The first stage of data analysis will be to conduct data coding and data management activities. The goal of this phase is to develop a codebook for data processing of all measures. The second phase will involve conducting psychometric and other descriptive analyses to study the reliability, validity, and distributions of key variables. This phase includes creating summary scores and examining the distributions, internal consistencies, and inter-correlations of these scores as indices of reliability and validity. The third phase will focus on evaluating the impact of random assignment on producing essentially equivalent groups for the intervention and control conditions. These analyses will include tests of a series of single factor, condition (intervention, control) random effects ANOVA models estimated for each variable with a random intercept at the school level. The fourth phase will examine missing data at each time point. Missing data will be handled with an appropriate imputation method, and estimates and standard errors will be adjusted for imputations, if warranted (Schafer, 1997).

Main Analyses. First, the immediate and short-term effectiveness of the MDF computer program will be evaluated. A series of analyses will be used to examine if using the MDF computer program impacts the desired outcomes. Child outcome variables of interest will include intentions to use alcohol or tobacco products, media deconstruction skills, media literacy knowledge, and MIP-related variables (e.g., realism, similarity). Parent outcome variables of interest will include media deconstruction skills, media literacy knowledge, media mediation behaviors, and amount of skills continuation. The model for the mean of each outcome will contain fixed effects representing the influence of (1) the pretest outcome score, (2) sex, and (3) race/ethnicity. Demographic variables found to be nonequivalent between conditions will be included as covariates in these models. The models will also examine multiple observations over time to examine immediate (posttest) and short-term (3-month follow-up) outcomes. The effect sizes will be calculated by dividing the appropriate contrast parameter by the sample standard deviation of the outcome.

The second set of main analyses involves examining important moderators of program effectiveness. Moderator analyses will examine subpopulations, defined by the categorical variables of location, grade, child's gender, prior child substance use experimentation, and adult substance use. Separate models will examine each individual moderator variable in interaction with treatment condition, controlling for the pretest variable and other covariates. These findings will provide evidence regarding how the effectiveness of the program varies as a function of the aforementioned variables.

The third set of main analyses address the impact of program dosage on the effectiveness of the MDF computer program. Variations in the frequency and amount of core program usage as well as the extent to which extension activities were completed may moderate the magnitude of effects observed on child and parent outcomes. A measure of program dosage will be added to the statistical models described above to determine if

families who used the computer program more often demonstrated better posttest skills and healthier attitudes and behaviors than those who used the computer program less often.

The fourth set of main analyses will evaluate whether the cognitions described in the MIP model mediate the effectiveness of MDF for producing positive outcomes. Mediator analyses will test MIP model components in multiple models to determine if the set of cognitions mediates the effectiveness of the program and will follow the procedures outlined in Bauer, Preacher, and Gil (2006) using a random intercept-only model. Mediation will be examined for both immediate post-test outcomes as well as for the 3-month follow-up outcomes.

Finally, consumer satisfaction with the program will be evaluated. Mean scores for each dimension including comprehensibility, appearance, content, and overall satisfaction will be calculated. Responses to qualitative items will be summarized, and similar patterns of responses will be grouped by content.

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

The OMB expiration date will be displayed on all assessment instruments.

A.18 Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification statement identified in OMB Form 83-I, item 19, "Certification for Paperwork Reduction Act Submissions."