

Supporting Statement B for

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

February, 2015

Name: Augusto Diana, PhD

Address: Prevention Research Branch, Division of Epidemiology, Services &
Prevention Research, NIDA, 6001 Executive Blvd., Room 5163, MSC 9589,
Bethesda, MD 20892-9589

Telephone: 301-443-1942

Fax: 301-443-2636

Email: dianaa@nida.nih.gov

Table of Contents

B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS.....4

B.1 RESPONDENT UNIVERSE AND SAMPLING METHODS..... 4

B.2 PROCEDURES FOR THE COLLECTION OF INFORMATION..... 4

B.3 METHODS TO MAXIMIZE RESPONSE RATES AND DEAL WITH NON-RESPONSE.....6

B.4 TEST OF PROCEDURES OR METHODS TO BE UNDERTAKEN.....7

B.5 INDIVIDUALS CONSULTED ON STATISTICAL ASPECTS AND INDIVIDUALS COLLECTING AND/OR ANALYZING DATA.....7

LIST OF ATTACHMENTS:

- Attachment 13: Recruitment Materials

B.1 Respondent Universe and Sampling Methods

Target Respondents:

The target sample will be a convenience sample of adult-child pairs (one adult and his or her child in 3rd, 4th, or 5th grade) who live in one of six selected rural counties in North Carolina and Texas. Adult-child pairs must meet the following eligibility criteria to participate: (a) include a child in grade 3-5 who lives in the same home as the adult, (b) live in one of the six selected rural counties, (c) speak English fluently, and (d) have a method for using the intervention and control program (access to a computer with CD-ROM drive and internet access). The study will be advertised in diverse community locations and media outlets (see B.2, Recruitment of Non-Probability Sample), and potential respondents will contact the research staff at iRT if they are interested in participating. The convenience sample will be made up of the first 33 adult-child pairs in each study county to be screened as eligible and who agree to sign up.

A total of approximately 400 participants will be recruited to complete the study: 200 adults and 200 children, with these adult-child pairs randomly assigned to either the intervention or control group. Selection of participants will partly be based on insuring balance of child gender across study locations. Approximately equal numbers of male and female child participants will be recruited from each county (i.e., ~16-17 boys and ~16-17 girls from each county). Mothers tend to participate in educational research and school-based events with their children more frequently; therefore, we expect more adult female participants. An effort will be made to recruit participants of racial/ethnic minority groups in the proportions that exist at the community level.

State	County	Geographic Location Type ¹	Estimated Sample (~50% in intervention and ~50% in control group)
Texas	Ellis	outside metropolitan area	33 adult-child pairs
North Carolina	Chatham	outside metropolitan area	33 adult-child pairs
Texas	Navarro	outside micropolitan area	33 adult-child pairs
North Carolina	Moore	outside micropolitan area	33 adult-child pairs
Texas	Hill	no metro/micropolitan area	33 adult-child pairs
North Carolina	Montgomery	no metro/micropolitan area	33 adult-child pairs
Total			200 adult-child pairs

Targeted/Planned Enrollment			
Total Planned Enrollment: 400			
Ethnic Category	Gender		Total
	Females	Males	
Hispanic or Latino	41	27	68
Not Hispanic or Latino	201	131	332
Ethnic Categories Total*	242	158	400
Racial Category	Females	Males	Total
American Indian/Alaska Native	2	0	2
Asian	2	0	2
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	32	21	53
White	206	137	343
Racial Categories Total*	242	158	400

B.2 Procedures for the Collection of Information

Determination of Sample Size:

Based upon a medium effect size (.40), a desired power of .80, and a 4-group design (intervention/control, North Carolina/Texas), a power analysis ($\alpha = .05$) revealed that we will need 162 parent-child pairs to be randomly assigned to the intervention and control groups. With an estimated participation

¹ Using the US Office of Management and Budget definitions, a metropolitan area is one with a core urban area of at least 50,000 residents, and a micropolitan area is one with 10,000 – 50,000 residents.

attrition rate of 20% between pretest and 3-month follow-up (based on several previous RCTs conducted by iRT), it is proposed that recruiting 200 pairs will achieve the required sample size at the 3-month follow-up data collection.

Recruitment of Non-Probability Sample:

Participants will be recruited using paid and unpaid newspaper/magazine advertisements, internet sources (i.e., Facebook advertisement), bulletin board flyers in public and community spaces, and flyer distribution. As shown in Attachment 13, recruitment text for a 115 character-limit Facebook ad will state, “Families needed for study/Participate with your elementary school-aged child and earn up to \$95”. Recruitment text for newspaper/magazine advertisements will state, “Live in XXX County? Have a child in 3rd, 4th, or 5th grade? Earn up to \$95 for participating in a study about family media use and substance use prevention in childhood. Visit our website or call 919-493-7700 and ask for the Family Media Project. www.familymediaproject.com” Recruitment text for flyers will state, “You and your child may be eligible to participate in the Family Media Project, an evaluation of family interaction surrounding the use of a computer program designed for families to use together. Researchers at innovation Research and Training, Inc (iRT) are interested whether using media together as a family can have a positive effect on children’s health and reduce children’s alcohol and tobacco use experimentation.” Text will indicate that any child in the 3rd through 5th grade and one of his or her parents/guardians are eligible to participate, that they will be asked to complete three questionnaires that take about 45 minutes, and that parent-child pairs will be asked to play a computer game together for about 3 hours over a month-long period.

For newspaper/magazine recruitment, we will place advertisements recruiting participants in community newspapers and magazines that are read by local families and church bulletins. For internet-based recruitment, we will place notices on local websites including Facebook, Craigslist, local parenting websites, and local news websites.

We will also place flyers on bulletin boards in public and community spaces, including libraries, community colleges, doctors’ offices, and rural health clinics, as well as local businesses that are frequented by families with children. We will use active flyer distribution as well; engaging elementary schools, parent teacher organizations, YMCAs, Boys and Girls Clubs, and 4-H to either send home our recruitment flyers with their students/members or send the flyer via email to parents of their students/members.

All recruitment methods will direct interested adult participants to call or email a project staff member directly, or to visit a website (See Attachment 13 for screenshots of the website) for more information. The website will allow potential participants to view the informed consent materials (including consent and assent forms). Staff members who are contacted directly will use screening questions, and will offer to email or mail informed consent materials (including consent and assent forms) to potential participants. Potential adult participants will be screened for eligibility on the following inclusion criteria: (a) have a child in grade 3-5 who lives at home, (b) live in one of the six selected rural counties, (c) together with their child, speak English fluently, and (d) have a method for using the intervention and control program (access to a computer with CD-ROM drive and internet access). Eligible adult participants will then be provided a brief explanation of the study. If they indicate willingness to participate, a project staff member will schedule the initial data collection (i.e., pretest).

Data Collection Cycle:

This is a single-time research study in which participants will complete questionnaires three times over a four-month research period: at pretest, 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 program.

Data Collection Procedures:

Data collection will occur at scheduled times with a trained local data collector (contracted and trained by iRT) in a community location that is convenient to participants, such as a library, community college, or community center. Data collection will occur in a private room at each location, selected to be safe and free

from distractions. Overall, the data collection procedures are designed to increase respondents' sense of privacy and their ability to answer the questions honestly.

At the pretest, prior to collecting data, the data collector will obtain: (1) written consent for parent participation, (2) written parent permission for child participation, and (3) written assent for child participation. The data collector will demonstrate how to use the laptops and headphones for questionnaires using ACASI technology, and will then allow participants to complete the questionnaires on separate laptops. The adult participant will remain in the same room as the child participant throughout the data collection. Separate laptops and headphones will be used by the adult and child participants to provide privacy and allow for simultaneous data collection. In addition, seating will be arranged so that the adult participant and child participant do not see each other's laptop screens while answering questions. The trained local data collector will remain in the room with participants to answer questions during data collection and to assist with the technology. Responses will be captured as participants complete the questionnaires and sent over a secure mobile hotspot internet connection to iRT password-protected servers; no data will be saved or stored on the local laptop hard drives. All data captured through ACASI questionnaires and sent over the mobile hotspot internet connection will be identifiable only by unique numbers, not names or email addresses.

After participants complete the pretest questionnaire, they will receive access to their assigned computer program to use at home (including simple installation instructions). The intervention group will have access to the MDF computer program and the control group will have access to a computer game that can be played together as a family but does not teach about media or discuss alcohol, tobacco, or other drugs. All family members are welcome to use the programs; however, the parent and the child who are research participants are asked to always be part of program use. Intervention families will be asked to complete the MDF program together within 30 days (estimated to take about 3 hours). Control families will be asked to play the control computer program together for approximately 3 hours during the 30-day period. Both intervention and control families will be able to use their assigned program in multiple sittings, rather than all at once, if they choose.

Also at the pretest data collection, all participating families will receive a paper-based questionnaire to take home to log the amount of time that they spend playing the assigned computer program. They will be asked to complete the questionnaire and bring it with them to the posttest data collection, which will occur about 30 days after the pretest.

At the end of each data collection appointment local data collectors will prepare to mail signed assent and consent forms to the iRT offices for secure storage. Local data collectors will also communicate with iRT staff to have participants' incentives mailed to them.

There are three additional strategies that may be used to increase the response rate. The first strategy involves partnering with a community organization (e.g., churches, YMCAs) to invite interested families to participate in the research study where trained data collectors will administer questionnaires to parents and children in a group setting. It is proposed that more than one family will complete their ACASI questionnaires at the same time, and most likely, in the same room. However, despite the group setting, participants will still complete the questionnaires as individuals. They will be provided a private space to work in within the larger room, which will afford them confidentiality in completing the questionnaires. In addition, the community organization may offer childcare or activities for the entire family to participate in after the data collection takes place, and this could encourage participation and reduce attrition. The Contractor already pays a fee to rent a safe, community space in the rural counties for data collection, and will now provide an incentive to the partner organization to defray the costs of using the facilities to conduct a larger scale data collection event. The second strategy is allowing project staff to 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. The third strategy is giving parents the opportunity to complete the questionnaire online on their own time before the child. 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. In this case,

participants will be able to return signed consent forms through mail giving family participants more flexibility and allowing for the adult participants to complete their questionnaires at home without having to see a data collector in person.

B.3 Methods to Maximize Response Rates and Deal with Nonresponse

The MDF intervention is a substance use prevention program designed for families living in rural communities. It is intended to be used by children in grades 3 through 5 together with their caregivers. There are three potential sources of nonresponse error in this evaluation study: (1) bias in initial recruitment of study participants, (2) loss-to-follow-up among study participants, and (3) item nonresponse. We have established procedures to reduce the likelihood of each of these. First, the proposed data collection will maximize response rates among the target population of rural families with late elementary school-age children by recruitment through organizations and venues that the target population trusts and frequents (e.g., YMCAs, churches, Boys and Girls Clubs, and 4-H). Second, incentives and the incentive structure will also help to motivate initial participation and retention through the four months of participant involvement. In addition, attrition and loss to follow-up will be minimized through an established protocol for maintaining contact, including regular email or telephone contact with adult participants by trained staff on the research team. This is standard practice in research studies in order to retain participants for the duration of the study. We will also provide flexible scheduling for participants for the three data collection appointments, in order to achieve a diverse sample and reduce attrition. Third, our data collection procedures and use of simultaneous ACASI on separate laptops for the parent and the child were chosen to maximize participants' comfort, efficiency, and feelings of privacy so that they will be willing to answer all of the questionnaire items at each data collection point.

The sample size was calculated based on predetermined effect sizes and estimates of loss to follow-up (see B.2: Determination of Sample Size).

The use of a convenience sample is appropriate because the MDF program, when made commercially available, will target families who are interested and motivated to use a computer program together with their older elementary school aged child(ren).

B.4 Test of Procedures or Methods to be Undertaken

Not applicable.

B.5 Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

The data collection and analysis is part of a SBIR Phase II contract between NIDA and innovation Research and Training, Inc. The research team at iRT for this project includes Tracy Scull, PhD (Principal Investigator), Janis Kupersmidt (Co-Investigator), Tara Weatherholt, PhD (Project Director), Margaret Gichane (Research Assistant), Jennifer Eagan (Texas Data Collection Liaison), and the part-time data collectors located in rural Texas and North Carolina. Data analysis and supervision of data collection will be conducted by Drs. Scull and Erausquin. The research team at iRT will also receive statistical consulting from Antonio Morgan-Lopez, PhD, a Quantitative Psychologist with substantial expertise in quantitative methods for evaluating treatment and prevention programs. Dr. Morgan-Lopez will assist Drs. Scull and Erausquin with conducting analyses on data from the RCT.

Statistical Consultant: Antonio Morgan-Lopez, PhD
Senior Research Quantitative Psychologist, RTI International
amorganlopez@rti.org
(919) 316-3436