Attachment 17

Certification of Instructional Review Board

Modification Cover Sheet

1. IRT-IRB Number: **12-5-2 EFF MOD** Date Submitted: 8/26/2013

2a. ☐ This IRB form does not supersede any previous request.
2b. ☒ This IRB form RELATES to previous application **12-5-1-EFF** approved on **12/14/12**.
2c. ☐ This IRB form SUPERSEDES _____ which was most recently approved on _____

3. Principal Investigator	
Name: Tracy Scull	
Phone: 919-493-7700	**Email: tscull@irtinc.us**
Fax: 919-493-7720	**Affiliation:** innovation Research & Training

4. Project Title/Familiar Name: MDF
5. Grant Name: Web-based Media Literacy Parent Training for Substance Use Prevention in Rural Locations
6. Project Type: ☐ Just-in-Time Proposal ☒ Specific Project
7a. Timing: ☒ **Modification on JIT or Specific Project as needed** ☐ Modification at the time of Annual Renewal
7b. Number of Modification for this Project: __1___ (1 = 1st modification; 2 = 2nd modification, and so on)
8. ☐ Approval required from other institution (e.g., prison, school): ☐ is attached ☐ is pending
Name of institution(s): _____
9. ☐ Indicate grant number and funding agency: **NIDA N44DA-12-5567**
10. Principal Investigator's Recommendation:
☐ FULL Board Review
☒ Expedited Review; Category number __7__ IRB Manual Section VI.B.2
☐ Exempt from further review following initial IRB review; Category number ____ IRB Manual Section VI.A.2

Tracy Scull 8/23/2013 Janis Kupersmidt 8/23/2013
Signed by Principal Investigator Date Signed by IRT President Date

11. **IRB Decision:** (IRB use only)

☐ Modification does not change study status. Study remains **"**Exempt". No further review needed unless there is an additional modification.
☒ **Modification Approved** (does not extend expiration date of most recent approval)
☒ **45 CFR 46.404 applies to the modification—no more than minimal risk to children**
☐ 45 CFR 46.117 (c) (2) applies to the modification—waiver of requirement for documentation of consent through written signature
☐ Not Approved (this decision can only be made by the convened IRB)

Barbara Davis Goldman 8-27-2013 IRT IRB approval of this project EXPIRES **12-13-2013**
Signed by Chair, iRT IRB Modification Approval Date
Barbara Davis Goldman, Ph.D.

12. Investigator Assurance

Each investigator has read the iRT Institutional Review Board Manual and agrees to abide by those standards. Each investigator agrees to report any significant and relevant changes in the procedures and or instruments already approved for this protocol to the Board for additional review. Each investigator further agrees to report any significant participant complaints to the IRB as they occur.

Signature(s) _____ _____
Principal Investigator Co-Investigator

12. Project Staff: All project personnel must complete appropriate Human Subjects Research Ethics Training, as approved by iRT, prior to contact with research participants or access to identifiable data.

List below all project personnel (anyone) who will have contact with research participants or access to identifiable research data from participants.

Following each name, indicate the individual's role within this application (e.g., Principal Investigator, Co-investigator, Project Director, Research Assistant, and so forth) AND telephone numbers and email addresses for the PI, Co-I, Project Director, and anyone else who could help answer any questions about this application.

1. Tracy Scull, PhD (Principal Investigator) – tscull@irtinc.us; 919-493-7700
2. Janis Kupersmidt, PhD (Co-Investigator)-jkupersmidt@irtinc.us; 919-493-770
3. Margaret Gichane (Research Assistant)- mgichane@irtinc.us; 919-493-7700
4. David Kennedy (Web Applications Developer/System Administrator) dkennedy@irtinc.us; 919-493-7700
5. Tara Weatherholt, PhD (Project Director) – tweatherholt@irtinc.us; 919-493-7700
6. Glen Dawson (Research Assistant) – gdawson@irtinc.us; 919-493-7700
7. Richard Van Horn (Web Applications Developer/System Administrator) rvanhorn@irtinc.us; 919-493-7700

13. Potential Conflict of Interest

In reference to the research proposed in this form, will any of the study investigators or staff, or their immediate family members such as a spouse, significant other, dependent children, or parents, HAVE A CONFLICT OF INTEREST? Conflicts of interest could include an intellectual property interest, patent rights, copyright, ownership interest (equity, stock options), and/or personal compensation in the form of salary, consulting fees, honoria, royalties, and gifts THAT COULD POSSIBLY BE VIEWED AS COMPROMISING THE INTEGRITY OF THE RESEARCH.

If the answer is "yes," please include an explanation below, noting the individual(s), the nature of the possible conflict(s), and if relevant, how the conflict(s) has/have been minimized.

☐ No, not for anyone listed above as project personnel

☒ Yes (include explanation as above)

The Co-Investigator, Dr. Kupersmidt, is the owner of iRT and therefore has intellectual property interest in the Media Detective Family computer program (online, Smartphone, and tablet applications). The eventual sale of these products provide financial gain if marketed in any way. Dr. Kupersmidt's primary roles on this project are to oversee product development, to help supervise staff, and to collaborate with the PI on the interpretation of the results. She will not be directly involved in data collection or data analysis independent of her colleagues, so the objectivity of the data collection and results will not be affected by this potential conflict of interest.

The project personnel, including the PI, Tracy Scull, are employees of iRT and receive personal compensation in the form of salary partially based upon this project. Their conflict of interest is minimal, and is further minimized through careful training of data collectors and careful supervision of data collection procedures. The data for in this study will be collected by having participants enter their answers to study questionnaires using a web-based computer application. In addition, program usage data will be automatically captured by the web-based computer program and mobile applications. All data will be archived for analysis. Statistical analyses will be checked by two employees and the results of these analyses will be archived on the server. Both raw data and final statistical analysis will be available for independent review, if requested.

Project Description

(Describe the project by providing a brief summary and answering the requests for information below)

Use as much space as necessary to respond to each prompt. Attach all supporting documents (recruitment scripts; advertisements; consent, parent permission and assent forms; measures (interview questions; questionnaires/surveys, etc.). See the IRT IRB Manual, Section IV for specific instructions and elaborations.

1. **Project Description**

Purpose and Rationale:

The primary purpose of this project is to conduct a randomized controlled trial of the efficacy of Media Detective Family (MDF), a web-based media literacy substance use preventive intervention for use with families and their elementary school children. MDF is designed to:

1) encourage parents and children to work together,
2) encourage critical thinking about media messages in general and media messages about substance use in particular,
3) provide media mediation skills, and
4) overcome barriers to parent participation in prevention programming, especially for parents in rural communities.

The MDF program provides media literacy and media mediation skills to parents and their children, and it is hypothesized that media literate parents will be effective at helping their children to resist the media promotion of alcohol and tobacco products. The overarching goal is to make critical thinking about media messages easily integrated into families' everyday lives so that the media literacy skills practice has further reaching and longer lasting effects.

Procedure:

Data collection: Approximately two hundred parent-child pairs (one parent and their child in 3rd, 4th, or 5th grade) will participate in this study and will be randomly assigned to either the intervention or control group. As described in more detail below, in-person data collection will take place at three time points: pretest, posttest (30 days after pretest), and follow-up (3 months after posttest).

Pretest. Participants in both groups will be asked to meet a data collector at a convenient local data collection site (e.g., YMCA, public library, school) for pretest data collection. The parent and the child will complete separate online questionnaires at the same time, each using a laptop or tablet computer and headphones in an audio computer-assisted self-interview (ACASI) format.

After participants complete the pretest questionnaire, they will receive access to their assigned program to use at home. The intervention group will have access to the MDF 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, we will ask that the parent and the child who agreed to complete the questionnaires—that is, the parent and child who are research participants—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.

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. In addition to logging their program use, intervention group families will have usage data collected as part

of the MDF computer program. [Intervention families will use an email address, username, and password to access the MDF program. The iRT database will have this identifiable information linked to program usage data. iRT project staff will export this information and replace names with ID numbers to link to the pretest/posttest/follow-up data.] The usage data includes times and dates of use, answers to interactive portions of the computer program, and the amount of the total program completed, in addition to IP address and browser.

Posttest. Approximately 30 days after the pretest, participants will again meet with a data collector at the local data collection site to complete the posttest questionnaires using the same procedure as before. Participants will bring their paper logs to complete usage questions in the online posttest questionnaire. After the posttest, participants will be given another paper-based questionnaire to take home to log the amount of time they spend playing the assigned computer program in the time period between the posttest and 3-month follow-up. After the posttest, participants will continue to have access to the assigned program.

Follow-up. Approximately 3 months after the posttest, participants will meet with a data collector at the local data collection site to complete the follow-up questionnaires using the same procedure as before. At this third and final data collection, participants will again bring their paper logs to complete usage questions in the online follow-up questionnaire. After the follow-up, participants will continue to have access to the assigned programs for four months. In addition, control group participants will be offered access to the MDF program for four months.

Unique identification number system: Each local data collector across the two sites (NC and TX) will receive a set of envelopes with unique identification numbers inside. After adults and children have signed the appropriate consent, permission, and assent forms at pretest, the adult participants will choose randomly from the set of envelopes. Both the adult and child participant will use this number in place of their name on the web-based pretest questionnaire. The adult will open the envelope to see the identification number; the ACASI for both adults and children will prompt the adult to enter that number in order to begin the questionnaire. After the number has been entered on, the adult participant will then seal the number in the envelope and write his or her name across the seal and return the envelope to the data collector. The data collector will keep the envelope secure until the pair returns to complete the posttest data collection. At posttest, the sealed envelope will be returned to the adult participant. Once opened, the pair will again use the number in place of their name on the ACASI questionnaire. The data collector will give the adult participant an unused envelope. The adult participant will again seal the number in the envelope and sign their name across the seal. The same procedure will be used for completing the final ACASI questionnaire at the 3-month follow-up data collection. After the final data collection, the number and envelope will be separated and destroyed, thus eliminating the link between the participant's name and number at the local data collection site. Project staff members at the iRT office will be able to match participants' names and identification numbers by using the time stamp from the web-based data collection and will use this information to create a master list linking names and identification numbers that will be kept secure at the iRT office. For intervention group participants, this linking list will be used to match participants' questionnaire data across the three time points with the program usage data captured by the MDF computer program, described above. Using this procedure, the local data collectors will never need to see the participants' unique identification number and the linking list can be kept safely in one location at the iRT office.

Analyses of Quantitative Data:

First, the immediate and short-term efficacy of the MDF program will be evaluated. A series of analyses will be used to examine if using the MDF program impacts the desired outcomes. Child outcome variables of interest may include intentions to use alcohol or tobacco products, interest in alcohol-branded merchandise, media deconstruction skills, and variables related to the Message Interpretation Process (MIP) theoretical model (e.g., realism, similarity). Parent outcome variables of interest may include media deconstruction skills, media literacy knowledge, media mediation behaviors, and amount of skills continuation. The model for the mean of each outcome is planned to 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 are planned to also examine multiple observations over time to examine immediate (posttest) and short-term (3-month follow-up) outcomes.

The second set of main analyses involves examining important moderators of program effectiveness. Moderator analyses may examine subpopulations, defined by the categorical variables of location (Texas, NC), grade, child's gender, and prior child substance use experimentation. 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 is planned to address the impact of program dosage on the effectiveness of the MDF 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 program more often demonstrated better posttest skills and healthier attitudes and behaviors than those who used the program less often.

The fourth set of main analyses is planned to evaluate whether the cognitions described in the MIP model mediate the effectiveness of the MDF program for producing positive outcomes. Mediator analyses will test MIP model components (i.e., similarity, realism, deconstruction) 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 may be examined for both immediate posttest outcomes as well as for the 3-month follow-up outcomes.

Finally, consumer satisfaction with the program will be evaluated. Summary scores for each dimension (e.g., appearance, structure, content, perceived program impact, and overall satisfaction) will be calculated, with higher scores (on scales scored from 1-5 or 1-4, as appropriate) indicating greater satisfaction. Descriptive statistics on each item will be examined. Satisfaction will be concluded if participants report mean scores of 3.0 or above on 80% of the consumer satisfaction questions (CSQ) scales.

Measures

Child outcome variables of interest will include pre and posttest scores on constructs such as intentions to use alcohol or tobacco products, interest in alcohol-branded merchandise, deconstruction skills, and MIP-related variables (e.g., realism, similarity). Parent outcome variables of interest will include pre and posttest scores on constructs such as deconstruction skills, media literacy knowledge, media mediation behaviors, and amount of skills continuation. Consumer satisfaction measures will also be examined for both parents and children.

Parent Questionnaires (Pretest-Posttest-Follow-up) will include measures of participant and family demographic characteristics, family media use, alcohol and tobacco behaviors, media deconstruction skills, media literacy knowledge, media mediation behaviors, parent-child communication about alcohol and tobacco, family participation in the assigned computer program (program dosage), and (for the intervention group) program satisfaction.

Participant and Family Demographic Characteristics: Adult participants will be asked to report on several basic demographic characteristics for themselves and the participating child: age, sex, and race/ethnicity. They will also be asked to describe their relationship to the participating child (response categories are: biological mother/father, adoptive mother/father, stepmother/stepfather, grandmother/grandfather, sister/brother, other relative, foster parent, or parent's partner). Additional items will gather information on education and occupation of the participant (and his or her partner, if living in a two-parent household), annual household income, and who lives in the household (i.e., one or two parents; total number of children under age 18 living in the home; and total number of people supported by the reported annual income).

Family Media Use: Parents will be asked to complete an inventory of media and technology devices available in their homes (e.g., number of TVs, video game consoles, and computers in the home; number of newspapers and magazines received). They will also be asked specifically about media and technology use by the target child (i.e., television in the child's bedroom, computer in the child's bedroom, cell phone use, and use of social networking websites).

Alcohol and Tobacco Behaviors: This section will ask participants about their alcohol and tobacco use and about their readiness to change these behaviors. First, participants will be asked to report how often in the 30 days prior to the questionnaire they drank alcohol, smoked cigarettes, and used smokeless tobacco (3 separate items; possible responses are: "0 days," "1-2 days," "3-5 days," "6-9 days," "10-19 days," "20-29 days," or "all 30 days"). Respondents who reported any use of alcohol or tobacco in the past 30 days are then asked a follow-up question

about how much they typically use per day. Next, readiness to change alcohol use is assessed via the Stages of Change for Alcohol Use short version (Laforge, Maddock, & Rossi, 1998), which asks, "In the last month have you had [5 for males, 4 for females] or more drinks in a row?" Response categories correspond to different "stages" in the Stages of Change theoretical model: 1 (Precontemplation) = "Yes, and I do not intend to stop drinking 5/4 or more drinks in a row," 2 (Contemplation) = "Yes, but I intend to stop drinking 5/4 or more drinks in a row in the next six months," 3 (Preparation) = "Yes, but I intend to stop drinking 5/4 or more drinks in a row during the next 30 days," 4 (Action) = "No, but I have had 5/4 or more drinks in a row in the past 6 months," 5 (Maintenance) = "No, I have not had 5/4 or more drinks in a row in the past 6 months," and 6 (Non-bingers) = "No, I have never had 5/4 or more drinks in a row." Readiness to change smoking behavior is also based on the Stages of Change model, and is assessed through up to three questions (DiClemente, Prochaska, Fairhurst, Velicer, Rossi, & Velasquez, 1991): "Are you currently a smoker?", and for current smokers: "In the last year, how many times have you quit smoking for at least 24 hours?", and "Are you seriously thinking of quitting smoking?" Those who have never smoked are classified as nonsmokers; others are classified as follows: smokers who are not thinking of quitting (Precontemplation); smokers who plan to quit within the next 30 days to 6 months [but no quit attempt] (Contemplation); smokers who plan to quit within the next 30 days and have had a successful quit attempt (Preparation); former smokers who quit within the last 6 months (Action); and former smokers who quit more than 6 months ago (Maintenance). In addition to these items about parent use, the questionnaire includes 4 questions that are used in a scale of home alcohol access (Komro et al., 2007; α=.76). The individual items are: "How often is alcohol present in your home?" (possible responses: "Never," "Occasionally," "Fairly often," "Very often," "Always"); "Do you keep track of the alcohol supply in your home (Yes/No)?"; "Do you keep alcohol locked up (Yes/No)?"; and, "How difficult would it be for your child to obtain alcohol from your home?" (possible responses: "Very difficult," "Difficult," "Neutral," "Easy," "Very easy," and "There is no alcohol in my home.").

Media Deconstruction Skills: In an open-ended section, participants will be shown two advertisements--one for alcohol and one for tobacco—with the initial prompt: "Tell me about the ad (the more detail the better)." Subsequent items ask, "What are some possible messages that the advertisers want the the viewer to think after looking at [the ad]?", "How can you tell?", and "What type of person might be interested in [the ad]?" The open-ended responses are qualitatively coded (e.g., product, target audience, implied message, etc.) to form a composite deconstruction variable with high reliability (Scull & Kupersmidt, 2010, α = .94).

Media Literacy Knowledge: Participants will be asked factual, close-ended questions to assess their knowledge of media literacy concepts. Example questions include: (1) There are many types of media. Which of the following best shows an example of a medium? (2) Why might it be important for children to learn about who pays for TV shows and why? (3) Fill in the blank to define 'target audience.' The target audience is the people the advertisement is meant to _____(4) What do you think best describes 'hidden messages' in advertising, and (5) Which of the following steps are involved in the production of a counter-ad for alcohol and tobacco?

Media Mediation Behaviors: This section will assess of parents' use of evaluative and restrictive media mediation. Components include: Television mediation scale (Valkenburg et a., 1999) consisting of 5 items that measure parents' evaluative mediation of TV (e.g., "How often do you explain what something on TV really means?", r=.92) and 5 items that measure parents' restrictive mediation of TV ("How often do you say to your child to turn off the TV when s/he is watching an unsuitable program?", r=.87). Video game mediation scale is adapted from the television scale for evaluative (r=.87) and restrictive (r=.81) mediation of video games. Internet mediation scale is also adapted from the television scale for evaluative (r=.93) and restrictive (r=.77) mediation of Internet usage. We also developed four additional measures assessing other types of media restriction, such as using alternative methods of watching TV and/or controlling the content available on specific devices. Items include: "How often do you use an alternative means of watching TV (e.g., DVDs, DVRs, or services like Netflix or Hulu) to limit your child's exposure to commercials?", and "Do you put any controls on the televisions /computers/video game consoles in your home to ensure that your child is not watching any inappropriate content?"

Parent-Child Communication about Alcohol and Tobacco: This section will assess the frequency and types of communication between parents and children about substance use. The alcohol items are adapted from Miller-Day and Kam's Targeted Parent-Child Communication about Alcohol (TPCCA) scale (Miller-Day & Kam, 2010). Parents are asked to indicate the frequency with which they have engaged in several different types of communication about alcohol; responses are on a 4 point response scale (0 = "Never," 1 = "Once," 2 = "A few times," 3 = "A lot of times"). Items include: "[How much have you…] …Lectured or given your child a speech about drinking alcohol?" "…Warned your child about the dangers of drinking alcohol?" "…Given your child rules to obey about drinking alcohol?" and "…Asked for your child's thoughts and opinions about drinking alcohol?" To assess

communication about tobacco products, we created a parallel scale about tobacco. This adapted scale uses the same instructions, response categories, and items, with references to alcohol replaced with tobacco, as appropriate.

Family Participation (Program Dosage): This section will only appear on the posttest and follow-up questionnaires. Both intervention and control group participants will be asked to enter the information from their Program Usage Logs (see Appendix) into the ACASI questionnaires. Participants who did not bring their Program Usage Logs will be given the opportunity to recall or estimate their program use: "In the past [month/3 months], do you remember how often you used [the assigned computer program]?" Response options are: "Never. We didn't use the program during the past [month/3 months];" "We used the computer program, and I am able to remember the number of times we played it;" and, "We used the computer program, and I can estimate the number of times we used it by selecting from a range of choices." Respondents who selected the second choice are asked to fill in the number of times they used the program. Respondents who selected the final choice are asked to select the appropriate category of use: "Never," "Once", "2-3 times," "4-7 times," "8-10 times," or, "More than 10 times." Next, all respondents without a Program Usage Log are asked: (1) to indicate the amount of time they typically spent on the program when they used it (5 response categories in 15 minute increments, ranging from "Less than 15 minutes" to "More than 1 hour"); and (2) to indicate who used the computer program together at least once (respondent, study child, the other parent, the respondent's boyfriend or girlfriend, the child's grandparent, the child's aunt/uncle, the child's sibling, the child's friends, and/or someone else. Greater frequency, greater time per session, and more family members involved in the computer program will indicate greater family participation.

Program Satisfaction: This section will only appear on the posttest and follow-up questionnaires for the intervention group. This section will include questions regarding the comprehensibility of, appearance of, content of, and consumer satisfaction with the program.

> Perceived program impact on readiness for action: Parent participants rate their readiness in several areas, as compared to before participating in Media Detective Family. Responses are on a 5 point scale (1 = "Much less," 2 = "Less," 3 = "About the same," 4 = "More," and 5 = "Much more."). Items include talking with the child about media messages, assessing the realism of advertising, monitoring the child's media exposure, and helping the child understand the purpose of advertising.
>
> In the following two categories of program satisfaction, parent participants rate each item on a 5 pt. Likert scale (1 = "Strongly Disagree," 2 = "Disagree," 3 = "Undecided," 4 = "Agree," and 5 = "Strongly Agree"). Higher ratings indicate more positive feelings toward the program. Parents are asked to evaluate the following aspects of Media Detective Family (computer program and extension activities):
>
> Appearance/Structure: 1) Ease of use 2) Convenience 3) Thoroughness. 4) Amount of content 5) Quality of media
> Content: 1) Topic appropriateness 2) Appeal 3) Motivational/inspiring to parents
>
> Overall experience/Benefits: Parents will rate their overall experience with the course on a 4 point scale (1 = "Not at all satisfied," 2 = "Somewhat unsatisfied", 3 = "Satisfied", and 4 = "Very satisfied"). In addition, participants are asked to choose items that are true for them from a list of possible benefits of Media Detective Family. The list includes: time saving, no travel, convenience, start and stop when needed, engaged this child, engaged other members of the family, answered my questions, answered this child's questions, provided information I didn't know I needed, gave our family time to reflect, gave me confidence in talking about substance use with this child, extension activities helped to guide conversations, and was a fun activity to do as a family.

Student Questionnaires (Pretest-Posttest-Follow-up) will include measures of demographic and school achievement characteristics, parent-child communication, media literacy skills and knowledge, health outcomes (including substance use behaviors), mediators of health outcomes, family participation in the assigned computer program (program dosage), and (for the intervention group) program satisfaction.

Participant Demographic and School Achievement Characteristics: Child participants will be asked to report on two basic demographic characteristics: age (7, 8, 9, 10, 11, or 12 years old) and grade in school (3rd, 4th, or 5th grade). In addition, they will be asked about their grades received: "What grades did you get on your last report card?", with the following response categories: "Mostly As," "Mostly Bs," "Mostly Cs," "Mostly Ds," and, "Mostly Fs."

Parent-Child Communication: This section will assess the frequency and types of communication between parents and children from the child's perspective. For communication about alcohol, we have adapted items from Miller-Day and Kam's Targeted Parent-Child Communication about Alcohol (TPCCA) scale (Miller-Day & Kam, 2010). Children are asked to indicate the frequency with which the study parent has engaged in several different types of communication about alcohol; responses are on a 4 point response scale (0 = "Never," 1 = "Once," 2 = "A few times," 3 = "A lot of times"). Sample items include: "[How much has the parent who is with you today…]... Lectured me or given me a speech about drinking alcohol?" "…Warned me about the dangers of drinking alcohol?" "…Given me rules to obey about drinking alcohol?" and "…Asked for my thoughts and opinions about drinking alcohol?" To assess communication about tobacco products, we created a parallel scale about tobacco. This adapted scale uses the same instructions, response categories, and items, with references to alcohol replaced with tobacco, as appropriate. In addition to the scales for alcohol and tobacco-related communication, we include a three-item scale to measure general parent-child communication (Miller-Day & Kam, 2010; α=.82). Using a 5 point Likert scale (1 = "Strongly Disagree," 2 = "Disagree," 3 = "Neither agree nor disagree," 4 = "Agree," and 5 = "Strongly Agree"), children rate their agreement on the following: "The parent with me today listens to my point of view," "The parent with me today says it's important to get my ideas across even if others don't like it," and, "The parent with me today asks for my opinion when our family is discussing something."

Media Deconstruction Skills: In an open-ended section of the questionnaire, participants will be shown two advertisement mock-ups--one for alcohol and one for tobacco—and asked six questions about the ad: "What is being sold in this ad?", "What type of person do you think would like this ad (male or female, kid or adult)?", "What is the purpose of this ad?", "What did the people who made this ad do to make people stop and look at this ad?", "What do they want you to think about this product? Finish this sentence: If I get this product, then…" and "Is there anything this ad in not telling you about the product that you would need to know before buying or using it?" The open-ended responses are qualitatively coded (e.g., product, target audience, implied message, etc.) to form a composite deconstruction variable with high reliability (Kupersmidt, Scull, & Austin, 2010, α = .95).

Health Outcomes: Substance use [alcohol, tobacco, and energy drinks]: This section will ask participants about current and lifetime use of three types of substances: alcohol, tobacco, and energy drinks, using items adapted from Monitoring the Future. First, participants will be asked to report how often in the 30 days prior to the questionnaire they drank alcohol, smoked cigarettes, used smokeless tobacco, or drank an energy drink (4 separate items; possible responses are: "0 days," "1-2 days," "3-5 days," "6-9 days," "10-19 days," "20-29 days," or "all 30 days"). Respondents who reported any use of these substances in the past 30 days are then asked a follow-up question about how much they typically use per day. Then, all participants are asked if in their lifetime they have ever used alcohol, cigarettes, smokeless tobacco, or energy drinks (4 separate items; yes/no responses). Intentions to Use Alcohol and Tobacco: Eight items ask about plans to use alcohol (including beer, wine and hard liquor) and tobacco (including cigarettes and smokeless tobacco products), both before reaching the legal age and in the next year (Kupersmidt, Scull, & Austin, 2010; α= .85). Such intentions are significantly positively correlated with current substance use (Scull et al., 2010). Willingness to use alcohol and tobacco: Seven items ask about how willing participants are to try alcohol or tobacco in particular peer-group situations, based on Andrews et al. (2008; α=.86). Responses are on a 4 point scale from 1 = "Not at all willing" to 4 = "Very willing." For example, the alcohol items ask: "Suppose you were with a group of kids and there was alcohol you could have if you wanted. How willing would you be to do the following things?... Take a sip?", "Drink the whole drink?", and "Take some alcohol home to try later?" Measures of willingness for substance use are derived from social– cognitive theory and have been shown in several studies to predict substance use at later ages (e.g., Gerrard et al., 2008; Gibbons et al., 2003). Expectancies: Twelve items measure students' perceptions about either the positive or negative consequences of alcohol and tobacco use. Social Norms: We assess subjective and injunctive norms related to the child's parent and the child's peers, using a total of 12 items adapted from prior research (Hampson, Andrews, Barckley, & Severson, 2006; Elek, Miller-Day, & Hecht, 2006; α =.70-.80). Subjective norms for alcohol use and smoking are positively associated with intentions to use those substances. Peer and parental injunctive norms have been associated with recent substance use, lifetime substance use, and substance use intentions (Elek, Miller-Day, & Hecht, 2006).. A typical subjective norm item asks, "How many of the kids at school or in the neighborhood have tried a drink of alcohol (beer, wine, or hard liquor)?" with response categories of "None," "Some," "Most," or "All." A typical injunctive norm item asks, "How would your best friend act toward you if you… drank alcohol?" with response categories on a 4 point scale ranging from 1 = "Very unfriendly" to 4 = "Very friendly."Self-efficacy (Kupersmidt, Scull, & Austin, 2010; α = .78): Five items assess children's self-efficacy and feelings of personal control around drinking and smoking behaviors. These items were adapted from previous studies, which found self-efficacy to be an outcome of media literacy education and a predictor of substance use (e.g., Pinkleton, Austin, Cohen, Chen, & Fitzgerald, in press).

Moderators of Health Outcomes: Demographic information on the children will be collected and used in the moderator analyses including: location (TX, NC); grade (3, 4, or 5); gender (boy, girl), and current use of alcohol and tobacco (four items ask about alcohol and tobacco use within the past 30 days - adapted from Monitoring the Future measures).

Mediators of Health Outcomes: These measures stem from the Message Interpretation Process (MIP) Model (see Figure 1), the theoretical framework underlying the MDF program and have been used across previous evaluations of media literacy education programming (e.g., Kupersmidt, Scull, & Austin, 2010; Kupersmidt, Scull, & Benson, 2012). Perceived Realism: Six items ask students about the degree to which media portrayals are similar to real-life people and events (α = .93). Perceived Similarity: Four items ask students about whether media portrayals are similar to their *personal* experiences (α = .88). Identification: Six items measure the degree to which students *want* to be similar to the people portrayed in advertisements (α = .94). Desirability: Six items assess students' perceptions about the attractiveness of people and things seen in media portrayals (α = .94). Understanding of the Persuasive Intent of Advertising: Three items ask students about how often they believe the goal of advertising is to persuade people to buy a product rather than for altruistic reasons (α = .72).

Family Participation (Program Dosage): This section will only appear on the posttest and follow-up questionnaires for the intervention group. Children in the intervention group will be asked, "Did you use Media Detective Family with just the parent who is with you today, or with other people, too? Mark all the people who did Media Detective Family with you." Response options are: "This parent," "My other parent," "My parent's boyfriend or girlfriend," "My grandparent," "My aunt or uncle," "My brother or sister," "My friends," and "Someone else." Greater variety of friends and family involved will indicate greater participation. In addition to these measures that use child reports, we will use the time spent using the MDF program, the number of modules in the core MDF program that the families complete, and the number of extension activities that were completed (all information gathered through the MDF computer program) to measure program dosage. Control group participants will report the amount of time that was spent using the control computer program.

Program Satisfaction: This section will only appear on the posttest and follow-up questionnaires for the intervention group. First, child participants rate each item on a 4 point scale: 1 = "Not at all," 2 = "A little", 3 = "Very much," and 4 = "Yes, a lot.". Higher ratings indicate more positive feelings toward the program. The items are: "Did you learn anything new in this program?" "Were the cases interesting?" "Are you glad you learned the material included in the program?" "Would you tell your friends to try the program?" and, "Did you like the extension activities—the activities where you are your parent took what you learned and investigated advertising that you see?" In addition to these close-ended questions, there are two open-ended questions for program satisfaction: "What did you like best about Media Detective Family?" and, "What did you like least about Media Detective Family?"

2. Participants

Approximately two hundred parent-child pairs (one parent and their child in 3rd, 4th, or 5th grade) will participate in this study. For two-parent (or guardian) households, both parents will be invited to use the program with their child, but families will choose which parent will complete the questionnaires for the research study.

We will sample participants from the two states with the largest rural populations (Texas and North Carolina) in the United States. Half of the participant pairs (n= 100) will be recruited in each of two states. In order to increase the likelihood of a diverse sample, participants will be recruited across three counties in each state. Approximately equal numbers of male and female child participants will participate from each state and will be randomly assigned to either the intervention or control group.

Inclusion/Exclusion Criteria:

To be eligible to participate in the study, adult participants must: (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 (computer with CD-ROM drive and internet access).

Recruitment:

Recruitment procedures that have been used successfully in the past will be followed in this project. We will recruit via paid or unpaid print advertisements, internet sources, bulletin board flyers in public and community

spaces, and flyer distribution. As shown in the Appendix, example recruitment text will state, "Researchers at innovation Research & Training, Inc. (iRT) are interested in studying how 3rd- 5th graders and their caregivers use media together and we need your help! 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." 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 print recruitment, we will place advertisements recruiting participants in community newspapers and magazines that are read by local families (e.g., Dallas - Fort Worth Child, North Texas Kids, Carolina Parent) and church bulletins. For internet-based recruitment, we will place notices on local websites including 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 (e.g., http://www.familymediaproject.com) for more information. The website will allow potential participants to submit their contact information and answer screening questions, as well as to view and print the informed consent materials (including consent and assent forms). Staff members who are contacted directly will use the same screening questions, and will offer to email, mail or fax the 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 (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). At the pretest, prior to collecting data, the data collector will obtain signatures for: (1) written consent for parent participation, (2) written parent permission for child participation, and (3) written assent for child participation.

Incentives:

Families will receive a $20 incentive for completing the pretest; a $5 incentive for completing the assigned computer program; a $30 incentive for completing the posttest; and a $40 incentive for completing the 3-month follow-up (possible total of $95). Families will also be reimbursed for mileage to and from the data collection site.

3. Risks

A potential risk is the possibility that participants' identities will be matched to their data. However, specific measures will be taken to provide privacy to all participants. This is deemed a minor risk.

4. Describe steps to minimize risk (if 3. Is answered 'yes').

Privacy will be assured for all participants. All project staff members will be trained in ethical research procedures, as evidenced by completion of NIH-developed general ethics training, as well as Health Insurance Portability and Accountability Act (HIPAA) privacy rules training. In addition, project staff members are required to complete the NIH Computer Security Awareness Training Course before performing any work on this study.

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. 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, thus rendering the dataset anonymous.

With regard to the program usage data that are automatically collected as part of the MDF computer program, iRT will have a password-protected digital file containing program usage data. The digital file contains the same information that is gathered automatically by other online training programs housed by iRT: usernames, email addresses, times and dates of use, answers to interactive portions of the computer program, the amount of the total program completed, IP addresses and browsers. These data are collected for all participants who use the online, tablet, or Smartphone applications of MDF, and are collected for the duration of program use [not limited to the study period]. Only the iRT Web Applications Developer/System Administrator or other designated IT staff will have access to the program usage file that contains identifying information. Using the hard-copy linking list, names will be replaced with the appropriate unique identification numbers. Only this de-identified file will be used for data analysis purposes.

All electronic data relevant to this project will be stored on the iRT server. A password is needed to access the iRT server and only iRT employees have passwords. Access to the project folder is restricted to project staff members working on this project within the iRT company. Employee passwords must be changed every 90 days, and access accounts for terminated employees are disabled immediately upon separation. The server is connected to an uninterruptable power supply to prevent loss due to power outage or surge and backups are performed at the end of each night. The backup tapes are encrypted and password protected. There are no direct outside connections to the server.

All participants will also be instructed that they may choose to not answer any question for any reason, that they may quit their participation at any time, and will be notified that their responses will remain private. All de-identified data will be hosted offsite on a shared hosting service, and all applications will require employee usernames and passwords. Access to the host folders will be restricted only to designated employees, and direct access to the data will be restricted to the website administrator.

5. **Are illegal activities involved?**

There are no illegal activities involved.

6. **Is deception involved?**

There is deception involved, as we tell all participants that the Family Media Project is an evaluation of family interaction surrounding the use of a computer program designed for families to use together. Families only see the computer program that is randomly assigned to them. Our specific interest in evaluating the efficacy of the Media Detective Family media literacy education intervention will be withheld until the parent-child pair completes the study so that we can be sure that any changes we might find in parent or child attitudes, skills, or behaviors were not simply due to the families spending time using a computer program. All parent-child pairs will be debriefed after the completion of the study [see Debriefing Statement in Appendix], and control group families will be offered access to the Media Detective Family computer program free of charge for three months at that point. There are no potential risks to the participants regarding the deception in this study.

7. **What are the anticipated benefits to participants and/or society?**

Through receiving media literacy training by using the *MDF* program, parents and children may increase their awareness of the negative effects of alcohol and tobacco media portrayals and perhaps make children less vulnerable to media persuasion. Parent and children may improve in their critical thinking skills and may develop better family communication skills. The feedback received from child and parent participants will also contribute to a program that has the potential to be a great benefit to many children of late elementary school age and their parents. Thus, the benefits of participation in this study clearly outweigh the minor risks incurred by participants. In addition to the broader benefits of involvement outlined above, participants will receive an incentive for their time completing different phases of the study.

8. **How will prior consent be obtained?**

Adult participants will be asked to endorse a consent form that outlines the objectives of the study, describes the measures and procedures included for involvement as a participant in the project, and the absence of known risks and the potential benefits to be gained from the research. Parental permission and child assent will also be obtained prior to a child's participation. The assent forms will describe the goals of the study as well as the minor potential risks and the benefits of the child's participation. The assent forms will be read aloud to children. Participants will be encouraged to ask questions prior to participation and will be given contact information for program staff members so they can ask questions after their participation has been completed. Participants will be instructed that they can skip any question for any reason and they may terminate participation at any time.

9. **Confidentiality:**

Privacy will be assured to all participants and the consent/permission/assent forms will be stored in a separate location at the iRT office apart from the data. When completing study questionnaires, respondents will use a unique secret number in place of their names (i.e., de-identified). Although automatically-collected program usage data do contain identifying information, all identifiers will be replaced by a unique identification number prior to data analysis. Further, no personal information will be disclosed during the analyses of data, nor will personal information be included in any written reports stemming from the analyses.

Treatment of Files:

After the questionnaire data is collected at the 3-month follow-up and checked for errors, the document linking participants' unique identification number to their names will be destroyed. At that point, no one will ever be able to match participants' names with their responses and no one other than project staff members trained in ethical research will have access to the data. All electronic data relevant to this project will be stored on the iRT server will require a password available only to project staff members. Employee passwords must be changed every 90 days, and accounts for terminated employees are disabled immediately upon separation. The server is connected to an uninterruptable power supply to prevent loss due to power outage or surge and backups are performed at the end of each night. The backup tapes are encrypted and password protected. There are no direct outside connections to the server. All participants will also be instructed that they may choose to not answer any question for any reason, that they may quit their participation at any time, and will be notified that their responses will remain private.

10. Does your study require waiver of signature?

No. Parents will sign consent forms for their own participation and permission forms for their child's participation. Children will sign assent forms.

Appendices

- Appendix A: Recruitment text
- Appendix B: Parent Permission and Consent Form
- Appendix C: Child Assent Form
- Appendix E: Parent Pretest/Posttest/Follow-up
- Appendix F: Child Pretest/Posttest/Follow-up
- Appendix G: Program Usage Log