

The following is a list of concerns and how they have been addressed in the resubmission to OMB. The changes to the documents have been marked in red.

1. Missing Attachment 7 (Recruitment materials)
  - a. We have included "Attachment 13: Recruitment Materials" which contains the text for Facebook/newspapers/magazines print ads. In addition, the finalized flyer designs for Texas and North Carolina, as well as screenshots of the study recruitment website are included in this attachment.
2. Missing IRB protocol
  - a. The entire approved submission to IRB has been included. Note that the IRB is a modification to address the revisions based on OMB and NIDA review.
3. Missing PIA:
  - a. The NIH PIA Officer determined that a PIA is not necessary.
4. Missing Questionnaire screen shots
  - a. Files that include screenshots of all 12 questionnaires have been created. These are Attachments 1 through 12.
5. Language regarding purpose of the study in the consent form and recruitment documents.
  - a. The language regarding purpose of the study has been edited in the parent consent form to make it clearer that the project concerns substance use prevention. It has been moved to the first paragraph, which now states "In this study, we are specifically interested in whether using media together as a family can have a positive effect on children's health and reduce children's substance use experimentation."
  - b. The language regarding purpose of the study has been edited in the child assent form to highlight that children will be asked questions about alcohol and tobacco use.
  - c. Language has been changed for recruitment of families. Flyers now include "Researchers at innovation Research & 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".
6. Have questions been tested for this age level?
  - a. Yes, the questions used have been shown to be reliable and valid for the age group of children in this study. The IRB protocol included in Attachment 17 outlines clearly the psychometric properties of the measures, including references.
7. Please explain the inclusion of brand names in the study questionnaires. Would mock-up pictures with no brand names suffice?
  - a. This measure, which assesses interest in alcohol-branded merchandise (e.g., towels, glasses, T-shirts, toys), is commonly used as a pre-drinking intention measure in research on substance use prevention in childhood and early adolescence ( $\alpha = .85$ : Kupersmidt, Scull, & Austin, 2010; Austin & Johnson, 1997a, 1997b; and Austin & Knaus, 2000). Elementary school students are unlikely to report alcohol use behaviors or behavioral intent. This pre-drinking measure allows us to capture important information about children's risk for later alcohol use. Ownership of such items correlates with the initiation of adolescent drinking (McClure, Dal Cin, Gibson, &

Sargent, 2006) and risky behavior (Austin & Knaus, 2000). Unfortunately, eliminating the brand names would invalidate this measure because the measure depends on the child's recall of and preferences for soda brands versus alcohol brands. However, we have decided to cut this measure from the study. The respective questions have been deleted from the child questionnaires.

- b. In the original OMB submission, the questionnaires included two real advertisements that the participants were asked to describe in several questions. We have eliminated the real advertisements and replaced them with advertisement mock-ups (with made-up brand names) that were hand-drawn by a graphic designer at iRT.
8. Please provide insight regarding the requested expiration date (9/30/2015).
    - a. We have changed the expiration date to reflect a 12-month period. It is now 9/13/2014.