



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
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DIVISION OF EPIDEMIOLOGY, SERVICES AND PREVENTION RESEARCH

National Institute on Drug Abuse
6001 Executive Boulevard
Room 5153, MSC 9589
Bethesda, Maryland 20892-9589
(301) 443-6504

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TO: Office of Management and Budget (OMB)

Through: Keith Tucker, Report Clearance Officer, HHS
Seleda Perryman, Chief, Project Clearance Branch, NIH
Genevieve deAlmeida-Morris, PRA OMB Project Clearance Liaison, OSPC,
NIDA

From: Belinda E. Sims, Ph.D., COR, N44DA12-5567

SUBJ: Change Request for OMB 0925-0685 Expiration 11/30/2015

This is a change request in the data collection protocol for OMB 0925-0685 (Expiration 11/30/15) – *Web-based Media Literacy Parent Training for Substance Use Prevention in Rural Locations* (N44DA12-5567). This study is seeking approval for additional strategies to increase recruitment and enrollment into the study in order to meet their projected total of 200 families. The study is scheduled to end March 31, 2015. Data collection for this study is on-going, however participant enrollment has slowed down, and the sample size is considerably under the projected total of 200 families needed. Families are not responding to intensive recruitment efforts, and attrition rates are higher than expected for families currently enrolled and who have participated in a pre-test and/or some post-test assessments. The project now proposes to offer the option for adults and children to complete consent and questionnaires in the home or in a group setting at a community organization. In addition, adult participants will be offered the opportunity to complete the questionnaires online at their convenience without a data collector present. The following strategies are described below, and attempt to counter the main barriers to participation by rural families. The revised Supporting Statement A (SSA) and Supporting Statement B (SSB) are included with this request, and the additions are highlighted in yellow.

1. Administer questionnaires in a group setting (as an additional strategy to the original plan for adult and child to complete the questionnaires as an individual family pair – see SS-B.2): Currently, one family pair will meet project staff at a location in the community for administering of questionnaires, one pair at a time. This study will now partner 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.

2. Administer questionnaires in families' homes (see SS-A.3; SS-B.2): Currently, enrolled families meet project staff at a location in the community for administering of questionnaires, requiring families to make time for travel and possibly child care for siblings. With the change, project staff could 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.
3. Allow parents to complete questionnaires on own time – (instead of requiring the parent to be present at the child questionnaire – see SS-A.3; SS-B.2): Currently, a project data collector meets with the enrolled parent and child together in-person to administer questionnaires at a location in the community. With the change, parents would be given 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, consent forms can be signed at the participants' home and mailed back to the iRT office – (as an additional option to signing and returning consent forms to a data collector in person) (see SS-A.3; SS-A.11; SS-B.2). 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.

In conclusion, these changes to the data collection protocol will help to recruit the proposed sample size of 200 families and help to increase the likelihood that families participate in all three data collection time points. These additional strategies will not increase burden.

We look forward to receiving your response to this change request. In the meantime, please feel free to contact me, if you have any questions about this request.