Supporting Statement A

for

Testing Act Early Messages and Materials for "Learn the Signs. Act Early" – Phase II

New

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A. Justification

A.1. Circumstances Making the Collection of Information Necessary

This Information Collection Request is submitted under the classification "new" request. The length of data collection requested for OMB-PRA approval is one year. The National Center on Birth Defects and Developmental Disabilities (NCBDDD) is making this request as authorized by the Public Health Service Act, Title 42 United States Code—The Public Health and Welfare, Chapter 6A—Public Health Service, Subchapter II—General Powers and Duties, Part A—Research and Investigations (see *Public Health Service Act, 42 USC Sec. 241* **Attachment 1**).

Background

Developmental milestones are used to track growth and development in children. Various milestones correspond to specific stages in a child's growth and development (e.g. crawling, walking, smiling, and waving "bye-bye"). Not all children develop at the same pace; however, these developmental milestones serve as a guide in monitoring children as they grow.[1] According to the Centers for Disease Control and Prevention (CDC), approximately one in six children in the United States have developmental-behavioral disabilities such as autism, intellectual disability, or attention-deficit/hyperactivity disorder.[1] Despite the fact that most of these children will show mild developmental delays (i.e., failing to reach some of the milestones associated with their stage of development) by the age of two, less than half of these children will be identified before they start school.[2, 3, 4] Missing this window of opportunity for diagnosing developmental delays in children creates a serious public health problem. The late identification of developmental delays can lead to increased costs for future interventions and can be detrimental to the child's ability to learn.[5]

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[1] Centers for Disease Control and Prevention (2012a). Facts about Developmental Disabilities. Available at http://www.cdc.gov/ncbddd/developmentaldisabilities/facts.html

[2] Mackrides, P and Ryherd, S., (2011). Screening for Developmental Delay. American Family Physician. 2011 Sep 1;84(5):544-549. Available at http://www.aafp.org/afp/2011/0901/p544.html#afp20110901p544-b12.

[3] Glascoe, F.P. (2005). Screening for developmental and behavioral problems. Mental Retardation and Developmental Disabilities Research Review. 11(3): 173–179.

[4] Brothers, K.B., Glascoe , F.P., Robertshaw, N.S. (2008). PEDS: developmental milestones—an accurate brief tool for surveillance and screening. Clinical Pediatrics (Phila). 47(3): 271–279.

[5] Centers for Disease Control and Prevention (2012b). Data and Statistics. Available at http://www.cdc.gov/NCBDDD/autism/data.html

Many developmental delays and disabilities can be identified early if parents take an active role in monitoring their child's development. Developmental monitoring is accomplished through a very delicate and successful partnership between parent and health care professional. Research has shown that parents can serve as reliable sources of information when it comes to monitoring and reporting on their child's development. Several studies have found that parents' concerns about their child's development are generally valid and predictive of developmental delays.[6, 7, 8] These studies suggest that efforts can and should be made to encourage parents to take action if they suspect that their child could be showing signs of a developmental delay. Health care professionals are experts in assessing child growth and development in general and are often considered the most trusted messengers of health-related information; parents, however, are experts about their individual child. When these two expert perspectives come together, we can feel confident that the development of our children is being monitored to its full potential.

The CDC initiated the "Learn the Signs. Act Early." (LTSAE) campaign in 2004 in an effort to improve the likelihood that children with developmental disabilities are identified and connected with appropriate services at the earliest age possible. To this end, the campaign's overall goal has been to empower parents to "Act Early" if they have concerns about their child's development. Children from families insured by Medicaid and those from families with low incomes are at higher risk for developmental delays and disabilities,[9] and thus are the target audience for the campaign.

In collaboration with our contractor, Westat, we will conduct a two part evaluation to assess information needs, as well as relevance and comprehension of "Act Early" messages and materials among parents. Data collection for the first phase of this research study was approved by the Office of Management and Budget on March 28, 2014 (OMB # 0920-0919, expiration 01/31/2015). During the

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[6] Squires J, Nickel R, Eisert D. 1996. Early detection of developmental problems: strategies for monitoring young children in the practice setting. *Journal of Developmental and Behavioral Pediatrics.* 17. 420-427.

[7] Glascoe, F.P., (1997). Parents' concerns about children's development: Prescreening technique or screening test. Pediatrics 1997; 99: 522-528.

[8] Glascoe, F.P., (2003). Parents' Evaluation of Developmental Status: how well do parents' concerns identify children with behavioral and emotional problems? Clinical Pediatrics 2003;42:133-138.

[9] Boyle, C.A., Boulet, S., Schieve, L., Cohen, R.A., Blumberg, S.J., Yeargin-Allsopp, M., Visser, S., and Kogan, M.D. (2011). Trends in the prevalence of developmental disabilities in U.S. children, 1997–2008. *Pediatrics.* Available at htttp://pediatrics.aappublications.org/content/early/2011/05/19/peds.2010-2989.full.pdf+html

first phase, the Westat team worked to recruit from 6 primary care practices serving young children (3 in the Baltimore, Maryland (MD)/Washington, DC metropolitan area and 3 in the Atlanta, Georgia (GA) metropolitan area), who assisted us in the recruitment of parents/guardians for focus groups. The first phase of research was exploratory, examining what it means to parents/guardians to act early on a concern about development. We also gathered parents/guardians' feedback on "act early" messages; that is, messages that encourage parents/guardians to take action and not wait if they have a concern about their child's development. We hope to translate our findings into improvements and refinements to the existing campaign messages and materials, which will be tested further in the second phase.

Our evaluation plans for the second phase, the study described in this information collection request, seeks to assess the impact of "Act Early" messages embedded within LTSAE campaign materials. To achieve this goal, we will test revised draft messages and materials with low-income parents through focus groups. Parents will again be recruited from each of the same six clinics. Finally, intercept interview surveys with parents in clinic waiting rooms will serve as a final "gut check" of revised draft messages and materials based on any improvements made after the parent focus groups.

The study seeks to gather feedback on "Act Early" messages and materials from parents/guardians of children age 5 or younger attending the selected six primary care practices recruited for this study. Specifically, the focus groups will gather detailed information about 1) message comprehension, acceptability, and relevance; and 2) overall appeal of all design elements included in the materials, including photos, colors, print size, etc. The intercept interviews will be used to assess the potential impact or influence of the materials on parents' behavioral intentions regarding "acting early" to address concerns with their child's development. Thus, we will gather parents' feedback pre- and post-exposure to draft LTSAE materials. We are requesting approval for a data collection involving focus groups with parents and intercept interviews with parents to gather more in-depth feedback on "Act Early" messages and materials appeal.

1.1. Privacy Impact Assessment

I. Overview of the Data Collection System

The data collection involves 1) focus groups with parents/guardians of children age 5 or younger recruited from six primary care practices (3 in the Atlanta, GA metropolitan area and 3 in Baltimore, MD/Washington, DC metropolitan area) selected to participate in the study, and 2) an intercept interview administered via the web on a tablet computer device. Selected primary care practices will see children as part of their patient population and consist of a substantial number of low income families, geographically located in the metropolitan areas surrounding Atlanta, GA and Baltimore, MD. Each of the 6 selected practices will receive study promotional materials, including a poster to hang in the office and waiting room (see **Attachment 3**) as well as handouts to leave at the front desk (see **Attachment 4**). These materials will advertise the focus groups and outline eligibility criteria. Parents interested in participating will be advised to call an 800 number to be screened and scheduled for a group discussion (if eligible). The 800 number will be staffed by the Westat study team who will be responsible for screening and scheduling. Representatives from each of the practices will be provided with brief "talking points" and study FAQs to refer to if interested parents have any basic questions about the study. The intercept interviews will take place in the waiting rooms or right outside the waiting rooms. Parents will be recruited as they are waiting for their appointment. Intercept interviews will be administered via CAPI (computer-assisted personal interviewing) to ensure respondent confidentiality. For convenience purposes, we will use tablet devices rather than desktop computers and the interview will consist of mostly close-ended questions and take no more than 15 minutes to complete.

Parent (or Guardian) Focus Groups

Parent focus groups will consist of four (4) in-depth discussions to assess comprehension and appeal of "Act Early" messages as they appear embedded within existing campaign materials (brochure, booklet, and checklist). Two focus groups will be held in the metropolitan areas surrounding Atlanta, GA and two focus groups will be held in the Baltimore, Maryland/Washington, DC metropolitan area. The focus groups will allow participants an opportunity to 1) provide feedback on "Act Early" messages; 2) provide feedback on overall appeal of campaign materials; 3) offer suggestions for improvements to both the messages and the materials; and 4) indicate the degree to which each material was motivating or encouraging to them personally. The overall goal for these focus groups will be to test the "Act Early" messages as they appear in various campaign materials and solicit feedback from parents on message and material appeal, comprehension, acceptability, and relevance. This data will provide CDC

important information on how well the campaign message and materials are reaching the target audience. Target audiences for the parent focus groups will consist of parents of children age 5 or younger who receive services from one of the six primary care practices recruited for this study (see below for more specific inclusion/exclusion screening criterions).

Focus group participants will be recruited via promotional materials hung and displayed in the primary care practice offices. Those interested in participating in the focus groups will be asked to call the toll-free 800 number at Westat. Westat will be responsible for screening and scheduling eligible parents into one of the four focus groups. Focus group participants are eligible if they indicate they 1) are between the ages of 18-55; 2) be the parent/legal guardian of a child age 5 or younger; 3) do not have a child who has been diagnosed with a developmental delay or disability; 4) have never worked in the medical profession or in a clinic, hospital, or doctor's office; 5) do not work with children who have special needs or in special education; and 6) do not have an annual household income of more than $50K. See **Attachment 5** for a copy of the focus group screener. Westat will host the focus groups at the Westat offices in Rockville, MD, if convenient for participants. Otherwise, Westat will try to make arrangements to use the Baltimore, MD area clinic waiting rooms or a conference room after clinic hours to conduct the groups. Groups in the Atlanta area will be held at a focus group facility. Westat will continue to screen and schedule participants, and the facility will provide the space. The focus groups will be conducted with eight to ten participants in each group and will last no more than 60 minutes. Participants will be asked to arrive early to read through and sign a consent form (see **Attachment 6**). Participants will receive $40 as a token of appreciation for their interest. See Table 2 for the focus group research design.

Table A.1.B. Parent Focus Groups Research Design

	Georgia	Maryland	Total
Number of clinics	3	3	6
Number of Focus Groups (8-10 parents each)	2 (16-20 parents total)	2 (16-20 parents total)	4 (36-40 parents total)

The focus group data will be collected via the use of trained moderators and a structured moderator's guide to ensure that consistent data are collected across the groups (see **Attachment 7**). Upon completion of each focus group, audiotapes

and transcripts will be used to assist with report writing. Participant identifying information will be removed from the notes and transcripts before they are analyzed. All information gathered will be securely stored and maintained for the length of the project.

Parent Intercept Interviews

The parent intercept interview will be conducted as an online survey with 20 parents in Atlanta, GA and 20 parents in Baltimore, MD. Westat interviewers will recruit parents using the intercept interview recruitment script (see **Attachment 8**) in clinic waiting rooms as they wait to see their doctor. Interested parents will be screened based on similar screening criteria as the focus groups (see **Attachments 9 and 9a**). Parents cannot participate in both the focus group and the intercept interview; the intercept screener will screen out parents who participated previously in the focus groups. Parents/guardians will access the screener and intercept interview via the web on a tablet computer device. All data will be collected through a secure website hosted by Survey Monkey.

The purpose of the intercept interview will be to serve as a final "gut check" of draft messages and materials based on any revisions made after the parent focus groups. Intercept interviews will also be used to assess the potential impact or influence of the material on parents' behavioral intentions regarding "acting early" to address concerns with their child's development. Thus, we will gather parents' feedback pre- and post-exposure to draft LTSAE materials (booklet (**see Attachment 10a**) and brochure (**see Attachment 10b**). The pre-test portion of the intercept interview protocols will gauge parents' baseline or general sense of self-efficacy and intentions to act early if they have concerns about their child's development. The post-test portion of the protocols will assess any change in parents' self-efficacy and behavioral intentions as a result of their exposure to the materials (booklet or brochure) and gather their overall feedback on the draft materials. Intercept interview respondents will answer questions about one of the two materials (booklet (**see Attachment 10a**) or brochure (**see Attachment 10b**). The intercept interview has been programmed into two separate surveys; one asks questions about the booklet and one asks questions about the brochure. See **Attachments 10, 10a, and 10b** for a Word copy of the full intercept interview as well as screenshots from each of the two programmed versions of the intercept interviews (booklet and brochure).

Our contractor, Westat, will be responsible for setting up, programming, and maintaining the Survey Monkey website. Interview data will be delivered to Westat project staff for analysis purposes and then sent to CDC (with identifiers removed) at the close of the project. Respondents will receive a $10 gift card to a local department store as a token of appreciation for completing the interview. Gift cards will be handed out in person upon completion of the interview. Web interview data will be retained for the length of the project and then destroyed under Westat's policies and procedures for data retention and destruction. See Table 1 below for parent intercept interview research design.

Table A.1.A. Parent Intercept Interview Research Design

	Georgia	Maryland	Total
Number of clinics	3	3	6
Number of Intercept Interviews with Parents	20	20	40

The data collection system includes:

a) *Act Early Focus Group Screener* (**Attachment 5**)
b) *Act Early Focus Group Informed Consent (***Attachment 6***)*
c) *Act Early Focus Group Moderator's Guide* (**Attachment 7**)
d) *Act Early Intercept Screener and Screenshots* (**Attachments 9, 9a**)
e) *Act Early Intercept Interview and Screenshots* (**Attachments 10, 10a, 10b**)

II. Items of Information to Be Collected

Focus group participants will be parents of children age 5 or younger who receive services at one of the six clinics participating in our study. During the screening process for the focus groups, eligible participants will be required to confirm that they 1) are between the ages of 18-55; 2) are the parent/legal guardian of a child age 5 or younger; 3) do not have a child who has been diagnosed with a developmental delay or disability; 4) have never worked in the medical profession or in a clinic, hospital, or doctor's office; 5) do not work with children who have special needs or in special education; and 6) do not have an annual household income of more than $50K (see **Attachment 5**) If eligible, Westat staff

will schedule participants into one of the four focus groups. Names and phone numbers will be collected during the screening call in order to conduct reminder calls the day before and day of the scheduled group. Participants will be asked to arrive at the focus group location 15 minutes prior to the start of the focus group to read through and sign a consent form (see **Attachment 6**). Participants will only provide their first name during the focus group discussions. The focus group discussion guide (see **Attachment 7**) will collect the following information:

- Materials Testing on LTSAE Materials
    - Brochure (See **Attachment 11** for a copy of the LTSAE brochure)
        - Comprehension
        - Reaction to and feedback on the "Act Early" Message
        - Appeal
        - Improvements
    - Booklet (See **Attachment 12** for a copy of the LTSAE booklet)
        - Comprehension
        - Reaction to and feedback on the "Act Early" Message
        - Appeal
        - Improvements
    - Checklist (See **Attachment 13** for a copy of the LTSAE checklist)
        - Reaction to and feedback on the "Act Early" Message
        - Appeal
        - Improvements

Intercept interview respondents will also include parents of children age 5 or younger who receive services at one of the six clinics participating in our study. During the intercept interview screening process, eligible participants will be required to confirm that they 1) are between the ages of 18-55; 2) are the parent/legal guardian of a child age 5 or younger; 3) do not have a child who has been diagnosed with a developmental delay or disability; 4) have never worked in the medical profession or in a clinic, hospital, or doctor's office; 5) do not work with children who have special needs or in special education; 6) do not have an annual household income of more than $50K; and 7) have not previously received *Amazing Me*. (see **Attachment 9, 9a**) Participants' names will not be collected during the intercept interview. However, at the end of the web interview, participants will be asked a number of demographic items, including age range, education, and race/ethnicity. Participants will be given gift cards in the amount of $10 to a local department store as a token of appreciation upon completing the interview. Therefore no Information in Identifiable Form (IIF)

will be collected from interview respondents. The intercept interview questions have been carefully crafted to collect the following information (see **Attachments 10, 10a, 10b**):

- Pre-test Questions (before material)
  - How confident parents are in knowing what to do and talking to their doctor about concerns about their child's development
  - How likely parents are to take certain actions if they had concerns about their child's development
  - How comfortable parents are in taking certain actions if they had concerns about their child's development
  - Barriers to acting early
- Post-test Questions (after material)
  - Identification of the "Act Early" message in the campaign materials
  - Assess message appeal and effectiveness
  - How likely parents are to take certain actions if they had concerns about their child's development
  - How comfortable parents are in taking certain actions if they had concerns about their child's development
  - Assess how well the material addresses barriers to acting early
  - Assess effectiveness of the material in motivating parents to act early
- Demographics
  - Age range
  - Education
  - Race/ethnicity
  - Income

III. Identification of Website(s) and Website Content Directed at Children Under 13 Years of Age

No website content directed at children under 13 years of age is involved in this information collection request.

A.2. Purpose and Use of Information Collection

The CDC's NCBDDD will fund this research effort to conduct "Act Early" message and materials testing for the "Learn the Signs. Act Early." campaign. The findings will help CDC refine messages and improve materials aimed to deliver

information to parents about child development and how to act early if a parent is concerned about their child's development. Though previous research studies have been conducted with parents of children with developmental delay to assess how well the materials facilitated parents' role in the early identification of developmental delay, there has not yet been an evaluation of the "Act Early" messages specifically.[10] In addition, there has not been an evaluation of the messages as they appear embedded within campaign materials with the audience they are intended to reach. The target audience for this research consists of parents who do not have a child with a previously diagnosed developmental delay or disability. If the requested data collection was not conducted, CDC would be unable to collect feedback on 1) message comprehension, acceptability, and relevance; and 2) overall appeal of all design elements included in the materials, including photos, colors, print size, etc. from the audience who the messages and materials are intended to reach. The collection of this information will enable CDC to determine if the "Act Early" messages and materials are reaching the target audience and how effective they are at encouraging parents to take the intended actions if they have concerns about their child's development.

2.1. Privacy Impact Assessment Information

(i) Intended use of the information and how it will be shared

Intended uses of the parent focus group findings will be to 1) provide feedback on "Act Early" messages; 2) provide feedback on overall appeal of campaign materials; 3) offer suggestions for improvements to both the messages and the materials; and 4) indicate the degree to which each material is personally motivating or encouraging.

Intended uses of the parent intercept interview data will be to conduct a final "gut check" on revised "Act Early" messages as they are embedded in campaign materials by assessing the potential impact or influence of the material on parents' behavioral intentions regarding "acting early" to address concerns with their child's development. Findings will measure the effectiveness of the "Act

[10] RTI International. (2012). *Reassessing the Needs of Parents of Young Children to Facilitate Their Role in the Early Identification of Developmental Delay*. Focus Group Report, April 2012.

Early" message on the target audience, parents of young children who do not have a previously diagnosed developmental delay or disability.

All information collected as part of this study will be stored and safeguarded at Westat. Any Information in Identifiable Form (IIF) that is collected as part of the focus groups and/or intercept interviews will be stored securely at Westat. Westat will be responsible for analyzing all data and preparing summaries, reports, and manuscripts based on research collected. All information shared based on the research conducted as part of this project will be reported in the aggregate. No individual names will be used when citing specific quotes used to support findings.

(ii) Impact on Privacy to Respondents

No IIF collected will be transmitted to CDC. The only IIF being collected (respondent name and phone number for the focus groups) is to be used by Westat to conduct reminder calls to scheduled focus group participants. Limited demographic information will be collected in the intercept interview. All demographic information collected as part of the intercept interviews will be used to describe the sample in any study reports or manuscripts. Therefore, all IIF will be stripped from the data set prior to sending the data to CDC. Thus, the proposed data collection will have little or no effect on the respondent's privacy.

A.3. Use of Improved Information Technology and Burden Reduction

The parent intercept interviews will be administered via CAPI (using a tablet computer device) conducted electronically on the internet. All interview responses (100%) will be submitted through a secure survey website established for this project. A Westat programmer will program and maintain the Survey Monkey website. Minimum information will be collected from the respondents to ensure they are eligible for the interview. Online interviewing is a cost-effective way of surveying a large number of people by eliminating the need for data entry; the personal interviewing component (the tablet computer device) allows respondents the privacy of completing and submitting all interview questions on their own without the assistance of an interviewer.

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

CDC has done some formative research with parents of children with previously diagnosed developmental disabilities prior to the design of the current proposed information collection. This formative research was approved by OMB on January 5, 2012 (OMB # 0920-0911, expiration 01/31/2015). Findings from that research effort provided feedback on LTSAE materials from an audience that is not necessarily considered the target audience of the "Act Early" messages. The "Act Early" messages are intended to encourage parents who have concerns about their child's development to act on those concerns by taking the steps outlined by CDC. Parents of children with previously diagnosed developmental delays do not need to be motivated to "Act Early," as they are already receiving support to help their children. This proposed data collection is unique in that it seeks to gather feedback from parents of children who are growing and developing typically to test the effectiveness of "Act Early" messages and appeal of campaign materials. This data collection effort does not duplicate any past, current, or planned information collection by other federal government agencies. Findings will help CDC in the development of effective "Act Early" messages and materials aimed to reach parents of young children who do not have an identified developmental delay or disability.

A.5. Impact on Small Businesses or Other Small Entities

Clinics will not be asked to take an active role in data collection recruitment. Their involvement will be limited in an effort to avoid any unnecessary burden on clinic staff and any disruption in usual clinic practices. Clinics will be asked to hang and display promotional materials advertising the focus groups around the office and answer basic questions from interested parents. Clinic staff will be provided with a project factsheet (see **Attachment 14**) that they can refer to for basic talking points to answer questions from interested parents. Further, they can refer parents to call Westat at the toll-free number provided on the promotional materials for more information about the study or to be screened for the focus groups. The parent focus groups will be scheduled and conducted at a place and time that is convenient for the participants. If convenient and

feasible, the focus groups may be held at the clinic locations after normal business hours.

A.6. Consequences of Collecting the Information Less Frequently

This is a one-time data collection effort, and parents will be asked to respond only once to the focus group or intercept interview. If the requested data collection was not conducted, CDC would be unable to evaluate "Act Early" messages and campaign materials with members of the target audience. The collection of this information would provide CDC the data and evidence they need to be confident about the effectiveness of the campaign messages and materials they disseminate in the future.

There are no legal obstacles to reduce the burden.

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

This request fully complies with regulation 5 CFR 1320.5. The intercept interviews are not designed to produce results that can be generalized to the entire study population. Instead, the intercept interview results will be used as a final "gut check" for CDC to ensure the "Act Early" messages and materials they are disseminating are effective and the intended message is understood and accepted by the target audience. This message and materials testing information collection will provide CDC with an evidence-base of quantitative data.

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

A. A copy of the agency's 60-day Federal Register Notice is attached (*60-day Federal Register Notice* **Attachment** 2). The notice, as required by 5 CFR 1320.8 (d), was published on May 19, 2014 (volume 79, number 96, pages 28729-28730). No public comments were received in response to this notice.

B. Since September 2013, the CDC "Act Early" team has collaborated with Westat staff on the development of data collection instruments for this study.

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A.9. Explanation of Any Payment or Gift to Respondents

For the 60 minute parent focus groups, it is proposed that respondents will be given $40 as a token of appreciation for their interest. Focus group participants will have small children at home; the incentive for these focus groups will help defray the cost of transportation and potential child care needs. In addition, focus groups will be held at the Westat office in Rockville, MD, a professional facility, or at one of the clinics recruited to participate in the study. As such, none of these

locations offer childcare, further supporting the need for the aforementioned incentive.

There have been citations in the literature referencing the importance of monetary compensation for focus group participation. Krueger (1994) indicates that offering minimal levels of monetary compensation will help ensure that sufficient numbers of participants will attend thereby yielding useful results. Further, in a meta-analysis of 38 experiments and quasi-experiments, Church (1993) found that providing cash incentives for participation was far more effective than nonmonetary gifts in generating survey response, and prepaid monetary incentives yielded an average increase of 19.1 percentage points over comparison groups. Finally, findings related to the importance of monetary incentives is corroborated in the National Adult Literacy Survey by Berlin (1992) and colleagues (OMB No. 1850-0654, exp. 8/31/1993), and the National Survey of Family Growth.

Research has consistently shown the value of offering a modest remuneration for motivating respondents to participate in a research study: "Focus groups are unique from other data-gathering processes in terms of the investment that must be made by the individual. It is therefore no surprise that a tradition has been established to provide incentive for participation. From a practical aspect, it would be next to impossible to conduct focus groups without incentives in some situations. The incentive is not a reward and not really an honorarium or salary. It is an incentive. It serves as a stimulus to attend the session. The primary function of the incentive is to get the participants to show for the focus group—and to show up on time. The incentive serves to protect the promised time slot from being preempt."[11] If this research was attempted without an incentive, the cost to the government for recruitment alone would be substantial. The incentive not only encourages participants to show up for the group, but also helps keep project costs under control. The IRB approval of the study (see **Attachment 15** for the IRB Approval letter) included the review and approval of this level of remuneration.

To ensure that sufficient numbers participate in the parent intercept interviews, eligible respondents will receive a $10 gift card to a local department store in the Atlanta, GA or Baltimore, MD/Washington, DC area as a token of appreciation for completing the interview, estimated to take on average 15 minutes to complete.

[11] Krueger RA, Casey MA. Focus groups. A practical guide for applied research. Thousand Oaks (CA): Sage; 2009.

A.10. Assurance of Confidentiality Provided to Respondents

This submission has been reviewed by the NCBDDD Privacy Officer and determined that the Privacy Act does not apply. Minimal IIF will be obtained during the scheduling of the focus groups. Although interested parents will call Westat to be screened, if eligible, participants will be asked to provide their name and telephone number for reminder calls prior to their scheduled group. All names and contact information collected for this purpose will be stored on secure network computers and only staff at Westat working on the project will have access to it.

Focus groups will be audio taped and transcribed for use by the Westat research team in developing a report. All data will be maintained by Westat on project folders located on Westat's secured server. Study data will only be accessible to Westat staff assigned to this project. Any printed data or notes will be kept in a locked, secure cabinet located in Westat's Atlanta and Rockville offices for the duration of the study. All Westat employees have taken and signed the Confidentiality pledge. All electronic study data such as focus group audio recordings and survey data will be destroyed at the end of the study.

Participation in the focus groups or the intercept interview is voluntary and participants will be advised that their responses will be treated in a secure manner and will not be linked to their names.

Institutional Review Board Approval: Westat's Institutional Review Board (IRB) reviewed the study instruments and granted approval for the study due to minimal risk (see **Attachment 15**). The study was approved by Westat's IRB on April 4, 2014. Activity is research involving identifiable human subjects, but CDC involvement does not constitute "engagement" in the research. This project is conducted under a grant or cooperative agreement and CDC employees will not interact with living individuals for research purpose and CDC will not obtain individually identifiable private information. The Contractor has been reviewed by an IRB and has received a Federal Wide Assurance (FWA) number. (#00005551)

10.1. Privacy Impact Assessment Information

A. The Privacy Office within the NCBDDD has reviewed this submission and determined that the Privacy Act does not apply. Focus group participants will self-select themselves into the groups by calling a toll-free number at Westat to be screened and scheduled. Only names and telephone numbers of eligible and scheduled participants will be collected for reminder call purposes only. During the focus group discussions, only first names will be used, however, no names will be used in any report generated for this study. All audio tapes and transcripts will be destroyed at the end of the study. Intercept interview participants will be approached in clinic waiting rooms by a Westat interviewer. No identifiable information will be collected from the interviewees. Parents interested in completing the interview will be given a tablet to complete the interview online themselves. Minimal demographic information will be collected at the end of the interview to help researchers describe the intercept interview sample in a general way in any data reports and manuscripts that are prepared as part of the study.

B. All data (hard copy and electronic) will be stored at Westat, CDC's selected contractor. All study materials (e.g., research notes, participant consent forms and incentive receipts) will be properly filed, maintained, and secured in a locked file cabinet. Electronic data will be kept on the project-specific network on Westat's secure server, which is accessible only to users granted rights by the project director and in a secure location with restricted physical access to staff working on the project only.

C. An Informed Consent Form will be obtained from all of the participants participating in the focus group (see **Attachment 6**). Consent forms will be signed before the focus group begins. Project staff will be available to answer any questions that the participants may have prior to the beginning of the focus group. The trained moderator will assure participants that any comments made during the focus group will not be attributed to them by name in any of the reports resulting from this research.

   Further, the participants in both the focus group as well as the intercept interview will be reminded that their participation is voluntary and that they may withdraw from the study at any time. Should focus group participants decide to withdraw from the study, they will still receive their promised incentive. Intercept interview respondents will receive their incentive immediately upon completion of the interview. Focus group respondents will be informed during the screening process that all notes and transcripts from

the data collection will solely be used to write the final report. The focus group participants will receive their incentives in cash in person at the end of the group. All of the transcripts and notes from the focus groups will only be available to the project staff. In addition, this information will also be disclosed to the respondents in the informed consent form. The legal authority to collect and maintain this data is granted by Public Health Service Act, Section 301, "Research and Investigation," (42 U.S.C. 241); and Sections 304, 306 and 308(d) which discuss authority to maintain data and provide assurances of confidentiality for health research and related activities (42 U.S.C. 242 b, k, and m(d)).

A.11. Justification for Sensitive Questions

There are no items considered to be highly sensitive for respondents. Potential participants in the web survey will be asked about how likely, comfortable, and confident they are to take various "Act Early" steps both pre and post material presentation. Focus group questions asked will be intended to gather specific feedback on the "Act Early" messages and materials, as referenced in the moderator's guide. The focus group discussion protocol does not contain questions that ask participants to share any personal or sensitive information with the group, and participants may refuse to answer any question they wish. Our target audience includes parents of children age 5 or younger and do not have a previously diagnosed developmental delay or disability.

A.12. Estimates of Annualized Burden Hours and Costs

For the focus groups, it is estimated that 80 respondents will have to be screened in order to recruit 40 participants. The focus group screener can be found in **Attachment 5**. Each screening will take approximately 5 minutes. The estimated response burden for the screening process is 7 hours.

The focus groups will have 10 participants each. Four focus groups will be conducted in two locations (the metropolitan areas of Atlanta, GA and Baltimore, MD/Washington, DC) with a total of 40 participants. The informed consent (**Attachment 6**) will take approximately 15 minutes to review; the focus group discussion using the moderator's guide (**Attachment 7**) will take 60 minutes to complete. Both of these focus group activities will have a total burden of 50 hours.

For the intercept interviews, it is estimated that 80 respondents will have to be screened in order to recruit 40 participants. The intercept interview screener can

be found in **Attachments 9 and 9a**. The screening process should take approximately 5 minutes. The estimated response burden for the screening process is 7 hours.

We plan to conduct a total of 40 intercept interviews. Twenty interviews will be conducted in each of two locations (metropolitan areas of Atlanta, Georgia and Baltimore, Maryland/Washington, DC). The intercept interview and screenshots can be found in **Attachments 10, 10a, and 10b**. The intercept interview will be conducted as a CAPI and will take each respondent approximately 15 minutes to complete, for an estimated total burden of 10 hours. The total estimated burden for this data collection is 74 hours. There is no cost to respondents other than their time.

Table A. 12. A. Estimated Annualized Burden Hours

Type of Respondent	**Form Name**	**No. of Respondents**	**No. of Responses per Respondent**	**Average Burden per Response (in hours)**	**Total Burden Hours**
Focus Groups					
Parents/ Guardians	Screener	80	1	5/60	7
Parents/ Guardians	Informed Consent	40	1	15/60	10
Parents/ Guardians	Focus Group Moderator's Guide	40	1	1	40
Intercept Interviews					
Parents/ Guardians	Screener	80	1	5/60	7
Parents/ Guardians	Intercept Interview	40	1	15/60	10
Total					**74**

The annualized cost burden is shown in Table A.12.B. The mean hourly wage rate is based on the most recent (May 2012) National Occupational Employment and

Wage Estimates for all occupations, published on the Bureau of Labor Statistics website which is $22.01. See http://www.bls.gov/oes/current/oes_nat.htm.

Table A. 12. B. Estimated Annualized Burden Costs

Type of Respondent	Form Name	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Focus Groups				
Parents/ Guardians	Screener	7	$22.01	$154.07
Parents/ Guardians	Informed Consent	10	$22.01	$220.10
Parents/ Guardians	Focus Group Moderator's Guide	40	$22.01	$880.40
Intercept Interviews				
Parents/ Guardians	Screener	7	$22.01	$154.07
Parents/ Guardians	Informed Consent	10	$22.01	$220.10
TOTAL				**$1,628.74**

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

There are no costs to respondents associated with either capital and startup efforts or operation and maintenance of services for this project.

A.14 Annualized Cost to the Government

The average annualized cost to the Federal Government to collect this information is $88,263.50. Costs to the federal government ($53,248.75/yr) include labor costs for contract oversight and technical assistance. Contractor costs ($35,014.50/yr) direct labor for development of instruments, data collection, analysis, and reporting for the focus groups and intercept interviews. Other

direct costs for the contractor include transcription of focus group data, participant incentives, rental of focus group facilities, travel and copying/printing. Contractor indirect costs include fringe, overhead, general and administrative fees (See Table A.14).

Table A.14. Estimated Annualized Cost to the Government

Expense Type	Expense Explanation	Annual Costs (dollars)
Direct Costs to the Federal Government	Personnel	
	Epidemiologist-14 1 5%	$ 5,051.75
	Public Affair Specialist-14 1 5%	$ 5,051.75
	Health Communication Specialist-13 1 20%	$ 17,100.00
	Health Communication Specialist-13 1 15%	$ 12,750.00
	ORISE Evaluation Fellow-9 1 25%	$ 12,395.25
	Subtotal	$53,248.75
Contractor Expenses	Contractor labor, focus group facility rental, transcription, clinic and participant incentives, printing costs, travel, and contractor indirect costs	$35,014.50
	Total Annual Cost	$88,263.50

The personnel costs were calculated using the 2014 General Schedule.

A.15. Explanation for Program Changes or Adjustments

This is a new data collection; therefore, program changes and adjustments to not apply.

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

At the conclusion of the focus groups, notes and audio recordings from the sessions will be analyzed for common themes and divergent viewpoints among and between audiences. Qualitative analytical software, such as NVivo, will be used to facilitate the focus group data analysis. Interim findings, submitted via

topline summaries, will be presented to CDC approximately 5-6 months after OMB approval. These interim findings will allow CDC, if needed, to make final edits to messages or materials prior to the intercept interviews. Intercept interview responses will be summarized by question, using frequency tables.

A final report of the findings, including all focus group and intercept interview data, will be completed within 11 months after OMB approval. These findings will be used to inform the development and distribution of materials for the "Learn the Signs. Act Early." campaign. Table A.16.B. below outlines the project time schedule by activity.

Table A.16.B. Project Time Schedule

Activity	**Time Schedule**
Parent Focus Groups	
Recruit clinics	1 month after OMB approval
Clinics begin recruiting for focus groups	2 months after OMB approval
Westat screens and schedules focus group participants	2-5 months after OMB approval
Conduct the parent focus groups	3-5 months after OMB approval
Westat submits topline summaries to inform any final revisions to the messages/materials	5-6 months after OMB approval
Parent Intercept Interviews	
Conduct intercept interviews in clinic waiting rooms	7-8 months after OMB approval
Final report of research findings	11 months after OMB approval

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

Not applicable. The OMB expiration date will be displayed.

A.18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.