Supporting Statement A for:

Generic Clearance to Support the Safe to Sleep Campaign at the *Eunice Kennedy Shriver* National Institute for Child Health and Human Development (NICHD)

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A. JUSTIFICATION

1. Circumstances Making the Collection of Information Necessary

This is a request for a new generic clearance that would be used for submissions specific to the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD) Safe to Sleep® (STS) public education campaign. Submissions for the STS campaign will be used to assess the understanding and reach of STS campaign materials and messages, and to monitor and improve campaign activities.

Established in 1962, by the request of the President, the NICHD was initially founded to support investigations of human development throughout the entire life process, focusing on understanding developmental disabilities, including intellectual disabilities, and important events that occur during pregnancy. The Public Health Service Act, (P.L. 42 USC 285) describes the NICHD mission as "ensuring that every person is born healthy and wanted, that women suffer no harmful effects from reproductive processes, and that all children have the chance to achieve their full potential for healthy and productive lives, free from disease or disability, and to ensure the health, productivity, independence, and well-being of all people through optimal rehabilitation." Working towards this mission, the NICHD has achieved an array of scientific advances in its pursuit to enhance lives throughout all stages of human development, from preconception through adulthood, improving the health of children, adults, families, communities, and populations. Research supported and conducted by the NICHD has helped to explain the unique health needs of many, and has brought about novel and effective ways to fulfill them.

One area of research focus for the NICHD is sudden and unexpected infant deaths (SUID). Each year in the United States, more than 4,500 infants die suddenly of no immediately,

obvious cause.[1] Half of these deaths are because of Sudden Infant Death Syndrome (SIDS), the leading cause of SUID and of all deaths among infants aged 1-12 months.[2] In 1994, the NICHD launched Back to Sleep, a national public education campaign, to raise awareness to reduce the risk of SIDS. The overarching campaign was based on the recommendation by the American Academy of Pediatrics (AAP) to have babies sleep on their backs to reduce their risk of SIDS. In 2011, the AAP released recommendations for safe infant sleep that went beyond SIDS and addressed the shared risk factors for other sleep-related causes of infant death (e.g., suffocation, entrapment, overlay). The NICHD expanded the Back to Sleep campaign to incorporate these new messages and launched the Safe to Sleep® campaign in September 2012. In addition to reinforcing the message that back sleeping is best, the expanded campaign communicates the overall impact of a safe sleep environment on a baby's health. The new campaign also aims to address racial and ethnic disparities through tailored outreach and collaboration. Safe to Sleep includes new general and racial/ethnic tailored materials (e.g., brochures, fact sheets, door hangers) as well as a new campaign website that launched in the fall of 2013. The goals of the STS campaign are to:

- Improve knowledge of SIDS and other sleep-related causes of infant death and risk-reduction behaviors among parents, caregivers, and the medical community;
- Increase awareness of and educate stakeholder groups (e.g., parents, caregivers, health care professionals) on the expanded Safe to Sleep® campaign and its new resources; and
- Contribute to the reduction of the SIDS death rate and other sleep-related causes of infant death.

The STS campaign is supported by official campaign collaborators, which include federal

[1] Centers for Disease Control and Prevention, Sudden Unexpected Infant Death (SUID), http://www.cdc.gov/sids/
[2] Centers for Disease Control and Prevention, Sudden Unexpected Infant Death (SUID), http://www.cdc.gov/sids/

agencies and several professional and national organizations. The federal agencies include the Maternal and Child Health Bureau (MCHB) at the Health Resources and Services Administration (HRSA), the Division of Reproductive Health at the Centers for Disease Control and Prevention (CDC), the AAP, the American College of Obstetricians and Gynecologists (ACOG), First Candle/the SIDS Alliance, and the Association of SIDS and Infant Mortality Programs (ASIP). Also, nine federal agencies formed the Federal SUID/SIDS Workgroup in 2009 to address the public health challenges of SIDS and SUID and opportunities for prevention. The Workgroup agencies include the Administration for Children and Families (ACF); Division of Reproductive Health, National Center for Chronic Disease Prevention and Health Promotion, and Division of Unintentional Injury Prevention, National Center for Injury Prevention and Control, CDC; NICHD, National Institutes of Health (NIH); Food and Drug Administration (FDA); MCHB, HRSA; the Indian Health Service (IHS); Division of Information and Education, HHS Office of Minority Health (OMH); Consumer Product Safety Commission (CPSC); and the Office of the Deputy Assistant Secretary of Defense, Military and Community Family Policy, Family Advocacy Program, Department of Defense (DoD). Each agency develops and implements its own safe infant sleep outreach activities on an independent basis. For example, the CDC's Division of Reproductive Health has been working to improve the process by which a determination of SIDS as a cause of death is made.

The NICHD also has a number of campaign activities implemented nationally and several that are focused on target states with the highest state SIDS mortality rates or the highest absolute number of SIDS deaths. The NICHD STS campaign activities include trainings in African-American communities in Arkansas (NICHD provides mini-grant funding for these trainings); African-American faith-based training outreach; general STS training workshops

presented around the country as requested; an online nurse continuing education program on SIDS risk reduction; an online pharmacist continuing education program on SIDS risk reduction; a Healthy Native Babies train-the-trainer outreach program that targets American Indian/Alaskan Native communities; physician offices media promotions; and the Safe to Sleep Champions initiative. These STS campaign activities help to promote campaign messages to professional and lay audiences, train individuals and health professionals on safe sleeping positions and environments for infants, and teach ways to reduce SUID/SIDS.

In the past, the NICHD Back to Sleep and Safe to Sleep® campaigns have used several methods to test new messages and assess the usefulness of campaign materials and training workshops. These methods have included focus groups with target audiences to understand their knowledge, attitudes, and behaviors around safe sleeping environments (OMB #: 0925-0643), focus groups and interviews to test new campaign messages (OMB #: 0924-0643), and surveys with training participants' to learn about their activities and utilization of materials post-training (OMB #: 0925-0532). The information collected from these assessment activities have helped to modify campaign messages and improve overall implementation of campaign activities. With the expanded campaign, there is an increased need to assess activities frequently so feedback can be incorporated in a timely manner to better target campaign messages to audiences and improve training workshops. Frequent reporting creates opportunities for adjustments to prevent shortcomings and address concerns quickly. This generic clearance will allow campaign staff to: 1) gather feedback on campaign activities expeditiously and effectively; 2) be better able to monitor and improve campaign implementation; and 3) assess the utilization and practice activities of target audiences.

The NICHD has a number of generic clearances for the National Children's Study (NCS)

as well as a Fast Track Generic Clearance. The NCS generic clearances are specific to that study and do not have a broad enough scope for the STS information collection needs. The NICHD Fast Track generic clearance has a broader scope; however, the scope does not include sub-studies that assess utilization, practice, and implementation activities. Additionally, feedback from campaign staff and NICHD leadership indicated that sub-studies were often not done or delayed due to limitations of the scope and capacity of the NICHD Fast Track generic clearance. The STS campaign generic clearance will fill a need that exists at NICHD to assess the STS campaign activities, particularly the train-the-trainer, mini-grant, and continuing education programs.

Therefore, the NICHD seeks to create a generic clearance to collect information on the STS campaign activities, including materials, messages and training workshops, and overall campaign implementation. This generic clearance will enable the STS campaign and the NICHD to: 1) more efficiently assess the implementation of campaign activities; 2) better understand the target audiences' knowledge, attitudes, and beliefs toward STS messages and materials; 3) better understand how the campaign activities have influenced the target audiences' behaviors and practices; and 4) monitor and improve activities such as trainings, materials, and messages. Having a way to gather feedback on the STS campaign activities is critical to assessing the reach and effect of campaign efforts. Data collected for the campaign can inform where future STS campaign resources can produce the most meaningful results. Additionally, the sub-studies under this generic clearance will conform to the criteria determined by the Office of

Management and Budget (OMB) which states that generic clearances are "considered only when the agency is able to demonstrate that there is a need for multiple, similar collections, but that the specifics of each collection cannot be determined until shortly before the data are to be collected." Further, sub-studies will be low burden for the participants, non-controversial in nature, and are not performed with the intent to provide information for a report to Congress or influence policy decisions.

2. Purpose and Use of the Information Collection

The purpose of this information collection is to monitor and modify campaign activities, to plan future campaign activities, to develop messages and materials, and to develop distribution and outreach strategies that are effective at communicating their message and bring about the intended response, awareness, and/or behavioral change for the target audiences.

Data collected from the STS campaign information collections will be used by a number of audiences, including STS campaign staff, NICHD leadership, STS campaign collaborators, Federal SUID/SIDS Workgroup members, SUID/SIDS stakeholders, clinical and maternal and child health professionals, parents and caretakers, and the general public. These audiences may use the information collections to: 1) develop new campaign messages, materials, and/or training curricula; 2) monitor and improve campaign activities; 3) make decisions about campaign activities; 4) inform current campaign activities; and 5) inform/change target audiences' practices and behaviors. The STS campaign staff and the NICHD leadership will be the primary users of the information. Most of the information collections for this audience will be for campaign assessments. The campaign assessment data will not be generalizable, but will be contextually based. The information will also be used

internally to make decisions about on-going monitoring and to improve campaign components or the campaign as a whole.

Examples of the types of information collections that could be included under this generic clearance include:

1) ***Focus groups (in-person and/or telephone)*** with parents/caregivers and/or health professionals to get feedback on distribution and outreach activities, and/or campaign messages.
2) ***In-depth interviews (in-person and/or telephone)*** with parents/caregivers and/or health professionals to get feedback on distribution and outreach activities, and/or campaign messages.
3) ***Surveys*** with parents/caregivers and/or health professionals to:
    - Assess the usefulness of the new STS campaign materials, including print and on-line materials and a video;
    - Track outreach experiences of Safe to Sleep Champions and types of activities conducted;
    - Assess state SIDS outreach project mini-grantee outreach activities;
    - Assess training participants' changes in knowledge related to safe infant sleep behavior and implementation of outreach methods taught;
    - Assess nurses' and pharmacists' satisfaction with the continuing education programs and the programs' effect on practice changes in health care delivery settings; and
    - Assess health professionals' resource material needs.

In summary, the sub-studies for this generic will be small scale, designed to obtain results frequently and quickly to guide campaign development and implementation, inform campaign

direction, and be used internally for campaign management purposes.

3. Use of Improved Information Technology and Burden Reduction

Whenever possible, the NICHD will use advanced technology to collect and process data to reduce respondent burden and make data processing and reporting more timely and efficient. The majority of data collections will take place online using automated surveys or via the telephone. In all data collections, the number of questions will be held to the absolute minimum required for the intended use of the data.

Focus group participant recruitment will be conducted on the phone, using screening tools that ensure only the most qualified and eligible participants are selected. In-depth interviews will be conducted over the telephone to reduce travel costs and time burden for interviewees. Online survey promotion will be conducted via the Internet to a preselected universe of possible respondents.

4. Efforts to Identify Duplication and Use of Similar Information

The NICHD STS campaign works closely with the STS campaign collaborators and other national partners. The collaborators and partners represent the federal, professional, and national leaders in the field of SUID/SIDS. The collaborators and partners monitor campaign activities and meet regularly to provide updates on individual campaign activities as well as collaborative projects. The NICHD staff receives information on other collections of the collaborators and partners. As such, they are apprised of efforts in progress and can identify similar information collection efforts to avoid duplication. Additionally, because each organization has a different mission and function, it is unlikely information collection efforts will overlap. The NICHD staff will also perform an internal review of proposed information collections as a preliminary step in

avoiding duplication and will only conduct data collections after determining that similar information does not exist.

5. Impact on Small Businesses or Other Small Entities

The target groups for these sub-studies include, but are not limited to: parents/caretakers, clinical health professionals (e.g., doctors, nurses, pharmacists), maternal and child health professionals (e.g., professional and advocacy organizations, state, local and tribal governments), general public, and owners of small businesses such as independently-owned medical practices. It may be possible that small businesses or other small entities would participate in an information collection. As such, the sub-studies would be conducted in a manner that reduces the burden of time and effort, by keeping the forms brief, making the data collections voluntary, and by requiring fewer or less frequent collections from small businesses. Additionally, if a small business or other small entity is part of the population sample, the program staff for the individual sub-study will provide justification for participation of small businesses.

6. Consequences of Collecting the Information Less Frequently

The majority of the sub-studies planned for this generic are intended to be information collections from a single contact with participants. A single methodology (e.g., focus group, interview, survey) is planned to be administered once per project per specific respondent group. Any less frequent response would not yield useful data for campaign planning and management improvements. When instances occur that multiple contacts will be made, the submitter for the individual sub-study will make provisions for the additional contact and provide justification in terms or meaningful results.

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

NICHD recognizes the requirement of OMB review as a mechanism to reduce burden on

information collection participants and will ensure that information collections conducted under this generic clearance will comply with 5 CFR 1320.5. Investigators of specific sub-studies will provide indication of and justification for exceptions to these guidelines.

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

As required by 5CFR 1320.8(d), a notice of this proposed data collection appeared in the *Federal Register*, Vol. 78, No. 250, pg. 79472-79473, on December 30, 2013. No public comments were received.

The STS campaign collaborators at HRSA and CDC, as well as NICHD staff who have PRA experience have reviewed this package. Contact information for representatives from HRSA and CDC are below.

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9. Explanation of Any Payment or Gift to Respondents

There will be a few sub-studies that include remuneration to respondents for participation. For focus groups and in-depth interviews that are longer than 60 minutes, NICHD

may provide stipends of up to $30. In the case of in-person studies, the NICHD may provide stipends up to $75. If respondents participate in focus groups or interviews remotely, via phone, or Internet, any proposed stipend will be justified to OMB in the sub-study request, and this amount will be considerably less than that provided to respondents attending in-person studies who have to travel to the agency or other facility to participate. If such information collections include hard-to-reach groups, the NICHD may offer non-standard stipends. The NICHD will provide OMB with additional justifications in the request for clearance of these specific activities. There is extensive literature to support the use of incentives, primarily monetary incentives, as a supplement or complement to other efforts of persuasion to ensure recruitment of a representative sample, especially among not-yet-reached and minority populations.[3,4] In studies for both commercial market research and social sciences, findings indicate that respondents who receive these tokens of appreciation provide valid input, and their inclusion makes for a more representative sample. It is standard practice in commercial market research to offer recruited respondents some form of remuneration for the time they spend engaged in a focus group, in-depth interview, and sometimes an online survey. Small amounts of money, a free meal or snack, remuneration for parking and/or transportation, and/or a raffle are most often used.

10. Assurance of Confidentiality Provided to Respondents

In keeping with human subjects research protections, the information collections conducted under this generic clearance will take steps to guarantee that all personally indentifiable information (PII), and all data collected, are secure and private. PII will only be

[3] Singer E and Kulka RA. Paying respondents for survey participation. In Ver Ploeg M,.Moffitt RA, Citro CF (eds). Studies of Welfare Populations: Data collection and Research Issues. National Academy Press: Washington, DC 2001. Available at http://www.nap.edu/openbook/0309076234/html.
[4] Kovac MD, Markesich J. Tiered incentive payments: getting the most bang for your buck. Presentation at the Annual Conference of the American Association for Public Research, 2002.

collected to the extent necessary. Respondents will be informed of security through explanatory text on the cover of forms and applications. In addition, respondents will be advised of the purpose of the information collection, the use of information collection, NICHD sponsorship, that their participation is voluntary, and that they may choose to discontinue or have their name and/or related information withdrawn at any time. In instances where it is possible, information will be presented in aggregate form, without links to the identity of individual participants.

It may be necessary for some information collections to retain name and contact information collected on a screening form to be used to contact potential respondents. In these instances, the rationale for retention of PII will be fully explained. Most of the information collections to be conducted under this clearance are considered exempt from Institutional Review Board (IRB) review at NIH. However, if it is determined that the information collection involves non-exempt activities, the staff will be required to submit the information collection for review by the NICHD IRB for approval.

11. Justification for Sensitive Questions

Information collections may contain sensitive questions, most of a moderate nature. Factors such as income, age, education, race/ethnicity, and gender are critical to characterizing respondent groups. Each sub-study will provide a description of sensitive questions and justification for their use. Additionally, to avoid fear of disclosure of sensitive information, respondents will be told that their responses will be kept confidential to the extent allowed by law and will be reported in aggregate summaries. Respondents will also be informed that they do not need to answer any question that makes them feel uncomfortable or that they simply do not wish to answer. Interviewers administering telephone surveys and in-person interviews will be trained to ask questions in a sensitive manner and to handle any subsequent discussion

skillfully. Researchers that design the online survey questions and items will be professionals trained and experienced in this area.

12. Estimates of Hour Burden Including Annualized Hourly Costs

A variety of instruments and platforms will be used to collect information from respondents and each sub-study will vary by number of respondents and average time per response. However, the annual burden hours requested (3,000) are based on the number of collections we expect to conduct over the requested period for this clearance. Table 1 presents the annual burden hour estimates for this data collection.

Table 1: Estimates for Annual Burden Hours

Type of Data Collection Instrument	Number of Respondents	Frequency of Response	Average Time per Response	Annual Hour Burden
Focus Groups	500	1	1	500
Pre/Post Test	2,500	1	15/60	625
Survey	2,500	1	15/60	625
Interview	500	1	1	500
Tracking/Feedback Form	1,500	1	30/60	750
Total	7,500			3,000

The estimated annualized cost to respondents is based on the Bureau of Labor Statistics for June 2013[5]. The mean hourly wage for all occupations is $25.04. Table 2 below provides an estimate for costs to respondents annually ($75,120).

Table 2: Estimates of Annualized Cost to Respondents

Type of Respondents	Number of Respondents	Frequency of Response	Average Time per Response	Hourly Wage Rate	Respondent Cost
Focus Groups	500	1	1	$25.04	$12,520
Pre/Post Test	2,500	1	15/60		$15,650
Survey	2,500	1	15/60		$15,650
Interview	500	1	1		$12,520
Tracking/Feedback Form	1,500	1	30/60		$18,780

[5] Bureau of Labor Statistics, http://www.bls.gov/news.release/empsit.t19.htm

Total	7,500				$75,120

13. Estimate of Other Total Annual Cost Burden to Respondent or Record Keepers

No costs are anticipated. Respondents will not need capital equipment, on-going recordkeeping operations, or services to complete the information collection.

14. Annualized Cost to the Federal Government

The approximate annualized cost to the government for this data collection effort is $69,267.73. These costs are comprised of: federal employee salaries, contractor staff salaries, and operational expenses (e.g., equipment, printing, and postage). Table 3 below provides the cost breakdown for the annualized cost to the federal government.

Table 3: Annualized Cost to the Federal Government

Item	Grade/Salary	Percent Effort	Annualized Cost
NICHD Safe to Sleep Program Staff/Project Oversight	GS-14-3 ($113,346)	20%	$22,669.20
NICHD PRA/OMB Liaison	GS-14-4 ($116,887)	3%	$3,506.61
Contractor Staff (Account Director)	$262,620.80*	10%	$26,262.08
Contractor Staff (Account Director II)	$310,648	3%	$9,319.44
Contractor Staff (Health Communication Associate)	$130,208	5%	$6,510.40
Operational Costs for Data Collection Activities (e.g., printing, postage, equipment), non-labor			$1,000
Total			**$69,267.73**

*Contractor salaries are loaded and include fringe benefits (e.g., costs for health insurance, travel, paid vacation). The fringe rate is 38.5% for full-time staff and 11.5% for part-time staff.

The total estimated cost to the Federal government will be reported on every request. As certified in each request by the responsible program staff, the costs to collect the information will be low for the Federal government.

15. Explanation for Program Changes or Adjustments

This is a new, generic collection of information.

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

Analysis of sub-studies may be required and it will typically include quantitiave analysis such as frequencies, cross tabulations, and measures of central tendancy to yield descriptive statistics of demographic variables. Qualitative data analysis may also be included for focus group and in-depth interview data collections. A thematic analysis will be conducted to analyze the focus group and interview data. Analysis will highlight relationships across codes, patterns, contrasts, and similarities across key respondent groups to develop conclusions. These sub-studies will not involve inferential statistical analyses and parametric tests. The findings gleaned from the sub-studies are intended to be used by program staff to dissesimate information about the campaign, fine-tune STS campaign objectives and priorities for the NICHD, and improve campaign management and implementation.

Results from information collections may be presented in reports, briefs, executive summaries, and presenations to the NICHD Offices and Branches, NIH, or HHS. Additionally, some information, depending on the content (e.g., updated STS campaign brochures and dissemination materials), may be released to the campaign collaborators and the public through website, email, or a newsletter. The respondents will be informed of the plans to release, and the specific release plans will be requested in the sub-study templates for OMB review (Attachment 1A-1B).

Project timelines will vary according to campaign priorities and funds. Individual projects will depend on the number of respondents and the complexity or length of the data collection instrument. Information collection time periods can range from 1 month to 3 years.

Should the collection of information need to continue after the expiry date of the full generic, the campaign staff will submit another request to continue to collect the information.

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

No exemption is requested. All forms will display the OMB number and expiration date.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

No exceptions to the Certification for Paperwork Reduction Act submissions are requested.