

## Mini Supporting Statement A

Risk Reduction for Sudden Infant Death Syndrome (SIDS) and Other  
Sleep-Related Causes of Infant Death: Continuing Education Activity for  
Nurses

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## Mini Supporting Statement A

### A.1 Circumstances Making the Collection of Information Necessary

This is a request for a new sub-study clearance the general clearance for the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD) Safe to Sleep® (STS) public education campaign. Nurses and other health care providers (HCPs) are in a unique position to educate parents and caregivers about risk reduction of Sudden Infant Death Syndrome (SIDS) and other sleep-related causes of infant death. The STS campaign offers a free continuing education activity (CE Activity) for HCPs that explains the latest research on SIDS, other sleep-related causes of infant death, and ways to reduce the risk of both of these types of deaths. The CE activity also outlines how HCPs can communicate risk-reduction messages to parents and caregivers in just a few minutes. Submissions for the STS campaign will be used to assess CE Activity participants' understanding of the content; the reach of STS campaign materials and messages; to gauge the effectiveness of campaign continuing education activities and monitor uptake of safe infant sleep messaging by nurses and other HCPs. These STS continuing education activities help to promote campaign messages to professional audiences, train health professionals on safe sleep practices and environments for infants, and teach ways to reduce the risk of Sudden Unexpected Infant Death (SUID), Sudden Infant Death Syndrome (SIDS) and other sleep related causes of infant death.

### A.2 Purpose and Use of the Information Collection

Since the launch of the Safe to Sleep® campaign, NICHD has offered *Risk Reduction for Sudden Infant Death Syndrome (SIDS) and Other Sleep-Related Causes of Infant Death: Continuing Education Activity for Nurses* (formerly Nurse Continuing Education (CE) Program on SIDS Risk Reduction) to educate nurses and other health care providers on safe infant sleep and to help reduce the risk of SIDS and other sleep-related causes of infant death. The purpose of this new data collection is to assess the nurses' knowledge of safe infant sleep practices before and after completion of the education module. We also seek to gauge participants' satisfaction with the education activity and their satisfaction with using STS campaign materials and information in health care delivery settings.

For this data collection, all CE Activity participants will be asked to complete four electronic surveys: (1) a pre- CE Activity assessment to indicate their knowledge before their participation in the educational module; (2) a post-CE Activity assessment to gauge any change in knowledge after they have participated in the CE Activity; (3) a survey provided and required by the accreditation entity to indicate their satisfaction with the module immediately after completion of the CE Activity; and (4) a follow-up survey 6 months after completion of the CE Activity to gauge any sustained benefit in their delivery of safe infant sleep education to patients.

Data collected by the STS campaign will be used in aggregate by specific 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. Campaign assessment data is contextually based and not generalizable. As stipulated in the National Institutes of Health (NIH) System of Record Notice (SORN) 09-25-0156, *Records of Participants in Programs and Respondents in Surveys Used to Evaluate Programs of the Public Health Service, HHS/PHS/NIH/OD*) these audiences may use collected information only for specific and routine use, to:

- develop new campaign materials, and/or training curricula;
- monitor and improve campaign activities;
- make decisions about current and future campaign educational resources;
- inform current and future campaign activities; and
- inform strategies used to influence 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 collection 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 implementation effectiveness and to improve campaign components or the campaign, in general. CE Activity respondents may include clinical and maternal and child health professionals, specialized child care and other service providers, and the general public. Participants who complete the NICHD CE Activity and whose accrediting organization accepts contact hours will be eligible to receive 1.5 contact hours accredited by the Maryland Nurses Association (MNA). A completion report is sent to MNA every three months with the information (name, address, email, post-test percentage, course evaluation) required by the organization to confirm a participant's contact hours.

Frequent reporting creates opportunities for campaign adjustments, which will help campaign staff to prevent shortcomings and quickly address concerns. This sub-study 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; 3) assess the utilization and behavioral practices of target audiences; and 4) assess the effectiveness of the educational resources and effect on practice changes in health care delivery settings. The reports to MNA only contain information for those participants who submit for contact hours, meaning they have completed the CE Activity, passed the CE post-assessment, and completed the MNA post-CE course evaluation. Responses to each item are not recorded, and the system only accepts submissions from those who have passed the post-CE assessment.

Information collection under this sub-study consists of:

- any self-reported change in safe infant sleep knowledge, attitudes, and intent to update health care delivery practices after completion of the CE Activity;
- overall satisfaction with the format and content of the CE Activity;
- sustained changes in health care delivery practices 6 months after completion of the CE Activity

In summary, this sub-study for the generic clearance will be small in 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.

A Privacy Impact Assessment (PIA) is recommended and in process for the CE Activity. NICHD recognizes that while the collection and storage of source data, including Personally Identifiable Information (PII), will be collected, stored and maintained in electronic inventories only, subsequent use of collected aggregated data may involve use of federal information systems subject to federal law and guidance. Collected data will be stored in a secure database, with limited staff access, at NICHD offices or approved and secure off-site servers.

### **A.3 Use of Information Technology to Reduce Burden**

Whenever possible, the NICHD uses advanced technology to collect and process data to reduce respondent burden and make data processing and reporting more timely and efficient. Campaign activities associated with these data collections are designed to reach organizations, health care and service providers that have reliable access to computers and fast-speed internet. All data collections are completed on-line via electronic surveys and are completed at the learner's preferred pace, meaning they can save progress and come back to the last completed section at their leisure. Past participants expressed to campaign staff that electronic transfer of information is most practical because they may move from one patient care area to another and they need their progress to be saved in one central and secure online platform. Our CE module meets all these electronic mobility and safety preferences.

### **A.4 Efforts to Identify Duplication**

The NICHD STS campaign works closely with the campaign collaborators and other national partners, such as the National Institute of Nursing Research and the Association of Women's Health, Obstetric and Neonatal Nurses, both of which served as reviewers for the content of this CE Activity. Campaign collaborators and partners represent the federal, professional, and national leaders in the field of SUID/SIDS. The NICHD staff, collaborators and partners have reviewed other campaign data collections and have determined that the data collected by this CE Activity are unique.

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

N/A

### **A.6 Consequences of Collecting the Information Less Frequently**

This sub-study is intended to be an information collection from a limited number of encounters with participants. A single methodology (e.g., survey) is planned to be administered per respondent. In order

to assess change in knowledge and retention of information before and after completion of the CE Activity, and at 6-month follow-up to gauge the true benefit of participation in this educational module. Any less frequent response would not yield useful data for campaign planning and management improvements.

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

This survey will be implemented in a manner that fully complies with 5 C.F.R. 1320.5.

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

N/A

#### **A.9 Explanation of Any Payment of Gift to Respondents**

For this sub-study, participants are eligible to receive 1.5 continuing education contact hours, free of charge, accredited by the Maryland Nurses Association. These contact hours help participants to meet the continuing education requirements, set forth by their respective certifying organizations, to maintain their professional licenses. By making these contact hours available free of charge, we remove financial barriers to participation and contribute to the continued education on safe infant sleep and capacity building of our health care work force.

#### **A.10 Assurance of Confidentiality Provided to Respondents**

Authority for the collection of the information requested from mini-grantees and community members comes from the authorities regarding the establishment of the National Institutes of Health, its general authority to conduct and fund research and to provide training assistance, and its general authority to maintain records in connection with these and its other functions (42 U.S.C. 203, 241, 2891-1 and 44 U.S.C. 3101), and Section 301 and 493 of the Public Health Service Act. These records will be maintained in accordance with the Privacy Act System of Record Notice 09-25-0200 "Clinical, Basic and Population-based Research Studies of the National Institutes of Health (NIH), HHS/NIH/OD," published on September 26, 2002 (Vol. 67, pages 60742-60784).

PII will only be collected to the extent necessary. The course will be hosted on a FedRAMP certified, secure server protected with a Secure Sockets Layer (SSL) certificate and 128-bit encryption, the strongest online data encryption protection available. Individual contact information will be stored separately from the course, but also on a FedRAMP certified, secure, encrypted server. At minimum, the MNA requires first name, last name, email address, and course evaluation for those who pass the post-test to receive contact hours. The system does not store any information until the person submits for credit, at which point he or she is asked to provide PII, including the required information. These data

are submitted to a spreadsheet on a certified, encrypted server; access to these raw data is restricted to IT staff only. On a quarterly basis, selected campaign staff export the information into a report template provided by MNA and send the report to MNA. Campaign staff do not keep copies of the report and no reports are stored in the system. Raw data is anonymized every three years, as required for MNA. Project reports will not identify individuals who submitted for credit or who completed the post-activity survey. No names, university names, or personal identifying information will be used in any published reports of this study. Survey reports will present all findings in aggregate so individual responses cannot be identified.

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. Because the system does not store any information until a participant submits for credit, we will advise credit-seekers that they may choose to discontinue or have their name and/or related information withdrawn at any time. Information will be presented in de-identified and aggregate form.

#### **A.11 Justification for Sensitive Questions**

This data collection will not include sensitive questions

### A.12.1 Estimated Annualized Burden Hours

#### A.12-1 Estimated Annualized Burden Hours

Form Name	Type of Respondent	Number of Respondents	Number of Responses per Respondent	Average Burden Per Response (in hours)	Total Annual Burden Hour
<b>A. Pre CE Activity assessment (pre-test)</b>	Health care and other service providers	20,000	1	10/60	3,333
<b>B. Post CE Activity assessment (post-test)</b>	Health care and other service providers	20,000	1	10/60	3,333
<b>C. CE Activity satisfaction evaluation</b>	Health care and other service providers	20,000	1	10/60	3,333
<b>D. CE Activity follow-up survey</b>	Health care and other service providers	2,000	1	10/60	333
<b>Totals</b>		20,000	20,000		10,332

#### A.12-2 Annualized Cost to the Respondents

Type of Respondents	Total Annual Burden Hours	Hourly Respondent Wage Rate*	Respondent Cost
Health care and other service providers	10,332	\$27.87	\$287,952.84
<b>TOTAL</b>			\$287,952.84

\*\*Bureau of Labor Statistics: The wage rates were obtained from [http://www.bls.gov/oes/2017/may/oes\\_nat.htm#00-0000](http://www.bls.gov/oes/2017/may/oes_nat.htm#00-0000) Occupation title "All Occupations", accessed on May 25, 2018.

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

Expenses are not anticipated. Respondents will not need capital equipment, on-going recordkeeping operations, or services to complete the information collection.

**A.14 Annualized Cost to the Federal Government**

Staff	Grade/Step	Salary*	% of Effort	Fringe (if applicable)	Total Cost to Gov't
<b>Federal Oversight</b>					
NICHD Safe to Sleep Program Staff/Project Oversight	GS-13-7	(\$113,755)	2%		\$2,275.10
<b>Contractor Cost</b>					
Contractor Staff (Program Manager)		\$160,290	2%		\$3,205.80
<b>Other Cost</b>					
Operational Costs for Data Collection Activities (e.g., printing, postage, equipment), non-labor					\$200
Total Annualized Cost to the Federal Government					\$5,680.90

\*the Salary in table above is cited from <https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/18Tables/html/DCB.aspx>.

**A.15 Explanation for Program Changes or Adjustments**

To reflect the 2016 American Academy of Pediatrics guidelines on safe infant sleep, NICHD updated the CE Activity content. Specifically, the module was updated to reflect the latest evidence-base behind the safe infant sleep recommendations and the content was reviewed and revised for inclusion of plain language, removal of excessive jargon (where possible), and user-friendly electronic formatting.

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

The proposed sub-study may include quantitative summaries such as frequencies, cross tabulations, and measures of central tendency to yield descriptive reports of change in knowledge, attitudes, practices, and qualitative synopses to identify themes in recommendations for program improvement. This sub-study will not involve inferential statistical analyses and parametric tests. The findings gleaned from the



sub-study are intended to be used by program staff to disseminate information about the CE Activity, fine-tune STS campaign objectives and priorities for the NICHD, and improve campaign management and implementation across all educational resources, including this CE Activity.

Results from information collections may be presented in reports, briefs, executive summaries, and presentations 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 CE Activity collaborators, reviewers, and the public through website, email, or a newsletter.

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

We are not requesting an exemption to the display of the OMB Expiration date.

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

This survey will comply with the requirements in 5 CFR 1320.9.