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

OMB #0925-0701, Exp: 02/28/2021

February 12, 2020

Check off which applies:

- New
- X Revision
- Reinstatement with Change
- Reinstatement without Change
- Extension
- Emergency
- Existing

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Table of Contents

Α.	JUSTIFICATION	4
A1.	CIRCUMSTANCES MAKING THE COLLECTION OF INFORMATION NECESSARY	4
A2.	PURPOSE AND USE OF THE INFORMATION COLLECTION	9
A3.	USE OF IMPROVED INFORMATION TECHNOLOGY AND BURDEN REDUCTION	12
A4.	EFFORTS TO IDENTIFY DUPLICATION AND USE OF SIMILAR INFORMATION	12
A5.	IMPACT ON SMALL BUSINESSES OR OTHER SMALL ENTITIES	13
A6.	CONSEQUENCES OF COLLECTING THE INFORMATION LESS FREQUENTLY	13
A7.	SPECIAL CIRCUMSTANCES RELATING TO THE GUIDELINES OF 5 CFR 1320.5	14
A8.	COMMENTS IN RESPONSE TO THE FEDERAL REGISTER NOTICE AND EFFORTS TO COMOUTSIDE THE AGENCY	ISULT
A9.	EXPLANATION OF ANY PAYMENT OR GIFT TO RESPONDENTS	15
A10.	Assurance of Confidentiality Provided to Respondents	16
A11.	JUSTIFICATION FOR SENSITIVE QUESTIONS	17
A12.	ESTIMATES OF ANNUALIZED BURDEN HOURS AND COSTS	18
A13.	ESTIMATES OF OTHER TOTAL ANNUAL COST BURDEN TO RESPONDENTS AND	
	RECORD KEEPERS	20
A14.	Annualized Cost to the Federal Government	20
A15.	EXPLANATION FOR PROGRAM CHANGES OR ADJUSTMENTS	21
A16.	PLANS FOR TABULATION AND PUBLICATION AND PROJECT TIME SCHEDULE	22
A17.	REASON(S) DISPLAY OF OMB EXPIRATION DATE IS INAPPROPRIATE	23
A18.	EXCEPTIONS TO CERTIFICATION FOR PAPERWORK REDUCTION ACT SUBMISSIONS.	23

A. JUSTIFICATION

Abstract:

The Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD), along with its partners, has led efforts on safe infant sleep education since the 1990s. Beginning as the Back to Sleep campaign in 1994 and becoming the Safe to Sleep[®] (STS) campaign in 2012, these programs have helped raise awareness about ways to reduce the risk of Sudden Infant Death Syndrome (SIDS) and other sleep-related causes of infant death, such as suffocation. The NICHD Back to Sleep and STS campaigns have used several methods to test new messages and assess the usefulness of campaign materials and training workshops. The campaign regularly assesses activities 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. A revision for the Generic Clearance to Support the STS Campaign at the NICHD will allow campaign staff to gather feedback on campaign strategies and messages expeditiously and effectively, be better able to monitor and improve campaign implementation, and assess the utilization and practice activities of target audiences. The STS campaign generic clearance will fill a need that exists at NICHD to assess STS activities, particularly the continuing education program for nurses, new/revised campaign messages, Web development(i.e. website content, social media messages, videos, etc.), and materials (i.e. brochures, fact sheets, conversation guides, etc.) development.

A.1 Circumstances Making the Collection of Information Necessary

This is a request to revise a generic clearance that would be used for submissions specific to the NICHD STS public education campaign. A revision is requested, as the STS campaign is

ongoing and continues to update and refine information collection materials as needed.

Information collections for the STS campaign will be used to assess the understanding,

effectiveness, impact, and reach of STS campaign materials and messages; monitor and improve

campaign activities; and gauge the need for additional resources or activities.

Established in 1962 by the request of the President of the United States, NICHD was initially founded to support investigations of human development throughout the entire lifespan, focusing on understanding developmental disabilities, including intellectual disabilities, and important events that occur during pregnancy. As part of its strategic planning process, NICHD updated its mission plan in 2020 to "lead research and training to understand human development, improve reproductive health, enhance the lives of children and adolescents, and optimize abilities for all." 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 NICHD has helped explain the unique health needs of communities with special medical needs and has brought about novel and effective ways to address them.

One area of scientific priority for NICHD is Sudden Unexpected Infant Death (SUID). Each year, more than 3,500 infants in the United States die suddenly of no immediately obvious cause. ¹ Approximately half of these deaths are due to SIDS, the leading cause of SUID and of all deaths among infants age 1 to 12 months. ² In 1994, NICHD launched Back to Sleep, a national public education campaign, to raise awareness about ways to reduce the risk of SIDS. The overarching campaign was based on the recommendation from the American Academy of

¹ Centers for Disease Control and Prevention. Sudden Unexpected Infant Death and Sudden Infant Death Syndrome. http://www.cdc.gov/sids/. Accessed November 6, 2020.

² Ibid.

Pediatrics (AAP) to have babies sleep on their backs to reduce their risk of SIDS. In 2011, the AAP released updated recommendations for safe infant sleep that went beyond reducing SIDS risk and addressed the shared risk factors for other sleep-related causes of infant death (e.g., suffocation, entrapment, overlay). NICHD expanded the Back to Sleep campaign to incorporate these new messages and launched the STS campaign in September 2012. In addition to reinforcing the message that back sleeping is the safest for babies, the expanded campaign communicates the overall importance and impact of a safe sleep environment on a baby's health. STS also aims to address racial and ethnic disparities through tailored outreach to audiences of interest, such as healthcare providers, and collaborations with state and local organizations that serve underrepresented and disenfranchised groups. STS includes general and racial/ethnic tailored materials (e.g., brochures, fact sheets, door hangers), as well as a campaign website that launched in the fall of 2013 and is continually updated to reflect evidence-based research and the AAP safe sleep recommendations. The goals of the campaign are to:

- Improve knowledge of SIDS and other sleep-related causes of infant death and risk reduction practices among parents, caregivers, and the medical community
- Increase stakeholder groups' (e.g., parents, caregivers, healthcare professionals)
 awareness and understanding of the STS campaign and its resources
- Contribute to the reduction of the SUID and SIDS rates

The STS campaign is supported by official campaign Collaborators, which include federal 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), and the Consumer Product Safety Commission (CPSC). National and

professional organizations that serve as official Collaborators include the AAP, the American College of Obstetricians and Gynecologists (ACOG), and First Candle. In addition, a Federal SUID/SIDS Workgroup representing nine federal agencies was formed in 2009 to complement the efforts of NICHD's STS campaign by addressing the public health challenges of SUID and SIDS and advancing opportunities for prevention. The nine Workgroup agencies are the Administration for Children and Families (ACF); the Division of Reproductive Health, National Center for Chronic Disease Prevention and Health Promotion, and the Division of Unintentional Injury Prevention, National Center for Injury Prevention and Control, CDC; NICHD, National Institutes of Health (NIH); the Food and Drug Administration (FDA); MCHB, HRSA; the Indian Health Service (IHS); the Division of Information and Education, Department of Health and Human Services (HHS) Office of Minority Health (OMH); the 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 activities on an independent basis. For example, CDC's Division of Reproductive Health has been working to improve surveillance of SUID by creating a standardized method for characterizing different types of SUID based on the levels of evidence available from death investigations.

NICHD also has a number of campaign activities implemented nationally and a few that are focused on the states or communities with the highest SUID/SIDS rates or the highest absolute number of SUID/SIDS cases. The NICHD STS campaign activities include virtual training workshops presented to different audiences around the country (as requested), a national online nurse continuing education activity on SUID and SIDS risk reduction, a Healthy Native Babies train-the-trainer outreach program that is tailored to meet the learning needs of American

Indian/Alaskan Native communities across the United States, particularly in the areas or states where the SUID/SIDS rates are highest, and a portfolio of tailored social media activities to engage specific stakeholder groups and the public at large on SUID/SIDS risk awareness. These STS campaign activities help promote campaign messages to professional and lay audiences, train individuals and health professionals on safe sleep practices and environments for infants and teach ways to reduce SUID/SIDS.

In the past, the NICHD Back to Sleep and STS campaigns have several methods to test new messages and assess the effectiveness of campaign materials and training workshops. These methods included focus groups with target audiences to understand their knowledge, attitudes, and behaviors around safe sleep environments (OMB #0925-0643³, sub-study approved August 16, 2013), focus groups and interviews to test new campaign messages (OMB #0924-0643, substudies approved January 27 and February 2, 2015), and surveys with training participants to learn about their activities and utilization of materials post-training (OMB #0925-0701, substudies approved November 20, 2014; December 12, 2014; and November, 9, 2016). The information collected from these assessment activities helped to modify campaign messages and improve overall implementation of campaign activities. With a more nuanced and evolving campaign, there is an increased need to assess activities frequently so that feedback can be incorporated to more accurately tailor campaign messages to audiences, improve training workshops, and to revise messages as the AAP safe infant sleep guidelines are updated. Frequent reporting creates opportunities for adjustments to prevent shortcomings and address concerns quickly. This generic clearance will allow campaign staff to gather feedback on campaign activities expeditiously and effectively, be better able to monitor and improve campaign

³OMB #0925-0643 expires on 02/28/2021 and all substudies under this generic have been completed.

implementation, and assess the utilization and practice activities of target audiences.

NICHD seeks to revise the Generic Clearance to Support the STS Campaign at NICHD, which fills a need at NICHD to assess the STS campaign activities. The Generic Clearance to Support the STS Campaign at NICHD has provided a mechanism to request approval for information collection on STS activities, including materials, messages and training workshops, and overall campaign implementation. Revising this generic clearance will enable the STS campaign and NICHD to (1) more efficiently assess the implementation of campaign activities; (2) better understand target audiences' knowledge, attitudes, and beliefs about STS messages and materials; (3) better understand how campaign activities have influenced target audiences' attitudes, behaviors, and practices regarding infant sleep and the AAP guidelines; and (4) monitor and improve activities and resources such as trainings, materials, and messages. Having a way to gather feedback on 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 messaging, strategies, and resources can produce the most meaningful results. Additionally, the sub-studies under this generic clearance will conform to the criteria determined by OMB, which state 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." Furthermore, sub-studies will be low burden for the participants, noncontroversial in nature, and not performed with the intent to provide information for a report to Congress or influence policy decisions.

A.2 Purpose and Use of the Information Collection

OMB approval is being sought for a revision, for a period of 3 years, to continue to monitor and modify campaign activities, plan future campaign activities, develop messages and

materials, and 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.

Since the last original submission for clearance, information collections have been gathered for the STS campaign activities listed below.

- 1. The Healthy Native Babies Project
 - Project materials distribution tracking forms (continuing)
 - Train-the-Trainer Follow-Up Assessment Survey (to be discontinued)
- 2. Risk Reduction for Sudden Infant Death Syndrome (SIDS) and Other Sleep-Related Causes of Infant Death: Continuing Education Activity for Nurses (all continuing)
 - In-course pre- and post-test
 - In-course satisfaction survey
 - Follow-up survey

Data gathered from the STS campaign information collections were and will continue to be used by a number of audiences, including STS campaign staff, NICHD leadership, STS campaign Collaborators, Federal SUID/SIDS Workgroup members, SUID/SIDS stakeholders, and clinical and maternal and child health professionals. These audiences used and, in the future, 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 and/or change practices and behaviors of program participants. 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 ongoing 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:

- Focus groups (in person and/or via telephone) with parents/caregivers and/or health professionals to get feedback on distribution and outreach activities, and/or campaign messages
- In-depth interviews (in person and/or via telephone) with parents/caregivers and/or health professionals to get feedback on distribution and outreach activities, and/or campaign messages
- *Surveys* with parents/caregivers and/or health professionals to:
 - Assess the usefulness of the new STS campaign materials, including print and online materials and a video
 - Track outreach experiences of campaign staff and types of activities conducted
 - Assess training participants' changes in knowledge related to safe infant sleep behavior and implementation of outreach methods taught
 - Assess health professionals' satisfaction with and knowledge gained from the continuing education programs and the programs' effect on practice changes in healthcare delivery settings
 - O Assess health professionals' resource material needs

In summary, the sub-studies for this 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.3 Use of Improved Information Technology and Burden Reduction

Whenever possible, NICHD will use advanced technology to collect and process data to reduce respondent burden and make data processing and reporting timelier and more efficient. The majority of data collections will take place online using automated surveys or via telephone. Privacy impact assessments will be completed for sub studies that collect and store PII. 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 via a virtual and secure meeting platform or by phone, using screening tools that ensure only the most qualified and eligible participants are selected. In-depth interviews will be conducted via a virtual and secure meeting platform or by phone 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.

A.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 receive information on other collections of the

Collaborators and partners; 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 that information collection efforts will overlap. The NICHD staff will perform an internal review of proposed information collections as a preliminary step in avoiding duplication and will conduct data collections only after determining that similar information does not exist.

A.5 Impact on Small Businesses or Other Small Entities

The priority groups for these sub-studies include parents/caregivers; clinical health professionals (e.g., doctors, nurses); maternal and child health professionals (e.g., professional and advocacy organizations); state, local, and tribal governments; the 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, so the substudies 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 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.

A.6 Consequences of Collecting the Information Less Frequently

When possible, most planned sub-studies for this generic clearance will 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 that require multiple contacts occur, the person submitting the

individual sub-study will make provisions for the additional contact and provide justification in

terms of meaningful results.

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

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

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.

A.8.1 Comments in Response to the Federal Register Notice and Efforts to Consult Outside

the Agency

As required by 5 CFR § 1320.8(d), a notice of this proposed data collection appeared in

the Federal Register, vol.85, no. 239, pp. 80123-80124, on December 11, 2020. NICHD received

no comments in response to the 60-day *Federal Register* notice.

A.8.2 Efforts to Consult Outside Agency

The STS campaign Collaborators at the Health Resources and Services Administration

(HRSA) and the Centers for Disease Control and Prevention (CDC), as well as NICHD staff who

have experience with the Paperwork Reduction Act (PRA), have reviewed this package. Contact

information for representatives from HRSA and CDC is provided below.

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13

Epidemiologist

Sudden Unexpected Infant Death Initiative

Maternal and Infant Health Branch, Division of Reproductive Health

National Center for Chronic Disease Prevention and Health Promotion

Centers for Disease Control and Prevention

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A.9 Explanation of Any Payment or Gift to Respondents

There will be a few sub-studies that include remuneration to respondents for

participation. For in-person focus groups or in-depth interviews 90 minutes long or longer,

NICHD may provide tokens of appreciation up to \$75. For focus groups/in-depth interviews that

run for up to 60 minutes, NICHD may provide tokens of appreciation up to \$40. 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 facilities to participate. If such information collections include hard-to-reach groups,

NICHD may offer nonstandard stipends. 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

14

and minority populations.^{4,5,6} 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, an in-depth interview, or 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.

A.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 PII and all data collected are secure and private to the extent permitted by law. PII will be collected only to the extent necessary. While most data collections will be conducted through secure digital platforms, if the need arises to collect hard copy data, paper copies will be stored in locked filed cabinets, with limited staff access, at NICHD offices or approved and secure offsite storage sitesFor digital collections via secure platforms data will be stored 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, but also on a FedRAMP certified, secure, encrypted server. Respondents will be informed of security through explanatory text on the cover of forms and applications. In addition,

⁴ Fomby, P., Sastry, N., & McGonagle, K. A. (2017). Effectiveness of a Time-Limited Incentive on Participation by Hard-to-Reach Respondents in a Panel Study. *Field methods*, *29*(3), 238–251. https://doi.org/10.1177/1525822X16670625.

⁵ Smith, M.G., Witte, M., Rocha, S. et al. Effectiveness of incentives and follow-up on increasing survey response rates and participation in field studies. *BMC Med Res Methodol* **19**, 230 (2019). https://doi.org/10.1186/s12874-019-0868-8.

⁶ Zheng, G., Oksuzyan, S., Hsu, S., Cloud, J., Jewell, M. P., Shah, N., Smith, L. V., Frye, D., & Kuo, T. (2018). Self-Reported Interest to Participate in a Health Survey if Different Amounts of Cash or Non-Monetary Incentive Types Were Offered. *Journal of urban health: bulletin of the New York Academy of Medicine*, 95(6), 837–849. https://doi.org/10.1007/s11524-018-0237-7.

respondents will be advised of the purpose of the information collection, of the use of information collected, of 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. Information will be presented in de-identified and aggregate form.

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 nonexempt activities, the staff will be required to submit the information collection for review by the NICHD IRB for approval.

A.11 Justification for Sensitive Questions

Information collections may contain sensitive questions of a moderate nature (e.g., income, age, education, race/ethnicity, gender). Such factors 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 virtual or telephone surveys or in-person interviews will be trained on confidentiality requirements, to ask questions in a sensitive manner, and to handle any subsequent discussion skillfully. Researchers who design the online survey questions and items will be professionals trained and experienced in this area.

A.12 Estimates of Annualized Burden Hours and Coasts

A.12.1 Estimates of Hour Burdens, 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 (13,305) 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 Estimated Annualized Burden Hours

	Type of	Number of	Number of Responses per	Average Burden per Response,	Total Annual Burden
Form Name	Respondents	Respondents	Respondent	in Hours	Hours
Focus Groups	General Public	<mark>215</mark>	<u>1</u>	1	<mark>215</mark>
Interviews	General Public	<mark>50</mark>	1	1	<mark>50</mark>
Pre-/Post-Tests	General Public	3,000	2	<mark>15/60</mark>	<mark>1,500</mark>
Pre-/Post-Tests	Health Professionals	20,000	2	15/60	10,000
Surveys	Health Professionals	<mark>3,000</mark>	<mark>1</mark>	<mark>30/60</mark>	<mark>1,500</mark>
Tracking/Feedback Form	Health Educators	20	2	1	<mark>40</mark>
Total		<mark>26,285</mark>	<mark>49,305</mark>		13,305

A.12.2 Annual Cost to Respondents

The estimated annualized cost to respondents is based on the Bureau of Labor Statistics for October 2020. The mean hourly wage for all occupations is \$25.72. Table 2 below provides an estimate for costs to respondents annually (\$508,974.40).

Table 2 Annualized Cost to Respondents

Type of Respondents	Total Annual Burden Hours	Hourly Respondent Wage Rate	Respondent Cost
General Public	<u>1,765</u>	\$25.72 ⁶	\$45,395.80
Health Professionals	11,500	\$40.21 ⁷	\$462,415.00
Health Educators	40	\$29.09 ⁸	\$1,163.60
TOTAL	<mark>13,305</mark>		\$508,974.40

⁶ U.S. Bureau of Labor Statistics/Occupational Employment and Wages, May 2019: Occupational Code 00-0000, All Occupations, national estimates: https://www.bls.gov/oes/current/oes nat.htm#00-0000

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

No costs are anticipated. Respondents will not need capital equipment, ongoing recordkeeping operations, or services to complete the information collections.

A.14 Annualized Cost to the Federal Government

The approximate annualized cost to the government for this data collection effort is \$43,657. These costs comprise federal employee salaries, contractor staff salaries, and operational expenses (e.g., equipment, printing, postage). Table 3 below provides the cost breakdown for the annualized cost to the federal government.

⁷ U.S. Bureau of Labor Statistics/Occupational Employment and Wages, May 2019: Occupational Code 29-000, Health Practitioners and Technical Occupations, national estimates: https://www.bls.gov/oes/current/oes290000.htm
⁸ Bureau of Labor Statistics/Occupational Employment and Wages, May 2019: Occupational Code 21-1091, Health Education Specialists, national estimates: https://www.bls.gov/oes/current/oes211091.htm

Table 3 Annualized Cost to Federal Government

Cost Descriptions	Grade/Step	Salary	% of Effort	Fringe (if applicable)	Total Cost to Government
Federal Oversight	Grade/Step	Suluiy	70 01 =11010	иррисцоте)	Government
NICHD Safe to Sleep®	GS-13-8	\$126,620	<mark>10%</mark>		<mark>\$12,662</mark>
Program Staff/Project					
<u>Oversight</u>					
Contractor Cost					
Project Manager	<mark>n/a</mark>	<mark>\$159,922</mark>	<mark>5%</mark>	\$42,831	\$10,137.65
Communications Associate	<mark>n/a</mark>	<mark>\$79,103</mark>	<mark>10%</mark>	<mark>\$21,186</mark>	\$10,028.90
Senior Digital Analyst	<mark>n/a</mark>	<mark>\$122,721</mark>	<mark>5%</mark>	<mark>\$33,854</mark>	\$7,828.75
<mark>Travel</mark>					
Operational Costs for Data					\$3,000
Collection Activities (e.g.,					
<mark>printing, postage,</mark>					
equipment, non-labor)					
Total		<mark>\$488,366</mark>		<mark>\$97,871</mark>	\$43,657

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.

A.15 Explanation for Program Changes or Adjustments

Changes have been made to the estimated burden hours based on anticipated activities for the next 3 years, including the (1) a revision to Risk Reduction for Sudden Infant Death

Syndrome (SIDS) and Other Sleep-Related Causes of Infant Death: Continuing Education

Activity for Nurses substudy, (2) discontinuation of one of the information collection forms for the Healthy Native Babies substudy, and (3) future substudies to get feedback on distribution and outreach activities, and/or campaign materials. We also anticipate using more virtual platforms and fewer in-person activities.

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

Analysis of sub-studies may be required and will typically include quantitative analysis such as frequencies, cross-tabulations, and measures of central tendency 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 of the focus group and interview data will be conducted. Analyses will highlight relationships across codes, patterns, contrasts, and similarities across key respondent groups to develop conclusions. These substudies 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 NICHD, and improve campaign management and implementation.

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 campaign Collaborators and the public through a website, email, or 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 (Attachments 2A and 2B).

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 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 clearance, the campaign staff will submit a request to continue to collect the information.

A17. Reason(s) the Display of the OMB Expiration Date is Inappropriate

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

A18. Exceptions to Certification for Paperwork Reduction Act Submissions

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