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)

OMB# 0925-0701, Exp: 7/31/2017

October 30, 2017

Check off which applies:

- New
- Revision

X **Reinstatement with Change**

- Reinstatement without Change
- Extension
- Emergency
- Existing

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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 expanding to 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 Safe to Sleep® 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 Reinstatement with Change for the Generic Clearance to Support the Safe to Sleep Campaign at the *Eunice Kennedy Shriver* National Institute for Child Health and Human Development 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 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.

A.1 Circumstances Making the Collection of Information Necessary

This is a request to reinstate with change a 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. Reinstatement with change is requested, as the STS 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 and reach of STS campaign materials and messages, and to monitor and improve campaign activities.

Established in 1962, by the request of the President of the United States, 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 3,500 infants die suddenly of no immediately, obvious cause.[1] Approximately, half of these deaths are due to Sudden Infant Death Syndrome

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

(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 in order 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). 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 importance and 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 to audiences of interest, such as health care providers, and collaborations with state and local organizations that serve disenfranchised groups. Safe to Sleep® 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 safe sleep recommendations. 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 stakeholder groups' (e.g., parents, caregivers, health care professionals) awareness and understanding of 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.

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

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), CJ First Candle, and the Association of SIDS and Infant Mortality Programs (ASIP). In addition, a Federal SUID/SIDS Workgroup representing nine federal agencies was formed in 2009 to complement the efforts of NICHD's STS by addressing the public health challenges of SIDS and SUID and advancing 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 activities on an independent basis. For example, the 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.

The NICHD also has a number of campaign activities implemented nationally and several

that are focused on states with the highest SIDS mortality rates or the highest absolute number of SIDS deaths. The NICHD STS campaign activities include trainings in African-American communities in Alabama (NICHD provides mini-grant funding for these trainings); African-American faith-based training outreach in states with high SUID/SIDS rates; general STS training workshops presented around the country as requested; a national online nurse continuing education activity on 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 in the Northern Plains region of the United States; and national physician office media promotions. These STS campaign activities help to 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 Safe to Sleep® campaigns have used several methods to test new messages and assess the effectiveness 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, sub-study approved 8/16/13), focus groups and interviews to test new campaign messages (OMB #: 0924-0643, sub-studies approved 1/27/15 and 2/2/15), and surveys with training participants' to learn about their activities and utilization of materials post-training (OMB #: 0925-0701, sub-studies approved 11/20/14, 12/12/14, 11/9/16). 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 that 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 seeks to reinstate with change the Generic Clearance to Support the Safe to Sleep Campaign at NICHD, which fills a need that exists at NICHD to assess the STS campaign activities.

The Generic Clearance to Support the Safe to Sleep Campaign at NICHD has provided a mechanism to request approval for information collection on the STS campaign activities, including materials, messages and training workshops, and overall campaign implementation. Reinstating this generic clearance will enable the STS campaign and the NICHD continue 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.

A.2 Purpose and Use of the Information Collection

This generic clearance was initially approved by OMB in 2014. OMB approval is being sought for a reinstatement, with change, for a period of 3 years; to continue 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.

Since the last original submission for clearance, information collections have been gathered for the STS campaign activities listed below. Reinstatement is requested for collections is requested for those labeled with an asterisk.

1. Healthy Native Babies Project*
    - Project Materials Distribution Tracking Forms
    - Train-the-Trainer Follow-Up Assessment Survey
2. Safe Sleep Outreach Project in states with high infant mortality rates (Alabama: 2015 to 2017)*
    - Activity/Tracking
    - Paperwork Checklist

- Sign-In Sheet
- Photo/Video Consent Form
- Pre-and post-training assessment on knowledge change and satisfaction with training materials

3. STS National Champions
    - Tracking form
    - Feedback form

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, 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 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 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:

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 campaign staff 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 health professionals' satisfaction with and knowledge gained from 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 clearance 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.

A.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. For these data collections, a privacy impact assessment has not been completed because the privacy act does not apply. All STS data collections exclude sensitive information and/or personally-identifiable information are not stored in a database. 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.

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 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 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 only conduct data collections after determining that similar information does not exist.

A.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 and nurses), 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.

A.6 Consequences of Collecting the Information Less Frequently

Most of the sub-studies planned for this generic clearance 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 require multiple contacts, the person submitting the individual sub-study will make provisions for the additional contact and provide justification in terms or meaningful results.

A.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.

A.8.1 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. 82, No. 165, pg. 40776-40777, on Monday, August 28, 2017. NICHD received one comment in response to the 60-Day Federal Register Notice [Attachment 2], questioning the overall utility of the proposed data collection.

A.8.2 Efforts to Consult Outside Agency

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.

Bethany D. Miller, LCSW-C, M.Ed.
Director, Child Injury and Violence Prevention Programs
MCHB/HRSA
5600 Fishers Lane, RM18N-44
Rockville, MD 20857
Phone: 301-945-5156
Email: bmiller@hrsa.gov

Sharyn Parks Brown, PhD, MPH
CDR US Public Health Service
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
4770 Buford Hwy, N.E. MS F74
Chamblee, GA 30341
phone: 770-488-4058
email: svp2@cdc.gov

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 or longer, NICHD may provide tokens of appreciation up to $75. For focus groups/in depth interviews 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 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.[3,4,5] 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.

A.10 Assurance of Confidentiality Provided to Respondents

[3] Yu S, Alper HE, Nguyen A-M, et al. The effectiveness of a monetary incentive offer on survey response rates and response completeness in a longitudinal study. *BMC Medical Research Methodology*. 2017;17:77. doi:10.1186/s12874-017-0353-1.

[4] Knoll M, Soller L, Ben-Shoshan M, et al. The use of incentives in vulnerable populations for a telephone survey: a randomized controlled trial. *BMC Research Notes*. 2012;5:572. doi:10.1186/1756-0500-5-572.

[5.] Singer, E, and Cong, Y. 2013. "The Use and Effects of Incentives in Surveys." *Annals of the American Academy of Political and Social Science*, 645(1): 112-141.

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, to the extent permitted by law. PII will only be collected to the extent necessary. Data will be stored in locked filed cabinets, with limited staff access, at NICHD offices or approved and secure off-site storage sites. 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. 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 non-exempt 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, for example: income, age, education, race/ethnicity, and 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 telephone surveys and in-person interviews will be trained on confidentiality requirements, 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.

A.12.1 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 (12,920) 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 12-1 Estimated Annualized Burden Hours

Form Name	Type of Respondents	Number of Respondents	Number of Responses per Respondent	Average Burden Per Response (in hours)	Total Annual Burden Hours
Focus Groups	General Public	45	1	1	45
Interviews	General Public	45	1	1	45
Pre/Post Tests	General Public	3,500	2	15/60	1,750
Pre/Post Tests	Health Professionals	20,000	2	15/60	10,000
Surveys	Health Professionals	2,000	1	30/60	1,000

Tracking/ Feedback Form	Health Educators	40	2	1	80
Total		25,630	49,170		12,920

A.12.2 ANNUAL COST TO RESPONDENT

The estimated annualized cost to respondents is based on the Bureau of Labor Statistics for June 2016[6]. The mean hourly wage for all occupations is $23.86. Table 2 below provides an estimate for costs to respondents annually ($352,699.6).

Table 12-2 Annualized Cost to Respondents

Type of Respondents	Total Annual Burden Hours	Hourly Respondent Wage Rate	Respondent Cost
General Public	1,840	$23.86	$43,902.4
Health Professionals	11,000	$27.87	$306,570
Health Educators	80	$27.84	$2,227.20
TOTAL	12,920		$352,699.6

[6] National Bureau of Labor Statistics. https://www.bls.gov/oes/current/oes_nat.htm#00-0000 accessed on July 27, 2017.

A.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.

A.14 Annualized Cost to the Federal Government

The approximate annualized cost to the government for this data collection effort is $44,769. 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 12-3 Annualized Cost to Federal Government

Cost Descriptions	Grade/Step	Salary	% of Effort	Fringe (if applicable)	Total Cost to Gov't
Federal Oversight					
NICHD Safe to Sleep® Program Staff/Project Oversight	GS-13-7	$113,755	10%		$11,375
Contractor Cost					
Project Manager	n/a	$169,328	5%	$40,639	$10,485
Communications Associate	n/a	$90,946	10%	$21,682	$11,263
Senior Digital Analyst	n/a	$139,630	5%	$33,288	$8,646
Travel					
Operational Costs for Data Collection Activities (e.g., printing, postage, equipment), non-labor					$3,000
Total		$411,279		$ 95,609	$ 44,769

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 next 3 years. Because the STS National Champions substudy is no longer active, the need for tracking/feedback forms is greatly reduced. We do not anticipate needing many focus groups or interviews, so those are reduced as well. We do anticipate more pre-/post-tests under this generic clearance due to a plan to request clearance for the STS continuing education activity.

Previously, continuing education satisfaction surveys were approved under NICHD's fast track clearance (OMB #0925-0643; 18,400 respondents, 4,600 hours). This continuing education (CE) activity is now approved by the Maryland Nurses Association (MNA) for 1.1 contact hours. To receive full contact-hour credit for this CE activity, the learner will need to

complete the pre- and post-test and submit them via the NICHD's online module's Claim Continuing Education Credit page. The pre-/post-test is currently under development and will be submitted as a substudy upon approval of this generic clearance. Based on past annual participation levels, the forecasted number of health professionals that will complete this CE activity per year could be as many as 20,000. Therefore, we estimate that we will have approximately 20,000 pre- and 20,000 post-tests for this CE activity. However, the customer satisfaction survey is sent out approximately 6 months after the training and traditionally has low response rate. Therefore, we anticipate only 2,000 survey respondents.

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

Analysis of sub-studies may be required and it will typically include quantitative 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. Analyses 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 2A-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 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