Supporting Statement B for:

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

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ATTACHMENTS

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- 1A – Generic Information Collection Request (ICR) Template
- 1B – Sub-study Memo Template

B. COLLECTION OF INFORMATION EMPLOYING STATISTICAL METHODS

B.1 Respondent Universe and Sampling Methods

The respondent universe consists of individuals who have access to or used Safe to Sleep® (STS) campaign materials, training workshops, or other campaign resources and services. It is difficult to define and anticipate the types of potential respondents, but below are descriptions of the people who have and could represent the STS campaign's respondent universe in this generic submission:

- STS campaign collaborators, national partners;
- Sudden and Unexpected Infant Death (SUID) and Sudden Infant Death Syndrome (SIDS) related professional organizations;
- Physicians, nurses, pharmacists and other health care professionals;
- Maternal and child health professionals
- Parents/caretakers; and
- General public.

The sub-studies conducted using this generic clearance will not be collections that require large numbers of respondents. The STS campaign will collect information for the purpose of campaign assessment, monitoring, and improvement or to support the campaign activities.

A variety of sampling methods may be employed including, but not limited to: convenience samples, random sampling, and quota sampling methods. As such, the sampling methods will not be used to generalize the information beyond the scope of the sample. Similarly, results will not be used to make statements representative of the universe of the project. The methods, however, will ensure that the NICHD collects sufficient information to inform decisions about messages, materials, and overall campaign management and implementation. Additionally, statistical analysis will not be conducted beyond qualitative methods and descriptive statistics. Specifics about the respondents, universe, and sampling techniques employed, if used, will be requested in the sub-study template request (**Attachment 1A-1B**).

B.2 Procedures for the Collection of Information

The STS campaign information collections will involve a number of data collection methods, including focus groups, surveys, and interviews. Each data collection method is described below.

Focus Groups. Focus group discussions are used to obtain insights into target audience's perceptions, beliefs, and attitudes in the early stages of the communication process (e.g., concept, strategy, and materials development). Focus groups are usually composed of 8 to 9 individuals who have characteristics similar to the target audience (or subgroups of the target audience) and usually take place in an in-person format. The group discussions are conducted by a professional moderator that keeps the session on track while allowing participants to talk openly and spontaneously. The moderator uses a loosely structured discussion guide, which allows him/her to change direction as the discussion unfolds and new topics emerge. Focus groups are valuable in exploring target audience reactions to message concepts, materials, and materials distribution before additional resources are invested in those areas. Depending on factors such as geographic distribution and schedules of participants, and on the nature of the campaign materials and messages under investigation, focus groups may use a variety of technology-based formats, including videoconferencing, Internet, and teleconferencing.

Surveys. For each STS information collection, NICHD will employ the survey method that is best suited for the type of information collection. Surveys may be implemented in the following formats:

- Online/Web-based Surveys – Online or Web-based surveys are becoming an essential research tool for a variety of research fields, including social sciences and marketing. Online/Web-based surveys are convenient because the respondent can log in and complete the survey at any time. In most cases, access to the survey is limited to the study population through the assignment of a username and password. Several advantages of an online/Web-based survey include: the elimination of routing and looping problems within a paper-and-pencil questionnaire; respondents cannot accidentally skip questions; pop-up instructions can be provided for questions to offer help where and when assistance is needed; lists of answer choices can be used to provide immediate coding of answers; software can automatically perform mathematical calculations and tabulations; and software can check for inadmissible or inconsistent responses. An online/Web-based survey can eliminate errors that arise from separate data entry.
- Telephone Surveys – Telephone surveys are useful for collecting information in a short timeframe while maintaining high response rates, with resulting estimates generalizable to the universe of study. Trained interviewers will contact potential respondents to administer a questionnaire over the phone.
- In-person Surveys – In-person surveys will be administered in a central location by trained interviewers to elicit information on certain topics or issues. In-person surveys allow interviewers to administer the survey to respondents that do not have telephones or Internet access, or other hard-to-reach populations. Also, before and/or after training sessions, conferences, etc., surveys can be administered on-the-spot increasing the chances that more surveys will be completed and returned immediately versus waiting for

respondents to return home/work to respond to the online/Web-based survey.

- Mail Surveys – Mail surveys are distributed to program participants and trainees through the mail. Respondents complete the surveys and return them for tabulation and analysis.

Interviews. Interviews can be conducted individually, in triads, or in small groups. Using semi-structured interview protocols, interviews will be conducted to test message concepts, draft materials, and communication strategies. This methodology is appropriate for determining the target audiences attitudes, beliefs, and feelings on particular educational messages, print materials, or program activities being tested. Interview respondents are recruited to reflect members of the target audiences. They are also recruited based on meeting other appropriate screening criteria (e.g., race/ethnicity, length of service in a field, age of child), including their willingness to be interviewed. Specific written instructions in the screening form are used during the recruitment process. Once recruited, participants are contacted for the interview and interviews are conducted by skilled interviewers that follow a semi-structured guide/protocol. Many interviews are done by phone because this is a cost-effective way to elicit comments on print materials. For telephone interviews, participants receive a copy of the materials in advance, are asked to review it, and are informed that they will be called for an interview to gather their opinions on the materials.

For the focus groups, surveys, and the interviews, respondents will initially be contacted by telephone, in person, or through electronic mail. In most instances, the respondents will be asked to complete an interviewer- or self-administered screening form to determine if they possess the target audience characteristics of interest. Those who meet the eligibility criteria are informed of the purpose of the research and the date, time, and location of data collection (or asked what date and time is convenient for them) and asked if they wish to participate. Over-recruiting is done to compensate for respondents who do not show (the standard industry no-show rate is 20%). For data collection activities taking place in the future, respondents are sent a written reminder of the date, time, and location via email and/or contacted by telephone, along with procedures to follow if their participation needs to be canceled or rescheduled.

B.3 Methods to Maximize Response Rates and Deal with Non-Response

NICHD Safe to Sleep Campaign staff will ensure that each study population receives numerous requests to enable the highest response rate possible. This will help guarantee that NICHD is collecting sufficient data to make informed decisions about campaign messages, materials, and trainings. Several procedures have been proven effective in previous studies to help maximize response rates, particularly for focus groups, surveys, and interviews:

- Potential respondents will be informed about the importance of these information collections and encouraged to participate through a variety of methods, including newsletters from professional and community organizations, and letters of support from key individuals.
- Experienced, highly-trained staff will moderate all focus groups and conduct all interviews and surveys.
- Interviewers will participate in training sessions to discuss study objectives, reviews of the data collection instrument, strategies for engaging respondents, role playing, and techniques to foster respondent cooperation and survey completion.
- For telephone interviews, outgoing calls that result in a no answer, a busy signal, or an answering machine will be automatically rescheduled for subsequent attempts. Approximately three attempts will be made before declaring it a non-response.
- Should a respondent interrupt an interview for any reason, such as needing to attend a

personal matter, the interviewer will reschedule the interview for completion at a later time.

- The initial requests for participation in an interview, focus group, or survey will come from a NICHD staff person by mail or by email using a NIH email account. From past experience, this has increased participants' response because they are accustomed to the NICHD/NIH email account and the initial requests provides a NICHD point of contact to confirm the study's legitimacy and address any questions or concerns.
- For web-based surveys, non-responders will receive weekly reminder emails, for up to six weeks, containing the link to the survey website.
- For mail surveys, a self-addressed, stamped return envelope will be enclosed with each survey and follow-up mail or phone contacts will be made to encourage participation. Respondents will also be provided the option to complete the survey online or by faxing the completed survey.

B.4 Test of Procedures or Methods to Be Undertaken

Pretesting may be done with internal staff, a limited number of external colleagues, and/or customers who are familiar with the campaign and its materials. If the number of pretest respondents exceeds nine individuals, campaign staff will submit the pretest instruments for review under the generic clearance.

B.5 Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

Statisticians will be employed in the development, design, conduct, and analysis of campaign data collections instruments, when appropriate. This statistical expertise will be available from NICHD statisticians or from contractors. Names and contact information of persons consulted in the specific information collection requests will be included in the sub-study package under this generic clearance.