

Request for Approval under the “Generic Clearance for the Collection of Routine Customer Feedback” (OMB Control Number: 0925-0643)

TITLE OF INFORMATION COLLECTION: Safe to Sleep Campaign Focus Groups with the Breastfeeding/Lactation Support Community

PURPOSE:

Each year in the United States, more than 4,500 infants die suddenly of no immediately, obvious cause. Half of these sudden unexpected infant deaths (SUID) are due to Sudden Infant Death Syndrome (SIDS), the leading cause of SUID and of all deaths among infants aged 1-12 months.¹ In 1994, the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD) launched Back to Sleep, a national public health education campaign, to raise awareness to reduce the risk of SIDS. The overarching campaign is based on the recommendation by the American Academy of Pediatrics (AAP) to have babies sleep on their backs to reduce their risk of SIDS. In 2011, the AAP released recommendations for safe infant sleep that went beyond SIDS and addressed the shared risk factors for other sleep-related infant deaths (e.g., suffocation, entrapment, overlay). The NICHD expanded the Back to Sleep campaign to incorporate these new messages and launched the Safe to Sleep campaign in September 2012. In addition to reinforcing the message that back sleeping is best, the expanded campaign communicates the overall impact of a safe sleep environment on a baby’s health.

Before launching the Safe to Sleep campaign in 2012, in December 2011 the NICHD conducted several focus groups on the campaign name and logo (OMB Clearance #: 0925-0643) with parents, caregivers, and health care providers. The findings from these focus groups as well as the research literature indicated a need to gather feedback from the breastfeeding/lactation support community with respect to the 2011 AAP safe infant sleep guidelines. For example, a study using individual records of SIDS cases from five major case-control studies concluded that bed sharing increases the risk of a child dying from SIDS more than five times, even if parents are non-smokers and the mother did not abuse illegal drugs or drink alcohol before bedtime.² Moreover, researchers found that 9 of 10 SIDS deaths that involved sleeping with a parent or caregiver would not have occurred if the parents did not bed share.

The goals of the proposed focus groups are to:

- Understand the target audiences’ knowledge, attitudes, beliefs, and behaviors related to breastfeeding and the AAP guideline against bed sharing, even when breastfeeding.
- Gather feedback on messages we develop in support of the AAP guideline, such as:
 - The Centers for Disease Control and Prevention estimates that 4,500 infants die suddenly of no immediately, obvious cause each year in the United States.
 - Studies have shown that sharing a bed with your baby increases your baby’s chances of dying from SIDS [by five times].
 - The safest place for a baby to sleep for the first 12 months is in a crib, bassinet, or play yard in the same room as a parent or caregiver.
 - Room sharing is a safe and effective alternative to bed sharing.
 - You can successfully breastfeed and protect your baby from SIDS by room sharing, not bed sharing.

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

² Carpenter R, McGarvey C, Mitchell EA, Tappin DM, Vennemann MM, Smuk M, Carpenter JR. Bed sharing when parents do not smoke: is there a risk of SIDS? An individual level analysis of five major case-control studies. *BMJ Open* 2013;3:e002299.

- Discuss suggestions for effective communication channels and venues in which to raise awareness of the guideline against bed sharing among breastfeeding mothers.

The research questions guiding the focus groups include:

1. How can organizations that support the AAP guideline against bed sharing with babies,³ even when breastfeeding, most effectively communicate this message to targeted groups?
2. How can the NICHD better promote breastfeeding in accordance with the AAP Safe to Sleep guidelines?

Formative communications testing will ensure that the messages resonant with their intended audiences and increase the likelihood that the parents, caretakers, and health professionals will follow the recommendations when they put their infants to sleep.

DESCRIPTION OF RESPONDENTS:

This project will focus on the following target audiences:

- Individuals or Households
 1. Pregnant women/Expecting moms: This will include a mix of first-time mothers and mothers who have been pregnant before from diverse racial/ethnic backgrounds and geographic locations across the United States.
 2. Currently Breastfeeding Mothers: This will include first-time mothers and mothers who have been pregnant before from diverse racial/ethnic backgrounds and geographic locations across the United States.

TYPE OF COLLECTION: (Check one)

- | | |
|---|---|
| <input type="checkbox"/> Customer Comment Card/Complaint Form | <input type="checkbox"/> Customer Satisfaction Survey |
| <input type="checkbox"/> Usability Testing (e.g., Website or Software) | <input type="checkbox"/> Small Discussion Group |
| <input checked="" type="checkbox"/> Focus Groups (both telephone and in-person) | <input type="checkbox"/> Other: |

CERTIFICATION:

I certify the following to be true:

1. The collection is voluntary.
2. The collection is low-burden for respondents and low-cost for the Federal Government.
3. The collection is non-controversial and does not raise issues of concern to other Federal agencies.
4. The results are not intended to be disseminated to the public.
5. Information gathered will not be used for the purpose of substantially informing influential policy decisions.
6. The collection is targeted to the solicitation of opinions from respondents who have experience with the program or may have experience with the program in the future.

Name: ___Janelle E. Banks_____

To assist review, please provide answers to the following question:

Personally Identifiable Information:

³ SIDS and other sleep-related infant deaths: expansion of recommendations for a safe infant sleeping environment. Task Force on Sudden Infant Death Syndrome. *Pediatrics* 2011; 1030-1039.

1. Is personally identifiable information (PII) collected? Yes No
2. If Yes, is the information that will be collected included in records that are subject to the Privacy Act of 1974? Yes No
3. If Applicable, has a System or Records Notice been published? Yes No

Gifts or Payments:

Is an incentive (e.g., money or reimbursement of expenses, token of appreciation) provided to participants? Yes No

Respondents will receive remuneration through recruitment companies contracted to obtain participants. The amount of remuneration is based on pay scales these companies follow. Based on feedback from recruitment professionals, telephone participants will receive \$20 for participating in a 60-minute telephone focus group.

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. There is also extensive literature to support the use of incentives, primarily monetary incentives, as a supplement or complement to other efforts of encouragement to ensure recruitment of a representative sample, especially among not-yet-served and minority populations.^{4,5} Small amounts of money, a free meal or snack scheduled around the time of the focus group, and/or remuneration for parking and/or transportation are most often used. 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.

BURDEN HOURS

Category of Respondent	No. of Respondents	Participation Time (in hours)	Total Burden Hours
Individuals-Households	18	60/60	18
Totals	18	60/60	18

FEDERAL COST: The estimated annual cost to the Federal government is \$6828.

If you are conducting a focus group, survey, or plan to employ statistical methods, please provide answers to the following questions:

The selection of your targeted respondents

1. Do you have a customer list or something similar that defines the universe of potential respondents and do you have a sampling plan for selecting from this universe?
 Yes No

⁴ Singer E and Kulka RA. Paying respondents for survey participation. In Ver Ploeg M, Moffitt RA, Citro CF (eds). Studies of Welfare Populations: Data collection and Research Issues. National Academy Press: Washington, DC 2001. Available at <http://www.nap.edu/openbook/0309076234/html>. Accessed on May 13, 2008.

⁵ Kovac MD, Markesich J. Tiered incentive payments: getting the most bang for your buck. Presentation at the Annual Conference of the American Association for Public Research, 2002.

If the answer is yes, please provide a description of both below (or attach the sampling plan)? If the answer is no, please provide a description of how you plan to identify your potential group of respondents and how you will select them?

Using a structured recruitment screener, a professional recruitment vendor will identify eligible participants, contact them by telephone, explain the focus group study, invite them to participate, and schedule their focus group participation. The recruitment facility will recruit 12 individuals for each of the in-person focus groups with the aim of accepting a maximum of 9 per focus group. (Qualitative research experience has shown that no-show rates for focus groups are typically about 20%.)

The recruitment facility maintains a database of people who have participated in previous focus groups and/or who have volunteered to take part in research. This database includes demographic information such as gender, age, race/ethnicity, education, and job status. Using the approved screener criteria (e.g., currently pregnant women, breastfeeding mothers), the firm will contact individuals in the database to identify focus group participants. If additional people need to be identified, the recruitment firm will reach out to appropriate organizations (e.g., La Leche League) and screen and identify the focus group participants.

Administration of the Instrument

1. How will you collect the information? (Check all that apply)
 - Web-based or other forms of Social Media
 - Telephone
 - In-person
 - Mail
 - Other, Explain
2. Will interviewers or facilitators be used? Yes No

Please make sure that all instruments, instructions, and scripts are submitted with the request.