United States Food and Drug Administration
Generic Clearance for Qualitative Data to Support Social and Behavioral Research for Food, Dietary Supplements, Cosmetics, and Animal Food and Feed
OMB Control Number 0910-0891
Gen IC Request for Approval

Qualitative methods generally yield data that are not statistically generalizable. As such, they are useful for testing and refining ideas, and for developing hypotheses that can be further explored using quantitative methods, which is the preferred method for informing important policy and resource allocation decisions.

Title of Gen IC: In-depth Interviews with Healthcare Professionals and Health Educators on Environmental Contaminants in Food for Young Children

1. Type of Collection

   For this gen IC FDA will conduct in-depth, one-on-one interviews.

2. Statement of Need

   The U.S. Food and Drug Administration (FDA), Center for Food Safety and Applied Nutrition (CFSAN), Office of Analytics and Outreach is seeking OMB approval under the generic clearance 0910-0891 for the project titled, "In-depth Interviews with Healthcare Professionals and Health Educators on Environmental Contaminants in Food for Young Children."

   The FDA's Closer to Zero action plan outlines the steps the agency will take to reduce babies' and young children's exposure to environmental contaminants, such as arsenic, lead, cadmium, and mercury, in food. Previously, under contract with CFSAN, Westat, a social science research firm, conducted focus groups with parents and caregivers of children ages 6 months to 24 months to understand their knowledge of environmental contaminants in baby foods and to gather reactions to a draft educational piece from the FDA. We are currently seeking approval to conduct in-depth interviews with healthcare professionals and nutrition educators that regularly educate parents and caregivers of young children between the ages of 6 months to 6 years of age to further this effort. The interviews will collect information about the target audiences' knowledge, practices and information needs related to educating parents and caregivers about environmental contaminants in food. Specifically, the interviews will examine healthcare professionals' and nutrition educators' understanding and knowledge of environmental contaminants in foods consumed by babies and young children, their current practices and challenges related to providing information to parents and caregivers, and their reactions to FDA's Closer to Zero program and the agency's communication approach regarding environmental contaminants in food.

3. Intended Use of the Information

   The findings from these interviews will support FDA's Closer to Zero Initiative and provide educational resources to healthcare professionals and nutrition educators. These resources will enable healthcare professionals and nutrition educators to better communicate with parents and caregivers on how to protect their young children at various ages from the effects of environmental contaminants in foods and to convey the steps the agency is taking to ensure the safety of the food supply.

4. Description of Respondents

The 27 interviews will be conducted with English-speaking U.S. healthcare providers and nutrition educators whose patients and clients are parents or caregivers of young children. (See Appendix I – Participant Screener)

The interviews will be conducted with different types of healthcare professionals and nutrition educators, including pediatricians, pediatric physician assistants, pediatric registered nurses, pediatric registered dietitian nutritionists, educators from Women, Infants, and Children (WIC), Supplemental Nutrition Assistance Program (SNAP), and Expanded Food and Nutrition Education (EFNEP) programs (see Table 1 below). These participants will be screened to ensure sufficient experience and exposure to caregivers and parents of young children, defined as individuals between six months and through 5 years of age. Additionally, participants will be a mix of age, race/ethnicity, and gender.

These interviews will be conducted online. FDA has contracted with Westat to conduct these interviews. To ensure that interviews are completed in a timely manner, Westat will recruit up to 40 participants to achieve 27 complete interviews.

Table 1

Number	Professional Type
Healthcare Professionals and Educators	
1-4	Pediatricians (4 interviewees)
5-8	Pediatric physician assistants (4 interviewees)
9-12	Pediatric registered nurses (RN) (4 interviewees)
13-16	Pediatric registered dietitian nutritionists (RD/RDN) (4 interviewees)
17-20	WIC specialists (4 interviewees)
21-24	SNAP educators (4 interviewees)
25-27	EFNEP educators (3 interviewees)

5. How the Information is Collected

All recruitment will be conducted by a professional recruiting company, with which Westat will establish a purchase order agreement. Potential participants will be screened by telephone using the participant screener (Appendix I).

Westat will provide all necessary information and instructions to the participants to ensure successful login into the online platform on the agreed-upon date and time. They will ensure that eligible participants show up for their scheduled time slot by sending confirmation and reminder correspondences to recruited individuals. Participants will also receive a copy of the informed consent (Appendix II) in one or more of these correspondences and will be instructed to review the form prior to their scheduled interview.

Westat staff members will serve as interviewers for all interviews. FDA staff members will observe most, if not all, of the sessions remotely using streaming technology. The interviewer will use the attached interviewer guide (Appendices III) to ensure that all relevant topic areas are addressed. Westat will make audio and video recordings to ensure a verbatim record of the proceedings is captured.

6. Confidentiality of Respondents

This individual gen IC will collect personally identifiable information (PII). The PII collected consists of name, facial and voice recording, gender, race/ethnicity and contact information. PII is collected on behalf of the FDA by a contractor who will conduct a study aimed to better understand healthcare professionals' and heath educators' experiences and needs related to environmental contaminants in foods for infants and young children. Audio and visual recording of the survey takes place during the interviews which also includes participants first name. Information collected by the contractor will be sent to FDA that includes first name, gender, and race/ethnicity, information that is not reasonably linkable back to the participant and destroyed after the study or interview has been completed. Collected PII is used to notify potential respondents of their selection and includes name and contact information. Study interviews are conducted in video recordings that includes facial and voice recording. The first name is used during the interview too. All information collected will be kept secure by the contractor. FDA and the contractor will disclose identifiable information only to the extent authorized by the individual or required by law. Contractors maintaining information will destroy it in accordance with applicable records retention and other requirements per contract terms after the aggregate information has been provided to FDA and the interview has been completed. In keeping with IRB/Human Subjects Research protocols, the FDA clearance process ensures that study data is appropriately secured (e.g., housed on the Contractor's servers, password protected, separate storage areas for each study, access controlled).

FDA determined that although PII is collected it is not subject to the Privacy Act of 1974 and the particular notice and other requirements of the Act do not apply. Specifically, the contractor does not use name or any other personal identifier to retrieve records from the information collected.

7. Amount and Justification for Proposed Incentive

For this study, participants will be offered an incentive based on their healthcare specialty. Pediatricians will be offered an incentive of $225, pediatric physicians assistants will be offered $200, pediatric registered nurses will be offered $150, registered dietitian nutritionists will be offered $125, and WIC, SNAP, and EFNEP educators will be offered $125, with the possibility of offering an additional $50 if we struggle to schedule enough participants from this difficult-to-recruit population.

Although market incentive rates for physicians and other healthcare professionals are approximately $250 to $350 for similar research activities, with higher rates for specialists, the flexibility that our interview methodology affords— remote interviews in which healthcare professionals can participate around their schedules and from their offices— may help offset the lower token of appreciation. All interview participants will receive their tokens of appreciation after completion of their interview. This ensures that we can attract participants who meet our screening requirements to participate in the online interview and improve the likelihood that they will log on and participate in the discussion. The following additional factors contributed to the cost of our proposed incentive:

Burden on the participant: Our proposed incentive is based on participants spending approximately ninety (90) minutes of their time on this effort, which includes time spent for online and phone screening (10 minutes), time for testing the platform (10 minutes), time to participate in the interview (60 minutes), and the request to log in 10 minutes early to confirm technical operation. The Bureau of Labor Statistics (BLS) calculated that the average hourly wage of healthcare professionals in May 2021 was $39.78 for nurses, $56.75 for nurse practitioners,

$57.43 for physician assistants, $60.43 for pharmacists, $113.43 for primary care physicians, and up to $149.35 for specialty physicians (Bureau of Labor Statistics, 2021)[1]. At that hourly rate, compensation for 90 minutes ranges from approximately $60 up to $223 depending on the healthcare profession.

Improved coverage of hard-to-reach populations or rare groups: A finite number of healthcare professionals and dietitians and nutrition educators meet the eligibility requirements for this study. We are seeking to interview pediatric healthcare professionals and specialists who educate parents and caregivers about their children's nutrition and/or diet as related to child health and development. The use of adequate incentives can help improve coverage of hard-to-reach populations.

Historically, physicians and other healthcare professionals are one of the most difficult populations to recruit for research, partly because of the demands on their professional time. These demands have only increased during the last three years with the COVID-19 pandemic, which has put extreme stress on the health care workforce in the United States, leading to workforce shortages as well as increased health care worker burnout and exhaustion.[2] Consequently, incentives assume an even greater importance with this group. Several studies have discussed the challenges of conducting research with healthcare professionals and have concluded that offering substantial incentives is necessary to attain high response rates.[3,4]

Recruiting healthcare professionals to participate in research has been shown to be difficult for reasons related primarily to the time burden.[5] Healthcare professionals' time is limited and, thus, quite valuable. A meta-analysis on methodologies for improving response rates in physician surveys examined 21 studies published between 1981 and 2006 that investigated the effect of monetary incentives on response rates in surveys of physicians. The authors found that the odds of responding to a survey with an incentive were 2.13 times greater than responding to a survey without incentives.[6] Martins and colleagues conducted a review of published oncology-focused studies to investigate methods for improving response rates. Their meta-analysis also showed that monetary incentives were effective at increasing response rates.[7] Previous research also suggests that providing incentives may help reduce sampling bias by increasing rates among individuals who are typically less likely to participate in research (such as PCPs or physician specialists)[8,9]

[1] Bureau of Labor Statistics, U.S. Department of Labor, Occupation Employment Statistics, on the Internet at https://www.bls.gov/oes/current/oes_stru.htm#29-0000 (visited January 24, 2023).

[2] Impact of the COVID-19 pandemic on the hospital and outpatient clinician workforce: challenges and policy responses (Issue Brief No. HP-2022-13). *Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services*. May 2022. (https://aspe.hhs.gov/sites/default/files/documents/9cc72124abd9ea25d58a22c7692dccb6/aspe-covid-workforce-report.pdf)

[3] Dykema, J., Stevenson, J., Day, B., Sellers, S. L., & Bonham, V. L. (2011). Effects of incentives and prenotification on response rates and costs in a national web survey of physicians. *Evaluation & the Health Professions*, *34*(4), 434-447.

[4] Ziegenfuss, J. Y., Burmeister, K., James, K. M., Haas, L., Tilburt, J. C., & Beebe, T. J. (2012). Getting physicians to open the survey: Little evidence that an envelope teaser increases response rates. *BMC Medical Research Methodology*, *12*(1), 41.

[5] Asch, S., Connor, S. E., Hamilton, E. G., & Fox, S. A. (2000). Problems in recruiting community-based physicians for health services research, *Journal of General Internal Medicine*, 15(8), 591-599.

[6] VanGeest, J., Johnson, T. & Welch, V. (2007). Methodologies for improving response rates in surveys of physicians: A systematic review. *Evaluation and the Health Professions*, *30*, 303-321.

[7] Martins, Y., Lederman, R. Lowenstein, C. et al. (2012). Increasing response rates from physicians in oncology research: A structured literature review and data from a recent physician survey. *British Journal of Cancer, 106*(6), 1021-6.

[8] Converse, J. M. & Presser, S. (1986). *Survey questions: Handcrafting the standardized questionnaire* (No. 63). Thousand Oaks, CA: Sage.

[9] DeVellis, R. F. (2016). *Scale development: Theory and applications (Vol. 26)*. Thousand Oaks, CA: Sage.

and ensuring participation from a cross section of physicians, which will improve data quality by improving validity and reliability.

8. Questions of a Sensitive Nature

There will be no questions of a sensitive nature asked of participants.

9. Description of Statistical Methods

We will begin with a sample size of 80 possible respondents. After screening for different types of healthcare providers and nutrition educators (see Table 1 above), we will obtain a total of 27 interviewees. This process will identify specific healthcare professionals and nutrition educators based on their position and experience.

10. Burden

Activity	No. of Respondents	Participation Time (minutes)	Total Burden (hours)
Individual In-Depth Interviews (Screening)	80	10	14
Individual In-Depth Interviews	27	60	27
TOTALS	80	---	41

11. Date(s) to be Conducted

The 27 interviews will be conducted approximately two months from the date of OMB approval.

12. Requested Approval Date

November 2023.

13. FDA Contacts

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