Feeding My Baby and Me: Infant Feeding Practices Study III

Extension: OMB No. 0920-1333 04/30/2024

Supporting Statement A

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JUSTIFICATION SUMMARY

Goal of the project: The goal of the Feeding My Baby and Me: Infant Feeding Practices Study III (FMB&M- IFPS III) is to

(1) understand the current state of mothers' intentions, behaviors, feeding decisions, and practices from pregnancy through their child's first two years of life,
(2) assess how these change over the first two years of life,
(3) assess the impact of these practices on feeding and health outcomes during the first two years, and
(4) explore emerging issues related to infant and toddler feeding practices during the first two years of life.

Intended use of the resulting data: FMB&M- IFPS III is a recently designed study which builds upon work from previous efforts. The data can be used to: fill research gaps on how feeding behaviors, patterns, and practices change over the first two years of life and the health-related impacts; inform multiple federal agency efforts targeting maternal and infant and toddler nutrition through work in hospitals, with health care providers, with early care and education providers, and outreach to families and caregivers; and provide context to policy level documents such as the *U.S. Dietary Guidelines for Americans,* which included pregnant women and children birth to 24 months of age for the first time in *2020–2025*.

Methods to be used to collect: FMB&M- IFPS III is a longitudinal study following pregnant women and their new baby for two years. Data are collected using web-based surveys at multiple time points over two years. This includes 1) a prenatal survey, 2) 14 follow up surveys after the baby is born, and 3) 2-4 maternal dietary data recalls.

The subpopulation to be studied: FMB&M- IFPS III has enrolled pregnant women (20–37 weeks gestation) aged 18–49 years and their resulting healthy, singleton, full-term infants in the study with a goal of having complete information on 2,500 mother/child dyads at the end of two years.

How data will be analyzed: Data will be analyzed using standard descriptive statistics (e.g., means, frequencies, crosstabs), regression analyses (e.g., multiple and logistic regression), and repeated measures models.

A. JUSTIFICATION

A1. Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention (CDC) requests a one year extension without changes from the Office of Management and Budget (OMB) to continue information collection for a study entitled, “Feeding My Baby and Me: Infant Feeding Practices Study III”. Authority for CDC to collect this information is granted by Section 301 of the Public Health Services Act (42 U.S.C. 241) (Attachment 1). Previous Infant Feeding Practices Studies (“Infant Feeding Practices Study,” OMB No. 0910-0220, exp. 6/30/1998; “Infant Feeding Practices Study II,” OMB No. 0910-0558, exp. 12/31/2007) have been used to describe infant feeding practices and patterns. A Follow-up Study for Infant Feeding Practices Study II (“Follow-up Study for Infant Feeding Practices II,” OMB No. 0910-0696, exp. 11/30/2014) identified the original Infant Feeding Practices Study II cohort and followed them up six years later to assess later feeding and health outcomes. CDC engaged multiple federal agencies throughout the planning process of FMB&M-IFPS III to ensure that this study used lessons learned from previous efforts and represented the priorities and needs of other agencies. FMB&M- IFPS III builds upon the work of previous Infant Feeding Practices Study efforts and has updated the methodology, questions, and the length of data collection (from one year to two years); resulting in a study of a new cohort of pregnant women and their new baby.

A child’s first two years of life can have profound impacts on their later dietary behaviors and health outcomes [1]. There are benefits of breastfeeding for both mother and baby [2, 3]. In addition, early feeding behaviors (i.e., timing of complementary food introduction; intake of different foods and beverages such as fruits, vegetables, sugar sweetened beverages; and maternal and infant feeding styles) can play a role in the establishment of later dietary behaviors as well as their association with health outcomes (i.e., risk of infections, obesity, weight gain) [4-10]. However limited data are available to longitudinally track how prenatal and maternal practices impact infant feeding and health in the early years of life.

FMB&M- IFPS III is an integral part of CDC’s work to support optimal nutrition and feeding practices during the first two years of life. Specifically, FMB&M- IFPS III can inform CDC’s programmatic work in hospitals, with health care providers, with early care and education providers, and outreach to families and caregivers through our funding opportunities at the state and community level (e.g., “State Physical Activity and Nutrition (SPAN) Program”, “Racial and Ethnic Approaches to Community Health (REACH), and the “Hospital-based Quality Improvement Initiative to Improve Maternity Care Practices Support of Optimal Infant Nutrition”). Without this information, CDC would lack data to inform the

development and refinement of current programmatic efforts to improve feeding practices and promote health in children less than 2 years of age.

Data from FMB&M- IFPS III can also provide a broader impact including providing context to policy level documents such as the *U.S. Dietary Guidelines for Americans*, which for the first time will incorporate dietary guidelines for children birth to 24 months and pregnant women. In addition, this work is an integral part the US Health and Human Services' Healthy People 2030 objectives to increase the proportion of infants who are breastfed.

A2. Purpose and Use of the Information Collection

The purpose of this data collection is to understand the current state of mothers' intentions, behaviors, feeding decisions, and practices from pregnancy through their child's first two years of life and how these change. It also assesses the impact of these practices on feeding and health outcomes during the first two years, and explores emerging issues related to infant and toddler feeding practices. This is being done by conducting a longitudinal study following pregnant women and their baby for their first two years of life.

Use of information: Data can inform programmatic work as noted in A1 and fill scientific and research gaps on a number of areas, including:

- Maternity care practices and experiences:
    - How are current maternity care practices associated with infant feeding outcomes (e.g., breastfeeding, infant formula use)?
    - How are birth experiences (e.g., delivery mode, use of pain medications during delivery, COVID-19 precautions and/or diagnosis) associated with infant feeding outcomes?
    - Do maternity care practices differ by sociodemographic characteristics of participants?
    - After participants return home from the hospital, do maternity care practices impact later infant feeding outcomes?
- Breastfeeding, infant formula feeding, and breast milk use and sharing:
    - What, and how, are infants and toddlers being fed at each survey month?
    - How do these infant and toddler feeding outcomes (i.e., breastfeeding, infant formula use, or breast milk sharing) relate to health outcomes (e.g., weight status, food allergy/intolerance, dental caries, infections)?
    - What sociodemographic characteristics are associated with different infant and toddler feeding outcomes and practices?

    - When do infants and toddlers stop receiving breast milk or infant formula?
- Complementary food (i.e., any food other than breast milk or infant formula) introduction and transition to the family diet:
    - When, what, and how are infants and toddlers being fed complementary foods?
    - Why are these decisions being made and what impact do they have on dietary intake, dietary quality, and health outcomes?
    - How do dietary patterns change from their first year to the second year?
    - Are dietary patterns in the first year associated with dietary patterns in the second year?
- Parent and child feeding styles:
    - How are participants interacting with their child during feeding and how do these change over time?
    - How do these interactions impact dietary intake, dietary quality, and health outcomes?
- Infant and toddler food allergies:
    - When are infants and toddlers being introduced to allergenic foods?
    - What feeding practices are associated with a risk of food allergies?
    - What is the prevalence of food allergies in the first two years of life?
- Childcare and employment experiences that impact feeding:
    - How does the use and characteristics of childcare impact infant and toddler feeding intentions, practices, and health outcomes?
    - How does employment status (i.e., not working, working part-time, working full-time), work location (i.e., working from home or at a worksite), and workplace support for breastfeeding impact infant and toddler feeding intentions and practices?
    - How does maternity/family leave availability and use impact feeding intentions, practices, and health outcomes?
    - How do interruptions to availability of childcare due to the COVID-19 pandemic impact infant and toddler feeding practices?
- Maternal and child health outcomes:
    - Are there maternal characteristics (e.g., age, education, work status, birth control use, weight status) that impact their infant or toddler's dietary intake, dietary quality, or dietary patterns?
    - Are there maternal characteristics that impact their infant or toddler's health outcomes?
    - What is the prevalence of different health outcomes of infants and toddlers and how do these change over time?
- Dietary intake of mothers during pregnancy and postnatally

- Is prenatal diet associated with postnatal diet?
- Does maternal prenatal diet, or postnatal diet, impact their infant or toddler's dietary intake, dietary quality, or dietary patterns?
- Does maternal prenatal diet, or postnatal diet, impact the health outcomes of their infants or toddlers?

FMB&M- IFPS III recruited pregnant women (20–37 weeks gestation) using an Internet-based, paid social and digital media recruitment approach (Attachment 5b). This was done using social media ads to appeal to a diverse group of women, targeting women based on group memberships and interests, and distributing ads among census regions and zip codes. Potential participants were directed to an online screener questionnaire to determine eligibility. This questionnaire determined due date, demographic information, and contact information (Attachment 4a). At the time of enrollment, eligible participants must be (1) between 20 weeks to 37 weeks gestation, (2) not pregnant with multiples, and (3) between the ages of 18–49. Participants will complete a total of 14 web-based surveys over 24 months (Attachments 4b–4p). In addition, mothers complete an on-line assessment of dietary intake using an online, automated, self-administered tool developed by the National Cancer Institute called the ASA24 shortly after the prenatal survey and around the 3 month follow up survey (Attachments 4q). A sub-sample of 15% of participants were asked to complete a second dietary intake at the prenatal survey and around the 3 month follow up survey. Similar to previous IFPS efforts and following all data sharing requirements, FMB&M- IFPS III data will be made available, including documentation on appropriate statistical methods and approaches to use.

Since OMB approval, FMB&M- IFPS III has completed study recruitment, enrolled eligible participants, and completed data collection efforts through the 10 month survey. The remaining surveys (12 month, 15 month, 18 month, and 24 month) are being fielded for all age-eligible participants. Because the recruitment window allowed for eligible participants to enroll in the study at 20 weeks gestation, a subset of participants were born 4 to 5 months after initial OMB approval was provided. In addition, there were some recruitment and enrollment delays. Collectively, this has resulted in the need for an extension without changes. We are requesting a one year extension without changes to allow all study participants to complete the final monthly surveys. There are no changes to study methods or a change in burden.

A3. Use of Improved Information Technology and Burden Reduction

FMB&M- IFPS III uses web-based surveys to collect and process data directly via a secure server to the contractor. Using web-based surveys reduces respondent burden and makes data processing and reporting more timely and efficient. Web-based surveys are programmed with dynamic skip patterns and constraining response options to reduce inadvertent errors. Participants see only those questions they are eligible to answer, eliminating the problem and burden of participants needing to follow complex skip patterns. Individual survey items are programmed to promote usable data. For questions that are closed-ended and require the participant to choose a single option, the question is programmed to unselect an already selected option if another is subsequently selected. For open-ended responses, such as numbers, acceptable ranges of values for the free entry of text are programmed into the data collection system to prevent the participant from inadvertently offering improbable or impossible responses. In all data collections, the number of questions are held to the absolute minimum required for the intended use of the data. Electronic responses are expected for 100% of respondents. Sample screen shots of questions that are administered electronically can be found in Attachment 5m.

A4. Efforts to Identify Duplication and Use of Similar Information

CDC reviewed other government and institutional sources of data and determined that no current studies duplicate the data collection within this study. CDC identified four studies that were relevant to FMB&M- IFPS III and reviewed all questions related to infant and toddler feeding for any potential duplication. The studies reviewed were either cross-sectional studies, had a more limited scope, or focused on a more limited segment of the population. FMB&M- IFPS III is a longitudinal study, includes mother/child dyads from pregnancy through 24 months, includes a broad range of topics from dietary practices to behaviors or experiences that impact feeding, and will begin approximately 5 to 8 years after the other relevant studies started. The four relevant studies and how they are different from FMB&M- IFPS III are described below. Additionally, a crosswalk of common items from FMB&M- IFPS III and potentially relevant studies can be found in Attachment 4r.

- The National Health and Nutrition Examination Survey (NHANES): This is a national level cross-sectional survey that includes a more limited set of questions on infant feeding practices and a limited sample of pregnant women and young children. (“National Health and Nutrition Examination Survey”, OMB No. 0920-0950, exp. 11/30/2021)

- Nestle Nutrition Institute's Feeding Infants and Toddlers Study (FITS 2016): This is a cross-sectional study which does not allow for the understanding of causality between exposures and outcomes over time.

- United States Department of Agriculture's Infant and Toddler Feeding Practices Study-2 (2013): This is a longitudinal study that focuses on the impact of the WIC program on infant and toddler feeding practices. The study contains a more limited set of topics that are specific to WIC feeding practices and the study population is limited to women and infants enrolled in WIC. Participants in WIC tend to have different infant and toddler feeding practices than children not eligible for WIC or those who are not participating in WIC [11, 12]. ("WIC Infant and Toddler Feeding Practices Study-2 (WIC-ITFPS-2)," OMB No. 0584-0580, exp. 3/31/2022)

- Maternity Practices in Infant Nutrition and Care (mPINC) (2018): This is a cross-sectional study of all hospitals in the U.S. Data are collected on hospital practices that promote and support breastfeeding. The study reports on practices at a hospital level; limiting the ability to understand individual practices and experiences of the mother/child dyad. ("Assessment & Monitoring of Breastfeeding-Related Maternity Care Practices in Intrapartum Care Facilities in the United States and Territories," OMB No. 0920-0743, exp. 10/31/2021)

CDC gathered input from multiple federal agencies on (1) the study design and methodology, (2) the identification of existing and new topic areas that were relevant to both CDC and another agency and provided an opportunity for each agency to gain critical information to help support their efforts related to maternal, infant, and toddler nutrition, (3) designing the study to fill gaps in existing knowledge (e.g., maternal dietary intake during pregnancy and lactation; maternal dietary intake linked to child dietary intake and behaviors; milk sharing practices; breast pump cleaning practices), and (4) ensuring duplication was minimized or avoided. CDC did this through the following:

- CDC engaged the Federal Data Consortium on Pregnancy and Birth to 24 months. This consortium has representatives from 27 agencies and includes over ~100 federal agency subject matter experts who serve as a resource for federal agencies to inform decision-making on issues related to pregnant women and young children. CDC presented to this group three times to gather feedback on (1) topic areas/content to cover (August 21, 2017), (2) study design and approach for data collection methods (October 3, 2017), and (3) to report back how feedback had been incorporated (May 29, 2018).

- CDC engaged subject matter experts from the following agencies to assist with the development of survey questions and identify any potential duplicative efforts:
    - National Institutes of Health's National Institute of Child Health and Development: Feedback was provided on the overall survey, relevant content areas, and questions on responsive feeding and parenting styles.
    - National Institutes of Health's Office of Disease Prevention and Health Promotion: Feedback was provided on the overall survey, relevant content areas, and the need for maternal dietary intake during pregnancy and post-pregnancy.
    - National Institutes of Health's Office of Dietary Supplements: Feedback was provided on the overall survey, relevant content areas, and the need for maternal dietary intake. Specific feedback was also incorporated related to the development of questions on dietary supplements.
    - US Department of Agriculture's Food and Nutrition Service: Feedback was provided on the overall survey and relevant content areas. Specific feedback was incorporated related to the development of questions on WIC participation.
    - Food and Drug Administration: Feedback was provided on the overall survey and content areas. Specific feedback was incorporated related to the development of questions on infant formula preparation and storage practices.

Combined, these efforts led to multiple federal organizations financially supporting FMB&M- IFPS III, including:

- National Institutes of Health's National Institute of Child Health and Development
- National Institutes of Health's Office of Disease Prevention and Health Promotion
- National Institutes of Health's Office of Dietary Supplements
- US Department of Agriculture's Food and Nutrition Service
- Food and Drug Administration

A5. Impact on Small Businesses or Other Small Entities

The data collection does not involve small businesses or other small entities.

A6. Consequences of Collecting the Information Less Frequently

The information collection begins with a prenatal survey, monthly for the first 6 months, every other month through 12 months, and then every 3 months through 24 months of life (14 total surveys). The frequency and timing of surveys is based on the rapidly changing development of infants in the first months of life. Because of this rapid development, feeding practices and behaviors change very quickly which necessitate frequent data collection to ensure these changes are accurately and timely identified. The timing of each survey window is based on the need to ensure that each monthly survey is unique and does not occur during the succeeding month survey (i.e., month 1 does not get completed when the child is 2 months of age). The survey window increases in length as children get older and practices and behaviors are not changing as rapidly. Each survey has a window of time in which it must be completed; respondents may start and stop surveys during each survey window.

- Prenatal surveys must be completed before the child is born.
- For months 1 to 5 of the follow up surveys, the survey window is a 2 week period with the survey opening on the month anniversary of the baby's birth to 2 weeks after.
- For months 6 to 10 of the follow up surveys, the survey window is 3 weeks (from the month anniversary of the baby's birth to 3 weeks after).
- For months 12 to 24 of the follow up surveys, mothers have a 4 week window to complete the survey (from the month anniversary of the child's birth to 4 weeks after).

If data were not collected at this frequency, CDC would miss critical time windows to understand feeding practices and behaviors during a rapidly changing period of a child's life. This may lead to inaccurate identification of the timing of feeding practices and some feeding practices may be missed completely.

A7. Special Circumstances Relating to the Guidelines of 5 CRF 1320.5

This study complies fully with the guidelines of 5 CFR 1320.5. No exceptions to the guidelines are requested.

A8. Comments in Response to the FRN and Efforts to Consult Outside the Agency

Part A: PUBLIC NOTICE
A 60-day Federal Register Notice was published in the *Federal Register* on June 9, 2023, vol. 88 No. 111, pp. 37881 (Attachment 2). CDC received two non-substantive comments. One related to policies related to abortion. A second comment was overall support for conducting the study. One substantive comment requested that response options in a question were expanded to more clearly specify the categories of personnel who provide lactation support (Attachment 2a). The study is currently in the field and therefore, CDC is unable to change response options at this time, because it would not allow similar data collection efforts for all study participants. CDC can consider this comment for questions in future studies.

Part B: CONSULTATION

CDC consulted with persons outside the study design team during development of FMB&M- IFPS III. Beginning in 2016–2017, CDC consulted with academicians and federal agencies to gather input on the topic areas and potential survey questions to include in FMB&M- IFPS III. In 2018, CDC provided federal partners, through the Federal Data Consortium on Pregnancy and Birth to 24 months and other presentations and/or meetings, a more detailed assessment of the study methodology and survey topics and questions. Key input was provided by the following individuals and organizations throughout these processes:

Table A1. Consultations within CDC

Name, Title	Affiliation	Contact information
Jennifer Cope, Medical Officer	National Center for Emerging and Zoonotic Infectious Diseases, Division of Foodborne, Waterborne, and Environmental Diseases	Phone: (404)718-4878 Email: bjt9@cdc.gov
Mei Lin, Epidemiologist	National Center for Chronic Disease Prevention and Health Promotion, Division of Oral Health	Phone: (770) 488-5109 Email: hru3@cdc.gov
Naomi Tepper, Medical Officer	National Center for Chronic Disease Prevention and Health Promotion, Division	Phone: (770) 488-6506 Email: gdq2@cdc.gov

	of Reproductive Health	

Table A2. External Consultations

Name, Title	**Affiliation**	**Contact information**
Government agencies (alphabetical order by agency, institution, or organization)		
Robin McKinnon, Senior Advisor for Nutrition Policy	Food and Drug Administration Center for Food Safety and Applied Nutrition, Office of Foods and Veterinary Medicine	Phone: (240) 402-1888 Email: robin.mckinnon@fda.hhs.gov
Tonja Nansel, Staff Scientist	National Institutes of Health *Eunice Kennedy Shriver* National Institute of Child Health and Human Development	Phone: (301) 435-6937 Email: nanselt@mail.nih.gov
Nancy Potischman, Director of Population Studies Program	National Institutes of Health Office of Dietary Supplements	Phone: (301) 496-0187 Email: potischn@mail.nih.gov
Amy Subar (*now retired*)	National Institutes of Health National Cancer Institute	
Kelley Scanlon, Director of Special Nutrition Research and Analysis Division	United States Department of Agriculture Food and Nutrition Service, Office of Policy Support	Phone: (703) 457-7767 Email: kelley.scanlon@usda.gov
Academic institutions		
Julia P. Felice, Associate Director of Undergraduate Studies	Cornell University Division of Nutritional Sciences	Phone: 607.255.2651 Email: julia.felice@cornell.edu
Alison Stuebe, Distinguished Scholar in Infant and Young Child	University of North Carolina Gillings School of Global Public Health, Department	Phone: (919) 966-1601 Email: alison_stuebe@med.unc.edu

Feeding	of Maternal and Child Health	
Private organizations		
Nancy Weinfield, Research Scientist	Mid-Atlantic Permanente Research Institute	Phone: (301) 816-6848 Email: Nancy.S.Weinfield@KP.org

A9. Explanation of Any Payment or Gift to Respondents

Respondents receive monetary and non-monetary tokens of appreciation to balance motivating respondents to participate without offering a coercive sum (i.e., a sum that a low-income individual would find difficult to refuse [13]). Monetary tokens include $30 for each monthly survey and $50 for each maternal dietary recall via a vendor link after survey completion. A participant may request to receive the monetary token of appreciation via mail. If this research were attempted without a monetary token of appreciation, poorer quality data would be obtained because of lower response rates and retention and higher nonresponse bias. This would reduce the benefit of conducting a longitudinal study and limits the ability of the government to draw sound conclusions from the findings. The monetary token of appreciation encourages participants to sign up for the research, to consistently engage in this study and complete the various surveys, and is consistent with previous federal studies among similar populations during a similar time of life (i.e., infancy and early childhood).

Monetary incentives are requested in this study because mothers of infants and young children are busy, mobile, and challenging to retain in research during a period of life in which mothers face competing demands for their time and attention. Mothers are asked to complete 14 surveys, in addition to the recruitment/eligibility screeners (e.g., study screener and birth screener), during specified and brief windows of time with questions that are time-sensitive. These mothers are exerting unusual effort, and therefore the potential for nonresponse bias among subsets of participants must be avoided proactively to ensure high quality data. Mothers who are finding parenting a young child challenging, and who are experiencing high levels of stress and demands on their time, are both an important subgroup for this study and the most likely to drop out if they feel their effort is not valued by the study.

Monetary tokens of appreciation are a reliable way to recognize the burden and the challenges associated with recruitment and engagement of mothers, reduce nonresponse bias, and have been used successfully in other federal longitudinal studies among similar populations. Research has demonstrated that tokens of appreciation motivate people to start web-based surveys and, once those individuals have accessed the survey, they are more likely to complete the survey if a token of appreciation is offered [14, 15]. Similar monetary tokens were used in an 18 week longitudinal study conducted in 2015, CDC Essentials for Parenting ("Evaluation of Essentials for Parenting Toddlers and Preschoolers," OMB No. 0920-1086, exp. 10/31/2017). Participants received $20 for their first survey, $10 for surveys 2-17, $30 for the longer week 18 survey and a bonus of $40 if they completed all 18 weekly surveys. During 13 of the 18 weeks, the response rates were 79% or higher. Forty-three percent of participants (86 out of 200) received the $40 bonus for completing all 18 weekly surveys. Similarly, the United States Department of Agriculture's Infant and Toddler Feeding Practices Study-2 conducted in 2013 ("WIC Infant and Toddler Feeding Practices Study-2 (WIC-ITFPS-2)," OMB No. 0584-0580, exp. 3/31/2022), has provided $50 for enrollment, followed by a total of $30 for each survey completed through month 24 with increasing amounts for later surveys (e.g., participants received $70 for the 72-month survey). Participants could receive up to $740 for completing all surveys. Overall, response rates ranged from 90% (prenatal survey) to 70% (24 month survey).

In addition, we provide all participants with non-monetary token of appreciations in the form of a link to download a pdf or view an on-line free e-children's book at three different time points. This non-monetary token of appreciation help to continue to engage participants and provide an age appropriate book to share with their child. Books and time points are listed below (Attachment 5l):

- Survey month 6: Baby's Busy Day – Being One is So Much Fun! (pdf only)
- Survey month 12: Where is Bear? – A Terrific Tale for 2-Year-Olds (pdf only)
- Survey month 24: Amazing Me – It's Busy Being 3! (pdf or html options)

A10. Protection of the Privacy and Confidentiality of Information Provided by Respondent

NCCDPHP's Information Systems Security Officer has reviewed this submission and has determined that the Privacy Act applies (related Information Technology system is named IFPSIII). The applicable Privacy Act System of Records Notice

(SORN) is No. 09-20-0160 (Records of Subjects in Health Promotion and Education Studies).

Participants are subject to assurances as provided by the Privacy Act of 1974 (5 USC §552a), which requires the safeguarding of individuals against invasion of privacy; these assurances will be documented in an informed consent form (Attachment 5d). In addition, the Contractor project staff have signed a confidentiality and nondisclosure agreement (Attachment 6). The privacy and security of electronic data during the data collection and processing period are conducted following the system of record notice (SORN) titled Records of Subjects in Health Promotion and Education Studies.

Through the screening process, minimal information in identifiable form (IIF) are collected. The IIF collected is: name, telephone number, e-mail address, birth date of child, race/ethnicity, and zip code. IIF is collected for the following purposes: (1) contacting respondents (2) setting the monthly survey time schedule, and (3) monitoring study enrollment. Once participants are enrolled, the following IIF is collected: mailing address, zip code of birth hospital, military status, income categories, and employment status. These are collected for analytic stratification purposes only, with the exception of the mailing address, which is collected for contact purposes or sending monetary tokens of appreciation, if desired.

Data from web-based surveys are collected and processed directly via a secure server to the Contractor. Participants receive a text or email invitation, depending on the mode of communication they prefer, with a unique PIN code for each survey. Each survey starts on a screen that requires respondents to enter their assigned PIN code. PIN entry is required each time a respondent accesses their survey online. For the dietary recalls, participants log onto the ASA24 website using the link provided in the text or email message. All data submitted to the Contractor's website travels via secure data sockets and is stored in a database behind the Contractor's server firewall. Project files containing survey data are transferred to CDC using secure file exchange and access at the Contractor site is password protected and limited to authorized project staff.

IIF will be destroyed by Contractor at the end of the contract period of performance (approximately 5/2026). CDC will maintain a database, stripped of any identifiers other than a unique ID, as a permanent federal record in accordance with CDC's Scientific and Research Project Records Control Schedule.

No IIF are ever to be used in any published reports of this study. CDC presents all findings in aggregate so individual responses cannot be identified. Data are treated in a secure manner, unless disclosure is otherwise required by law.

Contractor staff receive training in data management and security. The Contractor's (Westat's) Institutional Review Board (IRB) serves as the organization's administrative body and all research involving interactions or interventions with human subjects is within its purview. Copies of the IRB approval letters are in Attachment 3.

A11. Institutional Review Board (IRB) and Justification for Sensitive Questions

This information collection request was deemed research with human subjects as defined by the US Code of Federal Regulations (45 CFR 46.102) and approved by the Westat IRB. A copy of the IRB approval letter is included as Attachment 3.

In general, the questions asked are not considered to be sensitive. Participants can choose to not answer any question, and to not participate in the study, as detailed in the consent form (Attachment 5d). Survey questions have been cognitively tested by nine mothers of children less than 24 months of age. None of the respondents indicated unwillingness or discomfort with providing a response. OMB race/ethnicity standards will be used.

We do assess the potential for postpartum depression using the Edinburgh Postpartum Depression Scale (administered at the prenatal and 2-month interview) which asks the mother -- *In the past week the thought of harming myself has occurred to me….quite often/sometimes/hardly ever/never.* We implement a strict protocol to immediately respond to mothers who indicate they have thought about harming themselves. The survey stops and provides mothers with a toll-free number for a hotline for postpartum depression. Mothers have a choice to access the toll-free number provided and leave the survey or complete the survey and access the resources at the end of the survey. For all other mothers, once the survey is completed, we provide a hotline number as a resource.

A12. Estimates of Annualized Burden Hours and Costs

Estimated Annualized Burden Hours

It is estimated that the annualized burden hours for the collection of information in this project will be 5,051 hours (annualized) and a total of 15,153 burden hours

over a three year period. A one year extension without changes is requested. There is no change in burden. Estimates were derived using the following assumptions:

- A total of 7,477 women will be screened for eligibility; 70% will meet eligibility and sample requirements and be offered the consent form.
- Of those who are offered the consent form, 90% will respond.
- Of those who are offered the consent form and respond, 90% will complete the prenatal survey.
- Of those who are offered the consent form and respond and who complete the prenatal survey, there will be an estimated 3.2% loss of participants for each remaining survey, including the birth screener, either due to loss to follow up or due to not eligible for that survey (i.e., child was not living with the participant) or the study (i.e., the child passed away).
- Following birth of the baby, we assume 10% of women who respond to the birth screener will be ineligible due to premature birth, extended NICU stay, or are unable to feed their newborn for ≥ 1 week due to a severe medical problem.
- Of women who complete the prenatal survey, 65% will also complete the first dietary recall and 65% of those who are offered the second dietary recall will complete it.
- Of women who complete the month 3 survey, 65% will also complete the first dietary recall and 65% of those who are offered the second dietary recall will complete it.

The time it will take to complete different surveys will range from 2 minutes to 24 minutes. This is based on testing that was done with nine mothers of children less than 24 months of age. The range in time is directly related to the amount of content on each survey.

Table A2 summarizes the burden hours for each data collection activity. The annualized number of respondents are used to estimate the annualized burden hours. The total estimated burden hours are 15,153 hours and the annualized total burden hours are 5,051 hours.

Table A2: Estimated Annualized Burden to Respondents

Respondents	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)	Total Annualized Burden Hours
Pregnant/Postpartum women	Study Screener	2,492	1	3/60	125
	Study Consent	1,570	1	5/60	131
	Prenatal Survey	1,413	1	20/60	471
	24-Hour Dietary Recall - Prenatal	919	1	24/60	367
	Replicate 24-Hour Dietary Recall - Prenatal	90	1	24/60	36
	Request for notification of child's birth	1,413	1	2/60	47
	Birth Screener	1,368	1	2/60	46
	1-Month Survey	1,231	1	20/60	410
	2-Month Survey	1,192	1	15/60	298
	3-Month Survey	1,153	1	15/60	288
	24-Hour Dietary Recall - Month 3	750	1	24/60	300
	Replicate 24-Hour Dietary Recall - Month 3	73	1	24/60	29
	4-Month Survey	1,117	1	15/60	279
	5-Month Survey	1,081	1	15/60	270
	6-Month Survey	1,046	1	15/60	262
	8-Month Survey	1,013	1	15/60	253
	10-Month Survey	980	1	20/60	327
	12-Month Survey	949	1	15/60	237
	15-Month Survey	919	1	15/60	230
	18-Month Survey	889	1	15/60	222
	21-Month Survey	861	1	15/60	215
	24-Month Survey	833	1	15/60	208
Total					**5,051**

Estimated Burden Hours

We have used the national average hourly wage of all employees on private nonfarm payrolls as of August 2023 ($33.82) to calculate the total value cost of time for respondents. This was obtained from the U.S. Department of Labor. The estimated cost to all respondents is $170,825 (Table A3).

Table A3: Estimated Annualized Burden Costs

Respondents	Form Name	Total Annualized Burden Hours	Average Hourly Rate	Total Burden Cost
Pregnant/Postpartum women	Study Screener	125	$33.82	$ 4,228.00
	Study Consent	131	$33.82	$ 4,430.00
	Prenatal Survey	471	$33.82	$ 15,929.00
	24-Hour Dietary Recall - Prenatal	367	$33.82	$ 12,412.00
	Replicate 24-Hour Dietary Recall - Prenatal	36	$33.82	$ 1,218.00
	Request for notification of child's birth	47	$33.82	$ 1,590.00
	Birth Screener	46	$33.82	$ 1,556.00
	1-Month Survey	410	$33.82	$ 13,866.00
	2-Month Survey	298	$33.82	$ 10,078.00
	3-Month Survey	288	$33.82	$ 9,740.00
	24-Hour Dietary Recall - Month 3	300	$33.82	$ 10,146.00
	Replicate 24-Hour Dietary Recall - Month 3	29	$33.82	$ 981.00
	4-Month Survey	279	$33.82	$ 9,436.00
	5-Month Survey	270	$33.82	$ 9,131.00
	6-Month Survey	262	$33.82	$

				8,861.00
	8-Month Survey	253	$33.82	$ 8,556.00
	10-Month Survey	327	$33.82	$ 11,059.00
	12-Month Survey	237	$33.82	$ 8,015.00
	15-Month Survey	230	$33.82	$ 7,779.00
	18-Month Survey	222	$33.82	$ 7,508.00
	21-Month Survey	215	$33.82	$ 7,271.00
	24-Month Survey	208	$33.82	$ 7,035.00
Total				**$ 170,825.00**

A13. Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers

No costs, other than those described in A12, will be incurred by the respondents to complete this data collection.

A14. Annualized Cost to the Federal Government

Table A4 presents the two types of costs to the Government that will be incurred: 1) External contracted data collection and analyses and 2) Government personnel. Total External (Contractor) project cost to the federal government for conducting this project is an annualized cost of $644,893. These costs cover combined labor, fringe, and indirect fees plus other direct costs (ODCs).

The government costs include personnel costs for federal staff involved in this study. The primary CDC staff members for this project are a health scientist (GS-14 at 20% per year), a medical epidemiologist (GS-14 at 5% per year), an epidemiologist (GS-12 at 10% per year), and a public health analyst (GS-13 at 2% per year). The total estimated annualized cost of Federal government employees is $41,554 per year. Federal employee pay rates are based on the 2023 General Schedule of the Office of Personnel Management (OPM) with locality pay for the Atlanta-Athens-Clarke County-Sandy Springs, GA-AL.

The total estimated annualized cost to the Federal government is $686,447.

Table A4: Estimated Annualized Federal Government Cost Distribution

Type of Government Cost	Annualized Cost
Contractor labor, fringe, and indirect fees plus ODCs	$644,893
Federal Staff (per year):	
GS-14 Health Scientist, Step 1 at 20%	$24,581
GS-14 Medical epidemiologist Step 1 at 5%	$6,145
GS-12 Epidemiologist Step 1 at 10%	$8,747
GS-13 Public health analyst Step 1 at 2%	$2,080
	(Total Federal Govt.=$41,554)
Total	$686,447

A15. Explanation for Program Changes or Adjustments

This is a request for a 1 year extension without changes. There is no change in burden.

A16. Plans for Tabulation and Publication and Project Time Schedule

The findings from the study will be analyzed in numerous ways based on the goals of this study. Detailed information is provided below by each over-arching study goal.

- Goal 1: Understanding the current state of mothers' intentions, behaviors, feeding decisions, and practices from pregnancy through their child's first two years of life.
    - Analytic approach: we will conduct frequencies for each variable at each survey time point.
- Goal 2: Assessing how these change over the first two years of life.
    - Analytic approach: we will assess changes in frequencies at each measured survey time point and conduct repeated measures analyses to determine relationships between exposures and outcomes. For example, we will look at how use of childcare changes over time (i.e., month 4, 8, and 15) and its relationship with feeding outcomes or how children are fed breast milk changes over time (i.e., months 1 – 10) and its relationship with health outcomes.
- Goal 3: Assessing the impact of these practices on feeding and health outcomes during the first two years.

    - Analytic approach: we will conduct regression analyses, repeated measures analyses, and/or survival analyses using an exposure (i.e., employment support for breastfeeding, maternity leave availability/use, or use of birth control) and its impact on a health outcome, health behavior, or feeding outcome (i.e., infant or toddler ear infections, antibiotic use, breastfeeding duration).
- Goal 4: Exploring emerging issues related to infant and toddler feeding practices during the first two years of life.
    - Analytic approach: we will assess the frequency of specific feeding practices such as breast milk sharing or prevalence of food allergies.

The results of the study will be reported in peer-reviewed journal articles, conference presentations, research briefs, webinars, and web-based papers for dissemination to researchers, states, and the public.

Table A5. Estimated Time Schedule for Project Activities

Activity	Timeline
Invitation/request sent	1-8 months after OMB approval
Information collection	2-36 months after OMB approval
Data cleaning	Ongoing throughout information collection
Data analysis and reporting	First report 24 months after OMB approval Second report 30 months after OMB approval Final report 48 months after OMB approval

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

The display of the OMB expiration date is appropriate.

A18. Exceptions to Certification for Paperwork Reduction Act Submission

There are no exceptions to the certification.

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