

SUPPORTING STATEMENT PART A FOR

Revision to OMB Number 0584-0580

**WIC Infant and Toddler Feeding Practices Study-2 (WIC ITFPS-2):
Age 6 Extension**

Danielle Berman

Office of Policy Support

Food and Nutrition Service

US Department of Agriculture

3101 Park Center Drive

Alexandria, VA 22302

Phone: 703-305-2698

Fax: 703-305-2576

E-mail: danielle.berman@fns.usda.gov

10/15/18

Table of Contents

<u>Part</u>		<u>Page</u>
A	Justification.....	1
A.1	Circumstances making the collection of information necessary.....	1
A.2	Purpose and Use of the Information.....	2
A.3	Use of Information Technology and Burden Reduction.....	7
A.4	Efforts to Identify Duplication and Use of Similar Information.....	8
A.5	Impacts Small Business or other Small Entities.....	8
A.6	Consequences of Collecting the Information Less Frequently.....	8
A.7	Special Circumstances relating to the Guidelines of 5 CFR 1320.5.....	9
A.8	Responses to the Federal Register Notice and Efforts to Contact Outside Agencies.....	10
A.9	Explanation of Any Payment or Gift to Respondents.....	11
A.10	Assurance of Confidentiality Provided to Respondents.....	16
A.11	Justification for Sensitive Questions.....	17
A.12	Estimates of Respondent Burden Including Annualized Hourly Cost.....	17
A.13	Estimates of Other Total Annualized Cost Burden.....	20
A.14	Annualized Cost to the Federal Government.....	21
A.15	Explanation for Program Changes or Adjustments.....	22
A.16	Plans for Tabulation and Publication and Project Time Schedule.....	22
A.17	Reason Display of OMB Expiration Date is Inappropriate.....	25
A.18	Exceptions to Certification for Paperwork Reduction Act Submissions.....	25

Appendices

- A1 Study extension consent age 6 - English
- A2 Study extension consent age 6 - Spanish
- B1 Study extension letter- English

Appendices (continued)

- B2 Study extension letter - Spanish
- C1 72-month advance letter - English
- C2 72-month advance letter - Spanish
- D1 72-month telephone interview - English
- D2 72-month telephone interview - Spanish
- D3 72-month replicate dietary intake interview - English
- D4 72-month replicate dietary intake interview - Spanish
- E1a Reminders for interview from Study Liaison - English
- E1b Reminders for interview from Study Liaison - Spanish
- E2a Reminders for non-locatable active interview - English
- E2b Reminders for non-locatable active interview - Spanish
- E3a Reminders for study participation refusal conversion - English
- E3b Reminders for study participation refusal conversion - Spanish
- E4a Reminders for study participation not answering calls - English
- E4b Reminders for study participation not answering calls - Spanish
- E5a Reminders for Telephone Research Center voicemail, first message - English
- E5b Reminders for Telephone Research Center voicemail, first message - Spanish
- E6a Reminders for Telephone Research Center voicemail, expiring interviews - English

E6b Reminders for Telephone Research Center voicemail, expiring interviews - Spanish

Appendices (continued)

- F1 72-month H/W measurement card - English
- F2 72-month H/W measurement card - Spanish
- G1 Height and weight reminders - English
- G2 Height and weight reminders - Spanish
- H1 72-month text or email provider measures - English
- H2 72-month text or email provider measures - Spanish
- I1 72-month thank you - English
- I2 72-month thank you - Spanish
- J1 Birthday card respondent year 6 - English
- J2 Birthday card respondent year 6 - Spanish
- K1 Birthday card child age 6 - English
- K2 Birthday card child age 6 - Spanish
- L1 Announcement of study extension to WIC State agencies
- L2 Announcement of study extension to WIC sites
- M Study extension webinar slides
- N Agenda for conference call on extension with State agency and sites
- O1 Study extension summary and agreement - Correspondence to State Agency with copy to site POC
- O2 Addendum A to study extension summary
- P Participant contact information request
- Q Crosswalk of previously approved and revised materials

R1a Federal Register Notice comment #1

**Contents
(continued)**

Appendices (continued)

R1b Federal Register Notice comment #2

R2a Federal Register Notice agency response to comment #1

R2b Federal Register Notice agency response to comment #2

S1 NASS review

S2 NASS review response

T Confidentiality and nondisclosure agreement

U Westat IRB approval letter

V Burden table

W Base study sampling methods

X Details of imputation, calculation of the survey weights, and nonresponse bias analysis

Tables

A2.1	Overview of Data Collection Activities.....	3
A8.1	Consultants from Outside the Agency.....	11
A9.1	Participant Incentives by Event.....	15
A9.2	Grant Amounts for WIC Sites.....	15
A16.1	Data Collection and Reporting Schedule.....	23

A16.2	Research Questions and Principal Data Sources for Year 6 Report.....	23
-------	---	----

Part A Justification

A.1 Circumstances making the collection of information necessary

Explain the circumstances that make the collection of information necessary. Identify any legal or administrative requirements that necessitate the collection. Reference the appropriate section of each statute and regulation mandating or authorizing the collection of information.

This is a revision of a currently approved study (informally named the “Age 6 Extension”). The currently approved study is **WIC Infant and Toddler Feeding Practices Study-2** (WIC ITFPS-2) ICR Reference No. 201208-0584-002, 201306-0584-008, 201408-0584-007; and 201601-0584-008; Expiration date: 07/31/2019. This revision will extend the longitudinal data collection of the original cohort of infants, previously extended to age 5, up to age 6.

The Base, Age 3 Extension, Age 5 Extension, and now the Age 6 Extension of the WIC ITFPS-2 (OMB No. 0584-0580, expiration date: 07/31/2019) affirm the USDA’s Food and Nutrition Service’s (FNS) 2010 fourth strategic goal which ensures that all of America’s children have access to safe, nutritious and balanced meals.¹ The Healthy, Hunger-Free Kids Act of 2010 (Public Law 111-296, Sec. 305) mandates programs under its

¹FNCS Corporate Priorities FY 2010 Guide (April 2010). USDA Food, Nutrition, and Consumer Services. Available at: <http://www.fns.usda.gov/ora/menu/gpra/FY2010PrioritiesGuide.pdf>. Accessed on: 5/13/2011.

authorization, including WIC, to cooperate with USDA program research and evaluation activities. The Age 6 Extension will follow children through the year following the end of their WIC age eligibility, and provide the data to answer research questions relevant to WIC program and policy as well as the nutrition and wellbeing of children up to the month of their 6th birthdays.

The United States Department of Agriculture's (USDA) Special Supplemental Nutrition Program for Women, Infants and Children (WIC) serves a highly-vulnerable population: low-income pregnant and post-partum women, infants, and children through their fifth birthday who are at nutritional risk. The program provides supplemental food packages, health referrals and nutrition education for participants. The goal of the current **WIC Infant and Toddler Feeding Practices Study-2 (WIC ITFPS-2)**, which includes the base study, the Age 3 Extension, and the Age 5 Extension (ICR Reference No. 201208-0584-002 , 201306-0584-008, 201408-0584-007; and 201601-0584-008; Expiration date: 07/31/2019) is to examine feeding practices and associated decision-making from birth to 5 years of age.

A.2 Purpose and Use of the Information

Indicate how, by whom, how frequently, and for what purpose the information is to be used. Except for a new collection, indicate the actual use the agency has made of the information received from the current collection.

Information collected in the study through age 5 will provide USDA's Food and Nutrition Service (FNS) with information on the factors that

influence feeding practices and the nutrition and health outcomes of children in the first five years of their lives, and during their time of WIC age eligibility. The Age 6 Extension study will expand the data collection to their sixth year of life, through the first year in which they can no longer receive WIC services. The Age 6 Extension will involve: (1) conducting one additional follow-up telephone interview with the mother/caregiver when the child is 72 months old; (2) conducting a second, replicate dietary intake interview with a 10 percent subsample of caregivers who complete the first interview, and (3) obtaining height and weight (H/W) measurements at 72 months on each child from caregiver's provision to the study of health care provider measurements, or from direct measurements taken at WIC sites.

The 72-month interview will include questions to address four research domains: the dietary behaviors and health outcomes of children at age 6, a year after they age out of WIC; the food security status of the children's households at age 6 years, considering the role of other food assistance programs from which they benefit; the feeding practices of caregivers for their children at age 6 years; and, the food and health-related environmental characteristics for children at age 6.

This collection is completely voluntary for individuals and households, and State and local government. Although the Healthy Hunger-Free Kids Act of 2010 requires cooperation by State and local WIC agencies in USDA studies, we have previously and will continue to allow States and sites to choose to reaffirm their cooperation.

Table A2.1. Overview of Data Collection Activities

Instrument	Source	Mode	Purpose	Length	Number of Respondents	Frequency
72-Month Telephone Interview (Appendix D1/D2)	Caregivers of former WIC Children	Telephone	Collect data on feeding practices, family circumstances, and nutrition and health outcomes	45 minutes	1,901	Once
72-Month Replicate Dietary Intake Interview (Appendix D3)	Caregivers of former WIC Children, who completed the 72-month interview	Telephone	Collect replicate data on dietary intake	30 minutes	190	Once
72-Month H/W Measurements at WIC Site (Appendix F1/F2)	WIC Site Staff	In Person	Collect data on child height/weight	10 minutes	80	6 times
72-Month H/W Measurements at Provider's Office (Appendix F1/F2)	Health Care Provider	In Person	Collect data on child height/weight	10 minutes	851	Once
72-Month H/W Measurements at WIC Site or Provider's Office (Appendix F1/F2)	Caregivers of former WIC Children	In Person	Collect data on child height/weight	60 minutes	1,331	Once

Research Design: The current cohort, recruited for the Base study, was a national probability sample of WIC participants. The target study participant is the child, but all materials are sent to the participating caregiver. We notify the caregivers in the existing cohort of the extension of the study to age 6, and will collect data on the participants at age 6 using two methods, interview and direct measurement.

- **Notification to Participating Cohort of Study Extension:** The study team will mail the study extension consent (Appendix A1/A2), and the study extension letter (Appendix B2/B2), within two weeks after OMB approval. All participants will be asked to sign and return one copy of the consent. Any caregivers who do not return the hard copy consent form will have another opportunity to consent verbally at the time of the 72-month interview. In total, an estimated 2,969 caregivers from the original cohort of live births will receive a study extension letter and study extension consent.
- **Interviews:** The study participants will be asked to complete a telephone interview when their child is 72 months old. Interview windows extend from two weeks prior to the child's 6th birthday to four weeks after. One to two weeks before the interview window opens, participants will receive an advance letter notifying them of the upcoming interview (Appendix C1/C2). The study team expects 2,969 participants from the existing cohort will receive the advance letter. The 72-month interview (Appendix D1/D2) will be administered by telephone, conducted using a Computer-Assisted Telephone Interview (CATI). The study team will attempt to reach participants through outgoing calls, and participants will also have the option of calling in at their own convenience to complete the interview. Participants whose interviews are not completed within 10 days of the opening of the window will receive reminders while the interview window is open and the interview is not complete (Appendices E1a/E1b, E2a/E2b, E3a/E3b, E4a/E4b, E5a/E5b, E6a/E6b). The study team expects that 1,901 study participants will complete the 72-month interview.

A 15 percent subsample of participants eligible for the 72-month interview (285 participants) will be randomly selected to complete the 72-Month Replicate Dietary Intake Interview (Appendix D3/D4)

within 10 days of completing the 72-month interview. Participants will be notified of their selection for the replicate interview at the end of the 72-month interview, and the interviewer will schedule a time to call the participant for the replicate interview, also administered using CATI. The study team expects 190 participants to complete a replicate dietary intake interview.

- **Height and Weight Measurements:** The study will collect data on children's H/W measurements at 72 months of age to calculate body mass index (BMI) in order to assess the impact of feeding practices on weight status. The study team will send the study participants information on the measurements in the 72-month advance letter (Appendix C1/C2) along with a self-addressed postage-paid measurement card (Appendix F1/F2). The study team will also send out reminders to study participants who have not submitted their measurement cards (Appendix G1/G2). The letter will ask them to take the card to a WIC site and have the WIC site measure the child, record the measurements, and send the sealed card back to the study team. For those children who are unable to visit a WIC clinic, we will ask the study respondent to go to the child's health care provider to be measured. For study participants who do not wish to visit either WIC or their child's health care provider (or who went to their provider but neglected to bring their measurement card) but who have a printout of a recent measurement by the health care provider, the study will accept a copy of that printout in lieu of the measurement card (Appendix H1/H2). Based on experience with the mode of return of the 48-month measurement cards and acknowledging that respondents may be less likely to return to WIC as their WIC experience becomes more distant, the study team expects about 480 study participants to return measurement cards completed by WIC, 451

study participants to return a measurement card completed at the health care provider's office, and 400 participants to send a printout of measurements taken recently at the provider's office.

In addition to the data collection activities, the study team will communicate with study participants to express appreciation for their engagement with the study. Study participants will receive a thank you note after the completion of the 72-month interview (Appendix I1/I2). Continuing a practice already in place on the study, the caregivers will receive birthday cards from the study on their own birthdays (Appendix J1/J2), and the children will receive birthday cards from the study on their sixth birthdays (Appendix K1/K2).

The study team will send an announcement of the study extension to the 27 WIC State Agencies and 80 WIC site points-of-contact who have been collaborating on the study to-date (Appendix L1 and Appendix L2). The study team will present a webinar for the points-of-contact (Appendix M), and follow up with conference calls to answer any questions (Appendix N). Following the webinar and conference calls, the study team will send a study extension summary and agreement and addendum (Appendices O1 and O2) describing study activities and roles and responsibilities requested from WIC, including providing updated contact information for participants with children still enrolled in WIC (Appendix P).

A crosswalk indicating which of the materials for the Age 6 extension are revisions of previously approved materials is presented in Appendix Q.

Purpose of the Information: The information through age 6 will be a valuable asset to policymakers, WIC Program Staff, health professionals, and the research community. This is the first time FNS will have followed a sample of WIC recipients longitudinally through and beyond the entire period of WIC age eligibility, including those who leave WIC prior to becoming age-ineligible. Policymakers and WIC Program Staff will use the findings to design and shape the program to ensure participants' health and nutrition needs are being met. Health professionals will be able to use the information to shape their interactions with this highly-vulnerable population and to better understand their needs in the year following the cessation of services. Researchers will be able to further analyze the study data and further contribute to the knowledge base regarding this high-risk, vulnerable population. Three reports on base study results were released to the public by FNS: prenatal findings (2015), infant year findings (2016), and second year findings (2018). The results have been presented at conferences to scientific audiences and stakeholder organizations interested in WIC, breastfeeding, nutrition, and maternal and child health, and have formed the basis for journal articles submitted to peer reviewed journals. The findings are available to the public on the FNS website both as full reports and 2-page summaries.

A.3 Use of Information Technology and Burden Reduction

Describe whether, and to what extent, the collection of information involves the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses, and the basis for the decision for adopting this means of collection. Also, describe any consideration of using information technology to reduce burden.

FNS is committed to complying with the E-Government Act of 2002 to promote the use of technology. The WIC participant interviews are designed to reduce participant burden through the use of Information Technology. Specifically, for the telephone interviews, WIC participants will speak with an interviewer on the phone and will not have to write down or enter any information other than notes to help with recalling information. We anticipate approximately 2,091 respondents across the 72 month interview, and the replicate interview with a subset of participants, will submit responses electronically. Thus considering respondents and non-respondents, 48 percent of the interview responses will be collected electronically. All other responses will be non-electronic. Measurements taken at WIC or health care providers' offices will be returned through sealable self-addressed postage-paid cards. These approaches are consistent with the data transfer protocols used in the Age 5 Extension study for study participants no longer receiving WIC services. Out of a total of 33,644 responses for this study, FNS estimates that 2,091 responses (6%) will be submitted electronically.

A.4 Efforts to Identify Duplication and Use of Similar Information

Describe efforts to identify duplication. Show specifically why any similar information already available cannot be used or modified for use for the purpose described in item 2 above.

Every effort has been made to avoid duplication. Through careful review of the data requirements, we have determined that no current data are similar to that proposed for collection in this study. Although we are asking the same or similar questions to those posed in the base study and/or the extensions through age 5, the aim is to obtain current data to continue to track issues in children's nutrition, growth, and environments as they unfold over the year after WIC age-eligibility ends, and to examine new issues that may arise during that year.

A.5 Impacts Small Business or other Small Entities

If the collection of information impacts small businesses or other small entities, describe any methods used to minimize burden.

Information being requested or required has been held to the minimum required for the intended use. The data collection plan has no impact on small businesses or other small entities. Out of the total 5,004 respondents for this collection, FNS estimates that none (0%) are small entities.

A.6 Consequences of Collecting the Information Less Frequently

Describe the consequence to Federal program or policy activities if the collection is not conducted or is conducted less frequently, as well as any technical or legal obstacles to reducing burden.

If the study is not conducted at this time, FNS will not have current information on the feeding practices and dietary intakes of children who received WIC services for making policy decisions about WIC services and nutrition education. Dietary patterns of WIC infants were examined nearly 20 years ago; much has changed during that time. With over 50 percent of the nation's infants enrolled in WIC and increasing rates of obesity in young children, it is critical to understand the nutritional intakes and feeding patterns of WIC participants. This extension provides the first opportunity for FNS to understand nutrition and feeding patterns of former WIC children during the first year when those children are no longer eligible for WIC services - national data on this population has never before been available through age 6. We are proposing collecting data at a reduced frequency (once during the year) as compared to that approved for the Age 5 extension. We still anticipate important changes as the children's diets, health, and environments diversify, but a one-year follow-up of dietary intake, household circumstances, health, and feeding behavior should be sufficient for longitudinal follow-up. Anything less than annual data may miss important turning points as the children transition fully into the elementary school environment. The information is essential for policy makers and

program staff making decisions about program design. They will use the information to develop appropriate and effective prevention strategies aimed at improving the health of young children.

A.7 Special Circumstances relating to the Guidelines of 5 CFR 1320.5

Explain any special circumstances that would cause an information collection to be conducted in a manner:

- **Requiring respondents to report information to the agency more often than quarterly;**
- **Requiring respondents to prepare a written response to a collection of information in fewer than 30 days after receipt of it;**
- **Requiring respondents to submit more than an original and two copies of any document;**
- **Requiring respondents to retain records, other than health, medical, government contract, grant-in-aid, or tax records for more than three years;**
- **In connection with a statistical surveys, that is not designed to produce valid and reliable results that can be generalized to the universe of study;**
- **Requiring the use of a statistical data classification that has not been reviewed and approved by OMB;**
- **That includes a pledge of confidentiality that is not supported by authority established in statute or regulation, that is not supported by disclosure and data security policies that are consistent with the pledge, or which unnecessarily impedes sharing of data with other agencies for compatible confidential use; or**
- **Requiring respondents to submit proprietary trade secret, or other confidential information unless the agency can demonstrate that it has instituted procedures to protect**

the information's confidentiality to the extent permitted by law.

There are no special circumstances relating to the Guidelines of 5 CFR 1320.5. The collection of information is conducted in a manner consistent with the guidelines in 5 CFR 1320.5.

A.8 Responses to the Federal Register Notice and Efforts to Contact Outside Agencies

If applicable, identify the date and page number of publication in the Federal Register of the agency's notice, soliciting comments on the information collection prior to submission to OMB. Summarize public comments received in response to that notice and describe actions taken by the agency in response to these comments.

Describe efforts to consult with persons outside the agency to obtain their views on the availability of data, frequency of collection, the clarity of instructions and recordkeeping, disclosure, or reporting form, and on the data elements to be recorded, disclosed, or reported.

In accordance with 5 CFR 1320.8(d), FNS published a notice on May 1, 2018 in the Federal Register Volume 83, Number 84, Pages 19039-19041. The public comment period ended on July 2, 2018. Two comments were received in response to the notice. Both Commenter #1 and Commenter #2 requested a copy of the draft interview in development for the data collection. FNS responded, and provided the draft interview once it was available, noting that the version provided was in draft format and therefore subject to change. Public comments in response to the 60-day Federal

Register Notice (FRN), and the FNS response to the comments, appear in Appendices R1a/R1b-R2a/R2b.

The information collection request has been reviewed by Doug Kilburg with the National Agricultural Statistics Service (NASS) of USDA with special reference to the statistical procedures (Appendices S1, S2). Expert guidance was sought from a key member of the study Peer Advisory Panel, and from experts at the Centers for Disease Control and Prevention on design and research questions intended to maximize the successful conduct of the extension. These consultants are described in Table A8.1.

Table A8.1. Consultants from outside the agency

Name	Affiliation	Area of Expertise
Maureen Black	University of Maryland 410-706-2136	Health disparities, nutrition, and child development
Jennifer Zubler	Centers for Disease Control and Prevention 404-498-3951	Developmental disorders and diagnoses
Camille Smith	Centers for Disease Control and Prevention 404-498-3951	Developmental delay and parental awareness of early development
Doug Kilburg	National Agricultural Statistics Service 202-720-3777	Statistical procedures

A.9 Explanation of Any Payment or Gift to Respondents

Explain any decision to provide any payment or gift to respondents, other than remuneration of contractors or grantees.

This study’s complex longitudinal design requires participation of the same individuals over time to produce high quality estimates of longitudinal patterns of behavior. Respondents will be asked to engage in multiple data collection events during the year, during specified windows of time, and

during a period in their lives when they face competing demands from work and as parents to young children. These respondents are exerting unusual effort, and therefore, the potential for response bias among subsets of participants must be avoided proactively to ensure high quality data. Preventing response bias in a highly mobile sample of low-income caregivers of young children can be particularly challenging, and incentives ensure that participants feel their burden is recognized, acknowledged, and appreciated. As approved under the previous OMB package, in the Base study WIC participant respondents were provided with incentives of \$20 for each interview from the prenatal through the 24-month interview, and an additional \$10 when using their own cell phones to offset the cost of use of personal cell phone minutes. During the 30-36 month period they received an incrementally increasing incentive of \$30 for the 30-month interview and \$40 for the 36 month interview, and were again provided with an additional \$10 per interview to offset the cost of use of their personal cell phone minutes. During the Age 5 Extension participants received \$45 at 42 months; \$50 at 48 months; \$55 at 54 months; and \$60 at 60 months, and were provided with an additional \$10 to offset the cost of use of their personal cell phone minutes. We remain concerned that the respondents will become fatigued with the burden involved in a longitudinal study, particularly those who are the most mobile and difficult to locate. Maintaining the size of the incentive for the final interview at 72-months should help keep respondents engaged and feel that their effort is appreciated, and therefore minimize

response bias in the study over time. Study participants will receive \$60 at 72 months, and will be provided with an additional \$10 to offset the cost of use of their personal cell phone minutes.² Participants selected to complete a replicate dietary intake interview within 10 days of the first interview will receive an additional \$60 for the second interview, with an additional \$10 to offset the use of cellphone minutes as applicable. Child height and weight measurements are critical outcome measures for the study. Consequently, study participants who are willing to bring their child to the WIC site or a health care provider's office for measurements and to have a measurement card completed, an activity requiring the burden of both time and travel with the child, will receive the same \$70 (\$60 as an incentive and \$10 as a transportation stipend³) at 72 months that they received for these activities at 60 months. Participants will continue to receive these incentives on their reloadable prepaid MasterCard provided originally for the Base study. Finally, women who do not have a telephone to use to complete the telephone interviews will be given a prepaid cellphone with 200 minutes valued at \$65.00 to complete each interview. We will ask participants to return the phone at the completion of the study. Table A9.1 shows the

²\$10 for personal cell phone use is based on costs for pay-as-you-go plans popular with lower income users who cannot always afford contracts. Specifically, TracFone, widely available at discount department stores, charges \$39.99 for 200 minutes of talk time. A 45-minute interview would therefore cost participants approximately \$10 for personal cell phone minutes.

³ In 2014, average public transportation cost in the US for a single segment of a trip was \$1.43, and historically costs have risen approximately \$0.06/year (US Department of Transportation, Bureau of Transportation Statistics, <https://www.bts.gov/content/fares-all-transit-modes-unlinked-trip-1990-2014>). We therefore anticipate the average public transportation cost for one adult and the study child, for a round trip, will be approximately \$7.00. Because this is an average, however, and many of our study participants live in more expensive areas for transportation or may need to bring more than one child to avoid child care costs, we round the total amount up to \$10.

events that involve participant incentives and the associated incentive amounts.

Our longitudinal incentive plan is comparable to that of other longitudinal studies with similar populations or similar data collection requirements, which have provided incremental increases in incentive amounts through the course of the study, though not necessarily at every data collection event. The Study of Mothers and Children in Palm Beach County, a non-federal study sponsored by local government in Palm Beach County, FL, was a 5-year longitudinal survey (2005-2009) of low-income mothers of newborns in Palm Beach County, with yearly in-person interviews. The mothers received a \$25 incentive in years 1-3. Response rates for eligible respondents were 94% for the baseline interview, 91% for Year 2, and 85% for Year 3. To help reduce the possibility of response bias, particularly through loss to follow-up of the most mobile participants, the incentive was increased to \$35 for Years 4 and 5. A response rate of 82% was achieved for Year 4 and 85% for Year 5, counteracting the potential response bias.

The CDC National Health and Nutrition Evaluation Survey (NHANES) is an example of a study that involves parents accompanying children to have physical measurements completed on the children. In the 2013-2014 data collection (OMB no. 0920-0950 National Health and Nutrition Examination Survey, expiration date 11/30/2015), NHANES provided young children and their parents a total incentive of \$60 for bringing children to be measured,

and an additional \$25 - \$70 for transportation costs depending on the distance traveled.

The current study is also a longitudinal study, and retaining the participants for an additional year without introducing response bias is essential to the success of the study. The study has offered incrementally larger incentives for each interview between 30 months and 60 months. Were the incentive to be reduced for this final interview below the level offered at 60 months, some groups of participants, particularly those with lower incomes or greater additional demands on their time, may choose not to participate, greatly increasing the risk of response bias.

Table A9.1. Participant Incentives by Event

Event	Average Hours per Response	Incentive Amount
Incentives for Caregivers		
72-Month Interview	.75	\$60
<i>Personal cellphone minute costs for 72-month interview</i>	N/A	\$10
72-Month Replicate Dietary Intake Interview (within 10 days)	.50	\$60
<i>Personal cellphone minute costs for 72-month replicate dietary intake interview</i>	N/A	\$10
72-Month Child Measurements at WIC Site or Provider's Office	1.00	\$60
<i>Transportation costs for travel to WIC site or provider's office for measurements</i>	N/A	\$10
Grants for WIC sites		
Grants to WIC sites to offset costs of measurements at Age 6	N/A	\$527 per site

In addition to the incentives offered to caregivers, we will again offer optional small grants to help WIC sites offset administrative costs associated with weighing and measuring children no longer on WIC at age 6. Such measurements, while not overly burdensome, are outside the regular duties of staff at the WIC sites. Grants will vary in size depending on the number of study participants enrolled at that site, and therefore the anticipated administrative burden needing to be offset to weigh and measure the study children. Grant amounts appear in Table A9.2. Sites were grouped by enrollment to approximate number of children projected to need measurements at the site. Based on these estimates, we anticipate the grants will be between \$250-\$2,000, with an average of approximately \$527 per site, the same as that offered for measurements at age 5.

Table A9.2. Grant Amounts for WIC Sites

Number of children enrolled	Grant Amount
-----------------------------	--------------

7-28	\$250
29-38	\$350
39-48	\$450
49-60	\$550
61-79	\$700
80-99	\$800
100-200	\$1,200
Over 200	\$2,000

A.10 Assurance of Confidentiality Provided to Respondents

Describe any assurance of confidentiality provided to respondents and the basis for the assurance in statute, regulation, or agency policy.

Study participants will be 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 have been documented in an informed consent form, along with procedures for handling and secure storage of information provided by participants (Appendices A1 and A2). For the 72-month telephone interview (Appendices D1/D2), the replicate dietary intake interview (Appendices D3/D4), and the measurement cards (Appendices F1/F2) personally identifiable information is collected, including names and contact information. For each form, a privacy act statement is included. In addition, all project staff and subcontractors have signed a confidentiality and nondisclosure agreement (Appendix T). We will ensure the privacy and security of electronic data during the data collection and processing period following the system of record notice (SORN) titled FNS-8 USDA/FNS Studies and Reports, published in the Federal

Register on April 25, 1991 (56 FR 19078). Names and phone numbers will not be linked to participants' responses, study participants will have a unique ID number, and analysis will be conducted on data sets that include only respondent ID numbers. All data will be securely transmitted to the study team via sealed mailings or phone; and will be stored in locked file cabinets or password-protected computers, and accessible only to project staff. If respondents provide any personally identifiable information via text or email, such as their child's name and date of birth from a health provider printout, all personal information will be immediately deleted from the electronic device (respondents are instructed to cover their child's name and date of birth prior to sending a picture of the health care record to the study liaison). Names and phone numbers will be destroyed within 12 months after the end of the collection and processing period (approximately 12/2021). Westat's Institutional Review Board (IRB) is the organization of record overseeing all human subjects' activities for the study. A copy of the IRB approval letter is in Appendix U.

A.11 Justification for Sensitive Questions

Provide additional justification for any questions of a sensitive nature, such as sexual behavior or attitudes, religious beliefs, and other matters that are commonly considered private. This justification should include the reasons why the agency considers the questions necessary, the specific uses to be made of the information, the explanation to be given to persons from whom the

information is requested, and any steps to be taken to obtain their consent.

In general, questions on the WIC participant questionnaires, and measures of child height and weight, are not considered to be sensitive. Participants can choose to skip any question, or to discontinue participation in the study. The majority of questions required for the interviews were cognitively tested for the Base study, and no participants expressed unwillingness to answer the questions, nor have study participants expressed concerns about the questions as they have answered them through the 48-month interview. The remaining questions were based on or drawn from established studies with similar populations and have undergone expert review for comprehensibility, and simulation testing for flow and timing.

A.12 Estimates of Respondent Burden Including Annualized Hourly Cost

Provide estimates of the hour burden of the collection of information. The statement should:

- A. Indicate the number of respondents, frequency of response, annual hour burden, and an explanation of how the burden was estimated. If this request for approval covers more than one form, provide separate hour burden estimates for each form and aggregate the hour burdens in Item 13 of OMB Form 83-I.**

This is a revision of a currently approved information collection. With this revision, FNS estimates that this collection will have 5,004 respondents,

33,644 responses, and 4,414.79 burden hours. The target participant is the child. We will collect information about the child from the mother/caregiver, and from WIC State agency and local site staff. The burden table (Appendix V) presents the number of respondents, frequency of response, and annual hour burden to collect these data. The assumptions used to estimate burden are based on the study team's professional experience, survey expert simulation testing for timing of the interviews, and input from Public Health Foundation Enterprise for WIC (PHFE WIC).

- **Individuals and Households - Caregivers of former WIC children.** The sample size of the study participants, who are caregivers of former WIC children, is 4,046 (from the Base sample cohort of live births). 2,969 study participants will respond to one study extension consent (0.08 hours per response) and one study extension letter (0.05 hours per response). As needed depending on individual response patterns, study participants will respond to the following study communications: one reminder about the interview from study liaisons (0.03 hours per response), one reminder about the interview for those who have no phone number (0.02 hours per response), one refusal conversion letter for those who refuse the interview (0.05 hours per response), one reminder about the interview from those who do not answer calls (0.05 hours per response), two interview reminders from the Telephone Research Center (0.02 hours per response), one reminder about child height and weight measurements (0.05 hours per response), and one reminder about texting or emailing provider measures if they have not returned to WIC or their provider (0.05 hours per response). An estimated 2,524 study participants will respond to

one advance letter for the 72-month interview (0.05 hours per response), approximately 1,901 study participants will respond to one 72-month interview (0.75 hours per response), and 190 will respond to one 72-month replicate dietary intake interview (0.50 hours per response). An estimated 1,331 participants will take their children to be weighed and measured once at 72 months (1.0 hours per response), and 190 will provide a de-identified text or emailed printout of measurements from a recent provider visit (0.05 hours per response). 1,901 study participants will read a thank you note from the study (0.03 hours per response), and 2,969 will read birthday cards for the caregivers (0.03 hours per response), and birthday cards for the children (0.03 hours per response). Estimates of burden for study communications are based on professional experience with similar materials, and simulation testing of timing for reading the materials. Estimates of burden for the 72-month interview and replicate dietary intake interview are based on a combination of extensive records of burden from previous administrations of the dietary intake interview on this study, and expert simulation testing of timing of non-intake questions. Estimates of burden for child measurements are based on professional knowledge from PHFE WIC.

- **State and Local Government - State WIC staff and WIC site staff.** We expect that all of the WIC State Agencies and WIC sites that have been collaborating with the study will continue to do so. A total of 27 WIC State Agency staff and 80 WIC site staff will read one study extension announcement (0.08 hours per response), attend one webinar briefing (1.00 hours per response), participate in one conference call about the study extension (1.00 hours per response), and read one study extension summary and agreement (0.18 hours per response) and one addendum to the study

agreement (0.08 hours per response). A total of 14 State Agencies will respond to requests for assistance with participant contact information (0.08 hours per response, 9 annual responses). A total of 80 WIC site staff will conduct measurements on study children who visit the clinic to be weighed and measured (0.17 hours per response, 6 annual responses), and 40 staff members will respond to requests for assistance with participant contact information (0.08 hours per response, 3 annual responses). Estimates of burden for the communication materials is based on professional experience with similar materials, and simulation testing of timing for reading the materials. Estimates of timing for the webinar and conference calls are based on actual timing for similar activities in the past on WIC ITFPS-2. Estimates of burden for child measurements are based on professional knowledge from PHFE WIC.

- **Profit/Non-Profit Business - Health care provider.** We expect that 851 study participants will take their children to health care provider to be weighed and measured at 72 months. Therefore, a total of 851 health care providers will conduct measurements on study children who visit their office to be weighed and measured (0.17 hours per response).

B. Provide estimates of annualized cost to respondents for the hour burdens for collections of information, identifying and using appropriate wage rate categories.

The total cost for the respondents is \$46,750.27. To account for fully loaded wage rates, FNS estimates that this total will increase by \$15,427.59 ($\$46,750.27 \times 0.33$), for a total estimated annualized cost for this collection of \$62,177.86. This includes \$28,429.19 for Individual/Household at \$7.25 per hour for Caregivers of former WIC children (average national minimum

wage); \$13,759.62 for State & Local Government at \$47.82 per hour for state and local WIC administrators (job category “Management Occupations” code #11-0000) and at \$16.19 per hour for WIC site staff (job category “Healthcare Support Occupations” code #31-0000); and \$4,561.45, for Profit/Non-Profit Business at \$32.16 per hour for Health care providers (job category “Registered Nurses” code 29-1141). The estimate of costs to state and local government is based on the burden estimates and utilizes the U.S. Department of Labor, Bureau of Labor Statistics, May 2017 National Occupational and Wage Statistics, NAICS Code 999000, State and Local Government (https://www.bls.gov/oes/current/naics3_999000.htm). The estimate of costs to Profit/Non-Profit Business is based on the burden estimates and utilizes the U.S. Department of Labor, Bureau of Labor Statistics, May 2017 National Occupational and Wage Statistics, NAICS Code 621100, Offices of Physicians (https://www.bls.gov/oes/current/naics4_621100.htm#29-0000). No respondents will be asked to keep records of data; therefore no burden hours have been estimated for recordkeeping.

A.13 Estimates of Other Total Annualized Cost Burden

Provide estimates of the total annual cost burden to respondents or record keepers resulting from the collection of information, (do not include the cost of any hour burden shown in items 12 and 14). The cost estimates should be split into two components: (a) a total capital and start-up cost component annualized over its expected

useful life; and (b) a total operation and maintenance and purchase of services component.

There are no capital/start-up or ongoing operation/maintenance costs associated with this information collection.

A.14 Annualized Cost to the Federal Government

Provide estimates of annualized cost to the Federal government. Also, provide a description of the method used to estimate cost and any other expense that would not have been incurred without this collection of information.

Total annual cost to the federal government, including contractor costs of \$772,207, FNS staff costs of \$43,213, and a fully loaded wage rate of \$269,089 ($\$815,420 \times 0.33$) is \$1,084,509. Contractor costs associated with this study total \$3,606,206 over 4.67 years, with an estimated \$772,207 annual cost to the federal government. This is based on an estimate of 30,324 labor hours, with a salary range of \$29.17- \$399.65 per hour, and includes instrument development; data collection and retention; analysis; reporting; and overhead costs, including computing, copying, supplies, postage, shipping, incentives, and other miscellaneous items. The cost of the FNS employee, Social Science Research Analyst, involved in project oversight with the study is estimated at GS-13, step 1 at \$46.46 per hour. We anticipate this person will work 832 hours per year for 4.67 years for a combined total of 3,885 hours. The annual cost for the FNS employee is \$38,655. Additionally, the Branch Chief who provides oversight for work

conducted by the Research Analyst is estimated at GS-14, step 1 at \$54.91 per hour. We anticipate this person will work 83 hours per year for 4.67 years for a total of 387.61 hours. The annual cost for this employee is \$4,558. Federal employee pay rates are based on the General Schedule of the Office of Personnel Management (OPM) for 2018 for the Washington DC locality (source for the federal hourly wage rates: https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2018/DCB_h.pdf).

A.15 Explanation for Program Changes or Adjustments

Explain the reasons for any program changes or adjustments reported in Items 13 or 14 of the OMB Form 83-1.

This is a revision of a currently approved data collection. This information collection is currently approved with 11,619 burden hours and 130,156 responses. As a result of this revision, FNS estimates that the annual burden for this collection will decrease by 7,204 hours, due to a program change. Responses have also decreased by 96,512 responses. This extension to Age 6 includes fewer participant contacts than the previous study extension, with only one interview and child measurement, resulting in decreased burden and responses. With this renewal, FNS estimates that this information collection will have 4,415 burden hours and 33,644 responses.

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

For collections of information whose results are planned to be published, outline plans for tabulation and publication.

The data collection and reporting for WIC ITFPS-2 Age 6 Extension will begin after OMB approval and when the cohort of study children reach their 6th birthdays, in April 2019, and extend until Spring 2022.

Table A16.1. Data Collection and Reporting Schedule

Activity	Schedule
Participant Notification of Study Extension	2 weeks following OMB approval or with 60 month advance letter
Data Collection	April 2019 - October 2020
Data Analysis	October 2020 - June 2021
Draft Report	June 2021
Final Report	December 2021
Publish Final Cleared Report	Spring 2022

FNS expects to release one report to the public for the findings of the Age 6 Extension, in spring 2022. The report will be posted on the FNS web site. The study team will conduct descriptive analyses, cross-sectional analyses looking at associations between key variables, and longitudinal analyses that fully leverage the study data. Table A16.2 presents an overview of the research questions that will be addressed in the report, and data collection activities that contribute to them. These analyses will aid FNS to understand and plan improvements to the WIC program, its technical assistance, and future research. Findings will be also be published in

professional journals and publications intended for general audiences such as nutrition educators.

Table A16.2. Research Questions and Principal Data Sources for Year 6 Report

Research Question	Main Sources of Data
1. What are the food/beverage (including water), energy, and nutrient intakes of the study children both overall and by subgroups of interest?	72-month caregiver interview
2. What are the meal and snack patterns, both overall and by subgroups of interest?	72-month caregiver interview
3. How many 5-6 year olds exhibit unhealthy eating patterns, and what characteristics, including weight-for-height status, are associated with these habits?	72-month caregiver interview Child Measurements
4. How do dietary intake patterns change once a child ages out of WIC? How do changes in these patterns vary across subgroups?	72-month caregiver interview
5. What is the relationship, if any, between (1) cumulative years of participation in WIC, (2) ages during WIC participation, and (3) continuity of WIC benefit receipt (e.g., constant vs. intermittent) and dietary behaviors and energy and nutrient intake after aging out of WIC? a. Are differences affected by eligibility for and/or participation in other food benefit programs (e.g., NSLP/SBP, Summer Food Service Program, SNAP)?	72-month caregiver interview

Table A16.2. Research Questions and Principal Data Sources for Year 6 Report (continued)

Research Question	Main Sources of Data
b. Do dietary patterns of children with longer durations of participation in WIC more closely reflect nutrients emphasized by WIC than those who have shorter duration/more intermittent benefits?	
c. Do early feeding practices, meal/snack patterns, or food and nutrient intakes between ages 0-24 months relate to feeding practices, meal/snack patterns, food and nutrient intakes at age 6 years? How do these vary based on characteristics of WIC participation of the child/household?	
6. How do early feeding practices impact children’s weight status and growth during the sixth year of life?	72-month caregiver interview Child Measurements
7. Do early feeding practices, meal/snack patterns, or food, energy, and nutrient intakes relate to the health status and weight trajectories or childhood overweight/obesity of 5-6 year olds?	72-month caregiver interview Child Measurements
8. What is the influence of caregiver practices at home and broader environmental factors—such as the media—on dietary behaviors that may affect childhood obesity?	72-month caregiver interview Child Measurements

9. What is the impact of participation in other Federal food assistance programs (e.g., NSLP/SBP, Summer Food Service Program, SNAP) on feeding practices and health outcomes (i.e., weight status, developmental outcomes) during the sixth year of life?	72-month caregiver interview Child Measurements
10. Estimate the food security status for children and their households overall and for key subgroups and characteristics of interest.	72-month caregiver interview
11. How does food security status change when the child ages out of WIC? To what extent does prior WIC participation, or current household WIC participation, influence food security status during the sixth year of life?	72-month caregiver interview
12. How does participation in other food assistance programs by the child or their household impact household food security overall and by subgroups of interest?	72-month caregiver interview
13. To what extent do feeding practices during the sixth year of life vary by household's continued participation in WIC (i.e. someone else in the household is receiving WIC benefits) and/or by the household's participation in other Federal food assistance programs?	72-month caregiver interview
14. To what extent do feeding practices during the sixth year of life vary by cumulative years of participation in WIC, and by reasons for exiting the WIC program?	72-month caregiver interview
15. Do caregivers continue to purchase the foods they previously received in their child's WIC food package, even when no one in the household is receiving WIC?	72-month caregiver interview
16. For caregivers who received referrals through WIC, how do they get referred or connected to other health, welfare, and social services once the household is no longer receiving WIC services? (This question is applicable to the time point at which the child stops receiving WIC services.)	72-month caregiver interview
17. Do caregivers seek out nutrition education services once their child is no longer receiving WIC services? (This question is applicable to the time point at which the child stops receiving WIC services.)	72-month caregiver interview
18. How do feeding practices vary with caregiver work/school status (e.g., part time, full time), family circumstances (e.g., number and age of household members, household member's participation in WIC, SNAP, etc.), and child care/preschool/school circumstances?	72-month caregiver interview

Table A16.2. Research Questions and Principal Data Sources for Year 6 Report (continued)

Research Question	Main Sources of Data
19. In what food environments (home, school, child care, etc.) do children consume meals and snacks during the sixth year of life? How do these environments vary by subgroups of interest?	72-month caregiver interview
20. What proportion of intake is consumed in the various food environments? To what extent does this vary across subgroups of interest?	72-month caregiver interview

A.17 Reason Display of OMB Expiration Date is Inappropriate

If seeking approval to not display the expiration date for OMB approval of the information collection, explain the reasons that display would be inappropriate.

All data collection instruments will display the OMB control number and expiration date.

A.18 Exceptions to Certification for Paperwork Reduction Act Submissions

Explain each exception to the certification statement identified in Item 19 “Certification for Paperwork Reduction Act.”

The agency is able to certify compliance with all provisions under Item 19 of the OMB Form 83-I.