

SUPPORTING STATEMENT PART A FOR

Revision to OMB Number 0584-0580

**WIC Infant and Toddler Feeding Practices Study-2 (WIC ITFPS-2):
Age 5 Extension**

Allison Magness

Office of Policy Support

Food and Nutrition Service

US Department of Agriculture

3101 Park Center Drive

Alexandria, VA 22302

Phone: 703-305-2098

Fax: 703-305-2576

E-mail: Allison.magness@fns.usda.gov

1/28/16

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.....	3
A.3	Use of Information Technology and Burden Reduction.....	5
A.4	Efforts to Identify Duplication and Use of Similar Information.....	6
A.5	Impacts Small Business or other Small Entities.....	7
A.6	Consequences of Collecting the Information Less Frequently.....	7
A.7	Special Circumstances relating to the Guidelines of 5 CFR 1320.5.....	8
A.8	Responses to the Federal Register Notice and Efforts to Contact Outside Agencies.....	9
A.9	Explanation of Any Payment or Gift to Respondents.....	10
A.10	Assurance of Confidentiality Provided to Respondents.....	15
A.11	Justification for Sensitive Questions.....	16
A.12	Estimates of Respondent Burden Including Annualized Hourly Cost.....	16
A.13	Estimates of Other Total Annualized Cost Burden.....	18
A.14	Annualized Cost to the Federal Government.....	19
A.15	Explanation for Program Changes or Adjustments.....	19
A.16	Plans for Tabulation and Publication and Project Time Schedule.....	20
A.17	Reason Display of OMB Expiration Date is Inappropriate.....	22
A.18	Exceptions to Certification for Paperwork Reduction Act Submissions.....	22

Appendices

- A1 Study extension flyer to age 5 - English
- A2 Study extension flyer to age 5 - Spanish
- B1 Study Extension Consent Age 2.5 to 5 - English
- B2 Study Extension Consent Age 2.5 to 5 - Spanish

Appendices (continued)

- C1 36-month survey: contact information module - English
- C2 36-month survey: contact information module - Spanish
- D1 39-, 45-, 51-, and 57-mo contact information form - English
- D2 39-, 45-, 51-, and 57-mo contact information form - Spanish
- E1 42-mo advance letter - English
- E2 42-mo advance letter - Spanish
- F1 42-month telephone survey - English
- F2 42-month telephone survey - Spanish
- G1a Reminders for non-locatable no active interview - English
- G1b Reminders for non-locatable no active interview - Spanish
- G2a Reminders for non-locatable active interview - English
- G2b Reminders for non-locatable active interview - Spanish
- G3a Reminders for study participation refusal conversion - English
- G3b Reminders for study participation refusal conversion - Spanish
- G4a Reminders for study participation not answering calls - English
- G4b Reminders for study participation not answering calls - Spanish
- G5a Reminders for Telephone Research Center voicemail, first message - English
- G5b Reminders for Telephone Research Center voicemail, first message - Spanish
- G6a Reminders for Telephone Research Center voicemail, expiring interviews - English

G6b Reminders for Telephone Research Center voicemail, expiring interviews - Spanish

G7a Reminders for interview from Study Liaison - English

G7b Reminders for interivew from Study Liaison - Spanish

Appendices (continued)

- G8a Reminders for contact information form - English
- G8b Reminders for contact information form - Spanish
- G9a Reminders for consent - English
- G9b Reminders for consent - Spanish
- G10a Letter to study refusals - English
- G10b Letter to study refusals - Spanish
- G11a Height and weight reminders - English
- G11b Height and weight reminders - Spanish
- H1a 42-mo thank you - English
- H1b 42-mo thank you - Spanish
- H2a 48-mo thank you - English
- H2b 48-mo thank you - Spanish
- H3a 54-mo thank you - English
- H3b 54-mo thank you - Spanish
- H4a 60-mo thank you - English
- H4b 60-mo thank you - Spanish
- I1 48-mo advance letter - English
- I2 48-mo advance letter - Spanish
- J1 48-month telephone survey - English
- J2 48-month telephone survey - Spanish
- K1 48-and 60-mo HT/WT measurement card - English

K2 48-and 60-mo HT/WT measurement card - Spanish

Appendices (continued)

- L1 48-and 60-mo HT WT measurement letter - English
- L2 48-and 60-mo HT/WT measurement letter - Spanish
- M1 HIPAA letter and form - English
- M2 HIPAA letter and form - Spanish
- N1 48- and 60-mo text or email provider measures - English
- N2 48- and 60-mo text or email provider measures - Spanish
- O1 48- and 60-mo home health agency visit - English
- O2 48- and 60-mo home health agency visit - Spanish
- P1 54-mo advance letter - English
- P2 54-mo advance letter - Spanish
- Q1 54-month telephone survey - English
- Q2 54-month telephone survey - Spanish
- R1 60-mo advance letter - English
- R2 60-mo advance letter - Spanish
- S1 60-month telephone survey - English
- S2 60-month telephone survey - Spanish
- T1a Birthday card respondent year 4 - English
- T1b Birthday card respondent year 4 - Spanish
- T2a Birthday card child age 4 - English
- T2b Birthday card child age 4 - Spanish
- T3a Birthday card respondent year 5 - English

T3b Birthday card respondent year 5 - Spanish

Appendices (continued)

- T4a Birthday card child age 5 - English
- T4b Birthday card child age 5 - Spanish
- U Burden Table
- V Study extension webinar slides
- W1 Agenda for State Agency conference calls
- W2 Agenda for WIC site conference calls
- X1 Study extension announcement to WIC State Agencies
- X2 Study extension announcement to WIC Sites
- Y1 Letter to State Agencies and Sites
- Y2 Addendum A to State Agency letter
- Y3 Addendum B to State Agency Letter for WIC administrative data
- Z WIC Site participant contact information request
- AA Provider data request form
- BB Research question crosswalk
- CC Confidentiality and nondisclosure agreement
- DD1 Federal Register Notice Comment 1
- DD2 Federal Register Notice Agency Response to Comment 1
- DD3 Federal Register Notice Comment 2
- DD4 Federal Register Notice Comment 3
- EE1 NASS Review
- EE2 NASS Review Response

FF Westat IRB Approval Letter

Contents
(continued)

Appendices (continued)

- GG Details of Imputation, Calculation of the Survey Weights, and Nonresponse Bias Analysis
- HHa 13-Month Food Model Booklet Letter - ENGLISH
- HHb 13-Month Food Model Booklet Letter - SPANISH
- II Crosswalk of previously approved and revised materials

Tables

A8.1	Consultants from Outside the Agency.....	10
A9.1	Participant Incentives by Event.....	13
A9.2	Grant Amounts for WIC Sites.....	15
A16.1	Reporting Schedule.....	20
A16.2	Research Questions, Principal Data Sources, and Reports.....	21

Part A Justification

Terms of Clearance:

In April 2014, a change justification was approved by OMB adding a \$5 incentive to return a 1-item survey asking if respondents were or were not willing to sign a HIPAA authorization, and if they were willing to enclose the signed authorization. At the time of the change justification memo, the study had already sent 2,514 HIPAA forms to active study participants. Only 1,098 (43.7%) had been returned, and only 19 participants (<1%) had explicitly refused to sign the form, leaving the study unsure whether the low response often seen for HIPAA forms was due to passive refusals or lack of motivation to mail the signed form. After OMB and the IRBs that oversee the study approved the change justification memo, we sent the 1-item survey, with a blank HIPAA form and the offer of the \$5 incentive for responding, to all active study participants who had either not yet received, or not yet returned, a HIPAA form. By June 30, 2015 we had sent HIPAA forms to 3,233 core study participants in total. Of the 2,888 active core study participants, 1,544 (53%) in total returned a signed form, and 105 (3%) in total explicitly refused to sign.

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 5 Extension”). This revision will extend the longitudinal data collection of the original cohort of infants, previously extended to age 3, up to age 5.

The Base and Age 3 Extension, and now the Age 5 Extension of the **Infant and Toddler Feeding Practices Study-2 (ITFPS-2)** affirms the USDA’s Food, Nutrition and Consumer Services’ (FNCS) 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 authorization, including WIC, to cooperate with USDA program research and evaluation activities. The Age 5 Extension will follow children through the entire period of their WIC 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 5th birthdays.

The United States Department of Agriculture’s (USDA) Special Supplemental Nutrition Program for Women, Infants and Children (WIC)

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.

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 both the base study and the Age 3 Extension, (ICR Reference No. 201208-0584-002 , 201306-0584-008, and 201408-0584-007; Expiration date: 05/31/2018) is to examine feeding practices and associated decision-making from birth to 3 years of age.

The Age 5 Extension will involve: (1) collecting participant contact information at the 36-month interview to ensure participants can be located and interviewed when their children are 42 months old; (2) conducting four additional follow-up telephone interviews with the mother/caregiver when the child is 42, 48, 54, and 60 months old; and (3) obtaining height and weight measurements at 48 and 60 months on each child from WIC administrative records, direct measurements at WIC sites or doctor's offices, or health care provider records.

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 3 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 three years of their lives. The Age 5 Extension study will expand the data collection to their fifth year of life. This collection is completely voluntary for individuals and households, State and local government, and profit/non-profit business. 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.

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. We will collect data on the participants through age 5 in two ways:

- **Interviews:** The mothers/caregivers of the cohort of children in the Base study/Age 3 Extension will be asked to provide updated contact information at the 36-month interview and complete telephone interviews every six months, when their child is 42, 48, 54, and 60 months old. All four interviews will include questions to address the three research domains: background and environmental characteristics that influence child feeding practices; the impact of WIC on infant feeding practices; and nutrition and health outcomes of children. All four interviews will be telephone interviews conducted using a Computer-Assisted Telephone Interview (CATI). All participant communication materials and surveys are included in Appendices (A1 to T4b). If we are unable to

contact WIC participants, we will request their contact information from WIC site staff (Appendix Z). All communication materials informing State and WIC site staff of the study extension are included in Appendices V to Y3. See Appendix II for a crosswalk of materials approved under the Base study/Age 3 Extension that have been revised for the Age 5 Extension.

- **Height and Weight Measurements:** The study will collect data from WIC sites concerning children's weight and height measurements at 48 and 60 months of age (Appendices Y1-Y3) to calculate body mass index (BMI) in order to assess the impact of feeding practices on weight status. At 48-months, about 60 percent of children will no longer be on WIC, and by the fifth birthday children are no longer eligible for WIC. Parents/caregivers will be asked at 48-months and 60-months to bring their child to the WIC clinic to be measured, regardless of whether they are still receiving WIC benefits. The contractor, Westat, will send parents/caregivers a letter (Appendix L1, L2) and self-addressed postage-paid measurement card (Appendix K1, K2) and ask them to take the card to a WIC site and have them record the measurements and send the sealed card back to Westat. For those children who are unable to visit a WIC clinic, we will ask the parent/caregiver to go to the child's health care provider for measurement (Appendices L1, L2, K1, K2), or to sign a Health Insurance Portability and Accountability Act (HIPAA) release form (Appendices M1, M2) to allow the study to request these measurements from the child's health care provider (Appendix AA). If there are children no longer receiving WIC, who cannot go to WIC or a provider, and do not wish to sign a HIPAA release, we will offer to send a Home Health Agency nurse to measure the child directly (Appendix O1, O2).

Purpose of the Information: The information through age 5 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 the entire period of WIC eligibility, including those who leave WIC. 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 researchers will be able to further analyze the study data and further contribute to the knowledge base regarding this high-risk, vulnerable population. Base study results for the prenatal interview were released to the public by FNS in May 2015. The results have been presented thus far to stakeholder organizations interested in WIC and in breastfeeding, and are available to the public on the FNS website both as a full report and a 2-page summary.

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. Almost all of the data collected for this study reduces participant burden through the use of Information Technology.

Specifically, this Age 5 Extension will collect data in the following ways:

1. Computer-Assisted Telephone Interviews (CATI) with WIC Participants
2. Height and weight data from WIC administrative records
3. Height and weight data from health care provider records
4. Height and weight measurements taken at WIC sites or health care provider offices, and
5. Height and weight measurements taken by a Home Health Agency Nurse.

For the CATI surveys, 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 100 percent of WIC participants (approximately 8,586 responses across the four interviews) will submit responses electronically. The State Agencies, health care providers, and WIC sites will provide height and weight data to the contractor using a secure file transfer protocol (FTP) site exchange, a sealable self-addressed postage-paid card, a secure fax machine, or a verbal report by phone. Because local WIC sites will submit measurement cards by mail, we estimate that State and Local Government will submit 3 percent of their data electronically (approximately 54 responses through FTP by WIC State Agencies), and 97 percent non-electronically (approximately 1,760 responses

by WIC sites through mail). We anticipate that all providers will submit data through fax or mail, therefore 100 percent (approximately 334 responses) will be non-electronic. In total, approximately 80 percent of the responses will be collected electronically. These approaches are consistent with the data transfer protocols used in the Age 3 Extension study.

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 Age 3 extension, the aim is to obtain current data to continue to track issues in children's nutrition, growth, and environments as they unfold over the full period of WIC eligibility.

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.

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 WIC children or WIC operations 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 throughout the full period of WIC eligibility – national data on this has never before been available through age 5. We are proposing collecting data at the same reduced frequency (twice per year) approved for the Age 3 extension. Children's diets and circumstances change more slowly at ages 2-5 than they do at ages 0-2,

,^{2,3} so data collection at a lower frequency than during the base study is warranted. We still anticipate important changes each year as the children's diets, health, and environments diversify, but annual collection of dietary intake and annual collection of household circumstances, health, and feeding behavior should be sufficient for longitudinal tracking. Anything less than annual data may miss important turning points. 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;**

² Siega-Riz, A. M., Deming, D. M., Reidy, K. C., Fox, M. K., Condon, E., & Briefel, R. R. (2010). Food consumption patterns of infants and toddlers: where are we now?. *Journal of the American Dietetic Association*, 110(12), S38-S51.

³ Fox, M. K., Condon, E., Briefel, R. R., Reidy, K. C., & Deming, D. M. (2010). Food consumption patterns of young preschoolers: are they starting off on the right path?. *Journal of the American Dietetic Association*, 110(12), S52-S59.

- **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 November 5, 2015 in the Federal Register Volume 80, Number 214, Pages 68493-68496. FNS received three comments that were germane to this information collection. Only Commenter #1 included contact information, and therefore we are only able to respond directly to one of the three comments. Commenter #1 expressed a desire to see the study incorporate outreach to preschools and kindergarten classes to teach nutritional knowledge and evaluate progress or change that occurs as a result. FNS responded, expressing appreciation for the thoughtful idea, but clarifying that such school-based activities fall outside the scope of this particular study. Commenter #2 expressed support for the extension of the study to ages 4 and 5, noting that little research on obesity focuses on feeding practices at these ages. Commenter #3 urged a focus on electronic data collection when possible, and recommended that we minimize the need for busy WIC staff to contact participants by phone. We agree, and are planning electronic data collection for study elements when possible. Additionally, WIC staff will not be asked to contact participants by phone during the study. Public comments in response to the 60-day Federal Register Notice (FRN), and the FNS response to the one comment with contact information, appear in Appendices DD1-4.

The information collection request has been reviewed by Chunlin Dong with the National Agricultural Statistics Service (NASS) of USDA with special reference to the statistical procedures (Appendices EE1, EE2). FNS convened a Peer Advisory Panel (PAP) of experts in September 2014. The panel discussed the possibility of an Age 5 Extension, and provided guidance on design and research questions intended to maximize the successful conduct of the extension. The panel represented a wide variety of expertise which is described in Table A8.1.

Table A8.1. Consultants from outside the agency

Name	Affiliation	Area of Expertise
Sally Findley	Columbia University 212-304-5790	Research design and methodology
Larry Grummer-Strawn	Centers for Disease Control and Prevention (now with the World Health Organization, Geneva)	Major population studies on infant feeding
Suzanne Murphy	Cancer Research Center of Hawaii 808-564-5861	Nutrition
Zoe Neuberger	Center on Budget and Policy Priorities 202-408-1080	WIC research and policy
Peggy Trouba	Nebraska State WIC Director 402-471-2781	WIC operations and data systems
Chunlin Dong	National Agricultural Statistics Service 202-720-8951	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.

The incentive amounts for this study are based on evidence from other studies which indicate that the potential for response bias in longitudinal

studies can be minimized with incremental increases in incentives over time. 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 per 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 acknowledged and appreciated. As approved under the previous OMB package, in the Base study respondents are 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 receive an incrementally increasing incentive of \$30 for the 30-month interview and \$40 for the 36 month interview, and are again provided with an additional \$10 per interview to offset the cost of use of personal cell phone minutes. We remain concerned that respondent fatigue with the burden involved in the number of interviews, and therefore, the potential for response bias has intensified as the study moves forward. Continuing to increase the size of the incentive slightly with each interview

should help keep more respondents engaged and feel that their effort is appreciated, and therefore minimize response bias in the study over time. Study participants will receive \$45 at 42 months; \$50 at 48 months; \$55 at 54 months; and \$60 at 60 months, and will be provided with an additional \$10 to offset the cost of use of their personal cell phone minutes each time they use their own cellphone to complete a telephone interview.⁴ 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 an additional incentive of \$60 (\$50 as an incentive and \$10 as a transportation stipend) at 48 months, and \$70 (\$60 as an incentive and \$10 as a transportation stipend) at 60 months. We will provide a smaller incentive of \$20 for signing a HIPAA release and agreeing to allow us to contact their child's health care provider for the measurements, providing a printout of a measurement taken already at a provider's office, or agreeing to a home health agency visit at 48 and 60 months. We will also provide participants with \$5 for completing and returning the contact information forms at 39, 45, 51, and 57 months. Participants will continue to receive these incentives on their reloadable prepaid MasterCard provided originally for the Base study. Finally, women

⁴\$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 \$19.99 for 60 minutes of talk time. A 30-minute interview would therefore cost participants approximately \$10 for personal cell phone minutes.

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 events that involve participant incentives and the associated incentive amounts.

Event	Average Hours per Response	Incentive Amount
Incentives for Caregivers		
39-Month Contact Information Form	.10	\$5
42-Month Interview	.50	\$45
<i>Personal cellphone minute costs for 42-month interview</i>	N/A	\$10
45-Month Contact Information Form	.10	\$5
48-Month Interview	.50	\$50
<i>Personal cellphone minute costs for 48-month interview</i>	N/A	\$10
48-Month Child Measurements at WIC Site or Provider's Office	1.00	\$50
<i>Transportation costs for travel to WIC site or provider's office for measurements</i>	N/A	\$10
48-month Return of HIPAA authorization for provider measurements, providing an existing provider measurement printout, or agreeing to a home health agency visit	.05	\$20
51-Month Contact Information Form	.10	\$5
54-Month Interview	.50	\$55
<i>Personal cellphone minute costs for 54-month interview</i>	N/A	\$10
57-Month Contact Information Form	.10	\$5
60-Month Interview	.50	\$60
<i>Personal cellphone minute costs for 60-month interview</i>	N/A	\$10
60-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
60-month Return of HIPAA authorization for provider measurements, providing an existing provider measurement printout, or agreeing to a	.05	\$20

home health agency visit		
Grants for WIC sites		
Grants to WIC sites to offset costs of measurements at Ages 4 and 5	N/A	\$527 per site

Table A9.1. Participant Incentives by Event

^aIf not able/willing to go to the WIC site or a provider for child measurements, participants will be asked to give permission for the study to request height/weight measurements from providers, to provide a copy of a recent provider printout, or to allow a Home Health Nurse to come measure the child directly.

This incentive plan is comparable to that of other longitudinal studies with similar populations or similar data collection requirements, although our incremental increases are somewhat smaller in magnitude than the increases in other similar studies. The USDA Healthy Incentives Pilot (HIP) surveyed SNAP participants in Massachusetts. Like the WIC ITFPS-2 sample, these participants were low-income and highly mobile. HIP respondents were provided a \$20 incentive for the baseline telephone interview, which achieved a 63% response rate; \$30 for the Round 2 interview (3-6 months after baseline) which achieved an 83% response rate; and \$40 for the Round 3 interview (11-13 months after baseline), which achieved an 81% response rate.

The Study of Mothers and Children in Palm Beach County 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.

The CDC National Health and Nutrition Evaluation Survey (NHANES) is an example of a study that involves having parents accompany children to have physical measurements completed on the children. In the 2013-2014 data collection, 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.

In addition to the incentives offered to caregivers, we will offer optional small grants to help WIC sites to offset administrative costs associated with weighing and measuring children no longer on WIC at ages 4 and 5. 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.

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 (Appendices B1 and B2). In addition, all Westat project staff and subcontractors have signed a confidentiality and nondisclosure agreement (Appendix CC). 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.⁵ Names and phone numbers will not be linked to participants' responses, survey respondents will have a unique ID number, and analysis will be conducted on data sets that include only

⁵Published in the Federal Register on April 25, 1991 (56 FR 19078).

respondent ID numbers. All data will be securely transmitted to Westat via secure fax, FTP site, sealed mailings, or phone; and will be stored in locked file cabinets or password-protected computers, and accessible only to Westat project staff. Names and phone numbers will be destroyed within 12 months after the end of the collection and processing period (approximately 12/2020). 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 FF.

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 surveys were cognitively tested for the Base study, and no participants expressed unwillingness to answer the questions. The remaining questions were drawn

from established studies with similar populations and have undergone expert review for comprehensibility.

A.12 Estimates of Respondent Burden Including Annualized Hourly Cost

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

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

The target participant is the child. We will collect information about the child from the mother/caregiver, WIC administrative records, WIC sites, and health care providers. The burden table (Appendix U) 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 Westat's professional experience, survey expert simulation testing for timing of the interviews, and input from Public Health Foundation Enterprise for WIC (PHFE-WIC), and are footnoted in Appendix U.

- **WIC Participants.** The sample size of WIC participants is 4,046 (from the Base sample). Approximately 2,319 WIC participants will complete the 42-month interview, 2,200 will complete the 48-month interview, 2,087 will complete the 54-month interview, and 1,980 will complete the 60-month interview. The sample size and expected number of respondents for each data collection activity is based on the response rates presented in Table B2.1 (in the Part B supporting statement). Participant burden includes time to read communication materials, provide contact information at the 36-month interview, complete contact information forms at 39, 45, 51, and 57 months, and complete four additional telephone surveys. It also includes time to have their child measured at the WIC site office or provider's office for height and weight (HT/WT); or sign the HIPAA form to allow the contractor to request their child's height and weight measurements from the child care provider, provide a past printout of child HT/WT, or allow a Home Health Nurse visit to measure the child.
- **WIC Program Representatives.** We expect that all of the sWIC State Agencies and WIC sites that have been collaborating with the study will continue to do so. A total of 27 State **WIC data managers** will complete requests for height and weight data from administrative records and 80 WIC site staff will provide contact information for the study participants and assist in weighing and measuring children who visit the clinic to be weighed and measured.
- **Health Care Providers.** The sample size of health care provider data managers who will receive requests for child measurements is 418. Of these, we expect up to 334 of them will respond to requests for child's height and weight data.

The estimated annualized cost for this collection is \$110,911.49. This includes \$76,562.85 for Individual/Household at \$7.25 per hour for WIC participants (average national minimum wage); \$33,866.10 for State, Local & Tribal Government at \$54.08 per hour for state and local WIC administrators and WIC data managers (job category “Management Occupations” code #11-0000)⁶; and \$13.86 per hour for WIC site staff (job category “Healthcare Support Occupations” code #31-0000), and \$482.54 for Business at \$13.86 per hour for health care provider data managers (job category “Healthcare Support Occupations” code #31-0000). 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.

⁶May 2014 National Occupational Employment and Wage Estimates for the United States, available at www.bls.gov/oes/current/oes_nat.htm.

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 is \$1,389,073. Contractor costs associated with this study total \$7,034,916 over 5.2 years, with an estimated \$1,352,868 annual cost to the federal government. This is based on an estimate of 67,451 labor hours, with a salary range of \$25.93- \$294.65 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 \$43.52 per hour based on 2,080 hours per year. We anticipate this person will work 832 hours per year for 5.2 years for a combined total of 4,326 hours. The annual cost for the FNS employee is \$36,205. Federal employee pay rates are based on the General Schedule of the Office of Personnel Management (OPM) for 2015 for the Washington DC locality.

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. The current burden inventory is 5,408 hours and the requested burden estimate as a result of program changes is 11,619.05 rounded down to 11,619 which is an increase of 6,211 burden hours. This request also reflects an increase in the number of responses. The current total number of responses is 45,077 and the requested number of responses is 130,156, an increase of 85,079 responses. The program changes are due to substantive revisions contained in this phase of the study (Age-5 Extension) as well as changes to the instruments (adding a contact information module to the 36-month interview added 5 minutes per response to the overall time for that instrument). As a result of the substantive revisions the number of respondents and responses increased, and as a result of the instrument changes the burden per response of the 36-month interview increased.

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.

Table A16.1 shows the reporting schedule for the reports related to the Age 5 extension.

Table A16.1. Reporting Schedule

Activity	Schedule
48-month Report	August 30, 2019
Final Report through 60 months	July 17, 2020

Table A16.2 presents an overview of the objectives, data collection activities, and study reports that will aid FNS to understand and plan improvements to the WIC program, its technical assistance, and future research. Findings will be published in peer reviewed reports, professional journals and publications intended for general audiences such as nutrition educators. Final reports will be posted on the FNS web site.

Table A16.2. Research questions, principal data sources, and reports

	Research questions	Data sources	Reports
1.	How do feeding practices vary with working and family care/childcare/preschool circumstances?	42, 48, 54, and 60 month Caregiver Interviews	48 Month Report Final Report
2.	What are the main barriers to eating healthy?	42, 54 month Caregiver Interviews	48 Month Report Final Report
3.	What is the influence of parenting and broader environmental factors on early dietary behaviors that may affect child obesity?	42, 54 month Caregiver Interviews	48 Month Report Final Report
4.	What is the impact of participation in other Federal food benefit programs on feeding practices and health outcomes?	42, 48, 54, and 60 month Caregiver Interviews	48 Month Report Final Report
5.	What is the food and nutrient intake of 4-5 year olds, both overall and by subgroups of interest?	48 and 60 month Caregiver Interviews	48 Month Report Final Report
6.	What are the meal and snack patterns, both overall and by subgroups of interest?	48 and 60 month Caregiver Interviews	48 Month Report Final Report
7.	How do feeding practices impact children's weight and growth?	42, 48, 54, and 60 month Caregiver Interviews WIC administrative data WIC site measurements Provider measurements	48 Month Report Final Report
8.	When do "unhealthy" eating habits	Earlier Caregiver	48 Month

	typically begin and are there early warning signs that a change is occurring?	Interviews 48 and 60 month Caregiver Interviews	Report Final Report
9.	Do early feeding practices, meal/snack patterns, or food and nutrient intakes relate to feeding practices, meal/snack patterns, food and nutrient intakes, and health status at ages 4-5 years?	Earlier Caregiver Interviews 42, 48, 54, and 60 month Caregiver Interviews	48 Month Report Final Report
10.	Do early feeding practices, meal/snack patterns, or food and nutrient intakes relate to weight trajectories or child overweight/obesity at ages 4-5 years?	Earlier Caregiver Interviews WIC administrative data WIC site measurements Provider measurements	48 Month Report Final Report
11.	Does continued participation in WIC lead to better eating behaviors and health outcomes?	Earlier Caregiver Interviews 42, 48, 54, and 60 month Caregiver Interviews	48 Month Report Final Report
12.	Does the nutrient intake of 4-5 year olds reflect nutrients provided in the WIC food package? ^a	48 and 60 month Caregiver Interviews IOM data on WIC food package nutrients	48 Month Report Final Report
13.	What is the impact of WIC experience on outcomes beyond nutrition and health such as developmental outcomes?	Earlier Caregiver Interviews 42, 48, 54, and 60 month Caregiver Interviews	48 Month Report Final Report
14.	Does continued participation in WIC have a positive corollary effect on access to healthcare and continuity of care?	Earlier Caregiver Interviews 42, 48, 54, and 60 month Caregiver Interviews	48 Month Report Final Report
15.	What factors lead to continued/discontinued/renewed participation in WIC through age 5?	Earlier Caregiver Interviews 42, 48, 54, and 60 month Caregiver Interviews	48 Month Report Final Report

^aBased on comparisons to external data expected to be available from IOM research.

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.”

There are no exceptions to the Certification for Paperwork Reduction Act (5 CFR 1320.9) for this study.