SUPPORTING STATEMENT FOR

WIC Infant and Toddler Feeding Practices Study-2 (WIC ITFPS-2)

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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.

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 current study is a new information collection titled the "**WIC Infant and Toddler Feeding Practices Study-2 (WIC ITFPS-2)**." The study is needed to update information in the WIC Infant Feeding Practices Study (WIC IFPS-1), which was conducted in the fall of 1994, and only collected data on infants. Since that time

WIC infant feeding practices may have changed in important ways, particularly since the new WIC food packages were introduced in 2009, and the program has instituted a greater emphasis on nutrition education and breastfeeding. This study, planned for Fiscal Years (FY) 2013-2016, 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

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.

2010 (Public Law 111-296, Sec. 305) mandates programs under its authorization, including WIC, to cooperate with USDA program research and evaluation activities.

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.

Research Design: The current study will employ a national probability sample of WIC participants and a longitudinal design to examine infant and toddler feeding behaviors and associated decision making. We will recruit and follow a core sample of infants and toddlers from birth through their second birthday and will oversample a supplemental group of WIC participants with low prevalence in the population to ensure representation of those groups (for instance, African-American mothers who breastfeed – a group with generally low levels of breastfeeding). The study will also gather information from key WIC Staff about the program, particularly about their breastfeeding policies and nutrition education activities. There are two categories of people from/about whom we will collect data – WIC Participants and WIC Program Representatives:

- **WIC Participants**: The target study participant is the infant/toddler, but we will recruit and conduct interviews with the mother (or primary caregiver). Participants much be at least 16 years old and parental consent and adolescent

assent will be obtained for those under the age of majority in their state. The study will collect data about WIC participants in two ways:

- **Interviews**: Sampled WIC participants will be recruited (Appendices A-H) and assigned to either a core or supplemental group. We will interview the core group up to eleven times over a two-year period, with a prenatal interview (for those enrolled prenatally) and interviews every two months from the child's birth through age one, and about every three months between ages 1 and 2 (at ages 1, 3, 5, 7, 9, 11, 13, 15, 18, and 24 months) (Appendices I-U). The supplemental group will only participate in four interviews (at ages 1 or 3, 7, 13, and 24 months). Study participants will also be asked at each interview about their child's food intake in the previous 24 hours using the USDA Automated Multiple Pass Method (AMPM)[2] (Appendix V) and supporting materials (Appendices W-X); and a 10 percent subsample of the core group will be asked to report a second day of intake 7-10 days after the initial interviews at 13, 15, 18, and 24 months. The interviews will be conducted over the phone using a Computer-Assisted Telephone Interview (CATI).
- **Health Data**: The study will also collect data from hospital birth records on the infants' weight at birth (Appendix AA); and from WIC

2 Moshfegh AJ, Rhodes DG, Baer DJ, Murayi T, Clemens JC, Rumpler WV, Paul DR, Sebastian RS, Kuczynski KJ, Ingwersen LA, Staples RC, Cleveland LE. The US Department of Agriculture Automated Multiple-Pass Method reduces bias in the collection of energy intakes. Am J Clin Nutr 2008; 88:324-32

administrative records on the infants' length and weight and WIC package prescription at three times during the study (at ages 6, 12, and 24 months) (Appendix BB). When participants consent to enroll in the study (Appendices Y-Z), we will ask them to sign a Health Insurance Portability and Accountability Act (HIPAA) form releasing the records for the study (Appendix H). If a child in the core sample has dropped out of WIC, we will request data from their health care provider (Appendix CC) or we will arrange for a home health agency to collect the child's length and weight in their home (Appendices DD-EE).

- **WIC Program Representatives**: Following the Sampling Plan described in Part B, the research team will recruit 80 WIC sites in 27 State Agencies to participate in the study and speak with them about the program.
    - **State and Local WIC Administrators**: The study will conduct one, hour-long, semi-structured key informant interview with a State WIC administrator in each sampled State Agency (Appendix LL.1), and a local WIC administrator for each sampled WIC site (Appendix LL.2).
    - **WIC Site Staff**: The study will also gather information from all staff (not to exceed 10) at sampled WIC sites through a one-time, 30-minute web-based survey (Appendix MM).

Eligibility and Recruitment: We seek to collect data from WIC mothers (or primary caregivers) about their infants/toddlers from birth through the second birthday. In

order to gather information starting at birth, the study will recruit women at the 80 sites who are enrolling in WIC either during pregnancy or just after giving birth. WIC Staff will identify participants eligible for the study during their WIC enrollment interview using the Participant Referral Form (Appendices C-D), show them a study poster or give them a flier (Appendices A-B), and refer them to research recruiters who will be located at the WIC site during the enrollment period. The research recruiters will speak with the eligible WIC participants, gauge their interest in the study, obtain consent from willing participants and conduct the enrollment interview (Appendix E). After enrollment, each participant will be mailed an enrollment package (Appendices F-G). Subsequent contacts will be via phone or text message to remind participants about, and conduct the longitudinal interviews (Appendix NN). They will also receive a thank you letter at the end of the study (Appendix OO).

Purpose of the Information: The information will be a valuable asset to policymakers, WIC Program Staff, health professionals, and the research community. 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 use the information to shape their interactions with this highly-vulnerable population, and researchers will have a vast data source to analyze and further contribute to the knowledge base regarding this high-risk, vulnerable population.

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.

Nearly all of the data collected for this study reduces participant burden through the use of Information Technology. Specifically, this study collects data in six ways:

1. Participant recruitment materials
2. Computer-Assisted Personal Interviews (CAPI) to screen and enroll WIC Participants
3. Computer-Assisted Telephone Interviews (CATI) with WIC Participants, including dietary recalls using the AMPM
4. Health record abstraction from Hospitals and WIC sites
5. Key informant interviews with WIC Staff
6. Web-based surveys with WIC Staff

For the CAPI enrollment interview, participants will speak to a research recruiter and be enrolled into the study at the WIC site. For the CATI surveys and AMPM recalls, 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. Most of the health record abstraction will occur through a data transfer between the hospital or WIC site and the research contractor over a secure file transfer protocol

(FTP) site exchange. We have experience with this from other studies and expect this will take less than a minute to complete. The web-based surveys will involve WIC Staff time, but will be conducted over the Internet, so there is a greatly reduced burden over a paper-based survey that requires completion and submission through postal mail. The participant recruitment materials and key informant interviews are the only data collection components that do not involve information technology. The recruitment materials will involve completing a one-page information sheet with participants' contact information. The key informant interviews will involve some open-ended questions, but the trade-off for burden is the depth of information the researcher will be able to collect from critical stakeholders about the WIC program.

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.

Through careful review of the data requirements, we have determined that no current data are similar to that proposed for collection in this study. The most relevant past research that focused exclusively on the WIC population is the WIC IFPS-1 which was conducted in 1994, almost 20 years ago. Since that time WIC infant feeding practices may have changed in important ways, particularly since the new WIC food packages were introduced in 2009, and the program has instituted a greater emphasis on nutrition education and breastfeeding. More recent infant and toddler feeding studies

such as the Nestle Nutrition Institute's Feeding Infants and Toddlers Study (FITS 2008) and the Food and Drug Administration's Infant Feeding Practices Study II (FDA IFPS-2) have collected important data; however, they did not focus on the WIC population, which is unique for several reasons, including being low-income and at nutritional risk.

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.

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.

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. 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. If the study is not conducted at this time, USDA's Food and Nutrition Service (FNS) will not have current information on the feeding practices and dietary intakes of WIC infants and toddlers or WIC operations for making policy decisions about WIC services and nutrition education.

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.**

Women in the core sample will be asked to report information more often than quarterly. Those recruited prenatally will be interviewed one time before the baby is born, six times over an 11 month period when the baby is 1, 3, 5, 7, 9, and 11 months old; and four times at 13, 15, 18, and 24 months. This data collection design is necessary to capture the rapid changes in children's eating patterns when they move from being breastfed and/or formula fed to being introduced to solid foods and subsequently to

table foods. There are no other special circumstances relating to the Guidelines of 5 CFR 1320.5. This request fully complies with 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 03/23/2012 in the Federal Register Volume 77, Number 57, pages 17002-17003 and provided a 60-day period for public comments. The Global head of Nutrition Science at Nestle Nutrition, sponsor of one of the key prior infant feeding practices studies (FITS 2008), reviewed the instruments and responded to the 60-day notice. The comments were helpful and resulted in the revision of some of the questions (Appendices PP-QQ). The information collection request has been reviewed by the National Agricultural Statistics Service (NASS) of USDA with special reference to the statistical procedures (Appendix RR). FNS also convened a Peer Advisory Panel (PAP) of experts in November 2011. The panel reviewed the study research and sampling plans and provided guidance on critical

issues related to the successful conduct of the WIC ITFPS-2. The six member 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
Maureen Black	University of Maryland	Child health and development
Sally Findley	Columbia University	Research design and methodology
Larry Grummer-Strawn	Centers for Disease Control & Prevention	Major population studies on infant feeding
Suzanne Murphy	University of Hawaii	Nutrition
Zoe Neuberger	Center on Budget and Policy Priorities	WIC research and policy
Peggy Trouba	Nebraska State WIC Director	WIC operations and data systems

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 methodological research about improving low response rates in longitudinal studies (Appendix SS). WIC participants will have the opportunity to receive up to $400 over the course of the study if they participate in all interviews, including: $50 for enrolling in the study, $20 for each telephone follow-up interview (up to 11 events), and an additional $20 if they are sampled to complete a second AMPM (at the 13, 15, 18 and 24 month surveys). They will also be reimbursed $10 each time they use their own cellphone to complete a telephone interview.[3] Further, study participants who drop out of WIC but are willing to have their infant measured and weighed by research staff will receive $20 for each measurement. Participants will receive a reloadable debit card with their enrollment

3 This strategy received OMB approval, and is being used successfully on the FNS Healthy Incentive Pilot (HIP).

package (Appendices F-G). The incentives will be loaded onto the card, as applicable, throughout the study. Finally, while not considered an incentive, women who don't provide telephone contact information at enrollment will be given a cellphone with a limited number of pre-paid minutes in order to communicate with study researchers. The participants may keep the phone after study completion (but will not receive additional minutes).

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.

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 be documented in an informed consent form for the core and supplemental samples (Appendix Y-Z). In addition, all Westat project staff and subcontractors will sign a confidentiality and nondisclosure agreement (Appendix TT). 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.[4] 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 respondent ID numbers. All data will be securely transmitted to Westat via secure fax, FTP site, or phone; and will be stored in

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

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 6/2017). Westat's Institutional Review Board (IRB) serves as the organization's administrative body and all research involving interactions or interventions with human subjects is within its purview. Copies of the IRB approval letters are in Appendix UU.

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 and WIC program representative questionnaires are not considered to be sensitive. Participants can choose to not answer any question, and to not participate in the study. WIC participant survey questions have been cognitively tested with WIC participants and WIC personnel. None of the respondents indicated unwillingness or discomfort with providing a response. Of note, the last question of the Edinburgh Postpartum Depression Scale (administered at the 3-month interview) asks the mother -- *In the past week the thought of harming myself has occurred to me….quite often/sometimes/hardly ever/never.* We will implement a strict protocol to immediately respond to mothers who indicate they have thought about harming themselves. We will stop the interview and provide the mothers with a toll-

free number for a hotline for postpartum depression. For all other mothers, once the interview is complete, we will provide them with the hotline number as a resource.

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**

Table 12.A presents the number of respondents, frequency of response, and annual hour burden for WIC participants, WIC program representatives, and hospital and health care provider data managers. The assumptions used to estimate burden are based on Westat's professional experience and input from Public Health Foundation Enterprise for WIC (PHFE-WIC), and are footnoted in Table A12.1.

- **WIC participants**. The sample size of WIC participants is 7,873 (33 in pretest and 7,840 eligible for screening). Of the **7,840** eligible WIC enrollees, **4,435** will consent and enroll in the study (71% core and 29% supplemental). As presented in Table B2.3, 3,416 (77%) WIC participants will consent and enroll in the study prenatally and 1,019 (23%) will consent and enroll postnatally. Of those in the core group who enroll prenatally (2,580), **2,193** will be sampled

for a prenatal follow-up interview. Approximately 87 percent of those consented and enrolled prenatally will have live births, so the expected cohort is 3,991 (2,972 prenatal live births and 1,019 postnatal enrollees). Participants enrolled postnatally will receive either the 1-month or 3-month as their first interview. The sample size and expected number of respondents for each interview is based on the response rates presented in Table B2.3. Participant burden includes being screened and enrolled, completing up to 11 participant interviews (and possibly one 2nd day 24-HR recall interview), reading associated communications about the study, and having their child measured in their home for length and weight (Lt/Wt) if they have dropped out of WIC.

- **WIC program representatives**. WIC program representatives include State and local WIC administrators, WIC site staff, and WIC data managers. About 180 **WIC State and local administrators** will receive an informational brochure (Appendix FF) and up to 294 will attend an informational webinar (Appendix GG). WIC sites in 42 State Agencies will be identified in the first stage of sampling described in Part B and State administrators in those State Agencies will receive a list of frequently asked questions (FAQs) (Appendix HH). Of those, 80 sites in 27 State Agencies will be sampled into the study and the State administrators will receive an email and voicemail invitation to participate (Appendix II-JJ); those not selected to support the study will receive a thank you letter (Appendix KK). Twenty-seven State and 80 local WIC

administrators will complete a Key Informant Interview (Appendices LL.1-LL.2). Two **WIC staff** in each site (160 in total) will complete recruitment referral forms on potential study participants (Appendix D) and up to 10 staff person per site (800 in total) will be asked to complete the Local Staff Online Survey (Appendix MM). Finally, 27 State **WIC data managers** will complete requests for data from administrative records (Appendix BB).

- **Hospital and provider data managers**. Up to 4,510 data managers will respond to requests for infant length and weight data (Appendices AA, CC).

The estimated annualized cost is $7.25 per hour for WIC participants(national minimum wage); $43.96 per hour for state and local WIC administrators and WIC data managers (job category "Management Occupations" code #11-0000)[5]; and $11.90 per hour for WIC staff and hospital/health 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.

5May 2010 National Occupational Employment and Wage Estimates for the United States, available at www.bls.gov/oes/current/oes_nat.htm

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

Table A12.1 Reporting Estimates of Hour Burden and Annualized Costs to Respondents

Respondent Type	Respondent Description	Type of Survey Instrument	Appendices	Sample size	Number of Respondents	Frequency of Response (annual)	Total Annual Responses	Average Hours per Response	Total Annual Burden	Number of non -	Frequency of Response	Total Annual Responses	Average Hours per response	Total Annual Burden	Total Burden Hours	Hourly wage	Total annualized cost
Individuals and Households.	WIC participants	Pretest (a)	XX	33	33	0.33	10.89	1	10.89	0	0.33	0	0	0	10.89	7.25	$78.95
		Screening/enrollment Interview (b)	A,B, E,Y,Z	7,840	4,435	0.33	1,463.55	0.38	556.15	3405	0.33	1123.65	0.15	168.55	724.70	7.25	$5,254.08
		Prenatal Enrollment package letter	F,TT	2,193	1,864	0.33	615.12	0.08	49.21	329	0.33	108.57	0	0	49.21	7.25	$356.77
		Postnatal Enrollment package letter	G,TT	3,339	2,794	0.33	922.02	0.08	73.76	545	0.33	179.85	0	0	73.76	7.25	$534.76
		Post Birth HIPAA letter & Form	H	2,414	1,979	0.33	653.07	0.05	32.65	435	0.33	143.55	0	0	32.65	7.25	$236.71
		Prenatal interview	I	2,193	1,864	0.33	615.12	0.45	276.80	329	0.33	108.57	0	0	276.80	7.25	$2,006.80
		1-Month interview	J	3,339	2,794	0.33	922.02	0.45	414.91	545	0.33	179.85	0	0	414.91	7.25	$3,008.10
		3-Month interview	K	2,414	1,979	0.33	653.07	0.45	293.88	435	0.33	143.55	0	0	293.88	7.25	$2,130.63
		5-Month interview	L	2,297	1,883	0.33	621.39	0.5	310.70	414	0.33	136.62	0	0	310.70	7.25	$2,252.58
		7-Month interview	M	3,221	2,595	0.33	856.35	0.5	428.18	626	0.33	206.58	0	0	428.18	7.25	$3,104.31
		9-Month interview	N	2,206	1,742	0.33	574.86	0.5	287.43	464	0.33	153.12	0	0	287.43	7.25	$2,083.87
		11-Month interview	O	2,162	1,665	0.33	549.45	0.5	274.73	497	0.33	164.01	0	0	274.73	7.25	$1,991.79
		13-Month interview (c)	P,W	3,002	2,263	0.33	746.79	0.52	388.33	739	0.33	243.87	0	0	388.33	7.25	$2,815.39
		15-Month interview	Q	2,076	1,536	0.33	506.88	0.5	253.44	540	0.33	178.2	0	0	253.44	7.25	$1,837.44
		18-Month interview	R	2,035	1,486	0.33	490.38	0.5	245.19	549	0.33	181.17	0	0	245.19	7.25	$1,777.63
		24-Month interview	S	2,757	1,914	0.33	631.62	0.5	315.81	843	0.33	278.19	0	0	315.81	7.25	$2,289.62
		Baseline module (d)	T	4,435	3,600	0.33	1,188.00	0.05	59.40	835	0.33	275.55	0	0	59.40	7.25	$430.65
		New Caregiver module (d)	U	4,435	3,600	0.33	1,188.00	0.03	35.64	835	0.33	275.55	0	0	35.64	7.25	$258.39
		2nd 24 HR interview (e)	V	1,228	818	0.33	269.94	0.17	45.89	410	0.33	135.3	0	0	45.89	7.25	$332.70
		Note sheet for AMPM (f)	X	3,339	667	3.33	2,221.11	0.01	22.21	2672	3.33	8897.76	0	0	22.21	7.25	$161.02
		Home health Care Agency Form – Length/Weight (g)	DD, EE	80	40	1	40	0.18	7.20	40	1	40	0	0	7.20	7.25	$52.20
		Participant reminder scripts	NN	4435	4,435	0.33	1,463.55	0.02	29.27	0	0.33	0	0	0	29.27	7.25	$212.21
		Thank you letter	OO	4435	4,435	0.33	1,463.55	0.01	14.64	0	0.33	0	0	0	14.64	7.25	$106.11
Individuals and Households				**7,873**	**4,468**		**18666.73**		**4426.31**	**3405**		**13153.51**		**168.55**	**4594.86**	**7.25**	**$33,312.70**

SUBTOTAL																		
State & Local Government	State & Local WIC administrators	Informational Brochure (h)	FF	180	90	0.33	29.7	0.02	0.59	90	0.33	29.7	0	0	0.594	43.96	$26.11
		Webinar (i)	GG	294	235	0.33	77.55	2	155.10	59	0.33	19.47	0	0	155.1	43.96	$6,818.20
		FAQs (j)	HH	42	21	0.33	6.93	0.17	1.18	21	0.33	6.93	0	0	1.18	43.96	$51.87
		Email/VM invitation letter (k)	II,JJ	27	27	0.33	8.91	0.03	0.27	0	0.33	0	0	0	0.27	43.96	$11.87
		Thank You; Not Selected (l)	KK	15	15	0.33	4.95	0.01	0.05	0	0.33	0	0	0	0.05	43.96	$2.20
		State Key informant interview	LL.1	27	27	0.33	8.91	1	8.91	0	0.33	0	0	0	8.91	43.96	$391.68
		Local Site Key informant interview	LL.2	80	80	0.33	26.4	1	26.40	0	0.33	0	0	0	26.4	43.96	$1,160.54
		Subtotal		294	235		163.35		192.50	59		56.1		0	192.50	43.96	$8,462.47
	WIC site staff	Complete referral form (m)	C,D	160	160	0.33	52.8	2.22	117.216	0	0.33	0	0	0	117.22	11.9	$1,394.92
		Local Staff Online Survey	MM	800	600	0.33	198	0.5	99	200	0.33	66	0	0	99.00	11.9	$1,178.10
		Subtotal		800	600		250.8		216.22	200		66		0	216.22	11.9	$2,573.02
	State WIC data manager	Administrative data Request	BB	27	27	1	27	0.33	8.91	0	0.33	0	0	0	8.91	43.96	$391.68
State/Local Government SUBTOTAL				**1,121**	**862**		**441.15**		**417.63**	**259**		**122.1**		**0**	**417.63**		**$11,427.17**
Profit/Nonprofit business	Hospital data manager	Hospital Data Request Form (n)	AA	3,991	3,991	0.33	1317.03	0.03	39.51	0	0.33	0	0	0	39.51	11.9	$470.17
	Provider data manager	Provider Data Request Form (o)	CC	519	519	1	519	0.08	41.52	0	0.33	0	0	0	41.52	11.9	$494.09
Profit/Non-Profit Business SUBTOTAL				**4510**	**4510**		**1836.03**		**81.03**	**0**		**0**		**0**	**81.03**		**$964.26**
TOTAL				**13504**	**9840**		**20943.91**		**4924.97**	**3664**		**13275.61**		**168.55**	**5093.52**		**$45,704.13**

(a) 6 instruments were tested in English or Spanish with no more than 9 participants

(b) Burden = Poster (App A) = .25 min + Flyer (App B) = .5 min + Screening Enrollment Participant Interview (App E) = 17 min + Consent (App Y or Z) = 5 min = *22.75 min (0.38 hour*)

(c) Burden = 13-month interview (App P) = 30 min + 13-month Food Model Booklet letter (App W) = 1 min = *31 minutes* (*.52 hour*)

(d) Baseline module administered to all respondents at prenatal, 1, or 3-month interviews (App I, J, **or** K); New Caregiver module administered if caregiver changes

(e) Sample size: 15% of core sample at 13, 15, 18, and 24 month (8185 per Table B2.3) = *1,228*; Number of respondents = 10% of 7,199 = *818*

(f) Sample size: Same as 1-mo interview; Frequency of response (annual) = 10 interviews/3yr study = *3.33*

(g) Sample size: 2% of 3,991 (cohort of infants) need length/weight by home health care agency = *80;* Frequency of response (annual) = 3 times collect/3yr = *1*

(h) Sample size: 90 State agencies x (1 director + 1 nutrition coordinator) = 180

(i) Sample size: 7 State WIC personnel x 42 State Agencies = *294*; assume 80% will attend

(j) Sample size: 42 States Agencies will be sampled; assume 50% will read

(k) Sample size: 27 State Agencies will be sampled and receive invitation or voicemail message

(l) Sample size: 15 State Agencies will not be selected to support the study

(m) Sample size: 2 WIC staff x 80 sites = *160*; Burden =training = 30 min + introduce study/ complete form (App C,D) = 98 min (49 referrals /staff @ 2 min) + send fax = 5 min (assume 10% will be faxed = 5 forms @ 1 min) = *133 min (2.22 hours)*

(n) Sample size: Cohort of infants (see Table B2.3)

(o) Sample size: 13% of 3,991 (cohort of infants) need length/weight from health care provider = *519*; Frequency of response (annual) = 3 times collect/3yr = *1*

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 $2,028,737. Contractor costs associated with this study total $9,966,221 over 5 years, with an estimated $1,993,244 annual cost to the federal government. This is based on an estimate of 93,142 labor hours, with a salary range of $23.05– $264.83 per hour and includes sampling; instrument development; data collection; analysis; reporting; and overhead costs, including computing, copying, supplies, postage, shipping, 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 $42.66 per hour based on 2,080 hours per year. We anticipate this person will work 832 hours per year for 4 years for a combined total of 3,328 hours. The annual cost for the FNS employee is $35,493. Federal employee pay rates are based on the General Schedule of the Office of Personnel Management (OPM) for 2012 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 new collection of information; estimated to add 5,094 burden hours to the OMB collection inventory.

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. Data Collection and Reporting Schedule

Activity	Schedule
Key informant interviews	1-2 weeks after OMB approval
WIC site staff survey	1-2 weeks after OMB approval
WIC participant data collection	1-2 weeks after OMB approval
Infant #1 Interim report	12 months after OMB approval
Infant #2 Interim report	21 months after OMB approval
Infant #3 Interim report	24 months after OMB approval
Infant #4 Interim report	30 months after OMB approval
Infant Final report	32 months after OMB approval
Toddler #1 Interim report	33 months after OMB approval
Toddler #2 Interim report	35 months after OMB approval
Toddler #3 Interim report	38 months after OMB approval
Toddler #4 Interim report	38 months after OMB approval
Infant & Toddler Final report	39 months after OMB approval

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. A final report will be posted on the FNS web site.

Table A16.2. Objectives, Principal Data Sources, and Reports

Objectives	Data Sources	Reports
1. Update data collected in WIC-IFPS-1	• Participant Survey: Prenatal	Infant Interim 1
	• Participant Survey: Prenatal, 1, 3mos	Infant Interim 2
	• Participant Survey: Prenatal, 1, 3, 5, 7mos	Infant Interim 3
	• Participant Survey: Prenatal, 1, 3, 5, 7, 9, 11mos	Infant Interim 4
	• Participant Survey: Prenatal, 1, 3, 5, 7, 9, 11, 13mos	Final Infant
	• Participant Survey: Prenatal, 1, 3, 5, 7, 9, 11, 13mos	Final Infant/Toddler
2. Compare new findings with other major	• Participant Survey: Prenatal	Infant Interim 1
	• Participant Survey: Prenatal, 1, 3mos	Infant Interim 2
	• Participant Survey: Prenatal, 1, 3, 5, 7mos	Infant Interim 3

Objectives	Data Sources	Reports
studies (WIC IFPS-1, FDA IFPS, and the Gerber/Nestle 2002 and 2008 FITS studies	• Participant Survey: Prenatal, 1, 3, 5, 7, 9, 11mos	Infant Interim 4
	• Participant Survey: Prenatal, 1, 3, 5, 7, 9, 11, 13mos	Final Infant
	• Participant Survey: 15mo	Toddler interim 1
	• Participant Survey: 15, 18mos	Toddler interim 2
	• Participant Survey:15, 18, 24mos	Toddler interim 3
	• Participant Survey: Prenatal, 1, 3, 5, 7, 9, 11, 13, 15, 18, 24mo	Final Infant/Toddler
3. Assess effectiveness of different education and breastfeeding promotion approaches in achieving recommended feeding patterns and behaviors	• Participant Survey: 1, 3mos • WIC Staff survey • State/Local Key Informant	Infant Interim 2
	• Participant Survey: Prenatal, 1, 3, 5, 7mos • WIC Staff survey • State/Local Key Informant	Infant interim 3
	• Participant Survey: Prenatal, 1, 3, 5, 7, 9, 11mos • WIC Staff survey • State/Local Key Informant	Infant Interim 4
	• Participant Survey: Prenatal, 1, 3, 5, 7, 9, 11, 13mos • WIC Staff survey • State/Local Key Informant	Final Infant
	• Participant Survey: 15mo • WIC Staff survey • State/Local Key Informant	Toddler interim 1
	• Participant Survey: 15, 18mos • WIC Staff survey • State/Local Key Informant	Toddler interim 2
	• Participant Survey: 15, 18, 24mos • WIC Staff survey • State/Local Key Informant	Toddler interim 3
	• Participant Survey: Prenatal, 1, 3, 5, 7, 9, 11, 13, 15, 18, 24mos • WIC Staff survey • State/Local Key Informant	Final Infant/Toddler
4. Assess conditions of overfeeding, overconsumption, underfeeding, and inappropriate feeding	• Participant Survey: 1, 3mos	Infant Interim 2
	• Participant Survey: Prenatal, 1, 3, 5, 7mos	Infant interim 3
	• Participant Survey: Prenatal, 1, 3, 5, 7, 9, 11mos	Infant Interim 4
	• Participant Survey: Prenatal, 1, 3, 5, 7, 9, 11, 13mos	Final Infant
	• Participant Survey:15mos	Toddler interim 1
	• Participant Survey:15, 18mos	Toddler interim 2
	• Participant Survey:15, 18, 24mos	Toddler interim 3
	• Participant Survey: Prenatal, 1, 3, 5, 7, 9,11, 13, 15, 18, 24mos	Final Infant/Toddler
5. Identify nutrition education influences	• Participant Survey: Prenatal	Infant interim 1
	• Participant Survey: 1, 3mos • WIC Staff survey • State/Local Key Informant	Infant interim 2

Objectives	Data Sources	Reports
	• Participant Survey: Prenatal, 1, 3, 5, 7mos • WIC Staff survey • State/Local Key Informant	Infant interim 3
	• Participant Survey: Prenatal, 1, 3, 5, 7, 9, 11mos • WIC Staff survey • State/Local Key Informant	Infant interim 4
	• Participant Survey: Prenatal, 1, 3, 5, 7, 9, 11, 13mos • WIC Staff survey • State/Local Key Informant	Final Infant
	• Participant Survey: 15mo • WIC Staff survey • State/Local Key Informant	Toddler interim 1
	• Participant Survey: 15, 18mos • WIC Staff survey • State/Local Key Informant	Toddler interim 2
	• Participant Survey: 15, 18, 24mos • WIC Staff survey • State/Local Key Informant	Toddler interim 3
	• Participant Survey: Prenatal, 1, 3, 5, 7, 9, 11, 13mos • WIC Staff survey • State/Local Key Informant	Final Infant/Toddler
6. Assess impact of WIC food packages on outcomes	• Participant Survey: 1, 3mos • WIC Staff survey • State/Local Key Informant	Infant interim 2
	• Participant Survey: Prenatal, 1, 3, 5, 7mos • WIC Staff survey • State/Local Key Informant	Infant interim 3
	• Participant Survey: Prenatal, 1, 3, 5, 7, 9, 11, 13mos • WIC Staff survey • State/Local Key Informant	Infant interim 4
	• Participant Survey: Prenatal, 1, 3, 5, 7, 9, 11, 13mos • WIC Staff survey • State/Local Key Informant	Final Infant
	• Participant Survey: 15 mos. • WIC Staff survey • State/Local Key Informant	Toddler interim 1
	• Participant Survey: 15, 18mos • WIC Staff survey • State/Local Key Informant	Toddler interim 2
	• Participant Survey: 15, 18, 24mos • WIC Staff survey • State/Local Key Informant	Toddler interim 3
	• Participant Survey: Prenatal, 1, 3, 5, 7, 9, 11, 13mos • WIC Staff survey • State/Local Key Informant	Final Infant & Toddler
7. Determine changes in	• Participant Survey: 1, 3mos	Infant Interim 2
	• Participant Survey: Prenatal, 1, 3, 5, 7mos	Infant interim 3

Objectives	Data Sources	Reports
maternal feeding practices and behaviors over time as infants and toddlers transition into or out of WIC	• Participant Survey: Prenatal, 1, 3, 5, 7, 9, 11, 13mos	Infant Interim 4
	• Participant Survey: Prenatal, 1, 3, 5, 7, 9, 11, 13mos	Final Infant
	• Participant Survey: 15mos	Toddler interim 1
	• Participant Survey: 15, 18mos	Toddler interim 2
	• Participant Survey: 15, 18, 24mos	Toddler interim 3
	• Participant Survey: Prenatal, 1, 3, 5, 7, 9,11, 13, 15, 18, 24mos	Final Infant/Toddler

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 approval 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.