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Supporting Justification for OMB Clearance for the WIC Nutrition Education Study

Part A

OMB Supporting Statement

October 16, 2014

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PART A. JUSTIFICATION

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. Attach a copy of the appropriate section of each statute and regulation mandating or authorizing the collection of information.

Background. The Healthy, Hunger-Free Kids Act of 2010 (Public Law 111-296, Sec. 305) mandates programs under its authorization to cooperate with U.S. Department of Agriculture (USDA) program research and evaluation activities. The mandate applies to Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) agencies. The Food and Nutrition Service (FNS), USDA, is requesting approval from the Office of Management and Budget (OMB) to conduct the WIC Nutrition Education Study. This is a new information collection request. Assisting in the project will be FNS's contractor, RTI International and its team members Altarum Institute and researchers from the Atkins Center for Weight and Health, University of California at Berkeley. The data collection will be conducted in calendar years 2014 to 2016.

Through Federal grants to States, WIC provides supplemental foods, health care referrals, and nutrition education to low-income pregnant, breastfeeding, and nonbreastfeeding postpartum women and to infants and children who are found to be at nutritional risk. WIC's mission is to safeguard the health of low-income women, infants, and children up to age 5 who are at nutritional risk by providing nutritious foods to supplement diets, information on healthy eating, and referrals to health care. By Federal directive, all WIC participants have the opportunity to participate in nutrition education at least two times during a 6-month period of eligibility or quarterly for a 12-month period.

Purpose and Need. In 2010, FNS commissioned the Institute of Medicine (IOM) to convene a workshop on "Planning a WIC Research Agenda," which consisted of a session that reviewed past research on WIC nutrition education; analyzed the strengths, weaknesses, and gaps in the past research; and made recommendations for future research (IOM, 2011). This review revealed that past evaluations of WIC nutrition education were limited to demonstration projects and studies that compared augmented WIC services or "best practices" to usual practice rather than assessing the impact of usual practice in WIC sites. Few studies have examined new technologies for delivering education, and no studies have critically compared the impact of one-on-one counseling with group education, which are the primary modes of delivery of education in most WIC clinics.

FNS is conducting the WIC Nutrition Education Study to provide a nationally representative description of how nutrition education is currently being provided to WIC recipients across the country. It will also conduct a pilot study to inform the design of a possible national evaluation of nutrition education on WIC participants' nutrition and physical activity behaviors. This study will provide FNS with a better understanding of nutrition education practices and methods used by WIC and of the effectiveness of current WIC nutrition education services. The study will document how nutrition education is being provided subsequent to several program changes,

including the 2009 food package changes, the implementation of the initiative to Revitalize Quality Nutrition Services, and the use of new technology. Understanding optimal educational topics and methods, how to maximize participant engagement, the best approaches for delivery and reinforcement of messages, and how to effectively prepare and support WIC nutrition educators is key to informing WIC nutrition education improvements.

2. Purpose and Use of the Information

Indicate how, by whom, 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.

Study Overview. The objectives of the study are to (1) provide a comprehensive nationally representative description of WIC nutrition education (Phase I) and (2) conduct a pilot study in six WIC sites to demonstrate and refine an evaluation of the impact of WIC nutrition education on participants' nutrition and physical activity behaviors (Phase II). Based on the findings from Phases I and II, FNS plans to design and conduct a nationally representative evaluation of the impact of WIC nutrition education.

In Phase I, we will conduct a nationally representative Web-based survey of local agencies (referred to as the Local Agency Survey) and WIC sites (referred to as the Site Survey) and in-depth telephone interviews with staff at a subset of WIC sites (referred to as Site Interviews). The Phase I data collection will provide a description of the current state of practice for WIC nutrition education. Additionally, the Phase I findings will help inform the site

selection for the Phase II pilot so that the six sites are inclusive of a variety of nutrition education modes and dosage levels delivered in different settings. In Phase II, we will conduct a pilot study with six WIC sites. There are two main purposes of the pilot study: (1) pilot an evaluation of the impact of WIC nutrition education on participants' nutrition and physical activity behaviors in six WIC sites (to test research questions) and (2) refine an evaluation of the impact of WIC nutrition education on participants' nutrition and physical activity behaviors in six WIC sites (to test methodology). The pilot study will not provide nationally representative information on the impact of WIC nutrition education; instead, FNS will use the pilot study to test the methodology to inform the development of a possible nationally representative evaluation of the impact of WIC nutrition education on participants' nutrition and physical activity behaviors.

The Phase II pilot study will include both a process and impact evaluation. The Phase II process evaluation focuses on describing the context for and implementation of nutrition education. Using semistructured interviews of site administrators, observations of nutrition education delivery, a Webbased survey of nutrition educators, and participant focus groups, we will collect information from local agency and site staff and WIC participants and will request administrative data from participating sites. The basic design for the Phase II impact evaluation is a longitudinal dose-response comparison, in which we will collect data from WIC participants at three time points (baseline, interim, final) over a 12-month period (referred to as the

Participant Surveys) and examine changes in the outcome of interest in relation to exposure to WIC nutrition education over time.

To inform the development of a possible nationally representative evaluation study, FNS will use the pilot study to test the operational data collection procedures for the Participant Survey; assess burden on WIC sites; assess respondent burden; evaluate participants' understanding of the instruments; determine whether the information collected from participants and sites can be used to develop an operational measure of dosage that is feasible for use in a national study to model the effects of dosage on behavior change; and provide empirical data on effect sizes and degree of intraclass correlation coefficient (ICC) that can be used to calculate statistical precision and power requirements for a national study.

Table A1.1 summarizes the data collection activities for the WIC Nutrition Education Study; each data collection component is briefly described in the following subsections.

Data Collection Activity	Number and Type of Respondents	Purpose	Data Collection Mode (Frequency)
Phase I National Surveys and Site Interviews			
Abstraction of State Plans ^a	Not applicable	Provide information on State agency policies for nutrition education staff, training, and methods	Not applicable
Request information for drawing sample	50 State agency directors and 50 local agency WIC directors/program managers	Request lists of WIC sites for constructing sampling frame	Email
Local Agency Survey	800 local agency WIC directors/ program managers	Collect information on policies, practices, staff qualifications and other features affecting NE across all sites	Self-administered, Web-based (1)

Table A1.1. Summary of Data Collection Activities for the WIC Nutrition Education Study

(continued)

Data Collection Activity	Number and Type of Respondents	Purpose	Data Collection Mode (Frequency)
Phase I National Surveys and Site Interviews (continued)			
Site Survey	1,600 local WIC site supervisors/ nutritionists	Collect information on logistics and features of NE service delivery, staff characteristics, modes of education, and site's facilities and resources (specific to each selected site)	Self-administered, Web-based (1)
Site interviews	80 local WIC site supervisors/ nutritionists (subset of respondents to Site Survey)	Collect additional descriptive information on site's NE practices	Telephone interview (1)
Phase II Pilot Study (WIC Pa	articipants from the Six Pi	lot Sites ^b)	
In-person recruitment for Participant Surveys	900 WIC participants	Determine study eligibility and recruit eligible participants	Interviewer administered using electronic screener, in-person (1)
Baseline Participant Survey	800 WIC participants	Collect information on nutrition and physical activity behaviors and receipt of NE	Self-administered, in-person (1)
Interim Participant Survey	640 WIC participants	Collect information on nutrition and physical activity behaviors and receipt of NE	Self-administered, mail with computer- assisted telephone interviews (CATI) for nonrespondents (1)
Final Participant Survey	600 WIC participants	Collect information on nutrition and physical activity behaviors and receipt of NE	Self-administered, mail with CATI interviews for nonrespondents (1)
Participant focus groups	96 WIC participants (subset of respondents to Baseline and Interim Participant Surveys)	Provide qualitative contextual information as well as implementa-tion information to complement the findings from the Participant Surveys	Group discussion (1)

Table A1.1. Summary of Data Collection Activities for the WIC Nutrition Education Study (continued)

(continued)

Data Collection Activity	Number and Type of Respondents	Purpose	Data Collection Mode (Frequency)
Phase II Pilot Study (State/Local WIC Staff for the Six Pilot Sites)			
Nutrition Educator Survey	30 WIC nutritionists/ nutrition assistants	Collect information on NE implementation	Self-administered, Web-based (1)
Baseline staff interviews	6 local WIC site supervisors	Update information provided in Phase I	In-person interview (1)
Interim and final staff interviews	6 local WIC site supervisors	Update information provided in Phase I and prior interviews	Telephone interviews (2)
WIC administrative data request	12 WIC site clerical staff	Collect information on subset of WIC participants' NE dosage	Request made via email and provided electronically to contractor (1)
Observations of nutrition education delivery	Not applicable, no burden	Collect information on delivery of NE	Observation (1)

Table A1.1. Summary of Data Collection Activities for the WIC Nutrition Education Study (continued)

NE = nutrition education

^a The State Plans are available electronically; however, we expect that we will need to contact some State agencies to obtain missing information. These contacts will be made in conjunction with the contacts made to State agency directors to request information for constructing the sampling frame.

^b WIC participants include pregnant women receiving WIC benefits, postpartum women receiving WIC benefits, and mothers or caregivers of child up to age four receiving WIC benefits.

Abstraction of State Plans and Information Request for Drawing

Sample. A limited number of email contacts will be made to State and local agencies to collect information missing from the State Plans and data needed to construct the sampling frame (Appendix A). (Note that State Plans are submitted to FNS as approved under OMB Control Number 0584-0043, expiration date 12/31/2015.)

Phase I Local Agency and Site Surveys. Following the Sampling Plan described in Part B.1, the research team will conduct a nationally representative Web-based survey of local agencies (Appendix B)¹ and WIC sites (Appendix C). The Site Survey includes two versions; approximately half of the respondents will be randomly assigned to complete Version 1, and the

¹ It is not necessary to provide a Spanish translation of the Local Agency Survey because all local agency directors speak English; however, a Spanish translation of the Site Survey will be needed.

remaining half will complete Version 2. For each selected local agency, one to three WIC sites (depending on the local agency's caseload) will be randomly selected to complete the Site Survey. The two surveys are expected to yield 800 responding local agencies and 1,600 responding WIC sites. Survey procedures include sending a prenotice letter and brochure to the WIC regional offices and State agencies (Appendices D through F), an email to the affected State agencies to request information needed for administration of the Local Agency and Site Surveys (i.e., contact information for local agencies and names of selected sites), along with a Frequently Asked Questions (FAQ) document (Appendices G and H), and emails/letters to the selected local agencies and sites requesting participation in the study (Appendices I and J). Nonrespondents will be contacted by email and phone to encourage response (Appendices K through N).

Phase I Site Interviews. A subset of responding WIC sites (n = 80) will participate in in-depth telephone interviews (Appendix O) to obtain additional descriptive information on nutrition education delivery. Respondents will be recruited by email and phone (Appendices P through R).

Phase II Recruitment of Six Sites for Pilot Study. To recruit six sites to participate in the Phase II study, the research team will follow the approach described in Part B.1 to select and contact affected State agencies, local agencies, and sites (Appendices S through W). The selection of the pilot sites will be designed to capitalize on the variability of WIC nutrition education to enable using a dose-response design and will be diverse in terms of geographic location and size.

Phase II Recruitment of WIC Participants. The research team will work closely with each of the six pilot sites to determine the best approach to implement recruitment and baseline data collection for the Participant Surveys while minimizing burden on the site. To recruit participants for the evaluation study, participating sites/clinics will be encouraged to post flyers about the study (Appendices X and Y), and staff members from the site will be asked to pass out a sheet describing the study (Appendix Z) beginning 3 months before the start of data collection. Two field representatives from the research team will be stationed in the clinic waiting room to screen WIC interviewer-administered recipients using an electronic screener (administered on laptop computer or tablet) (Appendix AA) and, if eligible, enroll them into the study including obtaining informed consent and the participant's contact information (Appendix BB). To be eligible for participation, individuals must speak English or Spanish, be 18 or older, and be a pregnant or postpartum woman receiving WIC benefits or the parent/caregiver for a child up to age 4 who receives WIC benefits.

Phase II Participant Surveys. There are three versions of the survey tailored to each subpopulation of interest: (1) caregivers of eligible child, (2) pregnant women, and (3) postpartum women. The research team will survey WIC participants at three time points during the 12-month study period (baseline, interim, and final) (Appendices CC through KK). A self-administered paper and pencil questionnaire (referred to as PAPI for paper-and-pencil-interviewing) will be used at baseline and completed in two parts. Section 1 will be completed before the participant's WIC appointment to

collect information on the study's primary outcomes before exposure to nutrition education, and Section 2 will be completed after their appointment. Participants will be allowed to take the survey with them and return it by mail or to the clinic if they are unable to stay at the clinic to complete the survey. For the interim and final surveys, a paper questionnaire will be mailed, and nonrespondents will be contacted and asked to complete the survey over the phone using computer-assisted telephone interviewing (CATI) (Appendices LL through QQ). Nonrespondent follow-up procedures include reminder postcards, emails, and a second mailing of the questionnaire for the interim and final surveys (Appendices RR through III).

Phase II Participant Focus Groups. The research team will conduct focus groups with a subset of the respondents to the Participant Surveys to provide a more in-depth understanding of their perception of WIC nutrition education (Appendix JJJ). The purpose of the focus groups in Phase II is to provide qualitative contextual information as well as implementation information to complement the findings from the Participant Surveys and to aid in our interpretation of the Phase II findings. Furthermore, focus group data will help us to ensure that the instruments for the Participant Surveys are actually capturing what is important for this study and to help refine the instruments for a national study. Another purpose of conducting focus groups in Phase II is to refine initial pilot-tested hypotheses for use in a future nationally representative impact evaluation. Moreover, some of the study research questions would be difficult to address via the Participant Surveys.

We will conduct two focus groups for each of the six sites near the end of the 12-month study period with participants who completed the baseline and interim surveys. In sites that have 25 percent or greater Spanish-speaking participants enrolled in the study, we will conduct one of the groups in Spanish and one in English; otherwise, both groups will be in English. We will recruit participants using two approaches: (1) mailing participants enrolled in the study a flyer and asking them to call if they want to take part in the focus groups and (2) contacting study participants by phone (Appendices KKK through MMM). Telephone reminders will be made to recruited participants (Appendix NNN). Participants will provide written consent for study participation (Appendix OOO).

Phase II Nutrition Educator Survey. At the beginning of the pilot study, the research team will conduct a Web-based survey (paper version available for staff without Internet access) of staff members who provide nutrition education (Appendix PPP). Research team staff will give nutrition educators an information sheet describing the survey and request their participation and contact nonrespondents by email and phone (Appendices QQQ through SSS).

Phase II Staff Interviews. At each pilot site, the research team will conduct an in-person interview (Appendix TTT) with the site supervisor (or his or her designee) during the baseline site visit. The purpose of the baseline interview is to obtain updates, if necessary, for some of the information provided in the Phase I Local Agency and Site Surveys and to obtain additional background information about the site and how nutrition

education is provided for the process evaluation. Because changes in agency policies and practices may occur between the Phase I and II data collection (about 8 to 12 months), it is important that the site visits be conducted as part of Phase II. As described below, observations of nutrition education will take place during the baseline site visits as well. To obtain updates on the delivery of nutrition education during the 12-month pilot period, the research team will conduct interim and final interviews by telephone (Appendix UUU). Participants will be contacted by phone and email to schedule the interviews (Appendices VVV and WWW).

Phase II WIC Administrative Data Request. To provide information on dosage of nutrition education received, each site will be contacted by email and asked to provide administrative data for a subset of WIC recipients participating in the evaluation study (Appendix XXX). The purpose of this data request is to assess the feasibility for sites to provide administrative data in a national study and to use the data to validate frequency of WIC visits as reported by participants in the Participant Surveys. The request will be made at the end of the 12-month study period. WIC participants will provide informed consent for release of this information (Appendix BB).

Phase II Observations of Nutrition Education Delivery. The research team will observe the delivery of nutrition education to collect objective data that will be used to rate or compare the nutrition education provided by the six pilot sites and to validate information about the availability of facilities, materials, and resources collected in the Phase I surveys (Appendix YYY). The observations will take place during the baseline

site visit and will take about 16 hours over a 2- to 3-day period. There will be no burden on WIC staff for this study component.

Purpose of the Information. The information collected in this study will be a valuable asset to policymakers; WIC program staff at the Federal, regional, State, local, and site levels; nutrition educators; and the nutrition research community. Policymakers and WIC program staff will use the findings to design and shape WIC nutrition education to ensure participants' health and nutrition needs are being met. Nutrition educators will use the information to shape their interactions with this population, and WIC nutrition researchers will have an important data source to analyze and further contribute to the knowledge base regarding this high-risk, vulnerable population.

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. Insert any applicable electronic Web address.

The last column of Table A1.1 (starting on page 3) provides the mode of data collection for each component of the study. As shown, when feasible, improved technology has been incorporated into data collection to reduce respondent burden and to improve data quality, efficiency, and responsiveness. The Web-based surveys for Phases I and II will involve WIC staff time, but by using a Web-based survey the burden compared with a paper-based survey is reduced and data quality is improved. With Web-

based surveys, skip patterns are automated so respondents can complete the survey more quickly and easily, and the quality of the data and efficiency of data collection are improved. Also, with Web-based surveys submission is automatic, while a paper-based survey requires respondent time to submit the survey by mail. Moreover, automated data collection will minimize processing time at the end of the field period. Electronic mail will be used to recruit and conduct follow-up activities with State and local agencies and sites whenever possible. Based on previous experience, we expect that no more than 10 percent of local agencies and 15 percent of sites will lack Internet access, so most agencies and sites will be able to respond via the Web. For Phase I, an estimated 87 percent of the responses (2,080 responses out of 2,400) will be collected electronically, and for Phase II, an estimated 83 percent of the responses for the survey of nutrition educators will be collected electronically (25 responses out of 30).

For the Phase II Participant Surveys, the research team will use an electronic screener to screen and enroll participants into the study, which will help expedite the screening process, thus minimizing respondent burden. The use of the Internet to administer the surveys was considered but not used because many WIC recipients may not readily have Internet access. Participants who do not return the paper-based interim and final surveys will be contacted by telephone and asked to answer the survey using CATI technology. Use of CATI will make possible accurate skip patterns, response code validity checks, and consistent checking and editing, all of which will improve the pace and flow of survey administration and thus reduce

respondent burden and improve data quality and the efficiency of data collection. An estimated 15 percent of the responses will be collected electronically (310 responses out of 2,040). The Phase II WIC administrative data request will be made by email with data provided to the contractor electronically through a secure file transfer protocol (FTP) site exchange.

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 examined the effectiveness of WIC nutrition education was conducted in the late 1990s (USDA, 1998); however, that study was not designed to provide a nationally representative description of WIC nutrition education delivery, and limitations in defining the intensity of nutrition education due to its great variability within clinics prevented comparisons of outcomes by dosage of education received. We plan to obtain information on state nutrition education policies by abstracting this information from State Plans instead of requesting this information in the Local Agency Survey, thus avoiding duplication and reducing burden.

5. Impacts Small Businesses or Other Small Entities

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

No small businesses or other small entities will be involved in this information collection.

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.

Without this effort, FNS will not have current information on the delivery of WIC nutrition education and its impact on WIC recipients' nutrition and physical activity behaviors. This information is essential for policymakers and WIC program staff making decisions about WIC nutrition education. The most relevant past research that examined the effectiveness of WIC nutrition education was conducted in the late 1990s (USDA, 1998); however, that study was not designed to provide a nationally representative description of WIC nutrition education delivery and had several limitations. Thus, without this effort, updated information on nutrition education strategies that are effective would not be available to FNS.

The Phase I data collection takes place one time only; however, for the Phase II pilot study, there are three data collection time points for the Participant Surveys, which are needed to evaluate the impact of WIC nutrition education on participants' behaviors, as described below. The interim survey will be administered approximately 6 months after baseline (after participants have received two of four nutrition education sessions) to capture early impacts on intermediate outcomes (i.e., readiness to change behavior).² The final survey will be administered approximately 12 months after baseline (after participants have received two received four nutrition education sessions) and to allow examination of the impact of WIC nutrition education

 $^{^{\}rm 2}$ For women who are pregnant at baseline, the interim survey will be administered approximately 1 month prior to delivery and the final survey approximately 6 months postpartum.

on distal outcomes (i.e., consumption of fruits and vegetables) and to control for seasonal factors that may impact diet such as price and food availability. Measuring outcomes at both an interim and final time period will inform the design of a national study to determine whether the shorter time frame (at 6 months) is sufficient to capture an impact of WIC nutrition education on intended outcomes. Additionally, as part of the Phase II pilot study, we are surveying each site supervisor at three time points (baseline, interim, final) to capture any changes in nutrition education delivery over the 12-month study period.

7. Special Circumstance Relating to the Guideline 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;

For the Participant Surveys, we ask that respondents complete the survey within 1 week. In our experience, such a quick turnaround encourages respondents to complete the survey when received instead of procrastinating, which may lead to nonresponse. Our follow-up procedures include a postcard, an email, a second mailing of the survey, and phone follow-ups if a response is not received.

- 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 3 years;

- in connection with a statistical survey, 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 other special circumstances.

8. Comments in Response to the *Federal Register* Notice and Efforts to Consult Outside the Agency

If applicable, provide a copy and identify the date and page number of publication in the Federal Register of the agency's notice, required by 5 CFR 1320.8(d), soliciting comments on the information collection prior to submission to OMB. It is no longer necessary to summarize public comments received in response to that notice. Submit original comments and FNS letter to the respondents which describe actions taken by the agency in response to these comments. Specifically address comments received on cost and hour burden.

Describe efforts to consult outside the agency to obtain their views on the availability of data, frequency of collection, the clarity of instructions and recordkeeping, disclosure, or reporting format (if any), and on the data elements to be recorded, disclosed, or reported.

Consultation with representatives of those from whom information is to be obtained or those who must compile records should occur at least once every 3 years even if the collection of information activity is the same as in prior periods. There may be circumstances that may preclude consultation in a specific situation. These circumstances should be explained.

In accordance with the 5 CFR 1320.8(d), FNS published a notice on 01/17/2014 in the Federal Register Volume 79, Number 12, pages 3164–3267, and provided a 60-day period for public comment. Of the 9 comments we received in response to Federal Register Notice Doc. 2014–00827, one was not directly relevant to the study, three were supportive of the study and did not recommend any changes, and five posed specific questions and/or recommended specific changes. The three supportive letters that did not recommend any specific changes came from Ms. Jacqueline Marlette-Boras and Rev. Douglas Greenaway of the National WIC Association, Ms. Smith from Daviess County Health Department, and Ms. McElwain. Appendix ZZZ provides copies of the Federal Register Notice comments and Appendix AAAA provides copies of the response to the comments.

The 60 Day Federal Register Notice comment from Sherrie Rosenblatt from the Can Manufacturers Institute inquired about the study's examination of consumption of canned foods among WIC participants. We clarified in response to this comment how we would be examining the consumption of canned foods in the study. The 60 Day Federal Register Notice comment from Ms. Crowley was a recommendation to use the Academy of Nutrition and Dietetics' new online nutrition education evaluation tool entitled, "GENIE" to determine the effectiveness of WIC nutrition education. We responded by informing the commenter that we would examine the tool and consider its applicability to our study.

The comment from Sue Woodberry from the Oregon Health Authority questioned the six-site sample, asked about recruitment and operations of

focus groups, asked about and expressed concerns about attrition and follow up, asked how we would measure exposure to nutrition education and participant health behaviors and outcomes, suggested that the study should be more focused on a particular topic, recommended that we pretest survey questions, suggested that we include both individual and group nutrition education approaches in the study, suggested that we consider additional delivery methods for evaluation including on-line nutrition education, suggested that we assure that the "nationally representative" sample includes analysis of different challenges and methodology for providing WIC nutrition education to participants of varying literacy levels and different spoken/written languages, recommended that there be an option for State Agency surveys to be directed to the State Nutrition Coordinator and/or the State Nutrition Education Coordinator instead of the State Director, asked for clarification regarding how "optimal" education topics and methods will be defined and determined, asked for clarification regarding what is meant by the "context for and implementation of nutrition education," asked why the six agencies to be selected in Phase II are called "pilot" agencies since they are not actually piloting an intervention, asked about the rationale for making WIC site supervisors in Phase II complete three interviews over the 12 month study period, questioned the burden estimate for the WIC administrative data request, and asked about the Phase II participant screening interview. We address each of these comments individually in a response back to Sue. In our response, we clarify information about the

study that addresses Sue's questions and concerns and we provide rationale for decisions we made that are being questioned by Sue.

Judy Hause, the Massachusetts WIC Program Director, also provided comments on this study. In her comments, Judy also expressed concern regarding Phase II of the study involving only 6 WIC sites. In our response to her, we clarified the rationale for including 6 sites in Phase II. Judy also recommended we consider a wide range of variables that may affect learning and behavior change. We noted in our response to her which of the variables she suggested we examine we were planning to examine in this study. She also asked if we had considered limiting the study to a particular participant subcategory (e.g. pregnant women) or mode of nutrition education (e.g. individual/group/online) if the local agency sample size for Phase II was due to budgetary constraints. We informed her that we considered limiting the study to a particular participant subcategory (e.g. of pregnant mode nutrition education women) or (e.g. individual/group/online), but decided against it because it would not necessarily result in cost savings as the length of time it would take to collect the data would increase. Also, given our purpose in Phase II was to test methodology that could be used nationally to evaluate impacts of nutrition education, we felt it was more important to include all participants and a mixture of sites in terms of size, location, and service delivery in the Phase II pilot. She also mentioned that since several interviews and surveys are planned, a 60 - 90 day advance notice would allow appropriate staff scheduling. We responded that the study team plans to follow this guidance

to the extent possible. Lastly, Judy mentioned that offering an incentive would improve participation. FNS clarified that for Phase II, which involves WIC participants, incentives are planned.

The final commenters on the 60 Day Federal Notice were Ms. Jeanne Blankenship and Mr. Pepin Tuma of The Academy of Nutrition and Dietetics. We responded to the specific issues raised by the Academy in a letter back to them. The Academy expressed interest in the actual content of specific nutrition education interventions and the interventions' objectives. In our response, we clarified this information as it applies to our study for the commenters. The Academy also suggested the study consider which specific features were best for fostering behavior change. We clarified that was not the focus of this study. Regarding **Phase I**, the Academy makes various recommendations in the areas of service delivery, cultural competence and participant demographics, dosage and duration of interventions, impact of facilities and resources, staff characteristics and gualifications, and modes of nutrition education. We clarified in our response to them how the WIC Nutrition Education Study plans to address these topics and the rationale for not including all suggestions for this study, such as evaluating the effectiveness of customized nutrition education programs for toddlers in inculcating healthy behaviors. In response to the Academy's comment that nutrition educators should have sufficient cultural competence to be effective, FNS agreed to adapt the Phase I local agency survey to gather data on foreign language training. Regarding **Phase II**, the Academy made various excellent recommendations for which we fully agree with and clarify

in our response back to them how we have considered them in planning this study. The Academy's concerns included that a good evaluation design must include clearly specified objectives to measure, that data collection instruments be valid and reliable, and that the evaluation methodology fully consider the multiple contributors to participant outcomes, including the content of nutrition education, the mode in which it was delivered, the qualifications, time, and resources of staff providing nutrition education, and other factors.

The information collection request has been reviewed by David Hancock, phone number: 202-690-2388, email: David.Hancock@nass.usda.gov] of the National Agricultural Statistics Service (NASS) of USDA with special reference to the statistical procedures (Appendix BBBB).

FNS assembled a five-member Advisory Panel (see Table A8.1) to provide guidance on critical issues related to the successful conduct of the WIC Nutrition Education Study. The panel met in person in January 2013 and subsequently provided written feedback on the study design and instruments in January-February 2013. Additionally, the panelists were contacted in July 2013 via email to provide additional feedback on the study design, in particular, the procedures for conducting the baseline survey of participants in Phase II and feedback on the instruments regarding question wording and content. Based on feedback provided by the panelists, we refined the study design and revised the instruments as suggested before conducting pretests of the instruments with individuals from the target audience.

Name	Affiliation	Area of Expertise
Tom Baranowski, PhD	Baylor College of Medicine	Child health and development; research design
Maureen Black, PhD	University of Maryland	Child health and development
Isobel Contento, PhD	Columbia University	Evaluation of nutrition education
Jacqueline Marlette- Boras, RD, LDN, MHS	Maryland State WIC Director	WIC operations
Margaret Saunders, MS, RD	WIC Director of Cook County	WIC operations

Table A8.1. Consultants from Outside the Agency

9. Explanation of Any Payments or Gifts to Respondents

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

Permission is requested to offer a financial token of appreciation (i.e., gift card) to promote cooperation and full participation in the longitudinal Phase II Participant Surveys and participant focus groups. Study participants will have the opportunity to receive up to \$50 in gift cards over the course of the study if they complete all three surveys: \$20 for the baseline survey, \$15 for the interim survey, and \$15 for the final survey. The subset of participants who take part in the focus group discussions will receive a \$50 gift card. We consider these amounts appropriate to offset costs for participation in the study (e.g., child care, transportation) and to reduce nonresponse bias. If we are to reduce nonresponse bias, it is important for incentives to be adequate. The next few paragraphs provide justification for the use of incentives and for offering a larger incentive at baseline/enrollment as proposed for the WIC Nutrition Education Study.

To begin, the larger incentives at baseline are important because they will help <u>offset potential transportation or child care costs</u> that may be associated with participating in the study. Participants may incur greater

transportation or child care costs if they decide to participate in the baseline survey at a WIC agency and therefore need to make alternate transportation arrangements or extend child care arrangements due to the extra time that day they are taking to complete the baseline survey.

In addition, offering incentives for all three surveys (baseline, interim, final) will help reduce nonresponse bias for a hard-to-reach population. WIC participants are considered hard-to-reach populations because their lowincome status means they are more likely to not have stable contact information (phone numbers and addresses). It is also uncommon and challenging to retain participants in longitudinal designs such as ours without the use of incentives. Many federally sponsored longitudinal surveys offer incentives to gain initial cooperation and minimize attrition, thus helping to reduce nonresponse bias. Examples of federally sponsored research offering incentives of \$10 to \$50 to minimize the potential for nonresponse bias and offset other participation costs include the National Survey of Child and Adolescent Well-Being (NSCAW, Administration for Children and Families), Childhood Longitudinal Study-Birth Cohort (ECLS-B, U.S. the Early Department of Education), and the National Longitudinal Survey of Youth 1997 (NLSY97, Bureau of Labor Statistics).

In support of a \$20 incentive at baseline, the U.S. Census Bureau funded studies investigating the use of varying incentive amounts (\$10, \$20, and \$40 incentive amounts compared to \$0 control group) for several of its longitudinal panel surveys, including the Survey of Income and Program Participation (SIPP) and the Survey of Program Dynamics (SPD). Overall, the

results suggest that \$20 incentives increase response rates. Incentive experiments have found that a \$20 prepaid incentive significantly lowered nonresponse rates in subsequent Waves and lowered cumulative household nonresponse, compared with both \$10 prepaid and \$0 conditions, even though no further incentive payments were made (James, 1997; Mack et al., 1998).

Furthermore, the literature supports the use of incentives to reduce nonresponse bias in self-administered surveys. Self-administered modes of data collection such as those proposed for the interim and final surveys for the WIC Nutrition Education Study have historically achieved lower response rates than classic interviewer-administered modes. The use of incentives is one of the common remedies used to counteract low response rates in selfadministered surveys (Armstrong, 1975; Church, 1993; Fox, Crask, and Kim, 1988; Dillman, 2007; Heberlein and Baumgartner, 1978; Levine and Gordon, 1958; Linsky, 1975; Yu and Cooper, 1983). Thus, we propose to offer \$15 for completing the interim survey and \$15 for completing the final survey.

An additional benefit of using incentives is the potential to decrease nonresponse bias by including people in the sample with low topic interest (e.g., Baumgartner and Rathbun, 1997; Groves, Singer, and Corning, 2000). For longitudinal studies with multiple data collection points, such as our design for the Phase II WIC Nutrition Education Study pilot, panel participation and maintenance are important concerns. To boost enrollment and improve participation over time, panels and longitudinal studies employ incentives. Poynter and Comley (2003) examined motivators for joining a

panel and found that incentives were viewed as the motive having the most impact (59%).

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, and 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.³ Assurances of data privacy and security will be documented in informed consent forms (Appendix BB for the Participant Surveys and request for use of WIC administrative data and Appendix OOO for the participant focus groups). Passive, rather than active consent, is being used for the data collection with WIC staff at State and local agencies and sites. All project staff and subcontractors will sign a privacy and nondisclosure agreement (Appendix CCCC) that conforms with requirements specified by the Privacy Act of 1974 (5 USC §552a) and the FNS-8 USDA/FNS Studies and Reports. 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 respondents' unique ID numbers. All data will be securely transmitted to the contractor via secure FTP site (electronic data) or Federal Express (hard copy data) and will be stored in locked file cabinets or password-protected computers and accessible only to

³ Published in the *Federal Register* on April 25, 1991 (56 FR 19078)

project staff who have signed the privacy and nondisclosure agreement in Appendix CCCC. Names and contact information will be destroyed within 12 months after the end of the collection and processing period (approximately 9/2017).

Approval for this research study was obtained from RTI's Committee for the Protection of Human Subjects, which serves as the organization's Institutional Review Board (IRB) (see Appendix DDDD). After selection of the pilot sites for Phase II, we will work with the sites' State and local IRBs, as necessary, to obtain the required approvals before study enrollment and data collection.

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, guestions on the Phase I and Phase II data collection instruments are not considered to be sensitive. The Phase I Site Survey and the Phase II Participant Surveys collect information on race/ethnicity, which some respondents may consider to be sensitive. The OMB Standards for Classification of Federal Data on Race and Ethnicity http://www.whitehouse.gov/omb/fedreg/ ombdir15.html and http://www.whitehouse.gov/omb/fedreg/1997standards.html will be followed to collect information on race/ethnicity. Participants can choose to not answer any question, and WIC participants can choose to not participate in

the study. As described in Part B.4, the survey questions have been cognitively tested with WIC participants and WIC personnel. None of the respondents indicated unwillingness or discomfort with providing a response to any questions.

As described in Part A.10, steps will be taken to safeguard files containing potentially sensitive information. These assurances will be documented in informed consent forms for each relevant data collection component (Appendix BB for the Participant Surveys and request for use of WIC administrative data and Appendix OOO for the participant focus groups), which describe the nature of the information collection, any voluntary aspects of the collection, and any risks/benefits.

12.Estimates of Hour Burden Including Annualized Hourly Costs

Provide estimates of the hour burden of the collection of information. Indicate the affected public number of respondents, frequency of response, annual hour burden, and an explanation of how the burden was estimated.

- Indicate the number of respondents, frequency of response, average time to respond, annual hour burden, forms number if applicable 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.
 - Provide estimates of annualized cost to respondents for the hour burdens for collections of information, identifying and using appropriate wage rate categories.

A total of 1,232.75 burden hours and a total annualized cost to respondents of \$28,334.83 are estimated for this study. Table A12.1 presents the number of respondents, frequency of response, and annual hour burden for each data collection component. Phase I is expected to take place over a 5-month period (starting in Calendar Year 2014, pending OMB

Part A: Justification

approval), and Phase II is expected to take place over a 15-month period (starting in Calendar Year 2015, pending OMB approval) so that the data collection for the two phases takes place within a 3-year period (2014 to 2016). Burden estimates for the recruiting and follow-up materials are based on the contractor's professional experience. Burden estimates for the data collection instruments are based on the pretests conducted by the contractor (described in Part B.4). For each instrument, the amount of time required by the participant to complete the instrument, including the need to consult other records or other individuals, was recorded. The average for all pretest participants was used to estimate burden.

					Resp	onsive				Ν	lonrespons	sive		enª	Ŧ	Part
Type of Respondents	Type of Survey Instruments	Appendix ^b	Sample Size	Number of Respondents	Frequency of Response (Annualized Based on 3 Years)	Total Annual Responses	Hours per Response	Annual Burden (Hours)	Number of Non- respondents	Frequency of Response (Annualized Based on 3 Years)	Total Annual Responses	Hours per Response	Annual Burden (Hours)	 Total Annual Hour Burden ^a	Total Annualized Cost of Burden (\$)	A: Justification
Phase I—National S	Survey and Interviews of	of Local WIC														-
Local agency WIC directors/program managers	Hard copy pretest of Local Agency Survey conducted by phone	N/A	3	3	0.33	1.00	2.33	2.34	0	0.00	0.00	0.00	0.00	2.34	105.59	
Local WIC site supervisors/ nutritionists	Hard copy pretest of Site Survey conducted by phone	N/A	5	5	0.33	1.67	2.50	4.18	0	0.00	0.00	0.00	0.00	4.18	110.89	
Local WIC site supervisors/ nutritionists	Site interviews telephone pretest	N/A	5	5	0.33	1.67	1.25	2.09	0	0.00	0.00	0.00	0.00	2.09	55.44	
WIC State agency directors	Email information request for developing sample frame ^c	A.1	50	50	0.33	16.70	0.50	8.35	0	0.00	0.00	0.00	0.00	8.35	377.00	
Local WIC site supervisors/ nutritionists	Email information request for developing sample frame	A.2	50	50	0.33	16.70	0.50	8.35	0	0.00	0.00	0.00	0.00	8.35	221.78	
WIC State agency directors	Study announce- ment email and brochure	E, F	90	90	0.33	30.06	0.08	2.51	0	0.00	0.00	0.00	0.00	2.51	113.33	
WIC State agency directors	Email invitation with information request, brochure, FAQ document	G, F, H	90	90	0.33	30.06	1.00	30.06	0	0.00	0.00	0.00	0.00	30.06	1,3	57.21
Local agency WIC directors/program managers	Local Agency Web- based survey and email invitation, brochure, FAQ document	B, I, F, H	1,000	800	0.33	267.20	0.75	200.40	200	0.33	66.80	0.08	5.58	205.98	9,29	99.90
Local WIC site supervisors/ nutritionists	Site Web-based survey Site Survey and email invitation, brochure, FAQ document	C, J, F, H	2,000	1,6	50 0 .33	534.40	0.75	400.80	400	0.33	133.60	0.08	11.16	411.96	10,94	41.54
Local agency WIC directors/program managers	Local Agency Survey reminder email #1	K.1	1,000	800	0.33	267.20	0.03	8.92	200	0.33	66.80	0.00	0.00	8.92	402.94	_

					Resp	onsive				Ν	lonrespons	sive		enª	Part,
Type of Respondents	Type of Survey Instruments	Appendix	Sample Size	Number of Respondents	Frequency of Response Annualized Based on 3 Years	Total Annual Responses	Hours per Response	Annual Burden (Hours)	Number of Non- respondents	Frequency of Response (Annualized Based on 3 Years)	Total Annual Responses	Hours per Response	Annual Burden (Hours)	 Total Annual Hour Burden ^a	Total Annualized Cost o Burden (\$) UCLETING (\$)
Local agency WIC directors/program managers	Local Agency Survey reminder email #2	K.2	600	400	0.33	133.60	0.03	4.46	200	0.33	66.80	0.00	0.00	4.46	201.47
Local agency WIC directors/program managers	Local Agency Survey reminder email #3	K.3	500	300	0.33	100.20	0.03	3.35	200	0.33	66.80	0.00	0.00	3.35	151.10
Local agency WIC directors/program managers	Local Agency Survey reminder email #4	K.4	400	200	0.33	66.80	0.03	2.23	200	0.33	66.80	0.00	0.00	2.23	100.74
Local WIC site supervisors/ nutritionists	Site Survey email reminder #1	L	2,000	1,0	5000.33	534.40	0.03	17.85	400	0.33	133.60	0.00	0.00	17.85	474.07
WIC State agency directors	State agency email notification of nonrespondents	М	20	20	0.33	6.68	0.17	1.12	0	0.00	0.00	0.00	0.00	1.12	50.37
Local agency WIC directors/program managers	Local Agency Survey final reminder call script	Ν	100	100	0.33	33.40	0.08	2.79	0	0.00	0.00	0.00	0.00	2.79	125.92
Local WIC site supervisors/ nutritionists	Site interviews email invitation	Ρ	100	80	0.33	26.72	0.03	0.89	20	0.33	6.68	0.03	0.22	1.12	29.63
Local WIC site supervisors/ nutritionists	Site interviews scheduling phone call script	Q	100	80	0.33	26.72	0.08	2.23	20	0.33	6.68	0.08	0.56	2.79	74.07
Local WIC site supervisors/ nutritionists	Site interviews email reminder	R	80	80	0.33	26.72	0.03	0.89	0	0.00	0.00	0.00	0.00	0.89	23.70
Local WIC site supervisors/ nutritionists	Interview guide for site telephone interviews ^d	0	80	80	0.33	26.72	0.30	8.02	0	0.00	0.00	0.00	0.00	8.02	212.90
WIC Staff Total			3,000	2,4	400	2,	14862	711.82	600		614.56		17.51	729.34	24,429.59

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Type of Respondents	Type of Survey Instruments	Appendix	Sample Size	Number of Respondents	Frequency of Response (Annualized Based on 3 Years)	Total Annual Responses	Hours per Response	Annual Burden (Hours)	Number of Non- respondents	Frequency of Response (Annualized Based on 3 Years)	Total Annual Responses	Hours per Response	Annual Burden (Hours)	 Total Annual Hour Burden ^a	Total Annualized Cost c Burden (\$)
Phase II—Pilot Eval	uation Study														
WIC State agency directors	Hard copy pretest of administrative data request conducted by email	N/A	4	3	0.33	1.00	0.50	0.50	1	0.33	0.33	0.00	0.00	0.50	22.62
Local WIC site supervisors/ nutrionists	Hard copy pretest of administrative data request conducted by email ^e	N/A	4	3	0.33	1.00	0.50	0.50	1	0.33	0.33	0.00	0.00	0.50	22.62
WIC nutrionists/ nutrition assistants	Hard copy pretest of nutrition educator survey conducted by phone	N/A	3	3	0.33	1.00	1.33	1.34	0	0.00	0.00	0.00	0.00	1.34	16.41
WIC State agency directors	Pilot study email notification and FAQ	S, W	12	6	0.33	2.00	0.08	0.17	6	0.33	2.00	0.08	0.17	0.33	15.11
WIC State agency directors	Pilot study telephone invitation script	Т	12	6	0.33	2.00	0.50	1.00	6	0.33	2.00	0.03	0.07	1.07	48.26
Local agency WIC directors/program managers	Pilot study email notification and FAQ	U, W	12	6	0.33	2.00	0.08	0.17	6	0.33	2.00	0.08	0.17	0.33	15.11
Local agency WIC directors/program managers	Pilot study telephone invitation script	V	12	6	0.33	2.00	0.50	1.00	6	0.33	2.00	0.03	0.07	1.07	48.26
WIC nutrionists/ nutrition assistants	Nutrition educator (NE) Web-based survey, information sheet ^f	PPP, QQQ	38	30	0.33	10.02	0.33	3.35	8	0.33	2.67	0.08	0.22	3.57	43.84
WIC nutrionists/ nutrition assistants	NE Survey reminder email/letter	RRR	38	30	0.33	10.02	0.03	0.33	8	0.33	2.67	0.00	0.00	0.33	4.11
WIC nutrionists/ nutrition assistants	NE Survey reminder phone call script	SSS	11	3	0.33	1.00	0.08	0.08	8	0.33	2.67	0.00	0.00	0.08	1.03
Local WIC site supervisors	Telephone invitation baseline interview	VVV	6	6	0.33	2.00	0.17	0.33	0	0.00	0.00	0.00	0.00	0.33	8.89
Local WIC site supervisors	Baseline in-person interview guide	TTT	6	6	0.33	2.00	0.75	1.50	0	0.00	0.00	0.00	0.00	1.50	39.92

Part A: Justification

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Type of Respondents	Type of Survey Instruments	Appendix	Sample Size	Number of Respondents	Frequency of Response Annualized Based on 3 Years	Total Annual Responses	Hours per Response	Annual Burden (Hours)	Number of Non- respondents	Frequency of Response (Annualized Based on 3 Years)	Total Annual Responses	Hours per Response	Annual Burden (Hours)	 Total Annual Hour Burden ^a	Total Annualized Cost c Burden (\$)	
Local WIC site supervisors	Email invitation interim/final interviews	WWW	6	6	0.33	2.00	0.03	0.07	0	0.00	0.00	0.00	0.00	0.07	1.78	-
Local WIC site Supervisors	Interim/final telephone interview guide	UUU	6	6	0.67	4.00	0.25	1.00	0	0.00	0.00	0.00	0.00	1.00	26.56	
ocal WIC site staff	WIC administrative data request email	XXX	12	12	0.33	4.01	1.40	5.61	0	0.00	0.00	0.00	0.00	5.61	68.91	
VIC Staff Total			87	66		46.08		16.96	21		16.70		0.69	17.65	383.43	
VIC participants	Hard copy pretest of participant survey conducted in person	N/A	9	9	0.33	3.01	1.50	4.51	0	0.00	0.00	0.00	0.00	4.51	32.69	
WIC participants	Hard copy pretest of participant focus groups conducted in person	N/A	3	3	0.33	1.00	0.50	0.50	0	0.00	0.00	0.00	0.00	0.50	3.63	
VIC participants	Participant flyer, 3 month advance	Х	550	550	0.33	183.70	0.03	5.51	0	0.00	0.00	0.00	0.00	5.51	39.95	
VIC participants	Participant flyer during enrollment	Y	550	550	0.33	183.70	0.03	5.51	0	0.00	0.00	0.00	0.00	5.51	39.95	
VIC participants	Participant flyer fact sheet	Z	1,100	1,1	.0 0 .33	367.40	0.03	11.02	0	0.00	0.00	0.00	0.00	11.02	79.91	
NIC participants	Electronic screener and hard copy informed consent	AA, BB	1,100	900	0.33	300.60	0.17	50.20	200	0.33	66.80	0.08	5.58	55.78	404.39	
VIC participants	Hard copy survey for baseline survey, English ^g	CC, DD,EE	608	558	0.33	186.37	0.33	62.25	50	0.33	16.70	0.03	0.56	62.81	455.34	
VIC participants	Hard copy survey for baseline survey, Spanish ^g	CC, DD,EE	292	242	0.33	80.83	0.50	40.41	50	0.33	16.70	0.03	0.56	40.97	297.05	
VIC participants	Reminder postcard for baseline survey	RR	900	800	0.33	267.20	0.03	8.92	100	0.33	33.40	0.00	0.00	8.92	64.70	
VIC participants	Reminder call script for baseline survey	SS	300	100	0.33	33.40	0.08	2.79	200	0.33	66.80	0.00	0.00	2.79	20.22	
VIC participants	Thank you letter for baseline survey	Π	800	800	0.33	267.20	0.03	8.92	0	0.00	0.00	0.00	0.00	8.92	64.70	

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Type of Respondents	Type of Survey Instruments	Appendix	Sample Size	Number of Respondents	Frequency of Response Annualized Based on 3 Years	Total Annual Responses	Hours per Response	Annual Burden (Hours)	Number of Non- respondents	Frequency of Response (Annualized Based on 3 Years)	Total Annual Responses	Hours per Response	Annual Burden (Hours)	Total Annual Hour Burden ^a	Total Annualized Cost o Burden (\$)
WIC participants	Ineligibility letter	UU	5	5	0.33	1.67	0.03	0.06	0	0.00	0.00	0.00	0.00	0.06	0.40
WIC participants	Advance letter for interim survey	VV	800	800	0.33	267.20	0.03	8.92	0	0.00	0.00	0.00	0.00	8.92	64.70
WIC participants	Interim survey— mail PAPI or CATI, English ⁹	FF, GG, HH, LL, MM, NN, WW, ZZ	477	397	0.33	132.60	0.33	44.29	80	0.33	26.72	0.03	0.89	45.18	327.56
WIC participants	Interim survey— mail PAPI or CATI, Spanish ^g	FF, GG, HH, LL, MM, NN, WW, ZZ	323	243	0.33	81.16	0.42	33.84	80	0.33	26.72	0.03	0.89	34.74	251.84
WIC participants	Reminder postcard for interim survey	XX	800	640	0.33	213.76	0.03	7.14	160	0.00	0.00	0.00	0.00	7.14	51.76
WIC participants	Reminder email for interim survey	YY	400	240	0.33	80.16	0.03	2.68	160	0.00	0.00	0.00	0.00	2.68	19.41
WIC participants	Reminder call script for interim survey	AAA	240	80	0.33	26.72	0.08	2.23	160	0.00	0.00	0.00	0.00	2.23	16.18
WIC participants	Thank you letter for interim survey	BBB	640	640	0.33	213.76	0.03	7.14	0	0.00	0.00	0.00	0.00	7.14	51.76
WIC participants	Advance letter for final survey	CCC	800	800	0.33	267.20	0.03	8.92	0	0.00	0.00	0.00	0.00	8.92	64.70
WIC participants	Final survey—mail PAPI or CATI, English ⁹	II, JJ, KK, OO, PP, QQ, DDD, GGG	472	372	0.33	124.25	0.33	41.50	100	0.33	33.40	0.03	1.12	42.61	308.95
NIC participants	Final survey—mail PAPI or CATI, Spanish ^g	II, JJ, KK, OO, PP, QQ, DDD, GGG	328	228	0.33	76.15	0.42	31.76	100	0.33	33.40	0.03	1.12	32.87	238.31
WIC participants	Reminder postcard for final survey	EEE	800	800	0.33	267.20	0.03	8.92	0	0.00	0.00	0.00	0.00	8.92	64.70
WIC participants	Reminder email for final survey	FFF	400	200	0.33	66.80	0.03	2.23	200	0.00	0.00	0.00	0.00	2.23	16.18
WIC participants	Reminder call script for final survey	HHH	320	120	0.33	40.08	0.08	3.35	200	0.33	66.80	0.03	2.23	5.58	40.44

Part A: Justification

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Type of Respondents	Type of Survey Instruments	Appendix	Sample Size	Number of Respondents	Frequency of Response Annualized Based on 3 Years	Total Annual Responses	Hours per Response	Annual Burden (Hours)	Number of Non- respondents	Frequency of Response (Annualized Based on 3 Years)	Total Annual Responses	Hours per Response	Annual Burden (Hours)	Total Annual Hour Burden ^a	Total Annualized Cost o Burden (\$)
WIC participants	Thank you letter for final survey		600	600	0.33	200.40	0.03	6.69	0	0.00	0.00	0.00	0.00	6.69	48.53
WIC participants	Mail invitation for focus groups	ККК	640	640	0.33	213.76	0.03	7.14	0	0.00	0.00	0.00	0.00	7.14	51.76
WIC participants	Focus group incoming recruitment calls	LLL	120	60	0.33	20.04	0.08	1.67	0	0.00	0.00	0.00	0.00	1.67	12.13
WIC participants	Focus group outgoing recruitment calls	МММ	120	60	0.33	20.04	0.08	1.67	60	0.33	20.04	0.03	0.67	2.34	16.98
WIC participants	Focus group reminder calls	NNN	120	120	0.33	40.08	0.08	3.35	0	0.00	0.00	0.00	0.00	3.35	24.26
WIC participants	Focus group session ^h	JJJ, 000	120	96	0.33	32.06	1.50	48.10	24	0.00	0.00	0.00	0.00	48.10	348.70
WIC Participant Total			1,100	900		4,25	59.50	472.16	200		407.48		13.61	485.77	3,521.8
ANNUALIZED TOTAL	or and poncil interview		4,187	3,3	366	6,4 1	54.2	1,2 4	00.9821	•••••	1,0	3874	31.82	1,2 5	232.7 28,334. 3

Notes: PAPI = Paper and pencil interviewing

^a Annual hour burden will need to be multiplied by 3 for the total 3 year data collection period.

^b Appendix D is an email from FNS to the FNS Regional Offices and is therefore not included in the burden.

^c Not included in the Total for Number of Respondents because these respondents are a subset of participants to the Local Agency Survey.

^d Not included in the Total for Number of Respondents because these respondents are a subset of participants to the Site Survey.

^e Not included in the Total for Number of Respondents because these respondents are a subset of participants to the Site Survey pretests.

^fSome of these individuals may have also participated in the Phase I Site Survey.

⁹ The distribution of Hispanic vs. non-Hispanic women WIC participants from the WIC 2012 Program Participant and Program Characteristics Study (Table II.7) (USDA, 2013a) was used to allocate participants for the English and Spanish versions of the survey because the burden is different for the two versions. This is likely an overestimation of surveys to be completed in Spanish because some Hispanics will complete the English version.

^h Not included in the Total for Number of Respondents because these participants are a subset of respondents to the Participant Surveys.

The estimated annualized cost is \$7.25 per hour for WIC participants (national minimum wage); \$45.15 per hour for state and local WIC administrators (job category "Management Occupations" code #11-0000); \$26.56 per hour for WIC site administrators (job category "Dietitian and Nutritionists" code #29-1031); and \$12.28 per hour for WIC site nutrition educators and local WIC site clerical staff (job category "Healthcare Support Occupations" code #31-0000).⁴ No respondents will be asked to keep records of data; therefore, no burden hours have been estimated for recordkeeping.

13.Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers

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 or maintenance costs

associated with this data collection.

14.Annualized Cost to Federal Government

Provide estimates of annualized cost to the Federal government. 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 \$799,045. Contractor

costs associated with this study total \$3,815,974 over 5 years, with an

estimated annualized cost of \$763,195 to the Federal government. This is

⁴ May 2012 National Occupational Employment and Wage Estimates for the United States, median hourly rates, available at www.bls.gov/oes/current/oes_nat.hm.

based on an estimate of 34,280 labor hours, with a salary range of \$35 to \$303 per hour, and includes sampling; instrument development; data collection; analysis; reporting; and overhead costs, including computing, copying, supplies, postage, shipping, travel, participant 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 \$43.09 per hour based on 2,080 hours per year. We anticipate this person will work 832 hours per year for 5 years for a combined total of 4,160 hours. The annual cost for the FNS employee is \$35,850. Federal employee pay rates are based on the General Schedule of the Office of Personnel Management for 2013 for the Washington, DC, locality.

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 that will add 1,232.75 burden hours to the OMB inventory as a result of program changes.

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. Address any complex analytical techniques that will be used. Provide the time schedule for the entire project, including beginning and ending dates of the collection of information, completion of report, publication dates, and other actions.

Table A16.1 provides the planned schedule for the WIC Nutrition Education Study. Findings will be summarized in peer-reviewed reports, and

the interim and final reports will be posted on the FNS Web site.

Project Activity	Months after OMB Approval
Phase I—National Surveys and Site Interviews	
Conduct abstraction of State Plans	Before OMB approval obtained
Conduct Local Agency and Site Surveys	1 month after OMB approval
Conduct site interviews	2 months after OMB approval
Prepare interim report	13 months after OMB approval
Phase II—Pilot Evaluation Study with Six Sites	
Conduct data collection with WIC participants and site representatives	9 months after OMB approval
Request administrative data from sites	21 months after OMB approval
Prepare final report	33 months after OMB approval

Table A16.1. Data	Collection and	Reporting	Schedule
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Tabulation Plan for Phase I. The analysis of the Local Agency and Sites Surveys will produce descriptive statistics using appropriate survey weights to provide national estimates of WIC nutrition education delivery and other key data constructs to address study research questions. Bivariate analyses will examine whether the frequency of use of various nutrition education processes varies by geographic location and local agency and site characteristics.

Tabulation Plan for Phase II. The analysis of the Phase II data will be used to inform the design of a national impact evaluation. To guide efforts to reduce the response burden in a national study, we will describe the distributions of variables and possible ceiling effects in order to inform recommendations about which variables may not be sensitive enough to detect changes over time and thus can be candidates for deletion from the national study. We will also conduct correlational and bivariate analyses among the potential indicators of the intensity of exposure to WIC nutrition education and use this information to develop a streamlined indicator of the dosage of WIC nutrition education that can be used for the national study. One of the key analyses that will inform the design of a national study will be information about the likely effect size we will need to detect the degree of intraclass correlation (ICC) within WIC clinics. We will also assess the degree of intraclass correlation (ICC) within WIC clinics on key variables such as the level of exposure to WIC nutrition education and key outcomes such as measures of dietary habits. This information can be used in power calculations to estimate the needed sample sizes for a national study.

17.Reason(s) 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.

The agency plans to display the expiration date for OMB approval of the

information collection on all instruments.

18.Exceptions to the Certification for Paperwork Reduction Act Submissions

Explain each exception to the certification statement identified in Item 19 "Certification for Paperwork Reduction Act" of OMB Form 83-I. Part V "Certification Requirement for Paperwork Reduction Act." If Agency is not requesting an exception, the standard statement should be used.

There are no exceptions to the certification statement.

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