

SUPPORTING STATEMENT - PART A for
OMB Control Number 0584-NEW:
WIC Nutrition Assessment and Tailoring Study
November 23, 2020

Alexander Bush
Office of Policy Support
USDA, Food and Nutrition Service
1320 Braddock Place
Alexandria, Virginia 22314
Email: Alexander.Bush@usda.gov
Telephone: (703) 305-2127

Table of Contents

A1. Circumstances that make the collection of information necessary.....4
A2. Purpose and Use of the Information..... 6
A3. Use of information technology and burden reduction.....10
A4. Efforts to identify duplication.....11
A5. Impacts on small businesses or other small entities.....11
A6. Consequences of collecting the information less frequently.....12
A7. Special circumstances relating to the Guidelines of 5 CFR 1320.5.....12
A8. Comments to the Federal Register Notice and efforts for consultation.....13
A9. Explain any decisions to provide any payment or gift to respondents.....15
A10. Assurances of confidentiality provided to respondents.....17
A11. Justification for any questions of a sensitive nature.....19
A12. Estimates of the hour burden of the collection of information.....20
A13. Estimates of other total annual cost burden.....24
A14. Provide estimates of annualized cost to the Federal government.....24
A15. Explanation of program changes or adjustments.....25
A16. Plans for tabulation, and publication and project time schedule.....25
A17. Displaying the OMB Approval Expiration Date.....27
A18. Exceptions to the certification statement identified in Item 19.....28

Tables

A2-1. Data Collection Activity Summary.....7
A8-1. Consultants from Outside the Agency.....14
A12-1. Summary of Estimated Total Burden.....23
A16-1. Analysis for research objectives.....26
A16-2. Project Time Schedule.....27

Appendices

Appendix A: WIC NATS Supporting Documents

- A1. Authorizing Statutes
- A2. Relevant WIC Policy and Guidance Documents
- A3. WIC NATS Objectives and Research Questions
- A4. WIC NATS Recruitment Summary

Appendix B: WIC NATS OMB Burden Table

Appendix C: Information Collections and Instruments

- C1. Call with State Agency Director and Request Documents
- C2. Local Agency Director Survey
 - C2a. Local Agency Director Survey (Screenshots)
- C3. Call with Local Agency Director and Request Documents
- C4. Clinic Site Information Form
- C5. Clinic Observation Form
- C6. Site Director Interview Guide
- C7. Nutrition Services Observation Form
 - C7a. Identified Risks Data Collection Form
- C8. Staff Interview Guide

- C9. WIC Participant Interview Guide
- C9a. WIC Participant Interview Guide-Spanish

Appendix D: State Agency Recruitment

- D1. Introductory Email from FNS to SA
- D2. Email to SA with Info Packet and Schedule Call
- D3. MOU for SA

Appendix E: Local Agency Director Survey Recruitment

- E1. Introductory Email from SA to all LAs with Info Packet
- E2. Email to LA with LA Director Survey Link
- E3. Reminder Emails to Complete LA Director Survey

Appendix F: Local Agencies Selected for Site Visits

- F1. Email to SA with LAs Selected for Site Visit
- F2. Site Visit Email from SA to Selected LA
- F3. Site Visit Email to LA and Schedule Call
- F4. Reminder Email to Submit Nutrition Risk Assessment Documents

Appendix G: WIC Clinic Site Visit and Participant Recruitment

- G1. Email to LA with Selected Site Name
- G2. Site Visit Email from LA to WIC Clinic
- G3. Site Visit Email to WIC Clinic and Schedule Call
- G4. Telephone Call with WIC Clinic
- G5. Informed Consent for Site Director Interview
- G6. Informed Consent for Observation and Staff Interview
- G7. Study Brochure for WIC Participant
 - G7a. Study Brochure for WIC Participant-Spanish
- G8. WIC Participant Screener
 - G8a. WIC Participant Screener-Spanish
- G9. Informed Consent for Observation and WIC Participant Interview
 - G9a. Informed Consent for Observation and WIC Participant Interview-Spanish
- G10. Reminder Text for WIC Participant Interview to be Conducted Over the Phone
 - G10a. Reminder Text for WIC Participant Interview to be Conducted Over the Phone-Spanish
- G11. Reminder Call for WIC Participant Interview to be Conducted Over the Phone
 - G11a. Reminder Call for WIC Participant Interview to be Conducted Over the Phone-Spanish

Appendix H: Comments

- H1. Public Comment from National WIC Association
- H2. Public Comment from 1,000 Days
- H3. Public Comment from Academy of Nutrition and Dietetics
- H4. Comments from NASS
- H5. Expert Review Panel Comments and Responses

Appendix I: FNS Response to Comments

- I1. FNS Response to National WIC Association
- I2. FNS Response to 1,000 Days
- I3. FNS Response to Academy of Nutrition and Dietetics
- I4. FNS Response to NASS Comments

Appendix J: Pretest Memorandum

Appendix K: Confidentiality Agreements and IRB Documents

- K1. Statement of Confidentiality and Non-Disclosure
- K2. Westat IRB Approval Letter

A1. 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.

The United States Department of Agriculture's (USDA) Food and Nutrition Service (FNS) seeks approval for a study of the nutrition assessment process used by the local agencies for the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) to identify nutrition risks and apply that information to the tailoring of participant benefits. The proposed study, the "WIC Nutrition Assessment and Tailoring Study (WIC NATS)," is a new information collection. The study will provide FNS with a comprehensive, detailed description of the WIC nutrition risk assessment process, and explore the ways in which WIC clinics tailor participant benefits to address the results of the assessment. It will also evaluate the relationship between this process and participant program satisfaction.

WIC serves low-income pregnant and post-partum women, infants, and children up to their fifth birthday who are determined to be at nutritional risk. As part of the Program's certification and recertification procedures, qualified WIC staff conduct a comprehensive nutrition assessment with each participant, during which staff identify and document participants' nutritional risks. In addition to contributing to the eligibility determination, 7 CFR 246.7(e) requires that staff use this information to tailor WIC Program benefits (i.e., nutrition education and breastfeeding support, supplemental food packages, and referrals to other health and social services) to the participant's needs (Appendix A1). Section 28 of the Richard B Russell National School Lunch Act (NSLA) as amended by the Healthy, Hunger-Free Kids Act (HHFKA) of 2010 (Public Law 111-296, Sec. 305) provides general statutory authority for this planned data collection (Appendix A1).

This study is an Agency priority given policy changes that have impacted the WIC Program's nutrition services processes and the ongoing goal of improving retention and customer satisfaction. In 2006, FNS published *Value Enhanced Nutrition Assessment (VENA) in WIC: The First Step in Quality Nutrition Services* (Appendix A2). Since its full implementation in 2010, VENA guidance has defined the WIC nutrition assessment and serves as a framework for a comprehensive and participant-centered approach to the assessment and tailoring processes. A key feature of VENA is that it allows each State Agency (SA) to use the guidance to implement nutrition assessment protocols that are best suited for their unique operations and participant needs. While this flexibility is a key strength of the WIC Program, it also complicates the evidence base, as there is no one prescribed way in which to conduct a nutrition assessment. FNS is currently updating VENA guidance, and in the coming years SAs will evaluate current VENA practices and implement refinements as needed. In October 2009, FNS revised the WIC food packages through an interim rule change—described in the attached final rule, which was published in 2014 (Appendix A2). As a result of these revisions, WIC staff were given more opportunities to tailor the supplemental food packages based on information gathered during the nutrition assessment. No comprehensive study has examined the nutrition assessment or nutrition services process since these policy changes were made, thus the current study aims to fill this gap by addressing the following research objectives (see Appendix A3 for a full list of research questions):

1. Provide in-depth descriptive information of the WIC nutrition risk assessment process;
2. Systematically describe how local WIC agencies use the collection of nutrition assessment information to tailor Program benefits, including: food packages, nutrition education, breastfeeding promotion and support, and referrals to health and social services;
3. Investigate relationships between WIC nutrition services processes (to include the nutrition risk assessment and the associated tailoring of program benefits), and the

clinic experience, participant and staff perceptions, and overall clinic flow and efficiency; and

4. Analyze study findings to identify specific practices or features of nutrition service processes that facilitate the use of nutrition assessment information for providing tailored Program benefits and are associated with participant and staff satisfaction.

A2. 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 how the agency has actually used the information received from the current collection.

Purpose of Information Collection. This is a new information collection request. The information collected will provide FNS with a comprehensive, detailed description of the WIC nutrition risk assessment process, including how WIC staff apply the process to tailoring participant benefits. The study will identify specific practices or features of the nutrition services process associated with participant and staff satisfaction, reduced staff burden, and improved Program efficiency. Specifically, the insights gained through WIC NATS can help to ensure that the rollout of updates to VENA guidance is driven by an evidence-based understanding of how the nutrition assessment process is operationalized in different contexts and the relationship between these practices and satisfaction with the clinic experience among both participants and staff. In general, the information gathered will be used to inform program guidance and technical assistance related to the nutrition assessment process to support the implementation of best practices that meet the goals ensuring satisfaction with the program experience, promoting self-sufficiency, and improving the nutrition and health of women and children who participate in WIC.

From whom the information will be collected. Information will be collected from a national, diverse sample of State agencies (SAs), local agencies (LAs), and clinics administering the WIC Program, as well as a small sample of WIC participants. The study is not designed to be

nationally representative, but rather provide in-depth information from a diverse range of program experiences. Criteria guiding the sample selection for different data collection activities in this study are described in Section B.1 of this request. Table A2-1 below describes each data collection activity, the associated respondents, the purpose for the collection, and the method of data collection. Appendix B summarizes the burden associated with data collection by respondent, target number of respondents, mode, estimated burden, target response rate, and starting sample size.

Table A2-1. Data Collection Activity Summary

Data Collection Activity	Number and Type of Respondents	Purpose	Data Collection Mode
WIC State Agencies			
Collect WIC State Plans¹ and Policy Documents (Appendix C1)	10 WIC State agency directors	Provide information on state-specific policies and guidance for nutrition assessment and tailoring protocols	Submit via email, fax, secure online file transfer, or by mailing hard copies
Collect Management Information System (MIS) Data (Appendix C1)	10 WIC State agency directors	Provide information on how the MIS is used by clinic sites structure and record information from the nutrition assessment and food package prescription, education provided, and referrals	Submit via secure online file transfer (occurs twice – once at the time of SA recruitment and once 6 months after SA recruitment)
WIC Local Agencies			
Local Agency Director Survey (Appendix C2 & C2a)	370 WIC local agency directors (approx.)	Obtain information on LA-specific protocols; this information will also contribute to sampling criteria when selecting 30 LAs to participate in site visits	Online survey
Collect Local Agency Nutrition Assessment Documents and Tools (Appendix C3)	30 WIC local agency directors	Obtain information on LA-specific nutrition assessment and tailoring protocols	Submit via email, fax, secure online file transfer, or by mailing hard copies
Collect Clinic Site Information (Appendix C4)	30 WIC local agency directors	Obtain information required to purposively select a diverse sample of WIC clinics for site visits	Submit via email, fax, secure online file transfer, or by phone call
WIC Clinic Sites			
Clinic Observation Guide	Not applicable;	Document observable information	Direct observation

¹ The State Plans are available electronically; however, we expect that we will need to contact some SAs to obtain missing information. These contacts will be made in conjunction with the contacts made to collect other policy documents and MIS data.

(Appendix C5)	passively collected through observation at 30 WIC clinic sites	about key characteristics of the clinic environment	
Site Director Interview Guide (Appendix C6)	30 WIC site directors	Describe unobservable variations in relevant clinic protocols and provide insight on promising practices and suggestions for improvements	Interview, conducted either in person during site visit
Nutrition Risk Assessment Observation Guide & Identified Risks Data Collection Form (Appendix C7 & C7a)	510 appointments passively observed ² after receiving WIC participant consent	Document key elements of the nutrition assessment, track the length of each observed clinic visit, describe ways in which staff demonstrate cultural sensitivity, and observe use of the MIS system.	Direct observation
Staff Interview Guide (Appendix C8)	150 WIC nutrition assessment staff ³	Describe how staff make decisions in the nutrition assessment and in tailoring benefits, staff satisfaction with current resources and protocols, and suggestions for improvements	Interview, conducted either in person during site visit
WIC Participants			
WIC Participant Interview Guide (Appendix C9; see Appendix C9a for Spanish translation)	300 WIC participants ⁴	Describe participant perspectives and satisfaction with key aspects of the nutrition assessment and benefit tailoring process and outcomes	Interview, conducted either in person during site visit or by phone call

The study team will recruit a diverse sample of 10 State agencies (SAs) that meet the study eligibility requirements: 1) has a fully operational Electronic Benefits Transfer (EBT) system for at least six months; 2) not engaging in any major overhauls of their Management Information System (MIS) during the study data collection window; and 3) located within the contiguous United States⁵. All LAs operating in the selected 10 SAs (approximately 370) will be invited to participate in the brief, online Local Agency Director Survey (Appendices C2 and C2a). Information provided through the survey will guide purposeful selection of a diverse set of

² 17 appointments observed at each of the 30 clinic sites chosen for site visits – although the appointment itself is passively observed, the field researchers will ask the clinic staff that conducted the nutrition assessment a few questions after the appointment to document nutrition risks that were recorded (Appendix C7a).

³ 5 WIC nutrition assessment staff interviewed at each of the 30 clinic sites chosen for site visits (estimated).

⁴ WIC participants interviewed will be the same participants that were observed in the Nutrition Risk Assessment observations. We estimate that 300 of the 510 participants that were observed will agree to participate in the subsequent interview.

⁵ State Agencies outside of the contiguous United States are excluded to minimize resources required for site visit travel.

30 LAs, from which one WIC site (or clinic) will be identified and recruited for a site visit. Site visits will include passive observation of the clinic environment (Appendix C5), an interview with the clinic site director (Appendix C6), direct observation of nutrition assessment appointments (Appendix C7), and interviews with WIC staff (Appendix C8). During the site visits, field researchers will also recruit an average of 17 WIC participants per clinic site for observation of their nutrition assessment (Appendix C7), for a total of 510 WIC participants; we expect approximately 300 of these participants will complete a subsequent interview (Appendix C9).

WIC was reauthorized under the Healthy, Hunger-Free Kids Act of 2010 (Public Law 111-296, Sec. 305), which mandates programs under its authorization to cooperate with USDA program research and evaluation activities, such as this study. However, State and local programs will not be penalized for non-participation. Participation by WIC program participants is voluntary.

How the information will be collected. There are four primary data sources for this study: SAs, LAs, WIC clinics, and WIC participants. Table A2.1 describes each data collection activity, the associated respondents, the purpose for the collection, and the method of data collection. The data collected from each of these entities is unique, thus minimizing burden to the greatest extent possible. Taken together, these data will provide the comprehensive information needed to address all of the study's research questions. A summary of the plan to recruit respondents and complete data collection is included in Appendix A4.

Frequency of information collected. Generally, all information will be collected only once (as shown in A2-1). However, the study team will collect MIS data from SAs at two points in time: first at the time of initial SA recruitment (early-2021), and then again six months after

SA recruitment. The second data request will allow us to analyze whether WIC program benefits are adjusted based on changes noted with respect to identified risks. A second data request is necessary because state MIS systems often overwrite old information with new and, therefore, the easiest way to obtain information on changes is to ask for data at two points in time and link the datasets.

Information shared with any other organizations inside or outside USDA or the government. Results will be presented in aggregated form in the study reports, which will not seek to make generalizations beyond the study sample. We will prepare de-identified public use quantitative data files that are associated with the final report. FNS will publicly share the resulting reports and data files on its website: <http://www.fns.usda.gov/ops/research-and-analysis>.

A3. Use of information technology and burden reduction.

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

FNS is committed to complying with the E-Government Act of 2002. Respondent burden will be reduced through use of information technology for data collection. SAs and LAs will have the option to upload study documents to a secure study drive (a File Transfer Protocol (FTP) site), as an alternative to email or fax. SAs will also upload MIS data extracts to an FTP site. The Local Agency Survey will be web-based, and screenshots are provided in Appendix C2a. The Clinic Site Information Form is an Excel spreadsheet provided to selected LAs. LAs will be able to easily add data for each site to the spreadsheet template and return via email or

secure online file transfer. Out of the 6,659 total responses for this collection, 460 (6.9 percent) will be collected electronically.

A4. Efforts to identify duplication.

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

There is no similar information collection. Every effort has been made to avoid duplication. FNS has reviewed USDA reporting requirements. FNS solely administers the WIC program. The information required for this study is not currently reported to FNS on a regular basis in a standardized form and is not available from any other previous, contemporary study. Furthermore, the study will rely on administrative data (such as MIS data and WIC State Plans – see Table A2-1) when available and appropriate, but existing sources are not sufficient to fulfill this study’s objectives alone.

A5. Impacts on small businesses or other small entities.

If the collection of information impacts small businesses or other small entities (Item 5 of OMB Form 83-I), describe any methods used to minimize burden.

We expect up to 78 percent⁶ of the LAs (295 out of 378 total LA respondents) and 100 percent of WIC clinic sites (39 in total) to be small entities. Out of the total number of 1,454 respondents for the study, we expect 23 percent (334 in total) to be small entities. In order to minimize burden on these small entities, we are not including LAs or clinics from SAs that have recently transitioned to EBT (i.e., that have had EBT for less than six months) or are in the process of a major overhaul of their MIS in this study. The study team will offer LAs multiple

⁶ Estimate is based on the following: assumes that all non-government administered LAs (e.g. businesses and non-profits) qualify as small entities, accounting for 30% of all LAs; of the remaining 70% of LAs run by local government entities, this assumes that nearly all are run through county or county-equivalent governments; according to 2018 U.S. Census estimates, 68.5% of U.S. counties and county equivalents are comprised of populations of fewer than 50,000 persons, which would qualify these governmental jurisdictions as small entities—representing approximately 48% of all LAs.

ways to submit information to the study team, including online file transfer, email, fax, postal mail or by telephone. To minimize burden on WIC clinics, we will work with the Site Director during the planning calls to optimize the plans for the site visit, so there is minimal disruption to clinic operations. We will offer Site Directors and clinic staff the opportunity to complete interviews either in-person or by telephone.

A6. 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.

This is a voluntary data collection activity in support of the FNS ongoing goal of improving retention and customer satisfaction in WIC programs. If this information collection is not conducted, FNS will not have information on the best practices for the nutrition risk assessment and benefit tailoring, nor on staff and participant satisfaction with the WIC nutrition services process. The data obtained through the study will help FNS to better meet the needs of WIC participants. Most of the information collected for this study is collected only once. However, MIS data must be collected at two time points (as explained in Section A2 of this memo).

A7. 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 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 special circumstances. The collection of information is conducted in a manner consistent with the guidelines in 5 CFR 1320.5.

A8. Comments to the Federal Register Notice and efforts for consultation.

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. Summarize public comments received in response to that notice and describe actions taken by the agency in response to these comments. Specifically address comments received on cost and hour burden.

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 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 years. There may be circumstances that may preclude consultation in a specific situation. These circumstances should be explained.

Notice of this study was published in the *Federal Register* (Volume 84, Number 139, pages 34849-34858) on July 19, 2019. The public comment period ended on September 17, 2019. FNS received comments from three organizations, the National WIC Association (NWA), 1,000 Days, and The Academy of Nutrition and Dietetics (AND), which are provided in Appendices H1 through H3. FNS's responses to the comments are provided in Appendices I1 through I3. None of the comments resulted in changes to the study.

All three commenters generally expressed support for WIC NATS. Both NWA and AND offered suggestions regarding best practices for conducting research, particularly among WIC State agencies, local agencies, clinics, and participants. They emphasized the need to ensure that research activities do not deter continued participation in WIC. Responses from FNS shared additional details regarding the careful development and pretesting of all study materials and data collection instruments, and clarified the study purpose, design, and approach in order to address their concerns. AND specifically noted that their members working in WIC clinics reported that the proposed data collection could pose challenges on both the State and local level, and recommended field testing the collection with a pilot group to ensure feasibility. FNS responded to this concern by indicating that all instruments and requests were indeed pretested with a pilot group of respondents and explained that adjustments were made based on the pretest input.

FNS also convened an Expert Review Panel (ERP) in November 2018. The ERP has provided guidance on the study design, data collection methods and sources, sampling, and efforts to reduce respondent burden. The ERP will also convene to provide guidance on reporting the findings of the study. The three-member panel represented a variety of expertise, as shown in Table A8-1. A summary of the ERP’s review of the study design and resulting changes can be found in Appendix H5.

Table A8-1. Consultants from Outside the Agency

Name	Affiliation	Area of Expertise	Contact
Angela Odoms-Young, PhD	Associate Professor, Kinesiology and Nutrition University of Illinois at Chicago	Knowledge of WIC clinical processes and interaction between WIC food package, dietary intake and nutrition status	773-391-3358
Joni Geppert, MPH, RD, LN	Senior Epidemiologist Minnesota Department of Health	State-level knowledge of WIC clinical processes including nutrition	651-201-3632

		assessment and nutrition services process	
Sarah Schwarzenberg, MD	Professor, Department of Pediatrics University of Minnesota Masonic Children's Hospital	Clinical expertise in pediatrics and nutrition	612-624-1133

In addition to comments from the public and the ERP review, FNS also consulted with Anthony Fischer, Mathematical Statistician in the Methodology Division of the National Agricultural Statistical Service (NASS), for expert consultation on methodology and study design. NASS comments and FNS responses are found in Appendices H4 and I4, respectively.

A9. Explain any decisions to provide any payment or gift to respondents.

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

Because the Healthy, Hunger-Free Kids Act of 2010 mandates that programs under its authorization, including WIC, cooperate with USDA program research and evaluation activities, FNS is not requesting any financial incentives for the participation of SAs, LAs, or WIC clinics in the study. However, due to the burden of hosting in-person site observations at WIC clinics, FNS is requesting approval to provide small thank you gifts from the study team to show their appreciation to each of the 30 WIC clinics. These gifts will include children's books or games for use in the clinic waiting areas, and be valued at \$40 or less per clinic. This amount was chosen because it provides for both a standalone, all-in-one toy for the waiting room (valued at around \$30 on average), as well as one children's book (valued at around \$10 on average). Clinics will receive their thank you gifts within two weeks of completing the site visit and staff interviews.

FNS is requesting that WIC participants who both allow their nutrition assessment appointment to be observed *and* complete the WIC Participant Interview receive incentives of \$20 each in the form of a Visa gift card. Participants will also be reimbursed \$10 if they use their own cellphone to complete the interview by phone to offset the expense of using cell phone minutes. Participants who complete the interview in person will receive the incentive immediately following the interview, while participants who complete the interview by phone will receive the incentive by mail after their interview. While not considered an incentive, participants who do not provide telephone contact information and opt for a telephone interview instead of an in-person interview during the site visit will be offered 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).

The incentive amount is based on burden to the participant as well as experiences of other recent FNS studies that interviewed WIC participants. The WIC Cost Containment Study (OMB Control No: 0584-0627; Expiration Date 09/30/2020) provided a \$30 incentive to WIC participants to complete a 30-minute telephone survey. The Third National Survey of WIC Participants (NSWP-III) (OMB Control No: 0584-0641; Expiration Date 09/30/2021) provided a \$25 incentive to WIC participants to complete a 30-minute survey either in-person or by phone. The incentive amount will reduce respondent burden because it can help offset the costs associated with participation, including childcare that may be needed while respondents complete the surveys and potential lost wages. The value of \$20 for this incentive is based on the average hourly cost of childcare of \$16.20 per hour (according to the Care.com 2020 Cost of Care Report), and using the Federal minimum wage of \$7.25 per hour to estimate potential lost wages. The value of the additional \$10 reimbursement for personal cell phone usage considers

the length of the 30-minute interview call as well as additional calls or text messages needed to set up appointments and reminders and is based on a conservative estimate of \$0.25 per minute for common prepaid phone providers (e.g., Tracfone and Straight Talk Wireless).

Incentives are believed to improve response rates for WIC participants. Incentives were added to the phone interviews in NSWP-III after low response rates in the telephone interviews for the Second National Survey of WIC Participants (NSWP-II) (OMB Control No: 0584-0484; Expiration Date 06/30/2012) led to potential non-response bias in the telephone surveys. NSWP-II obtained complete data for approximately 81 percent of participants for the in-person interviews with these respondents receiving an incentive of \$20 for completion. However, incentives were not provided for interviews conducted over the telephone, and a lower response rate, of only 51 percent, was experienced for the telephone surveys.

Based on the evidence of similar uses above, FNS feels strongly that the proposed incentives for the WIC participants are necessary to obtain a sufficient number of completed observations and interviews from a diverse group of respondents.

A10. Assurances 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 in this study will be subject to safeguards as provided by the Privacy Act of 1974 (5 USC 552a), which requires the safeguarding of individuals against invasion of privacy. The Privacy Act also provides for the privacy of records maintained by a Federal agency according to either the individual's name or some other identifier.

FNS published a system of record notice (SORN) titled FNS-8 USDA/FNS Studies and Reports in the Federal Register on April 25, 1991 (volume 56, pages 19078–19080). It discusses the terms of protections that will be provided to respondents.

All participants that share personally identifiable information (PII) will be provided and asked to sign an informed consent form (Appendix G9 and G9a). Participants will be notified that the information they provide will not be published in a form that identifies them. No identifying information will be attached to any reports. Identifying information will not be included in the public use dataset. The researchers will strip all documents of personally identifiable information (PII) before publishing or transmitting any public-use files. Names, dates of birth, addresses, phone numbers, or any other unique identifier, will not be linked to the data. The researchers will analyze the data in aggregate form without identifying individual participants. All respondents will be informed that the data will be securely stored, and that their responses will not be shared with others not involved in the study, except as otherwise required by law (explanation given at beginning of interviews, see Appendices C6, C8, and C9/C9a). All respondent data and audio recordings will be stored only on a secure network folder, accessible only to members of the study team. Any hardcopy notes from site visits will be securely stored in a locked file cabinet, accessible only to members of the study team.

FNS has contracted with Westat to complete this study. The Westat study team includes Westat and sub-contractors from Insight Policy Research, PHFE WIC, and Gabor and Associates. All members of the study team—Westat, Insight Policy Research, PHFE WIC, and Gabor and Associates—will sign a confidentiality and nondisclosure agreement (Appendix K1). 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.

The IRB approval letter from Westat is in Appendix K2. The study team will coordinate with state-level IRBs as required.

A11. Justification for any questions of a sensitive nature.

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.

No questions on the LA Survey, Site Director Interview, or Staff Interview are considered sensitive. The Nutrition Risk Assessment Observation Form and WIC Participant Interview collect and ask questions of a sensitive nature, such as nutrition risk status, which is likely to be related to health status, race/ethnicity, pregnancy status, and satisfaction with WIC services. This information is important for the study analysis. Participant nutrition risk status will allow us to determine the extent to which WIC benefits are being tailored to the results of the nutrition risk assessment. This is fundamental to the research in question and will help FNS learn when and how tailoring occurs and how it can be improved to help participants receive the WIC benefits that are the most valuable in terms of improving participant nutrition status.

All respondents will be informed that they can choose to have the observer step out of the room during the nutrition risk assessment or to not answer any question they do not wish to answer and that there are no penalties for not participating. All respondents will be assured privacy, and informed that the data will be securely stored, their responses will not be shared with others not involved in the study, except as otherwise required by law, and all data will be aggregated in reports. More information on the protection of participant information can be found in A10 of this supporting statement.

A12. Estimates of the hour burden of the collection of information.

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

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

This is a new information collection with an estimated 1,454 respondents, 6,659 responses, and 869.91 burden hours. Appendix B shows the estimates of the respondent burden for the proposed information collection. A summary appears below.⁷ These estimates are informed by pretesting of instruments and protocols and reflect consultations with FNS program officials and the agency's prior experience with data collection.

Estimated Number of Respondents and Non-Respondents: 865 respondents and 589 non-respondents (1,454 Total)

Estimated Total Annual Responses from Respondents and Non-Respondents: 4,462 for respondents and 2,197 for non-respondents (6,659 Total)

Estimated Frequency of Responses per Respondent and Non-Respondent: 5.16 annually for respondents and 3.73 annually for non-respondents

Estimated Time per Response per Respondent and Non-Respondent: 0.19 hours for respondents and 0.02 hours for non-respondents

Estimated Total Annual Burden Hours on Respondents and Non-Respondents: 832.55 hours on respondents and 37.36 hours for non-respondents

Grand Total Burden Estimate: 869.91 hours

⁷ Summary estimates listed here are an aggregate of the entire collection across all items and respondent groups. For information at the item- or respondent-level, see attached OMB Burden Table in Appendix B.

Table A12-1 presents the number of respondents, frequency of response, and annual hour burden for State/local/tribal governments, profit/non-profit businesses, and individuals/households. As reflected in Table A12-1, approximately 30% of WIC LAs are operated by businesses or other non-governmental organizations (including private hospitals and community service organizations). For this study, the information collected and respondent requirements will be the same for both government-run and non-government WIC LAs and clinic sites.

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

The total estimated annualized respondent cost is \$34,847.75. The estimates of respondent cost are based on the burden estimates and use the U.S. Department of Labor, Bureau of Labor Statistics, May 2019 National Occupational and Wage Statistics (available at: www.bls.gov/oes/current/oes_nat.htm). The estimated annualized cost includes 54.11 total burden hours for SA WIC Directors and a total of 293.66 hours for WIC LA Directors (206.05 hours for LA Directors employed by government agencies and 87.61 hours for LA Directors employed by profit/non-profit businesses) at a wage rate of \$58.88 per hour for State and local WIC administrators (job category “Management Occupations” code #11-0000). At the clinic level, the annualized cost includes 253.21 total burden hours for clinic staff (176.08 hours for WIC clinic staff employed by government agencies and 77.13 hours for WIC clinic staff employed by profit/non-profit businesses) at a wage rate of \$14.91 for WIC clinic staff (job category “Healthcare Support Occupations” code #31-0000). The total annualized cost for WIC staff across all levels (SA, LA, and clinic) is \$24,251.48. Adding in \$8,002.99 (33%) to account for fully loaded wages ($\$24,251.48 \times 0.33$), the total annual cost for WIC staff is \$32,254.47.

For WIC participants, the hourly wage rate used is \$7.25 (<https://www.dol.gov/whd/regs/compliance/posters/flsa.htm>), which is the Federal minimum wage for 2020. The total annualized cost for WIC participants is \$1,949.84. Adding in \$643.45 (33%) to account for fully loaded wages ($\$1,949.84 \times 0.33$), the total annual cost for WIC participants is \$2,593.29.

Table A12-1. Summary of Estimated Total Burden¹

Respondent Type	Respondent Description	Sample Size ²	Responsive				Non-responsive				Total Burden Hours	Total Annualized Cost
			Number of Respondents	Frequency of response (annual)	Total Annual responses	Average Hours per Response	Number of Non-respondents	Frequency of response (annual)	Total Annual responses	Average Hours per Response		
State and Local Agency	State Agency WIC Directors	13	10	8.0	80	0.68	3	2.00	6	0.02	54.11	\$ 3,185.89
	WIC Local Agency Directors	262	220	3.84	845	0.24	42	6.74	283	0.02	206.05	\$ 12,131.99
	WIC Clinic Staff	25	22	22.14	487	0.36	3	1.00	3	0.02	176.08	\$ 2,625.36
	Subtotal	300	252	5.60	1412	0.31	48	6.08	292	0.02	436.23	\$ 17,943.24
Profit/Non-profit Business	WIC Local Agency Directors	116	91	3.95	359	0.24	25	6.12	153	0.02	87.61	\$ 5,158.22
	WIC Clinic Staff	14	10	20.20	202	0.38	4	1.00	4	0.07	77.13	\$ 1,150.01
	Subtotal	130	101	5.55	561	0.29	29	5.41	157	0.02	164.74	\$ 6,308.24
Individuals and Households	WIC Participants	1024	512	4.86	2489	0.10	512	3.41	1748	0.02	268.94	\$ 1,949.84
TOTAL REPORTING BURDEN		1454	865	5.16	4462	0.19	589	3.73	2197	0.02	869.91	\$ 26,201.32
Additional 33% to Account for Fully Loaded Wage Rate											\$ 8,646.43	
TOTAL REPORTING BURDEN (FULLY LOADED)											\$ 34,847.75	

¹ Expected response rates are as follows: State Agencies: 77%; Local Agencies: 83%; WIC Clinics: 82%; WIC participants: 50%

² Includes pretest respondents

A13. Estimates of other total annual cost burden.

Provide estimates of the total annual cost burden to respondents or recordkeepers resulting from the collection of information, (do not include the cost of any hour burden shown in questions 12 and 14). The cost estimates should be split into two components: (a) a total capital and start-up cost component annualized over its expected useful life; and (b) a total operation and maintenance and purchase of services component.

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

A14. Provide estimates of annualized cost to the 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.

The total annualized cost to the Federal Government is \$610,165, or \$2,440,658 over the life of the project, including contractor and Federal government employee costs.

The total estimated cost to the contractor is \$2,275,956 over 4 years, representing an annualized cost of \$568,989. These costs include study design, preparation of the OMB clearance submission, survey instrument development, study participants' recruitment, and all aspects of data collection, analysis, and reporting.

The cost of the FNS employee, Social Science Research Analyst, involved in project oversight with the study, is estimated at GS-13, step 2 at \$50.83 per hour. The estimated time that will be spent on the project by this individual is an average of 510 hours (\$25,923) per year for 4 years for a combined total of 2,040 hours (\$103,692). Adding in \$8,555 (33%) to account for fully loaded wages ($\$25,923 \times 0.33$), the total annual cost for the FNS Social Science Research Analyst is \$34,478 or \$137,912 over 4 years. Additionally, the Lead Social Science Analyst who provides oversight for work conducted by the Research Analyst is estimated at GS-

14, step 2 at \$60.07 per hour. The estimated time allocated to this project is 102 hours per year (\$6,127) for 4 years for a total of 408 hours (\$24,508). Adding in \$2,022 (33%) to account for fully loaded wages (\$6,127 x 0.33), the annual cost for the Lead Social Science Analyst is \$8,149 or \$32,596 over 4 years. Federal employee pay rates reflect the general schedule salary table for 2020 for the Washington, DC, metro area locality (provided by the OPM 2020 General Schedule, available at: https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2020/DCB_h.pdf). .

A15. Explanation of program changes or adjustments.

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

This new collection of information is estimated to add 869.91 total annual burden hours and 6,659 total annual responses as program changes to OMB's inventory.

A16. Plans for tabulation, and publication and project time schedule.

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

The data will be analyzed using qualitative and quantitative analysis techniques, including descriptive, bi-variate, and multivariate analyses. The findings will be synthesized and published in a technical final report as well as an executive summary for the general public, both of which will be posted on the FNS website. The final report will address all research objectives.

The study team will prepare the quantitative and qualitative data for analysis separately prior to linking data at the SA, LA and clinic levels. They will use two quantitative data sources in the analysis—the LA survey and the WIC clinic's MIS data. Additional quantitative data will

come from the coding of data collected from observation forms and interview guides. Table A16-1 provides an overview of the analyses for each study objective.

Table A16-1. Analysis for research objectives

Objective	Source	Analysis
1. Provide in-depth descriptive information on how a large, diverse sample of local WIC agencies perform the WIC nutrition risk assessment.	State WIC plans	<ul style="list-style-type: none"> • Descriptive analyses of the basic components of the nutrition assessment process
	LA Procedures/tools	<ul style="list-style-type: none"> • Qualitative review resulting in flow chart of nutrition risk process
	LA web survey	<ul style="list-style-type: none"> • Descriptive analyses characterizing nutrition risk procedures • Quantitative analysis using frequencies of policies and procedures crossed by LA characteristics
	Observations and interviews	<ul style="list-style-type: none"> • Qualitative review resulting in an augmented flow chart of nutrition risk process with details • Comparison of clinic-level practices to State and local policies and guidance • Qualitative review of variation in practice between clinics and within clinics
2. Systematically describe how a national sample of diverse local WIC agencies use the collection of nutrition assessment information to tailor Program benefits.	State WIC plans	<ul style="list-style-type: none"> • Descriptive analysis of tailoring procedures
	LA Procedures/tools	<ul style="list-style-type: none"> • Qualitative review resulting in flow chart of tailoring process
	MIS data	<ul style="list-style-type: none"> • Calculation of rates of benefit tailoring • Calculation of rates of benefit tailoring conditioned on risk • Calculation of the probability of tailoring food package; education; and referrals
	Observations and interviews	<ul style="list-style-type: none"> • Qualitative review resulting in an augmented flow chart of tailoring process with details • Comparison of clinic-level practices to State and local policies and guidance • Qualitative review of variation in practice between clinics and within clinics
3. Investigate the relationship between WIC nutrition service processes and clinic experience, staff and client	MIS data	<ul style="list-style-type: none"> • Quantitative analysis of the association between clinic characteristics and increased probability of tailoring
	Observation	<ul style="list-style-type: none"> • Creation of flow chart of clinic flow and time estimates
	Interviews	<ul style="list-style-type: none"> • Descriptive analysis of staff and

Objective	Source	Analysis
perceptions, and flow and efficiency		<p>participant experiences, perceptions and satisfaction</p> <ul style="list-style-type: none"> Quantitative analysis of the association between these factors and the nutrition risk process and tailoring using data abstracted from interviews Quantitative analysis of the effectiveness of tailoring in terms of the association between tailoring and satisfaction using data abstracted from interviews
4. Analyze study findings to identify specific practices or features of nutrition service processes that facilitate the use of nutrition assessment information for providing tailored Program benefits and are associated with participant and staff satisfaction	Staff interviews Participant interviews	<ul style="list-style-type: none"> Quantitative analysis of the association between nutrition risk assessment practices for tailoring and staff and participant satisfaction using data abstracted from interviews Qualitative content analysis to determine commonality of suggestions for improvements

Table A16-2 presents the anticipated timeline for activities in the study.

Table A16-2. Project Time Schedule

Study activity	Schedule
Obtain State WIC Plans, State MIS data	Starting 1 week post-OMB approval
Recruit LAs, WIC clinics	Starting 2 weeks post-OMB approval and lasting 12 weeks
Conduct Data Collection	Starting 1 week post-OMB approval and lasting 32 weeks
Analysis and Prepare Data File	Starting 9 months after OMB approval
Prepare Final Report and Briefing Materials	Starting 12 months after OMB approval
Final Report Complete	Mid-2022

A17. Displaying the OMB Approval Expiration Date.

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 OMB number and the expiration date will be displayed on every form/instrument.

A18. Exceptions to the certification statement identified in Item 19.

Explain each exception to the certification statement identified in Item 19 of the OMB 83-I" Certification for Paperwork Reduction Act."

There are no exceptions to the certification statement.