Supporting Statement for OMB Clearance for the WIC Nutrition Assessment and Tailoring Study In-Person Site Visit Data Collection

Part A

Revision to OMB Control # 0584-0663: WIC Nutrition Assessment and Tailoring Study

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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

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Introduction

TERMS OF CLEARANCE: We thank the agency for agreeing to submit any additions to the number of respondents through a revision package. The clinic observation form cleared here could be used after submitting a revision package to visit WIC clinics in-person.

This information collection request is for a revision of the approved collection for the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) Nutrition Assessment and Tailoring Study (WIC NATS) (OMB Control Number 0584-0663; expiration date: 04/30/2024). WIC NATS was originally designed with a significant phase of data collection to be conducted through in-person site visits. The COVID-19 pandemic made it unsafe and, in many cases, not feasible to conduct in-person observations while many WIC clinics served participants through remote appointments. As a result, WIC NATS was initially approved for a remote-only data collection in April 2021. The following request seeks to revise the current approval to include in-person site visits and accounts for the burden associated with this data collection. As WIC clinics begin to resume normal in-person clinic services, this collection will provide FNS with a comprehensive account of the WIC nutrition risk assessment and benefit tailoring processes during in-person clinic services. The terms of clearance provided above also indicate that the Clinic Observation Form (Appendix C5), which was cleared under the original approval, but not yet used, may also be used after submitting the following revision package to allow for in-person site visits to WIC clinics.

A1. Circumstances that make 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.

The United States Department of Agriculture's (USDA) Food and Nutrition Service

(FNS) seeks approval for a revision to the currently approved collection for the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) Nutrition Assessment and Tailoring Study (WIC NATS) (OMB Control Number 0584-0663 WIC Nutrition Assessment and Tailoring Study; expiration date 04/30/2024). WIC NATS 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. The proposed revision adds data collection from in-person site visits, where the data collection activities planned for the currently approved remote site visits will be replicated for use with 30 WIC clinic sites for in-person site visits once WIC clinic sites safely resume in-person operations.

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*. 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. In 2020, FNS updated the guidance around VENA (Appendix A2), and in the coming years State Agencies (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:

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.

Additionally, information collected from in-person site visits under this revision will be compared to information collected during the currently approved WIC NATS remote site visits to explore similarities and differences between the remote and in-person nutrition services. This comparison is an agency priority because it will allow FNS to better understand if there were differences in service quality or participant and staff satisfaction with WIC during remote appointments under COVID-19 waiver flexibilities compared to traditional in-person clinic appointments. Specifically, data collected under this revision will be used to address two new research objectives:

5. Describe the nutrition assessment and benefit tailoring processes when conducted remotely and compare these to the same processes as they occur in an in-person setting.
6. Investigate participant and staff perceptions of WIC nutrition services when provided remotely and compare these to perceptions observed during in-person WIC services.

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 revision to the previously approved WIC NATS collection (OMB Control Number 0584-0663 WIC Nutrition Assessment and Tailoring Study; expiration date 04/30/2024). 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 during in-person clinic visits. 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. This proposed revision only includes data collection among WIC clinic staff and WIC participants. The study is not designed to be nationally representative, but rather to 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 Appendix A3. 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. In-Person Site Visit Data Collection Activity Summary

Data Collection Activity	Number and Type of Respondents	Purpose	Data Collection Mode
WIC Clinic Sites			
Site Director Interview Guide	30 WIC site directors	Describe unobservable variations in relevant clinic protocols and provide insight on promising practices and	Interview

(Appendix C1)		suggestions for improvements	
Nutrition Risk Assessment Observation Form & Identified Risks Data Collection Form (Appendix C2 & C2a)	510 appointments passively observed[1] 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 C3)	150 WIC nutrition assessment staff[2]	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
Clinic Site Observation Form (Appendix C5)	No respondent burden; passively collected through observation at 30 WIC clinic sites	Document observable information about key characteristics of the clinic environment	Direct observation
WIC Participants			
WIC Participant Interview Guide (Appendix C4; see Appendix C4a for Spanish translation)	300 WIC participants[3]	Describe participant perspectives and satisfaction with key aspects of the nutrition assessment and benefit tailoring process and outcomes	Interview (participant option for in-person or phone interview)

The in-person phase of site visits will utilize the same sample of 30 clinic sites recruited under the original WIC NATS collection (selection described in Appendix A3). Site visits will include an interview with the clinic site director (Appendix C1), direct observation of nutrition assessment appointments (Appendix C2), and interviews with up to 5 WIC staff per clinic site (Appendix C3). During the site visits, field researchers will also recruit an average of 17 WIC participants per clinic site to observe their nutrition assessment (Appendix C2), for a total of 510 WIC participants; we expect approximately 300 of these participants will complete a subsequent interview (Appendix C4).

[1] 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 C2a).
[2] 5 WIC nutrition assessment staff interviewed at each of the 30 clinic sites chosen for site visits (estimated).
[3] 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.

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. 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.

The study team will contact each of the 30 clinic sites previously recruited into the original WIC NATS sample by email (Appendix D1) to schedule an informational call (Appendix D2) to discuss the logistics of the in-person site visits, answer any questions, and schedule the site visit. Two trained field researchers will complete each of the 30 WIC clinic site visits. Prior to the site director interview (Appendix C1), the researchers will provide information about the study and ask the site director to provide their informed consent (Appendix D3). Likewise, WIC clinic staff will be given information about the study and asked to provide their informed consent (Appendix D4) prior to allowing the field researchers to observe their nutrition assessment appointments (Appendix C2) and participating in the staff interview (Appendix C3).

WIC participants will be provided an informational brochure about the study (Appendix D5). Those that express interest in participating in the study will be screened by the researchers (Appendix D6) and, upon review of the information, will be asked to provide their informed consent before proceeding with the observation (Appendix D7).

WIC participants are given the option of either completing their interview (Appendix C4) at the clinic immediately following their appointment or scheduling a phone interview for a later date. If the WIC participant schedules a phone interview, then the participant will receive a reminder text message ahead of the scheduled call (Appendix D8) and will receive a follow-up reminder call (Appendix D9) if the study team cannot reach them at the scheduled time. To facilitate informed participation among Spanish-speaking WIC participants, the following materials are also translated into Spanish: Study Brochure for WIC Participants (Appendix D5a); WIC Participant Screener (Appendix D6a); Informed Consent for Observation and WIC Participant Interview (Appendix D7a); WIC Participant Interview Guide (Appendix C4a); and the reminder text (Appendix D8a) and reminder call (Appendix D9a) for the WIC Participant Interview.

The study team will collect personally identifiable information (PII) from WIC participants during this collection. Participant names and mailing addresses will be collected so that the study team can send participant incentive gift cards (discussed below in Section A9). Telephone numbers will be collected to reach participants that elect to complete the WIC Participant Interview over the phone (Appendix C4). Dates of birth will be collected to calculate participant age in the study analysis. Names, dates of birth, addresses, phone numbers, or any other unique identifier, will not be linked to the data. See Section A10 for more information on measures to protect this data.

Frequency of information collected. This will be a one-time data collection. The frequency of 6 responses to Appendix D4 and 5 responses to Appendices C2a and C3 represent the number of clinic staff at each of the 30 clinics that will respond (e.g., an estimated 5 staff at each of the 30 clinic sites will respond to Appendix C3).

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.

The content of data collection instruments has not changed since the previous WIC NATS ICR was approved. The changes accounted for under this revision are as follows:

1. Burden associated with collections from State and local agencies was removed for the collection. These entities were involved in the original WIC NATS data collection, but they will not be included under this revision. See Section A15 for details on reduction in respondent burden.
2. The original WIC NATS data collection was approved for remote site visits. Under this revision, data collection instruments approved under the original WIC NATS data collection (Appendices C1-C5) will be used to collect information on WIC nutrition assessment services through in-person site visits.

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 was reduced where feasible in the initial phase of WIC NATS. Because the current proposed

revision depends on in-person observation and interviews, there will not be additional uses of technology to reduce burden in this phase of the study. Therefore, for this revision of the study, FNS estimates that none of the responses 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.

The topics addressed in this revision were covered under the remote site visit phase in the currently approved WIC NATS data collection. While some of the topics are duplicative, the operating context of the two phases differs substantially. Collecting comparable information from both remote and in-person nutrition services will allow FNS to compare outcomes of these two approaches and inform future guidance on the respective benefits and challenges of each approach. There is no other similar information collection. Every effort has been made to avoid duplication. FNS has reviewed USDA reporting requirements and FNS solely administers WIC. 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.

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 100 percent of WIC clinic sites (30 in total) to be small entities. Out of the total number of 1,050 respondents for the study, we expect 2.9 percent (30 in total) to be small entities. In order to minimize burden on these small entities, we are not including clinics from SAs that have recently transitioned to electronic benefits transfer (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. To minimize burden on WIC clinics, we will work with the site directors 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 flexibility in scheduling interviews.

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 ongoing 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 when conducted in-person. The data obtained through the study will help FNS to better meet the needs of WIC participants. All of the information collected under this revision is collected only once.

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.

Notice of this study was published in the *Federal Register* (Volume 86, Number 147, pages 41945-41948) on August 4, 2021. The public comment period ended on October 4, 2021. There were no comments submitted during the 60-day public comment period.

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.

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 F.

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 assessment and nutrition services process	651-201-3632
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 seeking public comment and expert input from the ERP review, the study team also consulted State level public health officials as a part of the State agencies' Institutional Review Board process between December 2020 and May 2021. State health officials reviewed the study plan, resumes of key research staff, and the content and burden of all data collection instruments and recruitment materials. See Table A8-2 for contact information of State agency officials consulted. The reviewers cleared all study materials with no substantive edits. One reviewer asked that the study team emphasize COVID-19 precautions in clinic site recruitment. The study team will tailor all discussions around COVID-19 precautions to meet the unique needs and requirements of each clinic site to the extent possible.

Table A8-2. State Agency Consultations

Name	Affiliation	Contact
Sundée Winder, Ph.D., MSPH	Louisiana Department of Health	225-342-8306
Socrates Touch, JD	Ohio Department of Health	614-995-0775
Bonnie Gaughan-Bailey, MPA, ASQ-CQIA	Florida Department of Health	850-245-4585

FNS also consulted with Jennifer Rhorer, Mathematical Statistician in the Methodology Division of the National Agricultural Statistical Service (NASS), for expert consultation on methodology and study design. NASS comments are included in Appendix H and FNS responses are included in Appendix I.

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 WIC clinics in the study. However, due to the burden of hosting site observations, 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. This gift was approved under the initial WIC NATS collection (OMB Control Number 0584-0663 WIC Nutrition Assessment and Tailoring Study; expiration date 04/30/2024).

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 by mail or via their choice of electronic payment platform (e.g., PayPal or Venmo). 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. While not considered an incentive, participants who do not provide telephone contact information and opt for a telephone interview 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 $20 incentive, the $10 reimbursement for cellphone minutes, and the offer of a pre-paid phone were all approved under the initial WIC NATS collection (OMB Control Number 0584-0663 WIC Nutrition Assessment and Tailoring Study; expiration date 04/30/2024).

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 WIC Food Package Costs and Cost Containment Study; Discontinued 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; Discontinued 5/31/2021) 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 National Survey of WIC Participants II; Discontinued 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.

The study will collect names, dates of birth, addresses, and phone numbers from WIC participants, as described above in Section A2. All participants that share personally identifiable information (PII) will be provided and asked to sign an informed consent form (Appendix D7/D7a). 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 C1, C3, and C4/C4a). All respondent data and audio recordings will be stored only

in a secure network folder, accessible only to members of the study team. If a participant refuses to allow the study team to record their interview, but still wishes to participate, then the interviewer will keep detailed notes from the interview. 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 G1). 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 G2. The study team will coordinate with state-level IRBs as required.

This ICR was reviewed by Michael Bjorkman, Privacy Officer in the FNS Information Management Branch. On December 3, 2021, the Privacy Officer determined that the WIC Participant Interview Guide (Appendix C4) required the inclusion of a Privacy Act Statement because it collects PII directly from participants. A Privacy Act Statement was added to both the English and Spanish language versions of the WIC Participant Interview Guide in response (Appendix C4/C4a).

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 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 revision to a currently approved information collection. This revision reduces the estimated burden to this data collection. While State agencies and local agencies participated

in the remote data collection, the collection activities for the in-person site visits do not collect information from them. As a result, they have been removed from the collection. Although the data collection from the in-person site visits actually adds burden to four currently approved elements of the collection: (1) direct observation of nutrition assessments, (2) interviews with clinic site directors; (3) interviews with clinic staff, and (4) interviews with WIC participants, this increase is offset by the removal of the State and local Agencies from this collection. This data collection includes an estimated 1,050 respondents, 4,865 responses, and 509.55 burden hours. Appendix B shows the estimates of the respondent burden for the proposed information collection. A summary appears below (the summary estimates listed here are an aggregate of the entire collection across all items and respondent groups; please see the OMB Burden Table in Appendix B for the item or respondent level information). These estimates are informed by the 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: 540 respondents and 510 non-respondents (1,050 Total)

Estimated Total Annual Responses from Respondents and Non-Respondents: 3,120 for respondents and 1,745 for non-respondents (4,865 Total)

Estimated Frequency of Responses per Respondent and Non-Respondent: 5.78 annually for respondents and 3.42 annually for non-respondents. The frequency across the entire collection is 4.63.

Estimated Time per Response per Respondent and Non-Respondent: 0.15 hours for respondents and 0.02 hours for non-respondents. The estimated time per response across the entire collection is 0.10.

Estimated Total Annual Burden Hours on Respondents and Non-Respondents: 480.41 hours on respondents and 29.14 hours for non-respondents

Grand Total Burden Estimate: 509.55 hours

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 clinics 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 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 $7,219.97. The estimates of respondent cost are based on the burden estimates and use the U.S. Department of Labor, Bureau of Labor Statistics, May 2020 National Occupational and Wage Statistics (available at: www.bls.gov/oes/current/oes_nat.htm). The estimated annualized cost includes 242.57 total burden hours for clinic staff (169.80 hours for WIC clinic staff employed by government agencies and 72.77 hours for WIC clinic staff employed by profit/non-profit businesses) at a wage rate of $14.40 for WIC clinic staff (job category “Healthcare Support Occupations” code #31-0000). The total annualized cost for WIC staff is $3,492.94. Adding in $1,152.67 (33%) to account for fully loaded wages ($3,492.94 x 0.33), the total annual cost for WIC staff is $4,645.61.

For WIC participants, the hourly wage rate used is $7.25, which is the Federal minimum wage for 2021 (https://www.dol.gov/agencies/whd/minimum-wage). The total annualized cost

for WIC participants is $1,934.42. Adding in $638.36 (33%) to account for fully loaded wages ($1,934.42 x 0.33), the total annual cost for WIC participants is $2,572.78.

The total estimated cost for the entire collection is $5,428.55. Adding in $1,791.42 to account for fully loaded wages ($5,428.55 x 0.33), the total annual cost for the entire collection is $7,219.97.

Table A12-1. Summary of Estimated Total Burden

Respondent Type	Respondent Description	Sample Size	Responsive					Non-responsive					Total Burden Hours	Total Annualized Cost
			Number of Respondents	Frequency of Response	Total Annual Responses	Total Burden Hours	Average Hours per Response	Number of Non-Respondents	Frequency of Response (Annual)	Total Annual Responses	Total Burden Hours	Average Hours per Response		
State and Local Gov't	WIC Clinic	21	21	21.00	441	169.80	0.39	0	0.00	0	0	0.00	169.80	$ 2,445.06
Profit/Non-profit Business	WIC Clinic	9	9	21.00	189	72.77	0.39	0	0.00	0	0	0.00	72.77	$ 1,047.88
Individuals and Households	WIC Participants	1,020	510	4.88	2,490	237.84	0.10	510	3.42	1,745	29.14	0.02	266.98	$ 1,935.62
TOTAL REPORTING BURDEN		**1,050**	**540**	**5.78**	**3,120**	**480.41**	**0.15**	**510**	**3.42**	**1,745**	**29.14**	**0.02**	**509.55**	**$ 5,428.55**
Additional 33% to Account for Fully Loaded Wage Rate														**$ 1,791.42**
TOTAL REPORTING BURDEN (FULLY LOADED)														**$ 7,219.97**

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 $611,911, or $2,447,644 over the four year life of the project, including contractor and Federal government employee costs.

The total estimated cost for contractor services is $2,275,956 over four 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 1 at $51.18 per hour. The estimated time that will be spent on the project by this individual is an average of 510 hours ($26,102) annually. Adding in $8,614 (33%) to account for fully loaded wages ($26,102 x 0.33), the total annual cost for the FNS Social Science Research Analyst is $34,716. Additionally, the Lead Social Science Analyst who provides oversight for work conducted by the Research Analyst is estimated at GS-14, step 1 at $60.49 per hour. The estimated time allocated to this project is 102 hours per year ($6,170). Adding in $2,036 (33%) to account for fully loaded wages ($6,170 x 0.33), the annual

cost for the Lead Social Science Analyst is $8,206. Total Federal employee costs are thus estimated at $42,922 annually, or $171,688 total over four years. Federal employee pay rates reflect the general schedule salary table for 2022 for the Washington, DC, metro area locality (provided by the OPM 2022 General Schedule, available at: https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2022/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 is a revision of a currently approved data collection. This information collection is currently approved with 867 total annual burden hours and 6,496 total annual responses. The proposed revision will reduce the total burden hours by 357 hours and the total responses by 1,631 responses. The overall reduction in the burden hours and responses is due to program changes and adjustments. The WIC State agencies and the local agencies were removed from this study since data will not be collected from these entities as part of the in-person site visits. This removed 358 hours and 1,792 responses from the collection. Changes in the number of WIC participants increased the burden by 1 hour and 161 responses due to an adjustment (this increase, however, was offset by the reductions resulting from the program change). Due to these program changes and adjustments, FNS estimates that this revision will have 510 burden hours and 4,865 responses.

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 collected under this revision will be combined with the SA, LA, site visit data collected under the currently approved WIC NATS information collection. The updated WIC NATS dataset 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	• Descriptive analyses of the basic components of the nutrition assessment process
	LA Procedures/tools	• Qualitative review resulting in flow chart of nutrition risk process
	LA web survey	• Descriptive analyses characterizing nutrition risk procedures • Quantitative analysis using frequencies of policies and procedures crossed by LA characteristics
	Observations and interviews	• 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	State WIC plans	• Descriptive analysis of tailoring procedures
	LA Procedures/tools	• Qualitative review resulting in flow chart of tailoring process

Objective	Source	Analysis
collection of nutrition assessment information to tailor Program benefits.	MIS data	• 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	• 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 perceptions, and flow and efficiency	MIS data	• Quantitative analysis of the association between clinic characteristics and increased probability of tailoring
	Observation	• Creation of flow chart of clinic flow and time estimates
	Interviews	• Descriptive analysis of staff and participant experiences, perceptions and satisfaction • 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	• 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
5. Describe the nutrition assessment and benefit	State WIC remote services	• Basic components of the nutrition assessment process and tailoring

Objective	Source	Analysis
tailoring processes when conducted remotely and compare these to the same processes as they occur in an in-person setting.	policy and procedures	procedures in the remote environment
	LA Procedures/tools, addressing remote processes	• Flow chart of nutrition risk and benefit tailoring processes during remote service provision
	Observations and interviews	• Augmented flow chart of nutrition risk and benefits tailoring processes with details • Comparison of on-the-ground practices to existing guidance • Variation in practice between clinics and within clinics
	In-person and remote analysis findings	• Comparison of finding from remote and in- person analysis of nutrition assessment and benefit tailoring processes
6. Investigate participant and staff perceptions of WIC nutrition services when provided remotely and compare these to perceptions observed during in-person WIC services.	Observation	• Time estimates
	Staff interviews Participant interviews	• Description of staff and participant experiences, perceptions and satisfaction • Association between these factors and the nutrition risk process and tailoring • Effectiveness of tailoring in terms of the association between tailoring and satisfaction • Association between nutrition risk assessment practices for tailoring and staff and participant satisfaction • Commonality of suggestions for improvements
	In-person and remote analysis findings	• Comparison of findings from remote and in-person analysis of staff and participant perceptions and satisfaction

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

Table A16-2. Project Time Schedule

Study activity	Schedule
Conduct In-Person Site Visits	Starting 1 week post-OMB approval and lasting 16 weeks
Analysis and Prepare Data File	Starting 6 months after OMB approval

Study activity	Schedule
Prepare Final Report and Briefing Materials	Starting 9 months after OMB approval
Final Report Complete	Mid-2023

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 control 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.