

SUPPORTING STATEMENT PART B FOR

**Revision to OMB Number 0584-0580
WIC Infant and Toddler Feeding Practices Study-2 (WIC ITFPS-2):
Year 9 Extension**

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12/14/2020**

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Part B

Collections of Information Employing Statistical Methods

B.1 Respondent Universe and Sampling Methods

Describe (including a numerical estimate) the potential respondent universe and any sampling or other respondent selection method to be used. Data on the number of entities (e.g., establishments, State and local government units, households, or persons) in the universe covered by the collection and in the corresponding sample are to be provided in tabular form for the universe as a whole and for each of the strata in the proposed sample. Indicate expected response rates for the collection as a whole. If the collection had been conducted previously, include the actual response rate achieved during the last collection.

Respondent Universe

This is a revision to an approved study, the Special Supplemental Nutrition Program for Women, Infants and Children (WIC) Infant and Toddler Feeding Practices Study-2 (WIC ITFPS-2) (OMB No. 0584-0580, expiration date: 03/31/2022). This revision is informally called the “Year 9 Extension” and referred to herein as the Y9 Extension. The Y9 Extension of WIC ITFPS-2 encompasses two (2) activities related to WIC ITFPS-2. The first activity is the Y9 Follow-up Study or Y9FU Study, which extends the data collection timeframe of WIC ITFPS-2 to study child age 9 years. The second activity is the Lost to Follow-up Study or L2FU Study, which involves collecting and examining WIC administrative data on former WIC ITFPS-2 participants. The respondent universe for the Y9 Extension includes children enrolled in the

base cohort of WIC ITFPS-2, the 27 currently participating State WIC Agencies, and the participating 80 WIC clinic staff. WIC ITFPS-2 uses a longitudinal design, and the revision will gather data about 9-year-old children via a telephone interview with their mothers/caregivers (Appendix F1, F2, F3, and F4) and will collect children’s height and weight data around age 9 years from direct measurements at WIC site offices or by other health-care professionals (Appendix H1,H2). We will attempt to interview mothers/caregivers within 14 days prior to the child’s birthday to 28 days after the child’s birthday. Since the children’s birthdays are spread out, the interview period will be from April 2022 to about August 2023. The mother/caregiver will return the height and weight measurement cards (Appendix H1, H2) at their convenience which may be before or after the phone interview(s). Additionally, the study will collect administrative data electronically from the 27 WIC agencies currently participating in the study.

Table B1.1. Respondent Universe, Samples, Expected Response Rates for Year 9, and Response Rates for Most Recent Completed Activity

Respondent	Universe	Initial Sample	Expected Response Rate Year 9	Target completed cases Year 9	Response Rates for Most Recent Completed Activity
Year 9 Follow-up Study					
Individuals/ Households					
Telephone Interview	442,905	4,046	26%	1,068	65% ^a
Replicate Dietary Intake Interview	442,905	160	67%	107	58% ^b
Height/Weight Measurement	442,905	1,068	67%	715	65% ^c
State & Local Government					
State WIC Staff	27	27	100%	27	100% ^d
WIC Site Staff	80	80	100%	80	100% ^d
TOTAL	888,822	6,339		3,719	

Lost to Follow-up Study						
State & Local Government						
State WIC Staff	27	27	100%	27		NA

^a The most recent completed interview is the 72-month.

^b The most recent completed replicate dietary intake was done at 72-months,

^c The most recent completed collection of height and weight data was at 60-months.

^d The most recent completed webinar with WIC staff was completed at the time of the Age 6 Extension

^e This is a new activity. A 100% response rate was obtained for a similar activity (administrative data on the study children) at child age 6, 12, 24, 36, and 48 months

Our base cohort sample was designed to obtain minimum detectable differences (MDDs) of 5 to 10 percentage points between subgroups of interest at the originally planned final measurement of 24 months. We project that during the period of the extension our current sample will yield 1,068 Y9 telephone interviews, assuming 50 percent attrition from the actual response to the 72-month interview.

Table B1.2. Response Rate for the 72-month Interview

Mother child events/interviews		Completed interviews	Rate
Cohort	Total live infants consented & enrolled pre/post-natal ^a	4,046	
	72-month Interview	2,135 ^b	

^a Total live births in Base study cohort

^b Expected number of completed interviews was 1,901

For estimating generic characteristics with 20 percent, 40 percent, and 50 percent prevalences using the interview data, our current cohort sample is expected to yield confidence interval half-widths ranging from 2.9 to 11.6 percentage points for 95 percent confidence intervals, and from 2.5 to 9.7 percentage points for 90 percent confidence intervals, and is expected to yield CVs ranging from 3.7 percent to 23.7 percent.

WIC program representatives in the WIC State and Local Agencies will provide important assistance to the study. A total of 27 State Agencies and 80 of their WIC Sites were originally selected as the recruitment sites for the study. Staff at these WIC sites will continue to support the study by conducting height and weight measurements on the study children, all of whom are former WIC participants. Moreover, the 27 State WIC administrators and 80 local WIC site staff will continue to support data collection efforts for the Y9 Extension through providing updated contact information for Y9FU Study participants still enrolled in WIC for another child. The 27 State Agencies will provide administrative data on the WIC

participation patterns on the study participants who left the study in the first five years.

Sampling Methods

The Y9 Extension will continue to collect data from both core and supplemental participants who were recruited in the base study.¹ All participants still enrolled in the Y9FU Study at the beginning of the field period April 2022, for the Y9 interview will be eligible for subsampling for the replicate dietary intake (AMPM) interview. Before the first Y9 interview is fielded, 15 percent of participants will be randomly selected for the replicate AMPM interview with the goal of obtaining a completed replicate AMPM interview for 10 percent of the sample who complete the initial AMPM. Some participants sampled for the replicate AMPM will not complete the initial AMPM at the Y9 interview, and thus will be ineligible for the replicate interview. We expect that around 67 percent participants who complete the initial AMPM will also complete the replicate interview.

The WIC ITFPS-2 enrolled 4,367 mother/child dyads during the recruitment period of July-November 2013. As the study progressed, study participation rates decreased. Some participants were released from the study because of

¹ The base study included a core sample and a supplemental sample. Through the 24-month interview the core sample was interviewed more frequently (up to 11 times) than the supplemental sample (up to 4 times). Since then, both the core and supplemental samples have participated in every interview.

ineligibility (e.g., pregnancy loss, child decease, foster care). However, the majority of study nonparticipation occurred either because the participant refused or the study was unable to contact them even after exhaustive efforts. At the close of the 60-month interview, there were about 1,093 study-eligible participants who left the study during the first 5 years when the child would have been age-eligible for WIC. This is the group of former WIC ITFPS-2 participants that is the focus of the L2FU Study.

Response Rates

We have undertaken many steps, both in already completed activities and for future activities, to ensure high response rates and reduce the risk of nonresponse bias. Full time study liaisons (SLs) serve as personalized points-of-contact for our participants. We provide incentives for study activities to communicate that we continue to value our participants. We strive to ensure flexibility in the time at which interviews are completed, and to express our appreciation of participants through thank-you notes and recognizing birthdays. These efforts are described further in Section B.3.

Table B1-3 lists the response rates of the interviews throughout the study.

Table B 1-3 Interview Response Rates

Interview	Weighted response rate, conditional on having been consented and enrolled
Prenatal	88.2%
1-month	85.2%
3-month	88.4%
5-month	82.6%
7-month	79.9%
9-month	78.9%
11-month	74.6%
13-month	72.2%
15-month	66.2%
18-month	64.3%
24-month	64.6%
30-month	67.8%
36-month	69.2%
42-month	70.0%
48-month	68.5%
54-month	68.7%
60-month	68.4%
72-month	58.2%

B.2 Procedures for the Collection of Information

Describe the procedures for the collection of information including:

- **Statistical methodology for stratification and sample selection,**
- **Estimation procedure,**
- **Degree of accuracy needed for the purpose described in the justification,**
- **Unusual problems requiring specialized sampling procedures, and**
- **Any use of periodic (less frequent than annual) data collection cycles to reduce burden.**

The Y9 Extension will involve: (1) conducting one additional follow-up telephone interview with the mother/caregiver when the study child is 9 years old; (2) conducting a second, replicate dietary intake interview with a 10 percent subsample of caregivers who complete the first interview, (3) obtaining height and weight measurements around the ninth birthday of each child from caregiver's provision to the study of healthcare professional measurements, or from direct measurements taken at WIC sites, and (4) Obtaining WIC administrative data on the WIC participation patterns of participants who left WIC ITFPS-2 in the first five years of the main study, the period when the study child would have been age-eligible for WIC .

Statistical Methodology for Stratification and Sample Selection

The Y9 Extension will continue to collect data from participants who were recruited in the base study, the first two years of WIC ITFPS-2 (ICR Reference No. 201208-0584-002). A description of the statistical

methodology for stratification and sample selection for the base study sample is given in Appendix Z.) A random sample of 15 percent of all participants who complete the first Y9 interview will be selected for the replicate AMPM interview.

Estimation Procedures

The estimation procedures for the extension are the same as those for the base study. We plan to use standard design-based methods for estimation and variance estimation that will lead to confidence intervals on means and percentages, and hypothesis tests on contrasts of means and percentages. We will prepare a separate set of cross-sectional weights for the Y9 interview. As with previous interviews in the base study and previous extensions, the only participants that will receive a positive weight for the Y9 interview will be those who responded to the Y9 interview. Weighting will be used to adjust for nonresponse to the initial interview and to adjust for attrition and other nonresponse that results in failure to complete the particular interview (in this case, the Y9 interview). Additionally, a few sets of longitudinal weights (which weight up respondents to particular combinations of interviews) may be developed for specific analyses. Imputation will be used to fill in scattered item nonresponse within completed interviews. We will limit imputation to a few select sociodemographic characteristics of participants. The imputed characteristics will be used in conjunction with the unimputed responses to define key sociodemographic subgroups. When defining key subgroups, sample size will be considered in order to ensure sufficient size for comparisons on broad

outcomes of interest (e.g., mean vitamin D intake). As with weighting, a carefully designed imputation procedure will reduce bias due to item nonresponse (i.e., missing data for particular survey items among those who respond to a given interview).

We will develop sampling weights aimed at yielding nearly unbiased estimates of population parameters. Although the base study includes separate sets of weights for analyses of the core sample by itself, the Y9 interview will be administered to both the core and supplemental samples. Thus, the cross-sectional weights for this extension will be developed for joint analyses of the core and supplemental sample samples. Details of the calculation of the weights and of nonresponse bias analysis are found in Appendix AA.

Degree of Accuracy Needed for the Purpose Described in the Justification

The sample size requirements for the WIC ITFPS-2 base study were determined based on power projections and precision requirements for estimates at 12 and 24 months. As noted in Section B.1, for generic characteristics with 20 percent, 40 percent, and 50 percent prevalences, the projected sample sizes at age 9 years are expected to yield confidence interval half-widths ranging from 2.9 to 11.6 percentage points for 95 percent confidence intervals, and from 2.5 to 9.7 percentage points for 90 percent confidence intervals, and are expected to yield CVs ranging from 3.7 percent to 23.7 percent (for the range of estimates considered).

The mathematical formula used to compute the half-widths of the confidence intervals is the following:

$$H_{1-\alpha} = z_{\alpha} \sqrt{\frac{P(1-P)}{n}}$$

where

$H_{1-\alpha}$ = half-width of 100(1- α)% confidence interval;

z_{α} is the value such that 100 $\left(\frac{\alpha}{2}\right)$ % of the standard normal distribution falls above that value;

P is a hypothetical value of the population proportion; and

n is the expected effective number of respondents (to the Y9 interview).

Unusual Problems Requiring Specialized Sampling Procedures

No specialized sampling procedures are involved.

Any use of Periodic (less frequent than annual) Data Collection

Cycles to Reduce Burden

All data collection activities described in this extension will occur within a 15-month period. The study design requires that participants be interviewed at multiple times, as described in Section B.1.

Procedures for Conducting Interviews

Participants will be contacted and interviewed using the same procedures that have proven successful thus far for them in this longitudinal study. Participants will receive an advance letter informing them of their upcoming Y9 interview (Appendix E1, E2). The window for the interview is six weeks long, and during that time highly trained interviewers, most of whom have been with the study since its inception, will make outbound calls to participants during varying days and time periods. Participants are also offered the opportunity to make inbound toll-free calls to complete the interview at their convenience, or they can request outbound appointment calls (see Section B.3 for further details). As is sometimes necessary with parents of young children, interviewers are trained to allow breaks for interruptions in the participants' environments, or to schedule call-backs to complete interviews not finished due to interruptions.

Estimation and Calculation of Sampling Errors

All WIC ITFPS-2 data files, including those associated with this extension, will contain the information necessary for analysts to use either replication or Taylor series linearization methods to compute standard errors

of estimates. For this study, 40 replicates were created, and the replication approach used was a modified balanced repeated replication (BRR) method suggested by Fay,² with $K=0.3$ (K is the perturbation factor known as “Fay’s factor”). To appropriately reflect the effects of the various stages of weighting on the variances of survey estimates,³ the procedures used to compute the full-sample weights will be repeated for each of the replicates.

B.3 Methods to Maximize Response Rates and to Deal with Issues of Nonresponse

Describe methods to maximize response rates and to deal with issues of non-response. The accuracy and reliability of information collected must be shown to be adequate for intended uses. For collections based on sampling, a special justification must be provided for any collection that will not yield “reliable” data that can be generalized to the universe studied.

WIC State and Local Administrators and Their WIC Sites

The 27 State Agencies and 80 WIC sites recruited for the base study will be invited to attend a 1-hour webinar that will share information on the study extension and highlight FNS-cleared key study findings to date (Appendices N1, N2, O). After the webinar, individual conference calls will be made with each State Point-of-Contact and representatives from the original 80 sites to discuss the study extension in more detail, including the logistics of conducting measurements of height and weight at individual WIC sites and

²Judkins, D. (1990). Fay’s method for variance estimation. *Journal of Official Statistics*, 6, 223-239.

³Ernst, L.R., and Williams, T.R. (1987). Some aspects of estimating variances by half-sample replication in CPS. *Proceedings of the Section on Survey Research Methods of the American Statistical Association*, pp. 480-485.

providing the administrative data on participants who left the study in the first five years (Appendix P). As was done with the Age 6 Extension (ICR Reference Number 201810-0584-001), we will discuss the possibility of participants returning to any WIC site in the State to have their child's height and weight measured around 9 years of age.

Caregivers of Former WIC Children

Successful retention of our sample for the extended study hinges on our ability to make participants want to continue in the study and our ability to locate participants over time. While many participants become more committed to the study with each interview they complete, others experience survey fatigue which may overwhelm their interest in continuing. We will employ these strategies to retain as many members of the sample as possible through the Y9 interview:

1. **Keep Participants Informed and Excited About the Study.** At the time of the 72-month interview, we informed the participants that we will contact them again if they are selected for another study and the information was received with enthusiasm by most of the participants. The possibility of re-engaging was also emphasized in our *ad hoc* interactions. Once OMB approval is obtained, we will send participants a letter about the study extension. We will include two copies of the study consent and a Contact Information Form (CIF) (Appendix C1/C2). Participants will be asked to return a signed consent and the completed CIF in the provided postage-paid Business Reply Envelope.
2. **Continue to Obtain Periodic Contact Information Updates.** We will encourage participants to notify us when their contact information

changes by sending out contact update mailings about once every four months until the Y9 interview. We will ask participants to provide their own current contact information and provide contact information for two additional persons (preferably family members). Upon receipt of the CIF, we will provide a \$10 check to the participant. Respondents will get electronic reminders by email and text, as well and can follow a link where they can complete the form online (Appendix D1/D2). Study Liaisons will follow up with the participants not returning the CIF and will complete the CIF over the phone.

3. **Utilize Study Liaisons Who Serve as the Westat Point-of-Contact for the Study.** Full-time study liaisons (SLs), who have been the points-of-contact for our participants since the start of the study, will continue to answer participant questions, offer encouragement for continued study participation, remind participants about expiring interviews (Appendix G1a, G1b), trace participants whose phone numbers and/or addresses have changed (Appendix G2a, G2b), help participants identify the nearest WIC office for height and weight measurements (Appendix I1, I2) and encourage them to send copies of measurements from recent health care provider visits (Appendix I1, I2). SLs will also conduct refusal conversion, following up on standard study refusal conversion letters (Appendices G3a, G3b G4a, G4b), as their longstanding relationships with participants help them in discussing and addressing personal circumstances that may interfere with participation.
4. **Increased incentive from the 72-Month Interview and increased Child Measurement as at 72-Months.** We will slightly increase the incentive for the Y9 interview from \$60 to \$70 to help combat survey fatigue, and continue to provide incentives to address personal cellphone costs for interviews (\$10). We will increase the incentive for taking the child for measurements by \$10 (\$70 plus \$10 for transportation costs), recognizing the extra effort and commitment

required to take a child who is likely to be in school for much of the day to be measured. Participants will receive their interview and measurement card incentives via gift cards.

5. **Attempt Interviews at Different Times of the Day and Week.** We will use telephone call scheduling procedures to call numbers at different times of the day (between 9 am and 9 pm in the participant's time zone) and week (Sunday through Saturday) during the 42 day window, to improve the chances of interviewing participants. When participants cannot be reached, we will leave voicemail messages periodically and provide a toll-free call-in number that participants can use to complete the interview (Appendices G5a, G5b, G6a, G6b).
6. **Encourage Participants to Call In.** We will send an advance letter a few weeks before the start of the interview to remind participants about the upcoming interview, and to provide the toll-free call-in number and hours the telephone center is open to encourage them to call in to complete the interview at their convenience (Appendix E1, E2).
7. **Send Texts and Reminder Emails 10 Days After Start of the Window.** We will send out reminder texts or emails on the 10th day of the interviewing window to participants who have not yet completed their interviews (Appendix G1a, G1b).
8. **Contact Participants Whose Interview Windows are Expiring.** The SLs will continue to make reminder calls and send reminder emails and texts (Appendix G1a, G1b, G4a, G4b) to participants whose interview windows are within 2 and then 1 week of expiring.
9. **Send Birthday Cards to Participating Caregivers and Children.** As part of the ongoing relationship building, the study liaisons will send birthday cards, either printed or electronic, to participants (Appendix

L1, L2). When the children reach age 9, we will also send birthday cards to the children (Appendix M1, M2).

10. **Send Thank-you notes.** We will send electronic thank-you notes after the Y9 interview, thanking participants for their continued engagement (Appendix K1, K2).

Details of projected response rates are discussed in section B.1. We experienced high cooperation rates for interviews that have been completed so far, with an overall cooperation rate of 79.5%. Given these high cooperation rates and the steps listed above to secure continued participation, we have good reason to expect that we will achieve the response rates described with no need for back-up plans.

Nonresponse Bias Analysis

The projected response rate for the Y9 interview is 50 percent. To the extent that respondents to the Y9 interview are systematically different from the population as a whole with respect to characteristics used in an analysis, the potential for nonresponse bias exists. Statistical methods used to compensate for missing data (weighting and imputation) aim to reduce nonresponse bias. Because there is generally no way to directly measure the difference in key survey characteristics between respondents and the population as a whole, various methods have been developed that aim to assess the potential for nonresponse bias.

We will use the approach proposed in the base study and the Age 3, Ages 3.5-5, and Age 6 Extensions (ICR Reference No. 201208-0584-002, 201306-0584-008, 201404-0584-005, 201408-0584-007, 201601-0584-008, and

201810-0584-001 ; Expiration date: 03/31/2022). to examine bivariate cross tabulations of data available for the eligible, enrolled cohort by response status for the Y9 interview to check for evidence of nonresponse bias. We also plan to compare unadjusted estimates (i.e., computed using weights that do not include the adjustment for nonresponse to the particular wave) to adjusted estimates. We will identify a few key variables (e.g., proportion of youth who are food insecure or proportion of youth who are overweight) to be used in these bias analyses.

The L2FUStudy is, by its very nature, a nonresponse bias analysis. However, because nonresponse to Westat's data request for information on former WIC ITFPS-2 participants is expected, we will also conduct a separate nonresponse bias analysis for the L2FU Study, using the same methods described above for the Y9 interview. Details of the assessment of nonresponse bias approach for the base study are found in Appendix AA of this submission, a reprint of an appendix originally submitted with the supporting statement for the base study, ICR Reference No. 201208-0584-002; Expiration date: 05/31/2016.

B.4 Test of Procedures or Methods to be Undertaken

Describe any tests of procedures or methods to be undertaken. Testing is encouraged as an effective means of refining collections of information to minimize burden and improve utility. Tests must be approved if they call for answers to identical questions from 10 or more respondents. A proposed test or set of tests may be

submitted for approval separately or in combination with the main collection of information.

The majority of items that will be included in the Y9 interview have either been cognitively tested for previously approved interviews on this study, or drawn from other established studies, including the U.S. Department of Agriculture's (USDA's) Automated Multiple Pass Method, a well-validated 24-hour dietary recall module that comprises more than half of the interview. A small number of new questions have not been pretested. Instead, new or modified items have undergone review by an expert survey methodology team to ensure methodological soundness and minimized burden on participants. Testing was done through simulation to evaluate timing and flow of the Y9 interview, confirming that the flow is logical and the estimated timing is accurate.

B.5 Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

Provide the name and telephone number of individuals consulted on statistical aspects of the design and the name of the agency unit, contractor(s), grantee(s), or other person(s) who will actually collect and/or analyze the information for the agency.

Individuals consulted on statistical aspects of the design are listed below.

Westat staff will be responsible for the collection and analysis of the study's data, in coordination with FNS.

Table B5.1. Individuals consulted on statistical aspects and individuals collecting and analyzing data

Name/ Title	Affiliation	Telephone number	e-mail
Janice Machado Senior Study Director, Project Director	Westat	240-314- 2480	JaniceMachado@Westat.com
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Jill DeMatteis Associate Director, Senior Statistician	Westat	301-517- 4046	jilldematteis@westat.com
Laurie May Vice President TBD	Westat NASS		LaurieMay@Westat.com
Amanda Reat COR, Special Nutrition Evaluation Branch, Office of Policy Support	USDA/ FNS	703-305- 2539	Amanda.Reat@usda.gov
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David Hancock (NASS OMB Clearance Officer) Peter Quan Alison Black Beth Schlein Linette Lanclos Bayazid Sarkar Duan Franklin	National Agricultural Statistics Service (NASS)	202-690- 2388	david.w.hancock@usda.gov