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FINAL Research and Analysis Plan
Deliverable 7b

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Study Overview 1

Many important developments in recent years concerning the Food and Nutrition Service's Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) program necessitate research to understand the nutritional intake and feeding patterns of infants and toddlers in WIC, including those associated with early determinants of obesity, in order to design appropriate and effective prevention strategies aimed at improving the health of young children. These developments include changes in the WIC participant population, changes in the program and the environment in which it functions, increasing rates of obesity among pregnant mothers and the very young, growing numbers of WIC mothers employed outside the home, and more than 43 percent of households that receive WIC benefits are food insecure.[1] The number of persons served by the WIC program has increased steadily from less than 100,000 in 1977 to almost 9 million today, of which about half are children age 1 to up to 5 years old and the other half about equally split between pregnant women and infants. In 2010, more than half of all pregnant women and their infants, and about 25 percent of all preschool children in the United States benefited directly from the WIC program.

To address this need for updated research, FNS has funded the WIC Infant and Toddler Feeding Practices Study (WIC ITFPS-2). The ITFPS-2 is designed to measure the feeding practices employed by caregivers and the nutrition outcomes of children who participate in WIC. By capturing data on caregivers and their children over the first two years of the child's life, the study will inform a series of research questions regarding feeding practices, the impact of WIC services on those practices, and the health and nutrition outcomes of children on WIC. Additionally, the study will update past analyses to assess changes in behaviors and trends that may have occurred over the past 20 years since the last major study of the diets of infants and toddlers who were WIC participants was conducted.

The study team includes several partners:

- Westat, the prime contractor, will lead the sampling, instrument design, all stages of data collection, and analysis associated with feeding practices and childhood nutrition.

[1] Coleman-Jensen A., Nord M, Andrews M, Carlson S. Household food insecurity in the united States. Economic Research Report #141, September 2012. http://www.ers.usda.gov/media/884525/err141.pdf)

- Dr. Gail Harrison, University of California Los Angeles (UCLA), is the Principal Investigator responsible for conceptual and scientific development of the study.
- Altarum Institute will prepare the sampling frame of WIC State and local agencies, and lead the instrument design and data collection associated with WIC state and local agency staff.
- Dr. Shannon Whaley, Public Health Foundation Evaluation (PHFE-WIC), will provide expertise in instrument design and operations.
- The Center for Weight and Health, UC Berkeley, will contribute to instrument development and the conceptual and scientific development of child weight and health.
- Dr. Jane Heinig of UC Davis, and Dr. Leann Birch of Penn State University, will serve as consultants to provide expertise in WIC breastfeeding/nutrition education and infant feeding practices and baby behaviors.

In addition to the study team, a Peer Advisory Panel (PAP) was convened to provide external expertise to ensure the study is temporally relevant and that the study findings will make meaningful contributions to FNS and to the WIC community. The six members of the PAP include Maureen Black, University of Maryland School of Medicine; Sally Findley, Mailman School of Public Health Columbia University; Laurence Grummer-Strawn, Nutrition Branch, Centers for Disease Control and Prevention; Suzanne Murphy, University of Hawaii Cancer Center; Zoe Neuberger, Center on Budget and Policy Priorities; and Peggy Trouba, office of Family Health, Nebraska Health and Human Services.

The Research Plan is divided into eight chapters. The remainder of this chapter describes the main objectives and presents an overview of the study design. Chapter two, **Conceptual Models Informing Study Analyses and Data Collection**, describes the two models that drive the study (Breastfeeding/Early Feeding Practices and Early Childhood Weight Gain) and guide the analysis and modeling. The third chapter, **Develop and Pretest Instruments**, briefly summarizes the content of the data collection instruments and sources, and the plans for testing the instruments. The details of instrument content can be found in the Draft Database Plan (Deliverable10a) and Draft Instruments (Deliverable 11a); and a description of the pre-testing protocols can be found in the Final Pre-test Memo (Deliverable 9b). The next chapter**, Data Collection,** describes our approach for selecting and recruiting WIC State and local agencies and recruiting and enrolling WIC participants at service sites; and the protocol for conducting key informant in-depth interviews, web surveys of WIC clinic staff, and telephone interviews with WIC participants. This chapter also includes our methods for obtaining and abstracting birth hospital records and WIC and provider medical records, and our plan for directly collecting weight and length of infants/toddlers who have

left WIC and for whom we have no data. Chapter five, **Create Data Files**, provides an overview of data flow and a description of data cleaning and editing; and chapter six explains our proposal for **Weighting, Nonresponse Bias Analysis, Missing Data Compensation, and Variance Estimation**. Chapter seven, **Analysis**, lists in detail the analyses we plan to conduct that will compare current findings to relevant past work and to current objectives and standards; and the final chapter, **Analysis Reports,** provides a brief summary of the analytical report schedule and the content of each report.

1.1 Objectives

The seven primary objectives for the ITFPS-2 include:

- Update results of data collected in WIC Infant Feeding Practice Study-1 (IFPS-1).
- Compare new findings with other major studies (WIC IFPS-1, FDA IFPS, and the Gerber/Nestle 2002 and 2008 Feeding Infants and Toddler Studies (FITSFITS).
- Assess effectiveness of different education and breastfeeding promotion approaches in achieving recommended feeding patterns and behaviors.
- Assess conditions of overfeeding, overconsumption, underfeeding, and inappropriate feeding.
- Identify nutrition education influences.
- Assess impact of WIC food packages on outcomes.
- Determine changes in maternal feeding practices and behaviors over time as infants and toddlers transition into or out of WIC.

We will answer 60 research questions articulated in the RFQ to meet these objectives. Table 7-2 in the Analysis section presents the data source for each analytic table by topic area based on the 60 research questions. Appendix A provides a summary of WICIFPS-1 analyses that will be repeated; Appendix B presents our proposed analyses for answering each research question; and Appendix C presents example tables by sociodemographics.

1.2 Overview of Study Design

The study design is heavily predicated on the designs used for IFPS-1 and FDA IFPS- II which are the two major previous longitudinal feeding practice studies. Building on the past longitudinal work maximizes the comparability between current study data and past work which facilitates assessing changes over time. We have also utilized aspects of the Feeding Infants and Toddlers Study (FITS) to address nutrition and feeding practices of toddlers. Additionally, we leverage many of the approaches previously used, such as rotating question modules, to ensure study efficiency. At the same time, we use some alternative approaches, such as onsite-recruiting of participants, to address challenges that occurred in the past. The current study also has a broader scope than the past longitudinal work in that it includes both infant and toddler feeding practices through 24 months and addresses new issues that have emerged such as the precursors to early childhood obesity.

Our study is a hybrid design, incorporating a core longitudinal sample (the "core" sample) and a supplemental cross-sectional sample (the "supplemental" sample) to ensure precision in estimates at key time points. The core longitudinal sample of women and their infants will be enrolled in the study as they enroll in WIC (either prenatally or before their infant is 2.5 months old if they did not enroll prenatally). They will be followed until the infants are 24 months old, with up to 11 interviews occurring prenatally, and at 1, 3, 5, 7, 9, 11, 13, 15, 18, and 24 months. The supplemental cross-sectional sample will also be recruited as the women and their infants enroll in WIC. This sample will be interviewed at four key time periods (1 or 3, 7, 13, and 24 months). We will collect birth hospital records and WIC record data at 7, 13, and 24 months for both samples. Concurrent with the start of WIC participant data collection, we will also collect data on WIC program features and personnel through a survey of WIC service site staff and key informant interviews at the State and Local levels.

Conceptual Models Informing Study Analyses and Data Collection 2

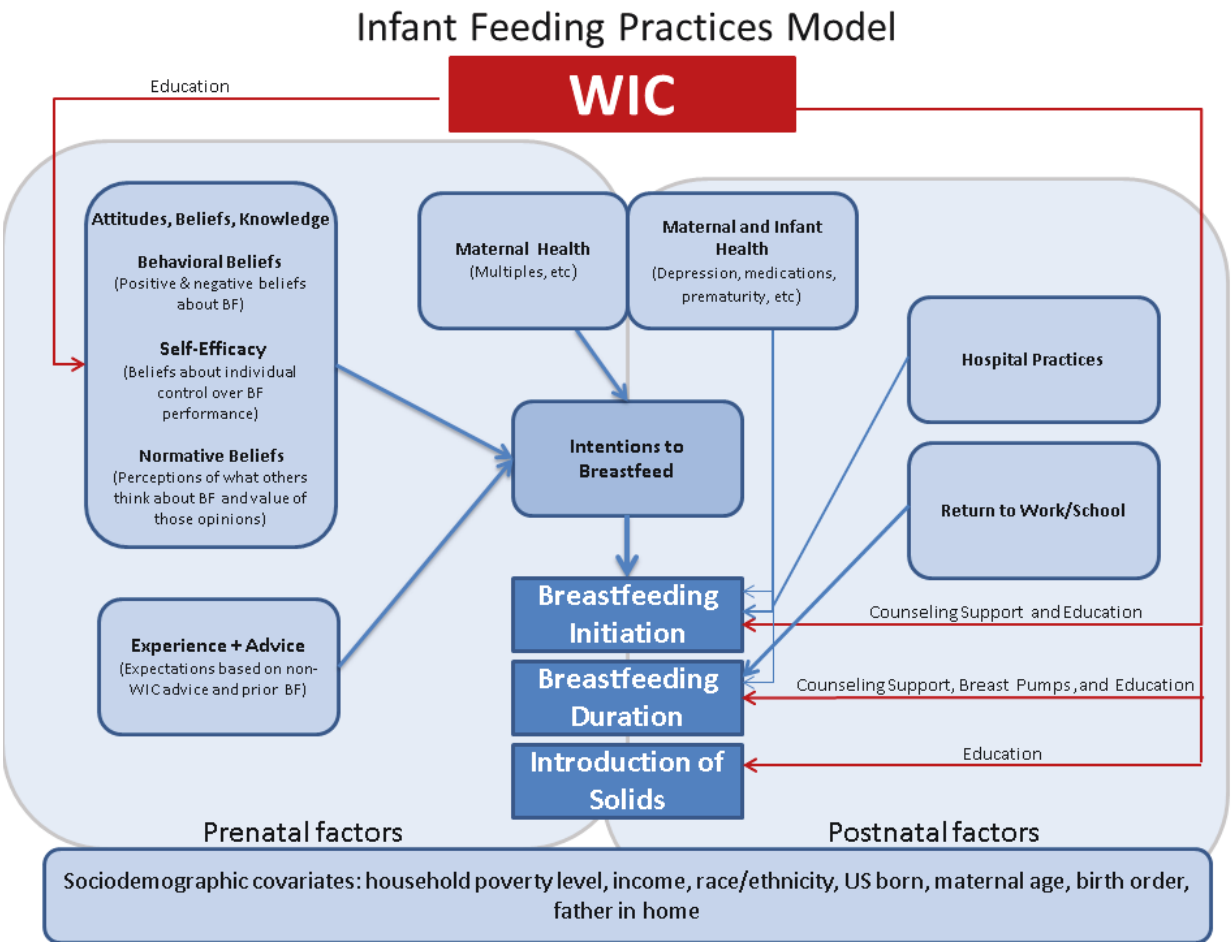
2.1 Overview

The research questions can be distilled to two major conceptual models that drive our study approach: (1) factors contributing to decisions about breastfeeding/early feeding practices and (2) factors contributing to early childhood weight gain and potentially subsequent obesity. These conceptual models do not specify every variable that contributes to key outcomes, but rather, they show the main causal drivers. Furthermore, the conceptual models help to guide the analysis and modeling by disentangling endogenous variables from exogenous variables and identifying the associated timing of decisions and outcomes that determine which relationships need to be addressed as simultaneous equations and which factors exert a lagged influence. The models also assist in identifying the influence path of the WIC policy variable. Each model is described below. The figures contain the categories of variables to be included in the models rather than an exhaustive list of all the potentially relevant individual variables. Chapter 7 includes a discussion of the variables and the Database Plan contains the complete list of variables.

2.2 Conceptual Model of Breastfeeding/Early Feeding Practices

Figure 2-1 depicts a conceptual model of the factors that affect early feeding practices employed by WIC mothers and their associated outcomes. Developed from the literature on predictors of breastfeeding and decision making about infant feeding practices, this model highlights two initial key decision points: the intention to breastfeed and the actual decision to breastfeed. As noted in the model, there are four major exogenous groups of factors that influence one's initial intentions about whether or not to breastfeed (1) Attitudes, beliefs, and knowledge about breastfeeding, (2) Past experiences and advice (3) Maternal health, and (4) Socio-demographic characteristics. Additionally, the actual decision to breastfeed can also be influenced by the infants' health, and hospital practices related to the promotion of breastfeeding. In addition to these background and environmental factors, the mother's WIC program experience (both current and previous) through education, and counseling support, can influence her breastfeeding intention and the decision to initiate breastfeeding.

Figure 2-1. Infant feeding decision model

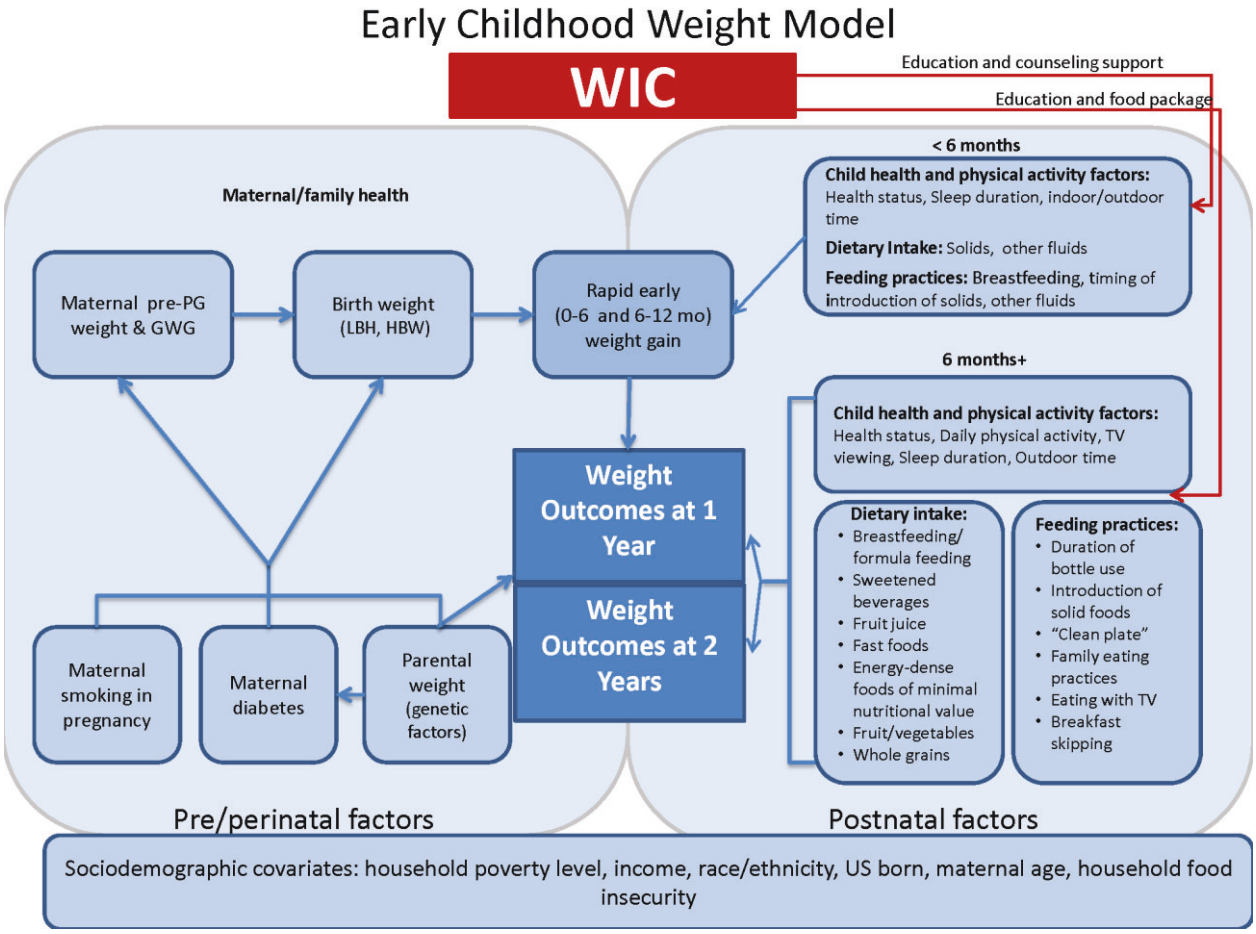


Subsequent feeding practice decisions, such as the breastfeeding duration and the time until the introduction of solid foods, are heavily dependent on the initial breastfeeding decision as well as the infant's response to the breastfeeding process. Subsequent feeding practices and outcomes also are affected by exogenous factors including one's lifestyle decisions about such things as employment and child care. Finally, the mother's WIC program experiences in terms of education, counseling support, and the provision of breast pumps, can affect subsequent feeding practice decisions.

2.3 Conceptual Model of Early Childhood Weight Gain

Figure 2-2 depicts a conceptual model of the factors that lead to high weight and potentially early childhood obesity. The childhood weight model was developed based on the literature on early predictors of childhood obesity, showing the factors that affect a child's risk of obesity.

Figure 2-2. Early childhood weight model



As depicted, maternal and family health characteristics along with socio-demographics affect one's predisposition to obesity. Similarly, it is believed that early life experiences can affect the "wiring" of the brain, creating a predisposition for obesity. According to this theory, prenatal experiences and feeding practices during infancy can affect the child's propensity for obesity. Although the factors affecting one's predisposition to obesity (family characteristics) are largely exogenous, other factors such as infant feeding practices are choices and can be influenced by the WIC program. In addition to the factors that affect a child's propensity for obesity, there are behavioral factors that directly affect the child's weight (1) the child's health and physical activity, (2) the child's dietary intake, and (3) the feeding practices employed.

The model shows how indicators of obesity can begin with prenatal and family background characteristics, and decisions made about first-year infant feeding. These contribute to both a lifetime propensity for obesity and childhood practices that promote or deter obesity. WIC has the

opportunity to influence this process both during the infant and toddler periods, and through promoting healthy nutrition and behavior during childhood.

2.4 Benefits of Using These Conceptual Models

Together these two models guide our study design and data collection strategy that emphasizes early feeding decisions and patterns and allows for a potential extension to explore the antecedents of childhood obesity. In line with the conceptual models that incorporate WIC influences, the recruitment target will be women enrolling in WIC for the first time for that pregnancy or infant. The majority of WIC participants enroll in WIC during pregnancy, and this approach of recruiting pregnant women into the study as they enroll in WIC will allow us to collect critical prenatal data on these women. This maximizes our ability to collect data prospectively, and to examine both influences of WIC services and characteristics of a group of WIC participants during pregnancy and infancy. This approach will also allow us to recruit women who enroll themselves or their baby after birth, and both to describe those families and to compare those families to the prenatal WIC group.

3 Develop and Pretest Instruments

Westat will collect data from multiple sources in order to accrue the variables needed to fit the conceptual models. The sources include WIC participants, State and local key informants, and WIC staff members who directly provide services. We will also abstract hospital and provider medical records; collect data from WIC administrative records; record measured weight and length on children; and document observational data at WIC service sites. To accomplish this we will develop instruments and forms for 11 WIC Participant interviews, two Key Informant interviews, one WIC Staff Survey, three abstraction activities, two anthropometric measurements, and one observation.

On January 20, 2012 Westat delivered a Draft Database Plan - Revised (Deliverable 10a) that defines the variables that will be collected from each data source. On May 18, 2012 we delivered final versions of the three types of instruments: WIC Participant instruments, Key Informant topic guides, and the WIC Staff survey (Deliverable 11a).

We pretested the instruments (WIC Participant interviews, Key informant interviews, and WIC Staff Survey) between February and May 2012 according to the testing protocol specified in the final Pre-Test Plan Memo (Deliverable 9b), approved on February 17. Following are brief summaries of each of the data collection components.

3.1 WIC Participant Survey

Table 3-1 provides an overview of the domains to be collected at each interview over the 2-year participant data collection period and Table 3-2 provides an example of the number and types of variables in a particular domain and our modular approach to collecting the variables.

As the first table shows, the Participant interviews include nine different domains. Each domain contains a range of 4 to 60 variables that are loosely grouped together into "modules." The checkmarks in the table indicate at which interviews at least one variable or module in each domain is asked. Not all modules within a domain will be asked at every interview. A complete list of the domains and variables within each domain can be found in the Final Database Plan (Deliverable 10b), delivered to FNS July 10.

Table 3-1. Topic domains collected at each WIC participant interview

WIC participant survey		Interview											
Variables by domain	Screening/ Enrollment	Baseline[a]	Prenatal	1 month	3 months	5 months	7 months	9 months	11 months	13 months	15 months	18 months	24 months
Socio-demographics and Background Characteristics	✓	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
WIC Program Awareness and Utilization			✓		✓		✓			✓			✓
Maternal Health and Lifestyle	✓	✓		✓	✓		✓			✓			✓
Feeding Experience, Knowledge, Attitudes, Beliefs, Information, Advice		✓	✓	✓	✓	✓	✓			✓	✓		✓
Hospital Feeding Related Practices				✓									
Current Feeding Practices				✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Child Health Behavior and Child Rearing Practices				✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Contact Updates			✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
New Caregiver Characteristics				*	*	*	*	*	*	*	*	*	*

[a] Questions will be asked at the first interview (could be prenatal, 1 month, or 3 month)

* These questions will be asked anytime someone permanently replaces the mother as the primary caregiver

The second table (Table 3-2) provides an example of our modular approach, in which we distribute questions across interviews in order to spread overall participant burden out across interviews. This table presents the Socio-demographic and Background characteristics domain which contains 33 variables. We have structured the domain such that questions are asked when they are most relevant, and are only repeated when they are needed.

- Of the up to 22 questions indicated for the Screening/Enrollment or Baseline interviews,[2] a module of 9 will not be asked again during the study either because the responses will not change, or because they are intended only to indicate status at the outset of the study (i.e., mother DOB, race/ethnicity, US born, parity, and prior WIC receipt,
- Similarly, maternal employment during pregnancy is asked only once, at 1 month.

[2] Of note: the baseline interview could be the Prenatal, the 1-month, or the 3-month interview, depending on when the mother was recruited. Furthermore, the screening/enrollment interview takes place on site and is not part of the prenatal, 1-month, or 3-month interviews.

Table 3-2 Example of modular nature of variables

Variables by Domain	Enrollment/ Screening	Baseline[a]	Prenatal	1 month	3 months	5 months	7 months	9 months	11 months	13 months	15 months	18 months	24 months
Socio-demographics and Background Characteristics													
Maternal birth date	✓												
Maternal ethnicity	✓												
Maternal race	✓												
US or foreign born		✓											
Marital status		✓								✓			
Parity		✓											
Interpregnancy interval/interpartum period		✓											
Number of children in household		✓											
Due date, if enrolled prenatally	✓												
Infant DOB[b]	[✓]			[✓]									
Single or multiple birth[b]	[✓]			[✓]									
Child name[b]	[✓]			[✓]									
Child sex[b]	[✓]			[✓]									
Child ethnicity[b]	[✓]			[✓]									
Child race[b]	[✓]			[✓]									
Respondent still caregiver/new caregiver information				✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
New pregnancy/due date							✓			✓		✓	
Household size	✓						✓			✓			✓
Household income	✓						✓			✓			✓
Presence of infant's father		✓								✓			
Receipt of public assistance		✓								✓			✓
Brief household food insecurity							✓			✓			
6-item food insecurity													✓

Table 3-2 Example of modular nature of variables (continued)

Variables by Domain	Enrollment/ Screening	Baseline[a]	Prenatal	1 month	3 months	5 months	7 months	9 months	11 months	13 months	15 months	18 months	24 months
Socio-demographics and Background Characteristics													
Use of emergency food sources													✓
Prior WIC receipt		✓											
Number of prior children on WIC		✓											
Duration of prior WIC receipt (mother and/or children total years)		✓											
Educational attainment		✓											✓
Current educational status					✓		✓			✓		✓	✓
Employment during pregnancy				✓									
Current employment status					✓		✓			✓		✓	✓
Age of child when mother began school or work[c]					[✓]		[✓]			[✓]		[✓]	[✓]
Continuation/discontinuation of WIC participation				✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Location of WIC service receipt				✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
If WIC discontinued, age of child when WIC discontinued				✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
If WIC discontinued, reasons for leaving WIC				✓	✓	✓	✓	✓	✓	✓	✓	✓	✓

[a] Questions will be asked at the first interview (could be prenatal, 1 month, or 3 month)

[b] Asked at enrollment if enrolled in study after child's birth; asked at 1 month if enrolled in study prenatally. The bracketed checks indicate times when this could be asked conditional upon time of enrollment.

[c] Asked the first time postnatally that the mother reports that she is currently working for pay. The bracketed checks indicate times when this could be asked.

- Some variables are asked only once during the study, but the timing is conditional upon participant characteristics such as questions asked at either enrollment/screening or 1 month depending on whether the mother is a prenatal or postnatal enrollee (i.e., due date, infant DOB, single or multiple birth, child name, child sex, child ethnicity, child race); the age of the child when the mother returned to work, asked the first time postnatally the mother reports currently working for pay; or questions about timing and reasons for leaving WIC, asked when the mother indicates she no longer receives WIC.

- Other variables will be asked periodically over the course of the 24 months to capture changes over time (i.e., marital status, new pregnancy, household size, household

income, presence of infant's father, receipt of public assistance, household food insecurity, educational attainment, educational status, and employment status).

- Only a small number of variables will be asked at every post-birth interview, as current status is required for each interview (i.e., respondent still the child's caregiver; continuation/discontinuation of WIC receipt; location of WIC service receipt)

The complete list of domains and variables can be found in the Database Plan (Deliverable 10b) delivered on September 7, 2012.

3.2 Key Informant interviews

There will be two key informant interview guides: one for state agency personnel and the other for local personnel. These interviews will confirm and supplement information extracted from State WIC Plans and local Nutrition Education Plans, to clarify state and local policies related to infant feeding, and to create profiles of local agencies for use in analyses. The key informant interviews will be framed by a hard copy topic guide that will be cross-matched to the research questions and analysis plan. The topic guide will include both open and closed-ended questions, along with follow-up probes to clarify and amplify responses.

These in-depth interviews will collect information about data included in the state's information system and how those data are used at the state and local level. In addition, the interviews will ask about policies regarding the content and timing of breastfeeding education and support, the qualifications and training of staff that provide nutrition and breastfeeding education and support, type of infant feeding information provided to participants, the use of breastfeeding peer counselors, policies for providing breast pumps and whether there are special breastfeeding promotion initiatives. In addition, we will ask about the policy and practice related to prescribing food packages including supplying any formula in the first month for breast-fed babies, and the content of educational materials. We will also obtain information about staffing, including local staffing characteristics and roles features (e.g., certifier, nutrition educator, clerical) use of professional and paraprofessional staff; length of WIC tenure of each staff member; number of staff performing different roles and training on infant nutrition, breastfeeding and nutrition educator skills provided to local staff. We expect these interviews will take about 60 minutes to complete.

3.3 WIC Staff Survey

We will develop a WIC Staff Survey to obtain information about the local WIC programs and the training and experience of the staff. In developing this survey, we will draw on some of Altarum's current work to collect similar information from WIC staff in the Midwest and Mid-Atlantic WIC State agencies. The survey will be programmed as a web-based instrument, but also prepared as a hard copy questionnaire for those who do not have Internet access. The survey will include demographic questions about WIC staff persons, including length of tenure at WIC, age range, education and training about their WIC related training and experience; and about their knowledge, attitudes, and beliefs about (1) breastfeeding and infant/toddler nutrition, (2) WIC foods, and (3) policies and approaches for providing nutrition education and breastfeeding support services. These interviews will take approximately 30 minutes to complete.

3.4 Hospital Record Abstraction Forms

We will develop medical record abstraction forms to capture hospital birth data, including infant birth weight/length, gestational age, Apgar score, head circumference, infant time in NICU, blood tests, amount of wet/soiled diapers, birth complications, type of delivery, and if infant fed other than human milk in hospital. In addition, an abstraction form will be developed to collect length/weight and date of measurement from child healthcare provider records. Finally, we will design a form for home health service staff to directly measure length and weight on infants in their home who do not have a health care provider. We plan to use standard forms from the National Health and Nutrition Examination Survey (NHANES) to document direct measures of length/weight. This will require the staff person to measure the child 2-3 times and document each measurement.

3.5 WIC Administrative Records

We will design data entry forms so the Westat research team can easily abstract data from WIC administrative records to capture information on maternal and infant/toddler characteristics at multiple points in time throughout the data collection period. Data to be collected on the mothers and children are listed below.

Table 3-3. WIC Administrative records variables

WIC Administrative Variables	Enrollment	Prenatal	1 month	3 months	5 months	7 months	9 months	11 months	13 months	15 months	18 months	24 months
Maternal Characteristics												
Food package prescribed	✓		✓			✓						
Infant/Toddler Characteristics												
Weight and date						✓			✓			✓
Length and date						✓			✓			✓
Food package prescribed	✓					✓			✓			✓

3.6 Local Site Profile Form

Altarum will develop a Local Site Profile form to document observational information about each service site at the onsite visit. The form will also be used to record information available from existing State and local reports and records, and to directly collect information from local site staff. The form will collect a variety of information, including the organization of the local WIC site, site-level participant demographics, services the sites provide, food packages available, and community resources, appointment scheduling protocols, availability of breast pumps.

3.7 Pre-test Instruments

As shown in Table 3-4, three types of instruments were pre-tested in February-May, 2012. All testing was done with 9 or fewer English and Spanish-speaking respondents. Using standard cognitive testing methodology, respondents were asked to answer the questions in the interview and the methodologist probed with follow-up questions to assess whether the question intent was clear, the terminology well-defined, and the responses unambiguous. We evaluated the length of the interviews to ensure the respondent burden was reasonable. Instruments were revised as needed and problematic questions retested. The details of the pre-testing plan are presented in the Final pre-Test Plan Memo (Deliverable 9a) delivered to FNS on January 20 and approved on February 17, 2012. In

addition, on May 6 Westat delivered the pre-testing results of a number of questions specified by FNS.

Table 3-4. Summary of pre-testing by instrument

Instrument	#Respondents	Recruitment location	Protocol
WIC Participant Interview	Total: ≤9/round	English: Sites in West, South, Midwest, and East Coast Spanish: NY, FL, and LA	▪ Phase 1: internal expert review ▪ Phase 2: telephone interview
Key Informant topic guides	Total: 8 Per state: 2 (state official & local nutrition professional)	4 states in different USDA regions	▪ Topic guide & interview protocol mailed ▪ Telephone interview
WIC Staff Survey	Total: ≤9	4 local agencies on East & Westat coasts	▪ Hard copy mailed ▪ Phone or in-person interview

Data Collection Protocol 4

4.1 Overview

Over the 3-year data collection period[3] the Westat team will conduct 11 key data collection activities to collect the information needed to answer the research questions represented by the causal models. These are summarized in Figure 4-1 in the sequence in which they occur. The details of each activity are described below.

4.2 Select and Recruit WIC State Agencies and their Service Sites

Westat will draw the sample of WIC service sites in a 2-phase process. First we will sample 160 WIC sites from the PC 2010 data. Altarum Institute will work with State and local agencies to obtain available information for each of the 160 sites, including average number of participants served at the site each month, average number of new prenatal and postnatal enrollees in the most recent month, the days of the week/month when enrollments are performed, and type of site (e.g. permanent, satellite, mobile). Since some of the sites in the first phase of sampling will be local agencies comprised of multiple service sites, Altarum will work with States to identify which are single service sites and which are a composite of multiple service sites. When a selected site is determined to be a composite of multiple sites, the State will be asked to provide a list of the single service sites in the composite and the publicly available information described above for each.

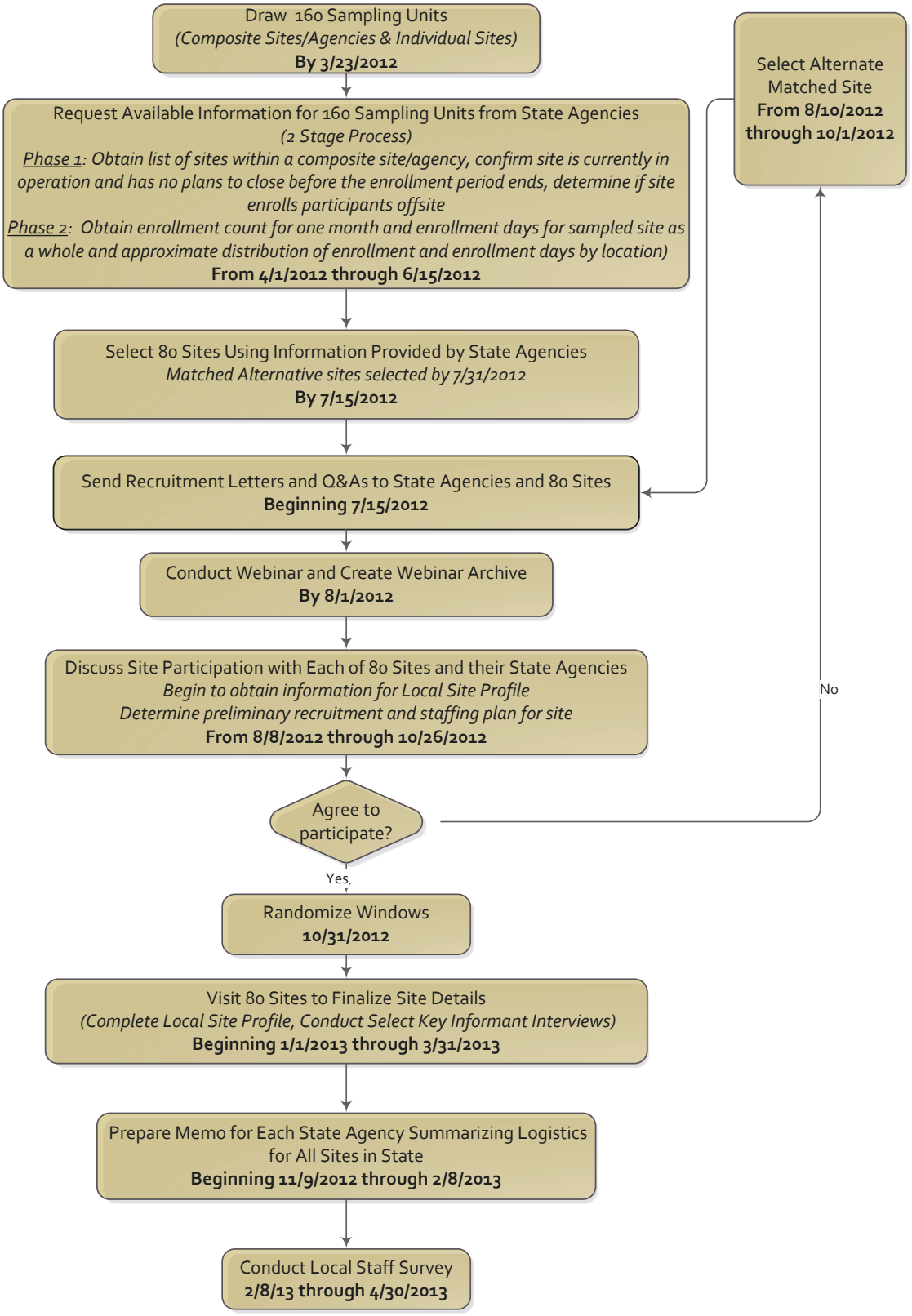
In the second phase of sampling Westat will use the information collected by Altarum to sample 80 sites. To be selected, the site will need to meet certain minimum criteria before they can partner with the ITFP-2 team. In particular each site must be a currently active site and enroll (on average) a minimum of 1.5 pregnant women/infants per day. If a site does not meet these criteria it will be replaced. Altarum Institute will enlist the cooperation of the 80 sampled sites through telephone and web meetings with State, local and WIC service site officials. Figure 4-2 illustrates the selection and

[3] Westat will collect data over a 3-year period, but the length of time a mother will be a participant is dependent on when she was recruited. Mothers reruited when they were 1-month pregnant will be participants for 2.7 years while mothers enrolled when their baby was 2.5 months old will be in the study for about 1.8 years.

Figure 4-1. Data collection activities

ID	Data collection activity	Mode	Start	Finish	Duration	2012 Q2	2012 Q3	2012 Q4	2013 Q1	2013 Q2	2013 Q3	2013 Q4	2014 Q1	2014 Q2	2014 Q3	2014 Q4	2015 Q1	2015 Q2	2015 Q3	2015 Q4	2016 Q1	2016 Q2	2016 Q3
1	Request available information from 160 sampling units	Phone, email	4/9/2012	6/22/2012	2 mo																		
2	Obtain/abstract State WIC plans for Information Systems Profile & Features Matrix for 80 sampled sites	Mail, email, web	7/2/2012	12/31/2012	6 mo																		
3	Collect selected site profile data	In-person, phone, email	1/1/2013	3/29/2013	5.5 mo																		
4	Conduct key informant interviews	In-person, phone	1/1/2013	3/29/2013	3 mo																		
5	Enroll women at WIC sites	In-person, phone	1/9/2013	5/31/2013	4.5 mo																		
6	Conduct WIC clinic surveys	Web, hard copy	2/1/2013	3/29/2013	2 mo																		
7	Obtain/abstract birth records	Mail, email, phone, fax	1/10/2013	3/20/2014	14.5 mo																		
8	Conduct WIC participants interviews	Phone	1/21/2013	2/29/2016	37.5 mo																		
9	Obtain/abstract mother/infant WIC records	Mail, email, fax	4/30/2013	3/31/2016	35 mo																		
10	Obtain/abstract mother/infant records from providers (those dropped out of WIC)	Mail, email, fax	4/30/2013	3/31/2016	35 mo																		
11	Obtain weight/length measurements directly on infants	In-person	4/30/2013	3/31/2016	35 mo																		

Figure 4-2. Flow for selecting and recruiting WIC service sites



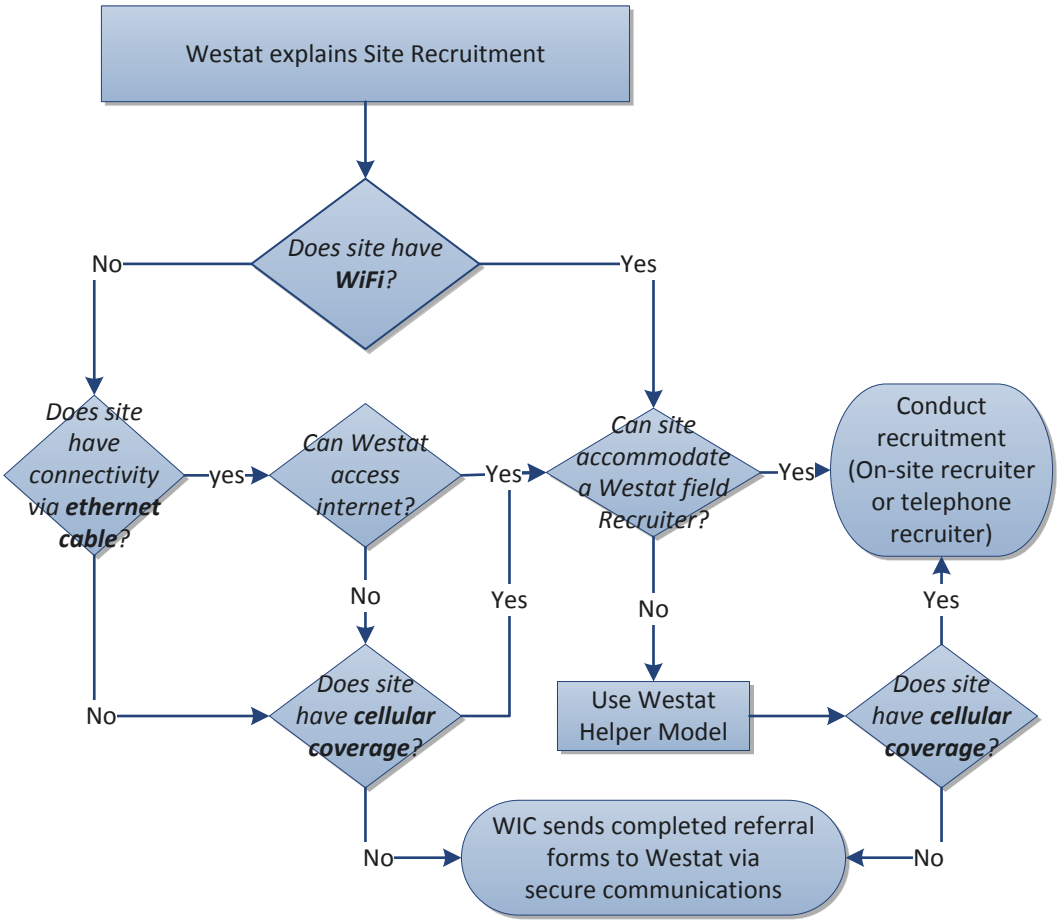
recruitment process of the sites. The recruitment of State agency directors will begin with a communication containing an advance letter, study fact sheet, answers to anticipated questions, and an invitation to participate in a 1-hour webinar (30-40 minutes for the presentation followed by a Q&A session of about 30 minutes). A follow-up letter will list the sampled sites under each State and will inform directors that they can invite key staff from the sampled local agencies and service sites to the webinar. The webinar will be recorded and be made available to those who could not attend the live session. During the webinar, Altarum will elaborate on information provided earlier and answer questions from those who participate. State agencies will be invited to be partners in the ITFPS-2 and State directors will be asked to assist with gaining the cooperation of their sampled sites. Approximately a week after the webinar, Altarum will begin to work with the States to finalize site participation details and to begin to compile a Local Site Profile Form for each site. The profile will include information such as hours of operation, percent of Spanish speaking participants and other information available from the State agency or local site. Altarum will summarize these details in a written communication with copies provided to the State agency, local site, and FNS. If a site requests, Altarum will prepare a memorandum of understanding (MOU).

In order to be chosen to participate in the ITFPS-2, a service site will need to identify all eligible WIC enrollees every day of the enrollment window. An eligible WIC enrollee is an English or Spanish speaking woman who is (1) pregnant and is enrolling in the WIC program for the first time for the current pregnancy; or (2) was not enrolled prenatally but is enrolling her infant who is less than 2.5 months old. We will consider sampled sites that cannot commit to identifying eligible women to be non-responders to the ITFPS-2.

Once sites are recruited Westat and Altarum staff will have multiple telephone conversations with the sites to work out the best arrangements for recruiting new WIC enrollees in that site. We will use one of two recruitment models in each site: either staff a Westat **field recruiter** or a Westat **helper** to recruit new enrollees into the study. The field recruiter's responsibility will be to explain the study to each new WIC enrollee and conduct the screener and enrollment interview using a laptop computer. The Westat **helper's** responsibility will be to explain the study and connect the new WIC enrollees to a Westat recruiter by cellphone. Our preferred staffing arrangement is to use a field recruiter since the recruiter can build more rapport while talking with the new enrollees in-person, and will more often be able to enroll the woman immediately into the study.

As shown in Figure 4-3, we will determine the best technology for conducting the recruitment interviews, which will partly influence the staffing model we use in a particular site. If a site has WiFi, accessible ethernet connectivity, or cellular coverage we can staff the site with a Westat field

Figure 4-3. Decision Tree for type of technology used for conducting recruitment interview



recruiter. If a site indicates they do not have enough space or privacy for a Westat field recruiter to have a two-way conversation with a WIC enrollee, but could accommodate a Westat person handing a phone to the woman for a one-way conversation, we will use the helper model. The helper will escort the woman to the pre-determined designated private space, hand the phone to the woman, and leave the area so she will have privacy. The Screener/Recruitment interview contains no sensitive questions and all responses are closed-ended; when answered by phone they will require the following responses: "yes/no," numbers, names, and contact information. If by chance, someone overhears a piece of the phone conversation, the responses will not be meaningful. If the participant does not fee there is enough privacy, she will be given the option to have the recruiter call her at a later time. If there is no cellular coverage we cannot accommodate either model and will request the WIC staff keep a referral form on each new enrollee (discussed in Section 4.5.3) and send to Westat on a regular basis in a secure communication mode (i.e., secure fax, encrypted email, or tracked mail).

To date 76 sites have indicated they have private space to accommodate a **recruiter** interviewing a respondent. Some sites have indicated the recruiter may have to move from space-to-space throughout out the day, but at any one time there will be private space to conduct an interview. Based on earlier conversations with the other 4 sites, we believe they will be able to provide private space to accommodate a **recruiter** as well. We expect to talk with the remaining 4 sites before November 1 and will update this information at that time.

Once recruitment begins a site may change its mind if it prefers a different type of Westat field staff. This will not be difficult to accomplish since we plan to train the recruiters and helpers on the same procedures. Altarum and Westat will also talk with the sites about options available to accommodate privacy for women who are being screened and recruited for the study. We understand that WIC sites are generally set up to provide space where WIC staff can talk to women and share confidential information even when clients and staff are visible to others. We will defer to the sites' recommendations as to the best way to accommodate a 15-20 minute recruitment interview. However, in order to ensure that the participant has been determined to be eligible for WIC and to make sure that there is no impact (real or perceived) of the study on the receipt of WIC benefits, the determination and flagging will occur at the end of the participant's WIC appointment. Westat will not approach the participant until she has completed all of their WIC business. The recruitment should not interfere with or interrupt any participants being certified, receiving benefits, or receiving nutrition education or breastfeeding support. For example, this includes interruptions or delays to the flow of WIC appointments and being approached in the waiting room when WIC business has not been completed. Furthermore, the recruitment will not, directly or indirectly, impact or change clinic hours (example: M-W, 8am-5pm) or clinic schedules (example: M-W are certification appts, Thu-Fri are nutrition education).

4.3 Obtain and Abstract State WIC Plans for Features Matrix

During the recruitment period, Altarum staff will request from each State agency available documents, including State plans, State program policy manuals, State nutrition education plans, and descriptive information about the State's information systems to complete the Information system profile and Features matrix. The Information System Profile and Features Matrix will be used to

determine the source and protocol for obtaining data from WIC administrative records for participants enrolled in the study. These are expected to include weight and length measures for infants and toddlers and food package prescription for mothers and babies. It will also be used to compile information about policies and features of nutrition education and breastfeeding services provided by the State agency and sites in the State.

4.4 Collect Local Site Profile Data

Altarum will collect Local Site Profile for each site during an onsite visit using information collected from State and local agencies, as well as observational data and interaction with staff during the site visit. The Site Profile will inform the communication and coordination with the service sites and will provide information about site operations and policies.

The onsite visit will be scheduled in the January-March timeframe, 2013. The visit will be conducted by Altarum Institute staff members who will be assigned as study regional coordinators to coordinate study activities with the site and to conduct the data collection (key informant interview and site profile). The visit will take approximately three hours. During the visit, the regional coordinator will conduct the key informant interview (which will include requesting information such as the appointment schedule template)., provide an overview of the staff survey, and respond to questions about study activities. The information for the local site profile will be collected through observation, (e.g. count the number of staff working at the site, record the hours of operation posted). We estimate the burden to complete the key informant interview will be approximately 1 hour of time. The remainder of the three hours will be used to observe the clinic activities and answer staff questions about the study.

4.5 Conduct Key Informant Interviews

Following OMB approval, Altarum staff will conduct key informant interviews with one State agency representative and one service site staff person for each State and site selected for the study. One key informant interview will be conducted per State agency regardless of the number of service sites selected in the State. The decision regarding who completes the interview will be made by the State Agency WIC Director. We will send the questions to the State Agency in advance of

scheduling the appointment. The interviews with State agency staff members will be conducted by telephone.

The key informant interview at the local level will most likely be with the site supervisor or coordinator or whoever is identified as the most knowledgeable about the nutrition education and breastfeeding policies, procedures, and staffing at the site. We will work with the State agency and the administration of the local site, e.g., local agency WIC director or manager, to determine the most appropriate person to interview. Interviews with the staff members at each service site will be conducted face-to-face. All interviews will be recorded for quality control purposes. If needed, a staff person from the local agency that oversees the site will be contacted in-person or by phone to respond to any questions the staff person at the service site could not answer. This interview will take approximately one hour to complete with each State and local key informant.

4.6 Recruit WIC Participants

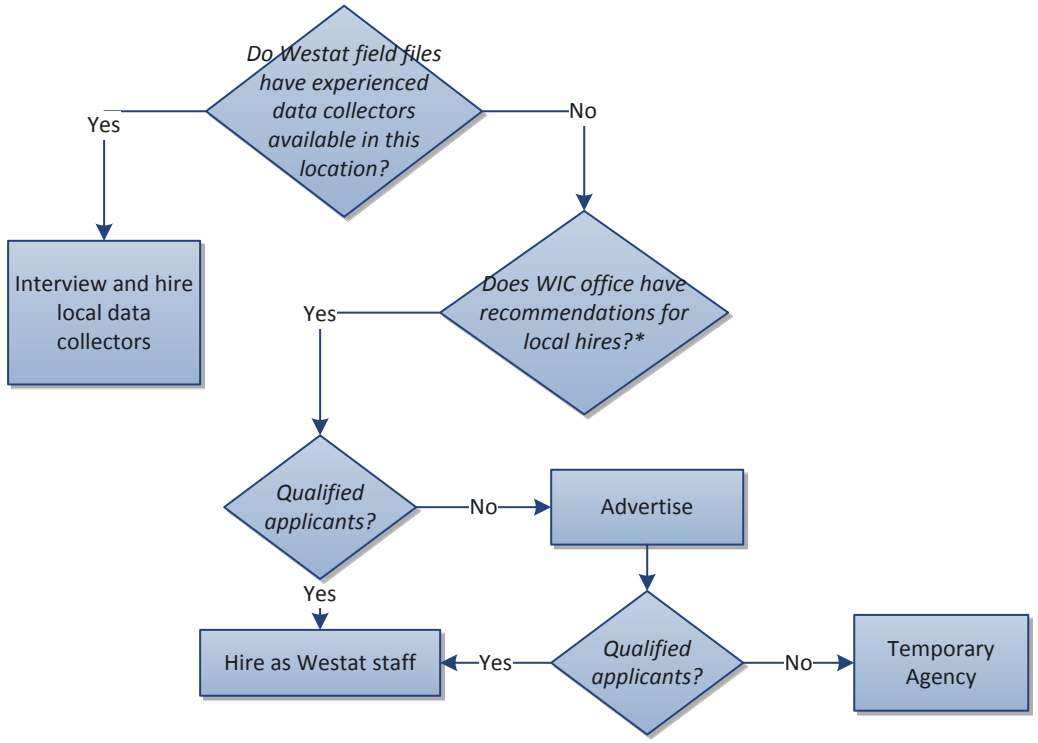
Over a 5 month period beginning in January 2013 Westat will screen about 98 new WIC enrollees at each of 80 selected WIC service sites during a pre-determined enrollment period. The new enrollees will include prenatal mothers and postnatal infants <2.5 months old (whose mothers were not enrolled prenatally) who are enrolled at the service site or at outreach locations (hospital, mall, satellite sites) by staff in the service site. We expect to recruit about 55.4 new enrollees per site. The 80 WIC sites will be of varying sizes and therefore have vastly different enrollment flows (from 1.5 new enrollees per day up to 14 or more new enrollees per day). To accommodate the differences in enrollment flow the recruitment window at each site will range from 7 to 66 days (about 1 to 13 weeks). The enrollment start dates will be staggered and slightly frontloaded to ensure the sites with longer windows begin enrollment early in the period. Details of the sampling process can be found in the Final Sampling Plan in Deliverable 8b, submitted to FNS on February 17, 2012. Following is a description of our process for recruiting and training Westat staff, and a discussion of the steps in recruiting new WIC enrollees into the ITFPS-2.

4.6.1 Hire and Train Westat Staff

As discussed above, we will staff the WIC sites with either Westat recruiters or helpers to conduct the ITFPS recruitment process. We expect many of the field staff will come from Westat's nation-

wide pool of several thousand part-time and fulltime field data collectors who are routinely trained for specific requirements of a study. For sites for which we don't have field staff living in the area of a WIC site, we will plan to hire locally. As illustrated in Figure 4.4, we will first ask WIC staff for referrals (e.g., friends, family, part time WIC employees, or past WIC employees). Part-time WIC employees who apply for a position must request approval from their local and State agency before Westat can hire them. If we don't find staff in that manner we will advertise in the local area or hire from temp agencies in the local area.

Figure 4-4. Recruiter and Helper hiring process



*local hires may include candidates who work for WIC part-time. Westat would consider employing these candidates during their off-duty hours. Potential candidates must request approval from their local and State agencies

The sites will begin recruitment on a rolling basis over a 9-week period. Westat will conduct 9 trainings with the field recruiters; each training will begin approximately 1-2 weeks before recruitment begins at each site. The training will be conducted using 25 self-paced training modules, real-time Webex sessions, and role plays. It will cover procedures to introduce the study to the potential WIC participant, gain their cooperation, connect potential enrollees with the Westat TRC center (helpers training), and how to work collaboratively with the local WIC site staff. Trainees will be required to complete a summary quiz at the end of the self-paced LMS training. They will be asked to review the materials and retake the summary quiz until they score with 100 percent

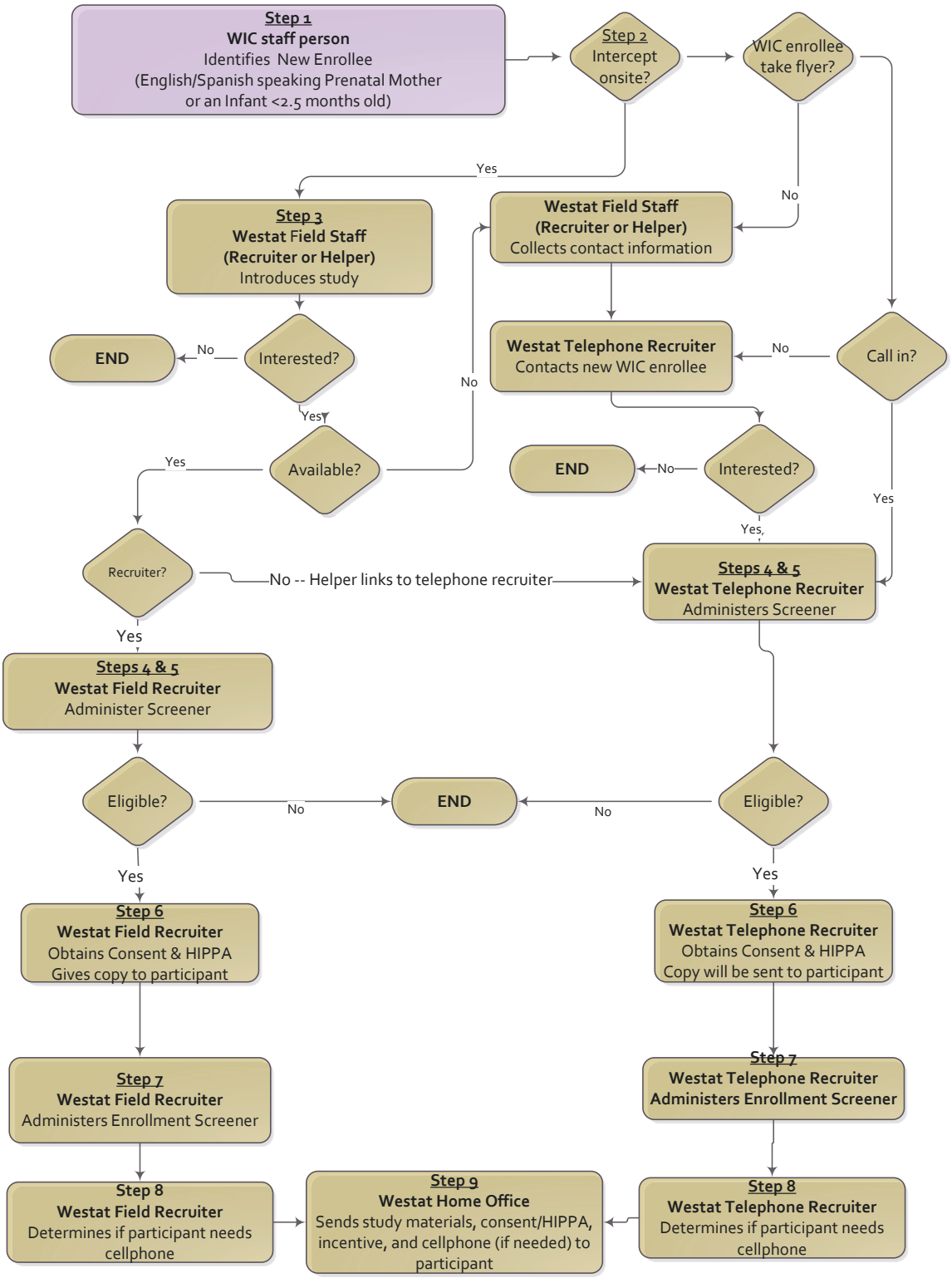
accuracy. This is a requirement before participating in the WebEx training sessions. Trainees will be monitored during the WebEx training role plays and corrective action will be provided. Following the WebEx training, trainees will be paired together in dyads to practice introducing the study and obtaining cooperation through scripted role plays. Trainees must demonstrate mastery of the contact procedures to the observing trainers in order to be approved to work on the study.

An important training module that all interviewers will receive is how to maintain confidentiality when collecting data or assisting a respondent in completing an interview. In addition, all Westat employees will sign a confidentiality agreement annually to ensure they understand what is considered confidential, the importance of privacy, and how to maintain confidentiality. Finally, finding space in the WIC sites that offers some privacy will be an important aspect of ensuring participants' responses are kept confidential.

4.6.2 ITFPS-2 Recruitment Protocol

The sites will begin recruitment on a rolling basis over a 9-week period. In the 1st week we will launch recruitment in 5 sites, in the 2nd-8th week we will launch in 10 sites weeks; and in the 9th week we will launch in 5 sites. Recruitment will be conducted over a 4.5 months. Figure 4-5 illustrates the recruitment protocol. The first step will be for a WIC staff person to identify a new WIC enrollee. From talking with the sites we understand that this will be a simple process for staff particularly because these participants have to be enrolled into the management information system. Based on our discussions with sites and Altarum's experience working with WIC programs in 31 States and over 200 clinics, we understand that the WIC enrollment process in most sites starts with a WIC staff person obtaining key information from the person seeking to enroll. This includes household family size and income, residence, and identification. The staff person will assess the income and residence information to determine if the applicant meets income and residence/service area requirements. The applicant will then participate in a nutrition assessment, including anthropometric and blood tests, to determine nutritional risk and, if they are determined eligible for the WIC program they will receive nutrition education and a food package. If the enrollee comes into the service site to enroll, the WIC staff person will identify all pregnant women in the designated study enrollment window who are enrolling in WIC for the first time for their current pregnancy and all infants less than 2.5 months whose mothers did not enroll prenatally. They will complete a 2-ply referral form that includes WIC ID, name, contact information, pregnancy status, age, and language. One copy will go to the woman (yellow); the other will be saved for the Westat recruiter/helper who will collect the forms at the end of the day. The Westat recruiter/helper will look for women holding a yellow referral form and attempt to intercept her at the end of her WIC visit in order to introduce

Figure 4-5. Recruitment flow



the study and screen the woman.. The strategy for notifying the recruiter/helper will be refined at each site, but the basic method is to have the Westat field recruiter/ helper look for the women with a yellow referral form and talk to them about the study once WIC business is conducted. In order to ensure that the participant has been determined to be eligible for WIC and to make sure that there is no impact (real or perceived) of the study on the receipt of WIC benefits, the determination and flagging will occur at the end of the participant's WIC appointment. Westat will not approach the participant until she has completed all of their WIC business. The recruitment should not interfere with or interrupt any participants being certified, receiving benefits, or receiving nutrition education or breastfeeding support. For example, this includes interruptions or delays to the flow of WIC appointments and being approached in the waiting room when WIC business has not been completed. Furthermore, the recruitment will not, directly or indirectly, impact or change clinic hours (example: M-W, 8am-5pm) or clinic schedules (example: M-W are certification appts, Thu-Fri are nutrition education).

Once a Westat field staff (recruiter/helper) makes contact with the woman they will find a pre-determined private place, and introduce the *Feeding My Baby Study* by showing the woman the study flyer. In addition they will explain that to participate in the study the woman will need to answer some questions that day and will be contacted by phone periodically to answer some questions about her baby's food consumption and feeding habits, until her child is two years old. The recruiter/helper will tell the woman that if she is confirmed to be eligible for the study, the interview today will take about 20 minutes and she will be compensated $50; all future telephone calls will take no more than 30 minutes, and she will be compensated $20 for each telephone interview. If the woman is interested and has time to spend talking about the study, she will be interviewed immediately in service sites that have a recruiter. In sites that have a helper, the helper will explain that the woman will be connected to a Westat telephone recruiter who will provide more detail about the study and will ask her some questions. The recruitment interview will take 20 minutes and the woman will be mailed $50 for her time. Women who are interested but don't have time to spend at the clinic will be asked by the Westat field staff person for a good time and way to contact them to talk about the study. That information will be transferred to a Westat telephone recruiter who will contact them by phone.

The Westat recruiter (field or telephone) will administer a recruitment screener to determine whether the woman is eligible, and if so will obtain her consent and explain the HIPAA form and the need for a signature. They will administer the enrollment interview and obtain an address to send the incentive and study materials, and a telephone number to contact the participant for the follow-up interviews. If a woman cannot provide a contact telephone number the recruiter will ask if she needs

a cellphone. The Westat home office will send study materials, a cellphone (if needed), and the study incentive.

We expect there may be a very small number of women who will be enrolled in locations other than at the service site (e.g., hospital, mall, mobile vans). In those cases, the WIC staff will fill out a referral form and the Westat recruiter/helper will send the information to Westat. A Westat telephone recruiter will contact the woman.

4.6.3 Recruitment and Enrollment Steps

Participant enrollment at the service site is presented in Figure 4.5, and described below.

1. **Identify Eligible WIC Enrollees.** WIC staff will identify all pregnant women in the designated study enrollment window who are enrolling in WIC for the first time for their current pregnancy and all infants less than 2.5 months whose mothers did not enroll prenatally. They will complete a 2-ply referral form that includes WIC ID, name, contact information, pregnancy status, age, and language. One copy will go to the woman (yellow); the other will be saved for the Westat recruiter/helper who will collect the forms at the end of the day.

2. **Intercept on site.** The Westat recruiter/helper will look for women holding a yellow referral form and attempt to intercept her at the end of her WIC visit in order to introduce the study and screen the woman. Barring that, they will make sure the woman gets a study flyer with a toll-free number she can call to learn more about the study. Barring that, they will make sure the woman gets a study flyer with a toll-free number she can call to learn more about the study.

3. **Introduce Study.** A Westat recruiter/helper will take the woman to a private space (designated for the ITFPS-2 recruitment activity by the site) and introduce the study. This will involve providing the woman with a study flyer that explains what participation in the study entails, the incentives, and how the mother can play an important role in understanding the health of all infants by joining the study. If a woman expresses interest in participating in the study but does not have time to go through the recruitment process, the recruiter/helper will obtain contact information and a Westat telephone recruiter will contact her to introduce the study and determine whether she is eligible.

4. **Assign to Core or Supplemental Sample.** The screener instrument will be programmed to assign participants to either the core or supplemental group in an alternating pattern. For sampling purposes it is necessary to assign a woman to one of these groups before we screen her. (See Sampling Plan, Deliverable 8 for details). In sites that have a Westat field recruiter, the recruiter will assign interested new enrollees to the core or supplemental sample using a laptop; in sites where a Westat helper has

introduced the study, the helper will call a Westat number to make contact with a Westat telephone recruiter who will assign the woman to the appropriate sample.

5. **Administer Screener.** Westat recruiters (in-person or telephone) will administer the recruitment screener. In sites where the helper calls into the Westat telephone center to connect with a telephone recruiter, we will minimize wait time by monitoring call volume hourly during peak enrollment periods to ensure that all calls are picked up and linked with an interviewer immediately. When needed, we will be prepared to make adjustments to both the number of available toll-free staff and responsible interviewers.

   The recruiter will confirm that the woman is eligible (i.e., has not been previously enrolled in WIC for her current pregnancy or that the infant is less than 2.5 months). Eligible respondents will be asked about their race, ethnicity, trimester of enrollment, pre-pregnancy BMI, household composition, and income. Core group participants will be retained irrespective of their responses to these questions. Participants assigned to the supplemental group may be found ineligible at this stage depending on their responses. Only rare population subdomains such as black mothers and infant who have no prenatal WIC exposure will be eligible for the supplemental group. Participants still eligible will also be asked questions to determine whether they plan to stay in the area during the study period, whether they are or will be the caregiver of the WIC infant, and their age. In addition, the interviewer will explain what participation involves; the number and types of interviews to be completed; and the incentive structure.

6. **Request Informed Consent and HIPAA Authorization.** The Westat recruiters will ensure the woman understands all aspects of the study, that her participation is confidential and voluntary, and her WIC services cannot be denied if she refuses to participate in the ITFPS-2. Consent procedures for mothers under age 18 vary by State, and will be determined based on the States identified for sampling. Women recruited in-person will sign the informed consent and receive a copy of the document for their records. Women recruited by telephone will provide verbal consent by agreeing to continue with the interview, and will receive a copy of the consent form through the mail. Westat recruiters will also request HIPAA authorization from participants assigned to the core group to allow access to medical records for enrolled women and their infants. Participants recruited in-person will sign the HIPPA form and receive a copy for their records; participants recruited by telephone will be sent a HIPPA form to be signed and returned in a postage-paid return envelope (see section 4.6.2. or 4-10).

7. **Administer Enrollment Interview.** Once a woman is determined eligible by the eligibility screener and has been recruited, the Westat field recruiter or Westat telephone recruiter will administer the enrollment interview which will collect detailed contact information (telephone numbers, email address, home address, contact information of friends and family members) and health data (due date if pregnant; name and birth date of infant if post-natal).

8. **Provide Cell Phone if Needed.** Since subsequent interviews will be by telephone, if a woman does not provide a phone number, a cell phone will be offered for the duration

of her participation. Westat will mail the phone to the participant prior to the first interview (i.e., prenatal, 1 month, or 3 months) with instructions on using it.

9. **Provide Incentive and Other materials.** Westat will send each participant an enrollment package that will include a $50 incentive in the form of a debit card (which will be loaded with $20 each time the participant completes an interview); a calendar with their interview dates; and measuring guides (for the 24-hour recall) to help them with the subsequent interviews. The measuring guides include measuring cups and spoons, a household teaspoon and tablespoon, and a ruler.[4]

4.6.4 Pre-Test Recruitment Protocol

We plan to test the recruitment protocol in the September -November 2012 timeframe at three different sites located in Los Angeles, Oklahoma, and Baltimore. The sites will be sampled into the study and will be chosen based on caseload and geographic location. While we will test the protocol at each site, we will not use WIC enrollees. The pretest will help us learn more about WIC sites. In particular, we will observe whether WIC site staff are able to accurately identify study eligible women and whether the referral form facilitates the entry of the information by WIC staff. We will also inspect the physical space available to accommodate enrollments by Westat staff while maintaining confidentiality. We will adjust our recruitment protocol as needed after conferring with FNS. We will also test prototypes of the data collection and communication tools we plan to use for recruitment (e.g., brochures/flyers, computer laptops, and cell phones) within these site environments to evaluate their feasibility. Details of our plans for pre-testing were delivered to FNS on September 11, 2012.

4.7 Conduct WIC Staff Surveys

Altarum will instruct staff to complete the WIC Staff Survey during the time period when participants are being recruited for the study. All staff persons at each WIC service site who have roles providing direct service to WIC participants (e.g., nutritionists, nurses, "competent professional authorities", site supervisors, support/clerical staff, peer counselors and others) will be asked to complete a survey. The survey will be confidential and completed on-line or by hard copy

[4] Of note, the peer Advisory Panel (PAP) purposely recommended not sending participants the USDA Food Model Booklet (FMB) which includes pictures of glasses, cups, and bowls, since it might influence a WIC mother's decision to begin solid foods earlier than appropriate. After discussion with S. Murphy of the PAP, FNS agreed that the FMB was not needed to collect data on children between 1-11 months; however, they questioned whether this would affect a comparison of the toddler data to the NHANES data (where the FMB is used for this age group). Westat has requested the NHANES data to determine the extent the FMB is used to report portion sizes for 12-24 month olds.

(if the service site has no internet access). Altarum will introduce the survey to service site staff at the in-person visit conducted when site has been recruited. Staff will be informed of the process for accessing the survey and of the availability of a Support Desk if they have questions. To maximize response rates, Altarum will send periodic notes to the site supervisor or designated point of contact to advise them of the number of responses received with a request to remind staff to complete the survey. This survey will take about 30 minutes for each staff member to complete.

4.8 Conduct WIC Participant Survey

The WIC participant sample includes a core and a supplemental sample. As shown in Table 4-1, WIC participants in the core sample who are enrolled prenatally will be interviewed up to 11 times over approximately a 2-year period. Women enrolled after giving birth will participate in up to 10 interviews. In the supplemental sample women enrolled prenatally will receive a 1-month interview while those enrolled after the baby is born will receive a 3-month interview, and possibly a 1-month interview, depending on the age of the infant at enrollment. Both will be interviewed at 3 additional time points. Three interviews will be completed during the toddler period.

Table 4-1. Interview events for core and supplemental sample

WIC enrollment	INTERVIEW											
	Infant										Toddler	
	Enrollment	Prenatal	1 month	3 months	5 months	7 months	9 months	11 months	13 months	15 months	18 months	24 months
Core Sample – Prenatal	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Core Sample – Infant <6 wks	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Core Sample – infant 6 wks-2.5 mos				✓	✓	✓	✓	✓	✓	✓	✓	✓
Supplemental Sample – Prenatal	✓		✓			✓			✓			✓
Supplemental Sample – Infant <6 wks	✓		✓			✓			✓			✓
Supplement Sample – Infant 6 wks-2.5 mos				✓		✓			✓			✓

We will conduct the telephone interviews in English and Spanish and participants will be paid a $20 incentive on completion of each interview. All post-birth interviews will include a 24-hour dietary recall using the AMPM. Participants will receive a package of measuring guides to help them report

their child's portion sizes during the interview. We will collect replicate intakes on a 10 percent subsample of toddlers at 13, 15, 18, and 24 months in order to estimate "usual" intake.[5]

We will follow the procedures developed by UC Berkeley for the NHLBI Healthy Communities Study for obtaining information about foods and drinks consumed by 0-2 year olds who may have been in childcare and away from parents on the day they will be reporting their child's food intake. When an interview is scheduled the interviewer will ask the parent/caretaker if their child will be in daycare the day before the scheduled interview. If yes, the interviewer will tell the parent/caretaker that Westat will send them a note sheet and request that they take it to an adult at the daycare and ask the adult to fill in the information (food names and amounts) about what their child consumed that day (the day before the scheduled interview). The interviewer will instruct the parent/caretaker to pick up the form when they pick up their child at the end of the day and refer to the information on the form when they report their child's intake during the interview the following day. For cases when the parent/caretaker cannot obtain the information from the caretaker, we will ask the parent/caretaker to provide a report of foods consumed based on their knowledge of what their child consumes at daycare. In situations where a parent/caretaker cannot report, we will attempt data retrieval with the daycare center. If the daycare cannot provide the information, it will be considered missing data. Discussions with the NHANES staff indicate that if the parent/caretaker was asked at the 1st 24HR interview about their child's intake at daycare, they were prepared to provide that information at the 2nd interview. Therefore, there is very little missing data in NHANES. We expect the same situation in the ITFPS.

At the end of each interview, interviewers will schedule an appointment for the next interview. We will remind participants of an upcoming interview through text and email messages, as well as telephone calls. Interviewers will make up to nine attempts to complete an interview, spread over different days of the week and weekend. Despite these attempts, we anticipate that we will not be able to complete every interview with each participant. However, skipping an interview will not make a participant ineligible for subsequent interviews. She will still be in the study and our interviewers will try to reach her for the next interview for which she is eligible.

Since this is a longitudinal study in which we want the women to remain in the study over a 2-year period (and more for women recruited prenatally) we are very sensitive to the need to form a

[5] We expect the food intakes of infants at 1, 3, 5, 7, 9, and 11 months to be very homogeneous and have no reason to believe this population will be different from NHANES. Therefore, we plan to use the data from NHANES 2007-08 & 2008-09 to adjust estimates of usual intakes of infants. We estimate the NHANES (2007-8 & 2009-10) represents a sample of about 275 cases 0-5 months and 300 cases 6-12 months old, which is greater than a 10 percent subsample of cases in ITFPS.

relationship with the women and stay in touch with them on a regular basis. To this end, we plan to staff *study liaisons* in this role. These liaisons will make contact via phone and email, with each woman after they are enrolled in the study to welcome them and answer any questions. They will make reminder calls for upcoming appointments and be available to "find" the woman if our telephone interviewers are unsuccessful in contacting her for an interview. They will use social media for tracing respondents who we cannot get in touch with to complete an interview during their commitment to the study. We will search for respondents on Facebook and send private emails to their Facebook email addresses that cannot be viewed by anyone else. In addition, the liaison will attempt to contact and schedule interviews with participants who demonstrate "soft refusal" tendencies, such as missing their appointments or breaking off in the middle of an interview. The liaison will try to address her concerns and hopefully schedule a convenient time to complete the interview.

Once a liaison realizes the participant is not communicating with her, she will begin a series of tracing steps. First, she will contact the WIC site contact to find out the current contact information on her WIC file(). If this does not yield new information, the liaison will attempt to call the contacts (generally family and friends) the participant provided during the enrollment interview. If these contacts fail to locate the participant, she will attempt to reach her via free on-line searches. Should our tracing indicate that a participant has left the country permanently, we will not attempt to contact her for subsequent interviews. We will continue to call and complete interviews with participants who have dropped out of WIC, enrolled in another WIC site, or moved from the area where she was originally sampled to a new area within the United States.

Finally, a second 24HR recall will be collected on a 10 percent subsample of participants from the core sample at the 13, 15, 18, and 24 month follow-up interviews to adjust for "usual" intake in infants.[6] The second interview will be scheduled for completion within 7-10 days of the first interview.

4.9 Obtain and Abstract Hospital and Provider Records

Throughout the data collection period Westat will request and abstract medical records from the birth hospital for all core sample enrollees, and child health care provider records for core sample enrollees if the infant is no longer in WIC. We will obtain a HIPPA release on completion of the

[6] Mod 2 memo (3/23/12) states that we will only do 2nd AMPM at 13, 15, 18, and 24 month interviews

enrollment interview and hospital and provider contact information at either the 1- or 3-month interview. We will request medical records from providers at 7, 13, and 24-months to obtain infant weight/length and health status for those infants who drop out of WIC. We estimate that 20 percent of enrollees in the study may leave WIC over the 3-year data collection period. Records will not be requested for those who did not sign a HIPAA form.

Obtain Records

The record acquisition process will involve sending a letter of request which will provide pertinent information about the ITFPS-2 and specify the type of records requested along with a copy of the signed HIPAA Authorization. The requests will be managed and tracked through the study tracking/management system. This system documents initial and follow up requests and generates reminders at specified times for follow up action. Requests that are unanswered after a certain time will be followed with a telephone reminder call and/or additional written requests, and resent if necessary.

We understand that individual institutions have established different rules regarding the release of medical records and authorizations. For example, the HIPPA is only valid for a specified time period, the institution has its own release form, copies of medical records must be paid for, and release form must be witnessed by a notary public. In each of these instances we will work with the individual institutions to meet their requirements in order to obtain the birth and provider records.

Abstract Records

Westat medical abstractors will identify and abstract pertinent data into a study-specific system that includes edit checks and verification capability. They will be trained on the specific abstracting procedures and how to self-edit their work. Westat supervisory staff will conduct verification on 10-20 percent of each abstractor's work to identify discrepancies both in selecting and in abstracting the data; any discrepancies will be discussed with the abstractors. If we identify a problem with an abstractor's work, the supervisor will provide additional training. A greater proportion of the abstractors work will be reviewed and problem items will be corrected in the database.

4.10 Obtain and Abstract WIC Administrative Records

Altarum will obtain administrative records from WIC during the data collection period for key milestones in the mother's and child's life as follows:

- Maternal Food Package Information: at enrollment, 1, and 7 months
- Child Food Package Information: at enrollment, 1, 7, 13 and 24 months.
- Child Weight and Length: requested at 7, 13 and 24 months. The measurement will be taken at ages 6, 12, and 24 months. We will obtain records at birth from hospital records;

These data requests have been timed to coincide with WIC clinic visits. The process for obtaining these records will vary from State to State. Altarum staff will work with the State and local agencies to determine how to best access the data in their WIC information systems, and will document that in a summary memo to the sites.

4.11 Obtain Weight and Length Measure Directly on Infants

Throughout the data collection period Westat will contract with a local home health service to obtain weight and length measurements on the core sample of infants who drop out of WIC and do not visit a provider for well baby checks. Infant weight will be obtained at 7, 13, and 24 months. The Westat study liaison will communicate with the participant to schedule the appointment. A $20 incentive will be provided once the health care professional obtains the measures.

Create Data Files 5

5.1 Data Overview

As discussed in Chapter 4, we will obtain administrative data and key informant data from State WIC agencies and from local WIC service sites. We will collect participant data directly from participants, from home health services visits and from hospital and provider records. A brief description of the data files to be used in the project is presented below and an overview of data collection is presented in Table 5-1.

1. ***WIC State Key Informant Interviews***: These data will be obtained from selected WIC staff in each State agency (determined by the State Agency WIC Director), and will contain data on WIC program and policies and activities for each State. Includes data collected to clarify information from State documents (plans, policies, descriptive information).

2. ***WIC Administrative Files:*** These data will be obtained from WIC State or local level sources and will contain data on mother and infant or toddler characteristics.

3. ***WIC Local Key Informant Interviews:*** These data will be obtained from WIC local level sources (probably WIC site coordinators and supervisors) and will contain data that clarify local site policies and attitudes related to infant and toddler nutrition education and services at the site. It will also be used to create a profile of the local site for use in analysis.

4. ***WIC Local Staff Survey Data***: These data will be obtained from local site staff (e.g., nutritionists, nurses, paraprofessional "competent professional authorities", site supervisors, support/clerical staff, peer counselors and others) and will contain data on local staff characteristics, attitudes, and knowledge about infant and toddler nutrition.

5. ***Participant Survey Data (Non-AMPM):*** These data will be obtained from enrolled study participants and will include nine different domains (described in section 3.1) providing the bulk of analytic data.

6. ***Participant Survey Data (AMPM Intake):*** These data will be obtained from enrolled study participants and will contain detailed nutritional intake data using the USDA Automated Multiple Pass Method (AMPM).

7. ***Weight & Length (Home Health Service):*** These files will be obtained from Home Health Services providers in cases where the measurements are not available through other means. The data will contain weight and length measures.

8. ***Hospital/Provider Data:*** These files will be obtained from hospitals or providers and will contain data on births and hospital stay characteristics.

In Table 5-1 below, we present an overview of the data files. We have outlined the timing of data collection for each data file, the primary owner of the data after data collection, and identifier variables in each data file in order to link files with each other. The primary owner of the data is the entity responsible for acquiring and processing the data. In Section 5.2, we will discuss the linkages and elaborate on identifiers where necessary.

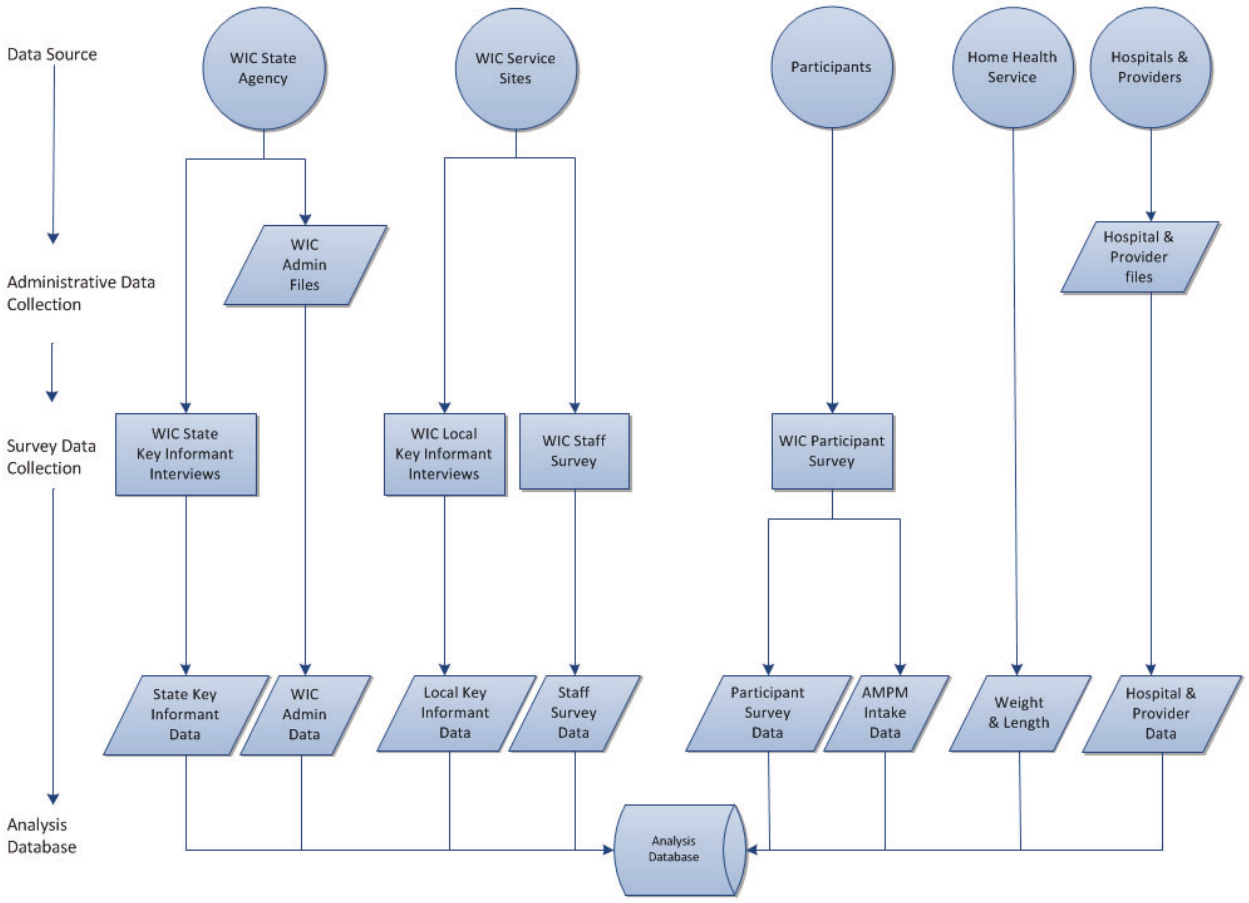
Table 5-1. Data files overview

Data	Source	Timing of collection (after OMB approval)	Primary responsibility	Identifiers
WIC State Key Informant Survey	WIC State Level Personnel	0.5-5 months	Altarum	State and Local Agency Id as available (or created)
WIC Local Key Informant Survey	Local Agency staff & service site staff	0.5-5 months	Altarum	Service site and local agency if needed
WIC Administrative Files	WIC State or local Level Personnel		Altarum	State and Local Agency
WIC Local Staff Survey	Service site staff	0.5-5 months	Altarum	Service site
Participant Survey (Non-AMPM)	Enrolled Participants	1-37 months	Westat	Case and person
Participant Survey (AMPM)	Enrolled Participants	1-37 months	Westat	Case and person
Home Health Service (Weight/Length)	Home Health Service providers	16-37 months	Westat	Case and person
Hospital/ Provider Files	Hospitals and Providers	12-37 months	Westat	Case and Person

5.2 Data Flow and Creating the Analysis Database

Figure 5-2 outlines the flow of data from the primary sources to the creation of an analysis database. The complete analysis database will be a relational database with multiple SAS data files, each with records at varying levels. While the data from the Participant Survey will be at the case and person level, the data from higher level entities (such as State and Local Agencies) will be at State or Local Agency level. The participant data will be collected up to 11 times over approximately a 2-year

Figure 5-2. Data flow from sources to analysis database



period as presented in Section 4. Thus the analysis database will be longitudinal in nature capturing multiple entries over time in different data files. All analysis files created will have flags indicating rounds of data collection and disposition status when necessary. These files will undergo a systematic review process that identifies outliers and tests for internal consistency.

5.3 WIC Key Informant Data Cleaning and Editing

Altarum will apply standard data handling processes to the qualitative data derived from key informant and other non-quantitative exchanges. The task leader will randomly select 20 percent of both the State and Local Key Informant Interviews to undergo a thorough review based on the recorded interview. Reviewers will listen to each interview in its entirety to ensure that the responses recorded into the database are accurate and consistent across the reviewed interviews. The reviewer will make changes as needed to the database, and maintain a log of entries to track the questions and

responses that posed particular problems for interviewers/recorders. After reviewing the selected interviews, the task leader will note whether any individual questions posed a problem for multiple respondents, and if so, a more thorough review will be conducted specific to the responses to those questions. Once discrepancies in data collection are resolved, Altarum will review responses to open-ended questions and develop coding schema (e.g., topics of trainings provided) for analysis. NVivo will be used for coding and analysis of the key informant data.

5.4 Administrative Data Cleaning and Editing

WIC, hospital, and provider administrative data on mother and infant/toddler characteristics will be subjected to rigorous data cleaning methods. It is anticipated that much of the data will need to be pre-processed either from hard copy (via abstraction), via phone calls with State or local agency administrative record sources, or from electronic files (via manipulation and data formatting). The issues and controls are well understood by the data management team and procedures to receipt, understand, prepare and load quantitative data are already part of the standard operating process.

5.5 WIC Staff Survey Data Cleaning and Editing

Altarum senior staff assigned to each State will review the survey data with the database manager for four potential problems:

1. **Completion of the Survey.** If the information is incomplete, it may be a result of a submission error or the respondent not understanding that they should complete all sections. If a survey is incomplete, Altarum will contact respondents to be sure they intended to submit an incomplete survey, and resolve any issues.

2. **Consistency of Responses.** Several of the questions are used as screening tools for matching respondents with appropriate questions. For example, different questions will be asked of those who conduct breastfeeding education than those that only issue food packages. We will be sure that all categories of respondent completed the appropriate sections that match their role in the WIC site.

3. **Errors in Matching State and Local Sites.** We will be sure that all data for local WIC sites are coded to the appropriate State in order to match State and local features when building the database.

4. **Other Coding Inconsistencies.** Should we identify any responses that do not make sense in terms of consistency or appropriateness, we will attempt to correct these prior to entry into the database by contacting respondents to resolve any issues

Once satisfied that the responses are complete and accurate, the data will be entered into the staff survey database for analysis.

5.6 WIC Participant Data (non-AMPM) Cleaning and Editing

Westat will apply meticulous data cleaning methods to ensure the participant data are of high quality. Many of the data cleaning tasks will be built into the computer assisted program. We recognize that in longitudinal studies it is possible to collect conflicting information about specific activities that will then need to be reconciled. To reduce the likelihood of this happening, we have structured the questions asked at each time period in such a way so as to avoid re-asking the same question. For example, once the respondent answers that they started/stopped an activity (e.g., breastfeeding), further interviews will not re-ask that information.

We will perform post-interview editing to identify anomalies, patterns as well as interviewer and programming errors. Automated reports will look at batches of data and based on pre-defined checks and output data to be reviewed. Key analytic variables will be compared and validated across forms. We will run frequencies and cross-tabulations on key variables which will be reviewed. As editing and data review begin and as scenarios are identified and investigated, we expect that the standard rules for correcting, deleting, or leaving data as is will develop as decisions are made in consultation with the program team and FNS. Once rules are identified, they can be systematically applied to future data reviews. Rules will be documented in the data management plan and changes will be documented in the data decision log. When appropriate, edit checks supporting the application rules will be incorporated into automated edit programs. Training will be provided to interviewers should they be the source of error and programming updates or additional edits will be coded as appropriate.

Built-In Edit Checks

Westat expects to use Blaise to build the WIC participant questionnaire. Blaise is a programming language specifically developed for computer assisted interviewing that features a full range of data editing capabilities during the interview. These edits will be specified as part of the development

process and will result in high-quality data since edit rules will be enforced and corrections made as the data are captured. To handle unforeseen situations where edits may not completely cover the situation or extreme out-of-range values are encountered, the interviewer may also enter a comment or remark at any item. These edits result in minimal missing data (typically the result of "don't know" or "refusal" responses in which the respondent is unable or unwilling to provide a response). We will also perform automated, post-collection editing using features internal to Blaise in conjunction with Westat's automated data editing systems and procedures to detect situations that may not be covered by the edits incorporated into the instrumentation. Using this approach preserves the variable ranges, skip patterns, and edits inherent to the interview while also allowing for the addition of edits and re-coding of open-ended responses within the editing process. The editing system also maintains a keystroke audit trail for each case.

Editing Process

The editing process used for the WIC participant data is divided into three sequential phases. The first phase is designed to create manageable editing tasks, review data within the construct of the computer-assisted interview, and resolve outstanding data issues found in the field during the actual interview. It allows the editor to review the interviewer's comments, to review all suppressed edits, to check for hard edit violations, to review all questions with a response of "don't know" or "refused," to review all open-ended responses, to determine possible errors in response entry, and to identify possible responses that could be coded. The second phase is designed to handle other-specify coding, coding of verbatim text, expanded ranges for unexpected responses, additional consistency edits that may have been too complex to handle during administration of the interview, and resolution of interviewer comments. The third phase involves generating SAS reports from the edited files which managers will review weekly to identify problems that require a systematic change. Edit problems will be addressed using the Blaise editing features or in SAS.

5.7 AMPM Response Data

Under the guidance of USDA Agricultural Research Service (ARS), Westat has well-established procedures for reviewing, consolidating, editing, and coding AMPM dietary recall responses. The dietary data processing tasks will take place outside of the Blaise editing process described above. This method has been applied to 10 years of National Health and Nutrition Examination Survey

(NHANES) collections, as well as other studies using the AMPM. During the data collection field period, Westat will receive Blaise data from the field on a daily basis that will be processed at Westat in batches using the USDA Post Interview Processing System (PIPS). The PIPS will convert the Blaise files to MS Access and apply food codes to about 60 percent of the foods. Once the files have been converted, the data will go to Westat's dietary coding shop, where the contents will be confirmed and tracked. Dietary coders will assign codes to foods that were not automatically coded during the PIPS process. Trained dietary coders will use standard procedures and established guidelines to code the intake data in the USDA SurveyNet coding system through a multiuser tracking system that assigns cases and enforces workflow rules to manage the internal editing and nutritional coding and third-party validation. Of note, after substantial research by Dr. Harrison and our consultant, Dr. Jane Heinig, we propose applying a standard gram weight to each breastfeeding occasion using the criteria/cutoff points set by the Gerber Feeding Infants and Toddlers Study (FITS).7 The best data available show that the variation in volume and energy intake among completely breast-fed babies is substantial, most particularly at 6 months of age, and estimates from the DARLING study at UC Davis,8 which utilized test-weighing of infants before and after each feeding, indicate that using the FITS cutoffs may substantially under-estimate energy take for fully-breastfed six-month-old infants.9 However, we estimate that the number of infants fully breast-fed in the WIC population is less than 15 percent so will apply a correction factor based on this study for this small number of infants, and see whether estimates of nutrient intake cutoffs are different with this correction.

In our experience with the AMPM and SurveyNet, there are very few foods that cannot be coded using the USDA Food and Nutrient Database for Dietary studies (FNDDS). This is because most new foods on the market are derivations of existing foods (e.g., new cereals, juice drinks, power bars, etc.). When a new food name cannot be found in the FNDDS, a similar food with the same nutrient profile can typically be matched to the new food. Therefore, these foods can be coded using existing food codes. This process involves researching the nutrient content of the new food (by searching the USDA Survey Database, manufacturer's websites, websites of other databases) and assigning an acceptable food code on the basis of macronutrients (kcal, protein, carbohydrate, fat) and selected micronutrients (e.g., carotenes, vitamin C). The match is considered acceptable if the nutrients are within 10 percent. We expect that acceptable matches can be determined for almost all

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[7] Butte NF, Fox MK, Briefel RR, Siega-Riz AM, Dwyer JT, Deming DM, Reidy KC. Nutrient intakes of US infants, toddlers, and preschoolers meet or exceed dietary reference intakes. J Am Dietetic Assoc.2010; 110: S27-S37.

[8] Dewey K and Lonnerdal B. Milk and nutrient intake of breast-fed infants from 1 to 6 months: relation to growth and fatness. J Pediatr Gastroenterol Nutr. 1983; 2: 497-503.

[9] Heinig J. Personal communication, 2012.

new foods. In instances when an acceptable match cannot be determined, we will assign the closest available food code and flag it as needing modification. In the nutrient output file, we will replace the nutrients for the flagged food item with the nutrients from USDA's database or a comparable nutrient database. For these modified food codes, we will also review the Food Patterns Equivalents assigned to the original food codes and determine if any servings need to be changed.

Additional steps to ensure the quality of the dietary data include significant review and editing efforts by senior coding and/or supervisory staff. Senior staff will conduct a 100 percent review of coded data, examining the data line-by-line to verify the accuracy of the work. Supervisory staff are responsible for the final quality control edits and reconciling intake data that are outside normal limits. Reports used to identify outlier values include the portion outlier report, which highlights unusually large or small portion sizes.

Weighting, Nonresponse Bias Analysis, Missing Data Compensation, and Variance Estimation 6

6.1 Overview

We plan to use standard design-based methods for weighting and variance estimation that will lead to confidence intervals on means and percentages, and hypothesis tests on contrasts of means and percentages. Base weights will be computed as the reciprocals of the probabilities of selection. We expect there will be missing data given the large number of planned interviews for each sampled member and the high likelihood that some individuals will miss some interviews. If analyses were restricted to only complete cases, information from the incomplete cases would be lost and the analyses would ignore the possibility that there are systematic differences between the complete cases and incomplete cases. We will address this potential nonresponse bias by a combination of nonresponse adjustments to the sampling weights and imputation of missing data.

Weighting adjustments can be used to reduce nonresponse bias. However, unless a separate set of weights is developed for each subsample being analyzed, weighting adjustments tend not to deliver much lower variance than the simple procedure of analyzing only complete cases. In fact, weighting adjustments tend to increase variances beyond what one sees in the simple procedure of only analyzing complete cases. Although weights are not as transparent as restricting the analysis to include only complete cases, they are still fairly easy to understand and are well accepted in the survey tradition, at least for cross-sectional surveys or cross-sectional analyses of longitudinal surveys.

Imputation is another tool we will use to address missing data and the associated nonresponse bias. Imputation has the important advantage that analyses based on imputed datasets can be exceptionally clear to a wide set of audiences. However, when imputation is done it is important to document clearly which data on microdata sets are imputed, and to explain the uses for which the imputed data are more or less well suited.

We begin our discussion with our approach to base weights (Section 6.2). This will be followed by a section on our plan for weighting and imputation (Section 6.3). Finally, we close with sections on nonresponse bias analysis (Section 6.4) and variance estimation (Section 6.5).

6.2 Base weights

We will develop sampling weights aimed at yielding nearly unbiased estimates of population parameters such as the breastfeeding initiation rate. These weights will be based on Horvitz-Thompson weights, equal to the inverse of the probability of selection. Layered over these will be adjustments for nonresponse across the interviews (called "waves" for weighting purposes) of the study. One set of weights will be developed for analyses of the core sample by itself. A different set of weights will be developed for joint analyses of the core and supplemental sample samples.

Core Sample

The Horvitz-Thompson core-sample weight for an infant will be

$$W_{Bijk} = \frac{52}{22}\frac{M_i}{4M_{ij}}\frac{E_i}{2}\frac{C_{ij}}{D_{ij}}\frac{22\square 5}{L_{ij}}\frac{N_{ij}}{n_{ij}},$$

where the first factor adjusts for the fact that the field period contains only 22 of the 52 weeks in a year,, M_i is the count of new enrollments[10] in the *i*-th stratum according to the PC2010, M_{ij} is the count of new enrollments (defined the same way from the same source) in the *j*-th first-stage sampling unit in *i*-th stratum, the 4 in the denominator adjusts for the fact of sampling four first-stage sampling units per stratum in the first phase of selection, E_{ij} is the number of eligible first-stage units among the 4 sampled in the *i*-th stratum, the 2 in the denominator accounts for the fact that 2 first-stage units will be selected in the second phase among the E_i eligible, C_{ij} is the count of clients[11] in same first-stage sampling unit according to local reports at the time of first-stage sampling unit scouting, D_{ij} is the count of clients in the sampled service site within the *j*-th first-stage sampling unit in *i*-th stratum according to the same local reports, 22 is the length of the field period in weeks, L_{ij} is the length of the window in days, N_{ij} is the number of new enrollees[12] during the window, and n_{ij} is the number of clients who are recruited into the evaluation study

[10] All newly enrolled pregnant women in April of 2010 plus 20 percent of newly enrolled infants. All from the PC2010.

[11] It is not necessary to define clients here as new enrollments although that would be best if possible. Of course, it is important to use whatever was used for sampling.

[12] New enrollees here means pregnant women enrolling for the first time during the current pregnancy plus new infant enrollees whose mothers appear not to have been on WIC during the gestation of the infant.

during the window. Here it is important to note that n_{ij} counts those who give informed consent and not just those who pass the screening test of not having previously enrolled for WIC during the current pregnancy or the pregnancy leading to the birth of the infant being enrolled.

Although this formula appears complex, we hope that the weights will have low variation. Various simplifications will come into play in different situations. For a given sampled service site, if the entries on the PC2010 identify the service site (rather than a composite site), the service site will have been sampled at the first stage of selection and no second stage of service site selection will have been needed; in this case we will have $\frac{C_{ij}}{D_{ij}} = 1$. Even when the second stage of service site selection is needed, , as long as the enrollment figures provided for second-stage selection are highly accurate, corr M_{ij}, C_{ij} should be large and therefore the ratio $\frac{C_{ij}}{M_{ij}}$ should be close to 1. If the PC2010 data or the local scouting data turn out to be inaccurate, weights will vary more. On average, we expect the weights to be on the order of 550. This is based on an assumption of two million new enrollees in a year, 78 percent coverage, and a recruited sample size for the core sample of 2804.

Of course, to the extent that there is bad information at any phase or that there is a shift in site operations that reduces the predictive value of past data, the weights will vary. This is a concern because highly variable weights reduce the precision of survey estimates, and there is the potential for the cases with large outlying weights to have undue influence on estimates. Note that these weights will be constant within service site but vary across service sites. If there are isolated incidences of sites with weights much larger than the predicted average of 550, we will consider trimming the weights to avoid the situation where the results from such an office dominate the national estimates on a weighted basis. We are hopeful that this will not be required, but will carefully check for the possibility and take appropriate steps if the condition is detected.

Total Sample

When analyses use both the core and supplemental samples, a different set of baseweights will be required. Let r_{ijk} be the retention rate in the supplemental sample for persons in the sampling domain that contains the infant. The baseweight for the infant in the total sample will be $W_{BTijk} = \frac{1}{1+r_{ijk}} W_{Bijk}$. This same formula will be used whether the infant was sampled as part of the

core or as part of the supplemental sample. Note that if the infant is from a rare group that is always retained when found (such as children of black mothers), the weight for the infant in the total sample will be half the weight it receives when the core sample is analyzed by itself. At the other extreme, when an infant belongs to a common group that is never retained when found in the supplemental sample (such as children of obese Hispanic mothers), then the baseweight for the infant is the same whether the core is analyzed by itself or in combination with the supplemental sample.

6.3 Missing Data Compensation

Given the large number of planned interviews for each sampled mother, it is inevitable that there will be missed interviews resulting in complex missing data patterns. We will attempt to mitigate the risk of ensuing nonresponse bias by a combination of nonresponse adjustment to the sampling weights and imputation. We will prepare a separate set of weights for each wave of data collection. The only respondents that will receive a positive weight for a wave will be those who responded to the wave and those who missed the wave but returned to the sample after missing no more than two consecutive waves. Respondents returning to the sample after one or two missed waves (interviews) will be asked some retrospective "catch-up" questions to get the timing of a few critical items where transitions are noted such as when nursing mothers stopped nursing, and when cereal was introduced into the child's diet.[13] Imputation will be used to fill in scattered item nonresponse within completed interviews. It will also be used to fill in data from other sources such as hospital records when we have questionnaire data from mothers.

Weights

Table 6-1 shows a planned set of weights. In addition to the cross-sectional weight for each wave, we will create some longitudinal weights for analyses that require analysis of linked data across waves. We note that simple change estimates (as in the percent still breastfeeding) do not require linked data. These change estimates will be prepared by forming point estimates for each wave with

[13] Respondents get the full interview for the month in which they are doing an interview, regardless of missed interviews or which sample they are in (core or supplemental). So questions that require reporting a "date" (e.g., cessation of breastfeeding, introduction of formula, or introduction of supplemental foods) will be asked at every applicable interview until the mother gives us a date or until the question is no longer part of the interviews.

Table 6-1. Weights to be prepared and delivered

Weight name	Core only or combined?	Positive for respondents at which waves?	Additional notes
PrenatalWgt	Core only	Prenatal	
Month1CoreWgt	Core only	1-mo	Only prenatally recruited infants and infants recruited postnatally within the window for the 1-mo interview
Month1CombWgt	Combined	1-mo	Only prenatally recruited infants and infants recruited postnatally within the window for the 1-mo interview
Month3CoreWgt	Core only	3-mo	
Month5CoreWgt	Core only	5-mo	
Month7CoreWgt	Core only	7-mo	
Month7CombWgt	Combined	7-mo	
Month9CoreWgt	Core only	9-mo	
Month11CoreWgt	Core only	11-mo	
Month13CoreWgt	Core only	13-mo	
Month13CombWgt	Combined	13-mo	
Month15CoreWgt	Core only	15-mo	
Month18CoreWgt	Core only	18-mo	
Month24CoreWgt	Core only	24-mo	
Month24CombWgt	Combined	24-mo	
HazardModelCoreWgt	Core only	Prenatal + 1-mo or 3-mo if postnatally recruited	Good for modeling hazard of weaning & introduction of various foods; also good for modeling of BF initiation
HazardModelCombWgt	Combined	At least one postnatal interview	Good for modeling introduction of various foods. Earliest weight that uses entire sample. Larger sample size than HazardModelCoreWgt but can't be used in conjunction w/prenatal data.
InfantCoreLongWgt	Core only	Responded every wave from birth through 13 mo.	Good for growth curve modeling of calories/other variables measured each wave. No plans for analysis, but would be expected by many users on a RUF.

Table 6-1. Weights to be prepared and delivered (continued)

Weight name	Core only or combined?	Positive for respondents at which waves?	Additional notes
ToddCoreLongWgt	Core only	Responded every wave from birth forward	Good for growth curve modeling of calories or other variables that are measured each wave. No plans to use in our analysis, but would be expected by many users on a RUF.
CritWaveLongWgt	Combined	1/3, 7, 13, 24	If prenatally recruited or recruited postnatally within the 1-mo interview window, responded at mos. 1, 7, 13, and 24. If postnatally recruited, after the 1-mo interview window responded at mos. 3, 7, 13, and 24. Good for growth curve modeling with procedures that cannot handle missed waves.

the wave-specific cross-sectional weight and then subtracting the two estimates at the macro level to get estimates of net change.

The weighting adjustments will be fairly standard. The approach entails giving a zero weight to the nonresponding case and redistributing the base weight of the nonrespondent to responding but otherwise similar cases. This process is done within nonresponse adjustment "cells." Nonresponse is assumed to be a perfectly random phenomenon within each cell. Once the cells have been defined, Westat has standardized software for making these adjustments that we have used very often over the last 20 years. The approach we propose to use to form the cells for nonresponse adjustment uses a class of procedures known as "doubly robust" adjustments. In contrast to traditional approaches for forming nonresponse adjustment cells, these procedures place greater emphasis on the modeling of critical outcomes in the development of cells and somewhat reduced emphasis on the modeling of nonresponse propensity. In a survey with many outcomes, the challenge is determining the key outcomes to use in this modeling exercise. For WIC ITFPS-2, we propose to develop a binary indicator at each wave for whether the mother is following recommended feeding practices for the age of the infant. We will then model this in terms of data from prior waves to obtain a set of cells that vary in maternal conformance to recommended feeding practices. We will then cross these cells with the cells defined more traditionally to predict nonresponse propensity. If we use five cells from each model, that will give us a total of 25 nonresponse adjustment cells at each wave that vary substantially in both propensity to follow recommended feeding practices and propensity for nonresponse. Adjusting for nonresponse within these cells will result in doubly robust nonresponse-

adjusted weights. Nonresponse bias will be reduced for a wide range of statistics with this approach but particularly for statistics about suboptimal feeding practices.

The key to effective nonresponse adjustments is the availability of good auxiliary variables to be used in the adjustment. The adjustment for those who initially consent but do not respond to the initial (prenatal or 1-month) interview is most limited in this regard. We will ask the service sites to provide a few key pieces of information about each potentially eligible WIC enrollee for use in nonresponse adjustment, including WIC ID; whether the enrollment was prenatal or postnatal; age; language; and income. In addition, the recruiter/helper will determine, with the help of the site, whether an enrollee refused a study flyer.

Also, we will build models of attrition at each wave based on the data collected to date. Various modeling methods could be considered, and these methods have been found to work approximately equally well (Folsom and Witt, 1994; Rizzo, Kalton, and Brick, 1996; Judkins, et al 2005); the real question is which variables to allow into the modeling and how to deal with missing data in the early wave data.

In many surveys, one step (generally the final step) in the sequence of weighting adjustments is to calibrate the weights (e.g., using poststratification or raking adjustments) to control totals from trusted sources, such as census totals or estimates from administrative record systems or larger surveys. In this case, no such trusted source exists, so this calibration step will not be possible.

Imputation

Imputation will be used to adjust for item nonresponse, i.e., missing data for particular items among those who respond to a given wave. By using imputation to "plug holes" due to item nonresponse, we mitigate issues analysts would encounter in trying to analyze data with "swiss cheese" patterns of missingness. As with weighting, a carefully designed imputation procedure will reduce bias due to nonresponse (in this case, item nonresponse). Further discussion will be needed to identify the particular set of items to be imputed but this set should include, at a minimum, variables needed for weighting as well as key survey outcomes and covariates.

For imputation, Westat has created new software over the past decade called AutoImpute, which uses a cyclical n-partition hot deck (an approach analogous to the Gibbs sampler but using the hot deck to generate the imputations). (See Judkins 1997; Judkins et al. 2007; Judkins, Piesse, and

Krenzke 2008; and Krenzke and Judkins 2008.) This software is designed to facilitate preservation of multivariate distributions while also ensuring that imputations maintain skip patterns and adhere to constraints. We have used it successfully on about a dozen major surveys, including one with a baseline and eight followup interviews. With virtually any imputation procedure, if there are outliers and inconsistencies in the data, these can become magnified after imputation. For this reason, it is important to carefully edit the data prior to imputation. After imputation, the same analytic edits that we ran on the raw data will be run again on the imputed data. As part of this process, will need to examine and possibly deal with outliers that could affect imputation. Dealing with outliers might involve setting them to missing and imputing for the newly missing data or setting them to reasonable boundary values. This type of detail will be worked out in consultation with subject-matter experts and FNS.

6.4 Nonresponse Bias Analysis

To the extent that respondents 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. Since 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.

One approach we will use is to examine bivariate cross tabulations of data from one wave by response status at a followup wave to check for evidence of nonresponse bias at followup. Since there will be eight waves of followup on the core sample after the first interview for infants recruited after birth, and ten waves of followup on the core sample for those required prenatally, there will be many possible cross-tabs that could be run. By the 24-month interview, there will be thousands of measurements from prior waves that could be used to check for nonresponse bias at the 24-month interview. Obviously the scope of these tabulations could quickly become unmanageable. We will need to establish a few sentinel variables from early waves to use as benchmarks for first-degree bias estimation. We will work with FNS to arrive at a set of key variables to be used for this purpose.

As discussed above, the weighting class adjustments for nonresponse aim to reduce nonresponse bias. Thus, while the subgroup response rate analysis described above may be useful in identifying the *potential* for nonresponse bias due to varying response propensities among key subgroups, this

nonresponse bias may be mitigated through the adjustments for nonresponse. To examine this, we will compare unadjusted estimates (i.e., computed using weights that do not include the adjustment for nonresponse to the particular wave) to adjusted estimates.

With a longitudinal study such as WIC ITFPS-2, another technique that can be used is to compare prior-wave estimates for key statistics for respondents to the given wave to the corresponding prior-wave estimates computed using the full set of prior-wave respondents.

Another method that could be considered is benchmarking estimates from WIC IFTPS-2 to estimates from other sources, provided such external estimates are available. Although benchmarking to external estimates is a method commonly included in a repertoire of nonresponse bias analysis techniques, it is recognized that this approach does not allow for isolation of bias due to nonresponse. Besides nonresponse bias, differences between the survey estimates and external estimates might be attributable to temporal differences, differences in survey populations or survey measures, or other sources of error such as coverage bias.

6.5 Variance Estimation

Two broad classes of methods have been developed for computation of standard errors of estimates from complex sample surveys: (1) replication methods and (2) Taylor series linearization. The WIC ITFPS-2 data files will contain the information necessary for analysts to use either of these approaches to compute standard errors. Several software packages are available for the analysis of data from complex sample surveys using one or both of these approaches to variance estimation. These include WesVar, SUDAAN, the survey procedures in SAS, Stata, and the *Survey* package in R. Users of the RUF from this project will particularly appreciate the ease of use afforded by the combination of replicate weights and one of these packages.

Replication

Replication methods provide a relatively simple way of estimating variances and have some advantages over other variance estimation methods (e.g., linearization approach). The basic idea behind the replication approach is to repeatedly select portions of the sample ("replicates"), to calculate the estimate of interest for each replicate, and then use the variability among these

estimates to estimate the variance of the full sample statistics. Different approaches can be used to creating these replicates.

For WIC ITFPS-2, 40 replicates will be created, and the replication approach that will be used is a modified balanced repeated replication (BRR) method suggested by Fay (Judkins 1990). When estimating the variance of ratios of rare subsets, one problem that occasionally arises from standard BRR is that one or more replicate estimates will be undefined due to zero denominators. Instead of increasing the weights of one half-sample by 100 percent and decreasing the weights of the other half-sample to zero as in standard BRR, Fay's method perturbs the weights by ±100(1-K) percent where K is referred to as "Fay's factor." The perturbation factor for standard BRR is 100 percent, or K=0. For WIC ITFPS-2, K=0.5 will be used.[14,15]

In order to create the replicates (and also to define the variables needed for Taylor series linearization variance estimates), it is necessary to define variance strata and variance units. Each stratum defined for the selection of first-stage sampling units will constitute a separate variance stratum. The two first-stage units selected each stratum will comprise the first and second variance units. For each set of weights defined in Table 6-1, we will develop a set of "replicate" weights in addition to the full-sample weights. In order to appropriately reflect the effects of the various stages of weighting on the variances of survey estimates (Ernst and Williams, 1987), the procedures used to compute the full-sample weights (described in Section 6.2) will be repeated for each of the replicates.

This procedure will slightly overestimate variances since it will not account for the first-stage finite population correction (fpc) factor. The first stage fpc factor is the reduction in variance due to the fact that the first-stage sampling units will have been selected without replacement rather than with replacement. A more complex version of Fay's method has been developed that captures this fpc (see for example Rizzo and Judkins, 2004, which all includes references to earlier related work). However, these have not been routinized at Westat and do not appear to be worth the extra difficulty in implementation for WIC ITFPS-2 given that most service sites are small and will have very small chances of selection, rendering the fpc negligible.

[14]Judkins, D. Fay's method for variance estimation. *Journal of Official Statistics*, 1990; 6: 223-240.

[15]Rao, J.N.K., and Shao, J. Modified balanced repeated replication for complex survey data. *Biometrika,* 1999:; 86:403-415.

Taylor Series Linearization

Taylor series linearization uses a mathematical approximation to approximate a nonlinear statistic with a linear form. The variance of the nonlinear statistic is approximated by the variance of the linear function. Software packages that use Taylor series linearization to estimate variances of statistics from complex sample surveys require the user to specify design information including "stratum" and "cluster" variables. Unlike those based on replication methods, variance estimates based on Taylor series linearization do not fully capture the effects of all of the weight adjustments; however, in most cases, the differences between Taylor series standard errors and replication-based standard errors are not large. The "stratum" and "cluster" variables that allow users to compute variance estimates using Taylor series linearization will be provided on the WIC ITFPS-2 files.

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Analysis 7

We will conduct analyses to answer the 60 research questions articulated in the RFQ as well as supplementary questions. Additionally, we will repeat most of the past analyses from the FNS-sponsored WIC-IFPS-1 and the two Gerber/Nestle Feeding Infants and Toddlers Studies (FITS). We will compare current findings to relevant past work and to current objectives and standards.

7.1 Repeating the Analyses of Past Studies

The most relevant past research is the WIC-IFPS-1 as it focused specifically on the WIC population while the other major studies of feeding practices were general population studies. Therefore, in repeating past analyses the focus is primarily on the WIC-IFPS-1. We then reviewed the Gerber/Nestle FITS studies I and II, the FDA-sponsored IFPS, and the WIC Birth Month Study from the perspective of the additional research questions and analyses they contribute beyond those addressed by the WIC-ITFPS-1. The FITS are substantially different from the WIC-IFPS-1 and focus primarily on nutrient intake, which complements the work done in the WIC-ITFPS-1 and provides more detail on nutrient intake. Additionally, although it uses cross-sectional data, the FITS include analyses of both infant and toddler feeding practices through 24 months. In contrast, the FDA-sponsored IFPS address basically the same research questions as the WIC-IFPS-1 but cover the general population. Additionally, these studies collected detailed information on topics that are only tangentially relevant to WIC objectives such as food safety practices, infant and mother sleep patterns, and infant food related-health problems. To include these topics in the data collection would increase the response burden beyond acceptable levels. Given the overlap in research question and the tangential nature of some of their additional research, we will not separately replicate the analyses from the FDA IFPS. Similarly, the WIC Birth Month Study also heavily overlaps with many of the topics addressed in WIC IFPS-1 but addresses them in more detail as the study only covers nutritional issues during the first month of life. We repeat analyses from the Birth Month Study to the extent that our data collection supports. Finally, because the schedule of interviews includes both infant and toddler data collection, some of the WIC-IFPS-1 analyses will be repeated using different time points. Table 7-1 provides a summary of the analyses we intend to repeat and those we do not intend to repeat. Additionally, in Appendix A, we provide a listing of all

the tables and figures in the final WIC-IFPS-1 report noting whether we will repeat this work or no. In the cases in which we will not be repeating the work we provide an explanation for this decision.

Table 7-1. Summary of analyses to be repeated from previous studies

Primary topics	Summary analyses repeated	Analyses not repeated
WIC-IFPS-1		
■ Breastfeeding patterns, intensity, and duration ■ Reasons for stopping breastfeeding ■ Transitional and complementary feeding ■ Timing of these decisions ■ Supplemental foods	■ Tabulations and comparisons (Chi2 tests) by subgroups (e.g., percentage initiating breastfeeding by socio-demographics) ■ Frequencies over time (e.g., percentage still breastfeeding by age of infant) ■ Factor analysis (e.g., dimensions for breastfeeding attitudes and knowledge)but items will be updated ■ Logistic regressions for probability of an event (e.g., initiating breastfeeding) ■ Survival analyses for time until an event (e.g., time until cereals are introduced)	■ Interim models that only use a subset of the covariates ■ OLS regressions of breastfeeding frequency (e.g., counts of number of breastfeed at month1)
FITS I and II		
Nutrient intake	■ Food and nutrient intake estimates ■ Frequencies over time(e.g., percentage consuming vegetables by age of infant) ■ One-day nutrient intake distributions (e.g., overall intake and prevalence of inadequate and excess)	■ Tabulations of developmental milestones
FDA		
As the FDA study significantly overlaps with the WIC-IFPS-1 and FITS, no additional analyses will be repeated from the FDA study		

7.2 Key Analytical Variables

Outcomes and Key Feeding Decisions

To answer the research questions and update past analyses, we will assess feeding practice decisions, child nutrient and food intake, and weight outcomes. As the variety of foods infants consume is very limited in the initial months of a child's life, the feeding practices the caregiver employ are key to nutrient intake. In contrast, once the child is eating a variety of foods, direct food intake measures become the most important measures of dietary quality. The main feeding practice decisions and outcomes are listed below. All variables will be examined by frequencies and how they vary by key

socio-demographics, however, only those that are not italicized will be used as outcomes in the causal model estimations.

- **Breastfeeding Decisions.** *Intent to breastfeed*, initiation of breastfeeding, *first hospital feeding*, breastfeeding at hospital discharge
- **For Those Who Breastfeed.** *Use of breast pump*, time until formula supplementation, time until breastfeeding cessation
- **Other Infant Feeding Practices.** *Number of feedings per day*, time until cereal, time until baby foods (by type), *duration of bottle use, timing of feeding transition*
- **Nutrient Intake and Weight Outcomes.** *Foods eaten by type*, *calorie intake per kilogram of body weight, usual nutrient intakes relative to Estimated Requirements (EARs) (where these exist and Adequate Intakes (AIs) otherwise), nutrient densities*, *nutrient intakes relative to UL (where these exist),* weight-for-length, *weight/length gain (0-6 months), weight/length gain (6-12 months).*

To translate the dietary data obtained from our interviews into measures of usual nutrient intake, we will use the NCI method[16] developed by researchers at the NCI, the USDA, and elsewhere. The NCI method is a unified framework for estimation of usual intake of nutrients and foods. It models usual intake as the product of the probability of consumption on a given day and the average amount consumed, which is conditional on having consumed a positive amount. It takes into account zero-consumption days and reported consumption-day amounts that are positively skewed, and distinguishes between within-person and between-person variation in consumption. It also allows for efficient estimation of usual intake for subgroups. Instead of stratifying the sample by subpopulation and estimating usual intake separately for each subgroup, covariates defining subgroups are included in the NCI model, such that (difficult to estimate) variance components may be estimated simultaneously for the full sample, and only covariate values differ. For subgroups of respondents comprising a relatively small proportion of the full sample, the efficiency gains from this capability are likely to be relatively substantial.

Comparison Groups and Covariates

We will assess participants' outcomes and decisions by subgroups to identify subpopulation differences. Using the conceptual causality models and the past research as a guide, we will model these outcomes and decisions as a function of a set of covariates that are possibly predictive of the outcome (or decision) under study. The core analytical comparison groups will be similar to the

[16] http://riskfactor.cancer.gov/diet/usualintakes/details.html

socio-demographic categories that were used in the past studies and will include race, ethnicity, mother's age, mother's education, mother born in the United States, father living in the home, poverty level, and infant's birth order. Our comprehensive data collection will allow us to explore the impact of a few additional socio-demographic variables such as household food security and acculturation on feeding practices and nutrition outcomes.

As we showed in the conceptual models, in addition to these socio-demographic variables, data on maternal and family health, the mother's attitudes, beliefs and knowledge, the mother's experience and receipt of advice, the mother's hospital experience, the mother's lifestyle choices, and toddler feeding practices, will serve as categories of covariates in the analyses. We expect that a large number of the potential individual variables within these covariate groups will be correlated as on many topics we are asking specific information about attitudes and behaviors. Therefore, many of the interview questions will be highly related. For example, to obtain information about the mother's attitudes, beliefs and knowledge regarding breastfeeding will require asking a battery of questions, with each question revealing a specific viewpoint. It is likely that women who are pro-breastfeeding answer the set of questions one way while those who are not answer differently which would result in highly correlated responses among participants. Including highly correlated variables in a regression model can make interpreting results difficult and lead to multicollinearity. We will explore using principal component analysis to transform sets of potentially correlated variables into a set of uncorrelated composite measures. We will explore using this data reduction technique to summarize the responses to questions regarding: (1) maternal attitudes, belief, and knowledge about breastfeeding, (2) hospital experience and (3) toddler feeding practices. Because the development of meaningful composite measures is dependent on the correlation between items, we are not able to guarantee, in advance, that this technique will yield useful composites in all cases.

WIC Program Variables

A key variable of interest in assessing infant feeding practices is the mother's experience with the WIC program. There is variation in participants' experiences with WIC because there are differences in: (1) the services and education provided at the local clinic, (2) the State polices and supplies provided (3) the training and attitudes of the local WIC clinic staff, and (4) the time spent in the program. Westat proposes to improve the measure of participants' WIC program experience and capture this variation by developing a series of composite measures. We propose five composite

measures for capturing program variation and identify the expected contributing factors to each measure as follows:

- **Variation in education offered** measured by the number of education contacts offered, educational topics offered, delivery method, training of the staff, knowledge and attitudes of the staff. (In addition to this program-offering composite, we will have information on the educational programs the individual attended which can be used as a separate covariate).
- **Variation in breastfeeding peer counseling** measured by the ratio of counselors to participants, education and training of the staff, and knowledge and attitudes of the staff; and
- **Variation in the provision and support for breast pumps** measured by types of pumps available, policies on issuance, support education provided, and knowledge and attitudes of the staff regarding pumps
- **Variation in the food packages** measured by package choice substitutions available based on the State plan and attitudes of the staff regarding the importance of the food packages, substitutes, and alternative diets.
- **Variation in time in WIC** measured by number of days of current participation, number of years of participation associated with previous children, joined pre-natal or post-partum.

We will use these composite variables to capture the cross-sectional variation in WIC program experience, or "dosage" of WIC exposure, among program participants.[17]

It should be noted that ultimately the variation in service delivery we observe between sites will determine which factors to include in our composite measures as well as whether the final measures are effective in capturing meaningful program variation that can be related to policies. Therefore, to some extent this work will be exploratory and we will assess alternative composites. For example, if we find the quality of sites' educational programs vary by phase we will consider having separate composites for newborn feeding, infant feeding transition, and toddler feeding. In contrast, if sites that deliver effective newborn feeding education, almost always also deliver strong infant feeding transition and toddler feeding programs, a single education composite will suffice.

[17]The WIC program variables will be composite measures. A composite measure is a combined metric that incorporates multiple individual measures to provide a single score. It is used as a way to measure concepts that are too complex to be measured simply with one item. Composite measures are also a data reduction technique used to avoid having many highly correlated variables in the same analyses which creates statistical challenges. The five WIC program variables will be composite measures of the component variables listed in the Research Plan and are intended to capture different aspects of how the program is being delivered and experienced. For each of the five composite measures, we will develop weights for the component variables and combine them into a single score (index variable). A simple approach for doing this is to take a straight average of all the component variables but this approach would not address the differing importance of the component items or their correlation with each other. We propose to use factor analysis (a statistical technique) to determine the relative weights to use in the creating the composite measure.

As we discuss in the study sampling plan, we will develop a typology and collect information from the States regarding WIC program features that will be used to stratify sites for sampling. Once the sample of service sites is selected, we will collect more detailed information from these sites regarding their WIC program features and operations through a series of key informant interviews. Together, these data will capture both State and local policies and offerings and will allow us to develop more refined categorical measures of the WIC program that reflect the variation in supplies, services, and educational offerings among service sites. Finally, through the staff survey, we will collect information on staff training and attitudes.

7.3 Main Types of Analyses

We will conduct both descriptive and causal analyses to answer the 60 research questions and update the analyses from past studies of the WIC program. Many of the research questions can be answered by descriptive analyses that tabulate the responses to specific questions (e.g., what are the mother's reported breastfeeding problems?) or characterize the attributes and behaviors of different subpopulations (e.g., what are the distributions of caregiver and participants health-related characteristics by race and ethnicity of the mother?). A small subset of the research questions focus on understanding the underlying population and program factors that drive nutritional outcomes and decisions. Therefore, we will conduct basically four types of analyses as follows:

- **Descriptive analyses**
  - Single month cross-sectional snap shots
  - Repeated monthly (or key month) cross-sectional snap shots
  - Longitudinal calculations (i.e. we read across several interview months to calculate the measure of interest such as the average age children start cereal)
- **Causal analyses**
  - Model estimations

We will use descriptive statistics (counts, proportions, means, medians, distributions (percentiles), means, medians,) and cross-tabulations) to examine key decisions and conditional outcomes by subgroups (e.g., how do the feeding practices of infants and children who continue in WIC compare

to those who leave the program[18] or have non-continuous participation?). For questions like these, the differences will be examined between subgroups by comparing descriptive statistics across subgroups such as the proportions that engage in given feeding practices. This will determine if the subgroup statistics are different using the appropriate statistical significance tests (e.g., Chi^2 test for proportions and t-test for means that are adjusted for the cluster sample design). The advantage of descriptive cross tabulations is they are straightforward but they will not capture the impact multiple factors may be having on a decision or outcome and therefore may overstate the importance of the subgroup variables.

For the subset of the research questions that focus on identifying the causal relationships that drive the outcomes and decisions observed, we will use multivariate analyses such as regression analysis to explore how choices and characteristics impact feeding practice decisions and nutrition outcomes while holding other contributing factors constant. We will use Ordinary Least Squares (OLS) regression, logistic and multinomial logistic regression, survival analysis, quantile regression, and growth models to answer these questions. We will apply OLS regression models to explore how continuous dependent variables are, on average, impacted by background characteristics, experiences, and decisions. We will use Logistic (and multinomial) regression to model how dichotomous (and categorical) decisions and outcomes (e.g., the decision to breastfeed) are impacted by background characteristics, experiences, and past decisions. Similarly, we will use survival analyses to model how background characteristics, experiences, and past decisions affect time duration until an event (e.g., number of day until breastfeeding cessation). Finally, for investigating weight outcomes, we will initially explore the relationships between predictors and outcome using OLS regression but then will use quantile regression to estimate impact that the explanatory variables have on the dependent variable quantiles (we propose using quintiles but will also explore other slices of the distribution). This will provide insight into how the explanatory variables affect each weight/length quintile (top 20 percent of the distribution, etc.) rather than the mean level as OLS regression does. Additionally, we will use growth models to estimate the impact that covariates have on the weigh/length growth trajectory.

[18] We will continue to interview women who leave the WIC program with the understanding that there may be a drop off in their interview cooperation rate.

7.4 Data Challenges

Over a two year data collection period, it is highly likely that participants will miss some of the interviews. First, we will minimize the number of missing variables by repeating questions across interviews and recording the date of change of critical behaviors. For example, if a woman stops breastfeeding in month 5 and misses the month 5 interview, we will capture when she stopped in the 7-month interview. Second, as we discuss in our sampling plan, we use a combination of imputation for key variables and weight to address issues of missing data.

In addition to missing specific interviews, we are likely to have some individuals for which the data are censored (all their data are missing either prior to or after a specific date). This is likely to occur for several reasons including (1) individuals drop out of the study, (2) the study timeline is not long enough to observe the variable of interest for all participants, and (3) mothers enter the study at different times during their pregnancy or postpartum. Left censoring will be an issue for women who join WIC after their babies are born and we will address these cases by separately examining relevant subsamples based on time period they entered the study. In cases of right censoring, as long as the censoring is independent—unrelated to the subsequent risk of the event— within a covariate group (e.g. women who return to work), the hazard function (the failure rate in survival analyses) can be estimated. For example, right hand censoring may occur because women drop out of the study and we do not observe a key outcome such as the when they stopped breastfeeding. In these cases, we will only know that they breastfed up to a point in time. As long as there are no unobservable factors that systematically affect who leave the study, we can still include the censored data in estimating the hazard function without bias.

7.5 Specific Proposed Analyses

Table 7-2 provides a summary of the analyses we will undertake that directly address the 60 research questions and repeat the past work of IFPS-1. The table is organized by topic area and documents how we will report the findings in table and figure shells, by title. To keep the interviews under 30 minutes and balance the length across interviews, we ask many questions only at select interviews. Additionally, depending on when women join WIC, their baseline interview can occur within the prenatal, month 1 or month 3 interview. In cases where there is a series of interview months listed (e.g. Month 1, 3), we will calculate the measure for each of those months. In contrast, when we refer to cumulative data (e.g., Cumulative; Months 1, 3) we intend on reading across those months of data

to calculate the measure of interest. For example, to determine the percentage of women who initiate breastfeeding we need to read both the month 1 and 3 interviews as the first interview may occur at month 3 for women who enter the study postpartum. If the analysis uses data sources other than the WIC participant interviews, we note this in the parenthesis as well. In the second column, we provide the source for the table which may be IFPS-1 or FITS or it may be new. Finally, in the last column we note whether we will use the both the core and supplemental sample, just the core sample, and other data sources. To the extent possible we will use both the core and supplemental samples together. There are some cases in which the data are not available from the supplemental sample (e.g. they do not participate in the prenatal interview) as it is not collected as frequently.

For the majority of proposed tabulations in Table 7-2, the percentage of participants following a given feeding practice or who have a certain attribute or experience will be compared among subgroups. We will use a Chi^2 test adjusted for the cluster sample design to determine if the proportions are statistically different between subgroups. In a few cases, such as the comparison of the average number of breastfeeds per day by socio- or pair wise comparisons and F-tests to determine if there are no differences across all the subgroups.

Table 7-2. Summary of analyses to be conducted

Table/Figure (Interview months)	Source	Sample
Study design and sample		
Table: Overall study participation counts and rates (Baseline)	IFPS-1 p20	Both
Table: Counts and percent of respondents by sample type and interview month (Baseline)	IFPS-1 p21	Both
Table: Percentage distribution of socio-demographic characteristics by maternal/caregiver race and ethnicity (Baseline)	IFPS-1 p25	Both
Table: Percentage distribution of reported health-related characteristics by maternal race and ethnicity of the mother (Month 1)	IFPS-1 p26	Both
Prenatal Views		
Table: Mother's intention to breastfeed by socio-demographics (Prenatal)	New	Core
Table : Items that constitute the perceived benefits of breastfeeding and perceived barriers to breastfeeding scales (factor analysis) (Prenatal)	IFPS-1 p71	Core
Table: Percentage of mothers agreeing with statements about perceived benefits of breastfeeding by breastfeeding decision (Prenatal)	IFPS-1 p73	Core
Table: Percentage of mothers agreeing with statements about perceived barriers to breastfeeding by breastfeeding decision (Prenatal)	IFPS-1 p74	Core

Table 7-2. Summary of analyses to be conducted (continued)

Table/Figure (interview months)	Source	Sample
Mother/Caregiver's WIC Experience		
Table: Percentage of mothers/caregivers who have previously participated in WIC by the length of participation (Baseline)	New	Both
Table: For the current child, percentage distribution of when the mother/caregiver joined WIC by infant age (Baseline, Screener))	New	Both
Table: Percentages of mothers reporting receipt of information about various aspects of infant feeding from WIC (Month 1)	IFPS-1 p28	Both
Table: Percentage distribution of the mothers' views of the relative importance of WIC food and educational benefits (Months 3, 13, 24)	New	Both
Table: Percentage of mothers reporting they changed specific feeding practices based on something they learned at WIC (Months 3, 13, 24)	New	Both
Table: Top eight most important change mothers made based on education you received from WIC (Months 3, 13, 24)	New	Both
Table: Percentages of mothers reporting receipt of information about infant feeding from other professional sources (Month 1)	New	Both
Table: Percentage of WIC participants using each type of WIC service (accounting for service availability) (Prenatal, Months 3, 7)	New	Both
Table: Percentage of caregivers/infants by type of food package (Months 1, 3, 7)	New	Admin. data
Knowledge, Attitudes, and Sources of Information		
Table: Percentage of mothers having certain knowledge and attitudes about nutrition and behavior (Month13)	New	Both
Table: Percentage distribution of mother's perception of physician's views about breastfeeding preemies (Month 1)	New	Both
Table: Percentage distribution of mother's perception of physician's views about breastfeeding (Month 1)	New	Both
Table: Percentage of mothers/caregivers reporting challenges getting nutrition information by source(Months 5, 15)	New	Core
Table: Percentage distribution of mothers/caregivers sources of nutrition information (Months 5, 15)	New	Core
Table: Percentage distribution of mothers/caregivers most helpful sources of nutrition information (Months 5, 15)	New	Core
Table Triggers for seeking nutrition information (Months 5, 15)	New	Core
Table: Percentage of WIC staff having certain knowledge and attitudes about infant and toddler nutrition (Staff survey)	New	Staff survey

Table 7-2. Summary of analyses to be conducted (continued)

Table/Figure (Interview months)	Source	Sample
Knowledge, Attitudes, and Sources of Information (continued)		
Table: Percentage of WIC staff with certain training and certifications (Staff survey)	New	Staff survey
Table: Percentage who Reported Information from Various Sources to be "Important or Very Important" in Deciding How to Feed Their Infant (Month 1)	WBM, p72	Both
Breastfeeding Decisions		
Table: Breastfeeding initiation rates by selected socio-demographic and health-related characteristics (Cumulative; Months 1,3)	IFPS-1 p53	Both
Figure: Breastfeeding initiation rates, by race and ethnicity of the mother (Cumulative; Months 1, 3)	IFPS-1 p54	Both
Table: Breastfeeding initiation rates by intention rates (Cross of prenatal and month 1)	New	Core
Breastfeeding Initiation, Overall and by Mother's Food Package (Cumulative; Months 1, 3)	WBM, p112	Both
Table: Percentage of WIC mothers by previous feeding practice experience for siblings (Baseline)	New	Both
Table: Average longest duration of previous breastfeeding experience (Baseline)	New	Both
Table (Model): Estimates of the relative odds estimated by logistic regression model of breastfeeding initiation (Cumulative; Months 1, 3)	IFPS-1 p58	Both
Figure (Model): Relative odds of initiating breastfeeding for WIC mothers who received breastfeeding information and advice from different sources (Cumulative; Months 1, 3)	IFPS-1 p63	Both
Hospital Practices and Neonatal Circumstances		
Table: Percentage of multiple births and type of delivery (Month 1)	New	Both
Table: Percentage distribution of infants' health characteristics (Month 1)	New	Both
Figure: Number of days of hospital stay for WIC mothers and infants (Month 1)	IFPS-1 p109	Both
Figure: Percentage of WIC infants who stayed in the nursery overnight (Month 1)	IFPS-1 p109	Both
Table: Percentage of mothers encouraged to breastfeed by family, WIC staff, or provider (Month 1)	New	Both
Table: The first feeding received by WIC infants in the hospital (Month 1)	IFPS-1 p110	Both
Table: Percentage of mothers who initiate breastfeeding in the hospital by time after birth (Month 1)	New	Both
Figure: The first feeding of WIC infants in the hospital, by race and ethnicity of the mother (Month 1)	IFPS-1 p111	Both

Table 7-2. Summary of analyses to be conducted (continued)

Table/Figure (interview months)	Source	Sample
Hospital Practices and Neonatal Circumstances (continued)		
Table: Percentages of mothers reporting nursing problems while in the hospital (Month 1)	IFPS-1 p113	Both
Table: Percentage of infants who received something other than human milk in the hospital by product, day and frequency (Month 1)	New	Core
Table: Percentage of WIC mothers who reported receiving various services from the hospital (infant in room, feeding on demand, referral for breastfeeding support, etc.) (Month 1)	New	Both
Figure: Percentage of WIC mothers who did not receive help from the hospital staff among those who had common nursing problems (Month 1)	IFPS-1 p114	Both
Figure: Percentage of WIC mothers who reported receiving various items in their gift packages from the hospital (Month 1)	IFPS-1 p115	Both
Table: Percentage of type of feeding at hospital discharge by type of first feeding (Month 1)	IFPS-1 p116	Both
Table: (Model) Relative odds of formula feeding at hospital discharge for WIC mothers who breastfeed at the first feeding (Month 1)	IFPS-1 p118	Both
Table:(Model) Relative odds of breastfeeding at hospital discharge for WIC mothers who formula feed at the first feeding (Month 1)	IFPS-1 p120	Both
Table:(Model) Estimates of relative odds of breastfeeding at hospital discharge for WIC mothers (Month 1)	New	Both
Formula Supplementation		
Figure: Percentages of only breastfeeding, combined breast-and formula feeding, and only formula-feeding WIC mothers at each month of interview (Months 1-13)	IFPS-1 p88	Both
Table: Transitions of Mother's Food Package Issued by Age of Infant (Months 1, 3)	WBM, p100	Core
Table: Percentage distribution of the perceived impact of food package choice on the breastfeeding decision (Months 3, 7)	New	Both
Table: Percentage distribution of the infants by initial diets at the time of each interview month; by selected socio-demographic characteristics (Months 1, 3)	IFPS-1 p90	Both
Table: Usual number of formula or combination feedings, by selected maternal socio-demographic characteristics(Months 1, 3, 5)	New	Both
Table: Usual number of solid food feedings , by selected maternal socio-demographic characteristics (Months 1, 3, 5)	New	Both
Figure:: Percentages of breastfeeding WIC mothers, by type of breastfeeding practice at each month of interview (Months 1-9)	IFPS-1 p92	Both
Figure: Percentage of breastfeeding WIC mothers who have not yet initiated formula, by the age of the infant (Months 1-9)	IFPS-1 p94	Both

Table 7-2. Summary of analyses to be conducted (continued)

Table/Figure (Interview months)	Source	Sample
Formula Supplementation (continued)		
Table: Breastfeeding frequency, intensity, and duration by initial breastfeeding status(breastfeed only or with formula) (Months 1, 3, 5, 7)	New	Both
Table: Intensity of Breastfeeding, Overall (Month 1)	WBM, p126	Both
Table; Intensity of Breastfeeding, by Mother's Food Package (Month 1)	WBM, p127	Both
Table: Median age in weeks of the infant at the time when formula supplementation is initiated, by selected socio-demographic characteristics and previous breastfeeding experience (Cumulative; Months 1-13)	IFPS-1 p94	Both
Table: (Model) Estimates of the relative risk estimated by the multivariate models of rates of formula supplementation (survival analysis) (Months 1-13)	IFPS-1 p96	Both
Breastfeeding and Formula Feeding Practices		
Table: Breastfeeding schedules of WIC mothers over the first five months of their infants' first year (Months 1, 3, 5)	IFPS-1 p128	Both
Table: Breastfeeding schedules of WIC mothers over the first 13 months of their infants' first year by mother's work status and child care status (Months 1-13)	New	Both
Figure: Percentage of WIC mothers who breast feed on a set schedule, when the infant cries or seems hungry, and on a mixed schedule (Months 3-13)	IFPS-1 p130	Both
Table: Usual number of daily breastfeeds, by selected maternal socio-demographic characteristics (Months 1, 3, 5)	IFPS-1 p131	Both
Table: Mean and standard deviation in the number of breastfeeds and intensity (% of feedings that are breast milk) per day by month (Months 1-7)	New	Both
Table: Percentage of caregivers who respond to different infant cues with appropriate understanding (Month 3)	New	Both
Table: Average amount of expressed milk for breasting mothers at 1 month in past 24 hours (Month 1)	New	Both
Table: Percentage distribution of what was done with the expressed milk (Month 1)	New	Both
Table: Percentage of WIC mothers who report expressing milk during the past week, by selected maternal socio-demographics (Months 1-7)	IFPS-1 p132	Both
Table: Percentage distribution of reason for pumping (Cumulative; Months 1-7)	New	Both
Figure: Percentage of breastfeeding WIC mothers expressing milk, using electric breast pumps, using manual breast pumps, and expressing milk by hand (Cumulative; Months 1-7)	IFPS-1 p133	Both
Table: Percentage of breastfeeding WIC mothers expressing milk, using electric breast pumps, using manual breast pumps, and expressing milk by hand by work status and receipt of WIC support services (Months 1-7)	New	Both

Table 7-2. Summary of analyses to be conducted (continued)

Table/Figure (interview months)	Source	Sample
Breastfeeding and Formula Feeding Practices (continued)		
Table: The average number of times a day women pump or express among those doing this (Months 1-13)	New	Both
Table: Percentage distribution of pumping/expressing milk by time of day and storage practices (Months 1-13)	New	Both
Table: Percentage distribution of sources for pumps (Cumulative; Months 1, 3)	New	Both
Table: Percentage distribution of reasons for using formula by infants age (Months 1-13)	New	Both
Table: Percentage distribution of formula-feeding WIC mothers by brand name of formula	IFPS-1 p145	Both
Table: Percentage distribution of formula types (Cumulative; Months 1-13)	New	Both
Table: Percentage distribution of formula source (Cumulative; Months 1-13)	New	Both
Table: Percentage distribution of formula source for women choosing the breastfeeding package (Cumulative; Months 1-13)	New	Both
Table: Percentage of caregivers who deviate from formula dilution directions by type of deviation, mixed formula with unboiled water, and kept mixed formula for more than 24 hours (Cumulative; Months 3,7,11)	New	Both
Table: Percentage of caregivers receiving doctor or nutritionist dilution guidance that deviate from recommendations by type of deviation (Cumulative; Months 1-13)	New	Both
Figure: Percentage of mothers who report adding other foods or liquids in the bottle with the formula at Month 3(Month 3)	IFPS-1 p142	Both
Figure: Percentage of mothers who report adding other foods in the bottle with formula at Month 1 among those who think that the amount of formula given by WIC is more than enough, the right amount, or not enough(Month 1)	IFPS-1 p143	Both
Table: Percentage of children using pacifiers and timing of introduction (Month 3)	New	Both
Table: Percentage distribution of pacifier use by reason (Month 3)	New	Both
Breastfeeding Problems		
Table: Reported breastfeeding problems by WIC mothers at the time of the month 1, month 3 and month 5 interviews (list of problems; including environmental) (Months 1, 3, 5)	IFPS-1 p153	Both
Figure: Percentage of breastfeeding WIC mothers who report experiencing breastfeeding problems in Months 1,3, and 5 (main types of problems) (Months 1, 3, 5)	IFPS-1 p154	Both
Table: Percentage of mothers reporting breastfeeding problems in first 5 months by type of problem and socio demographics (Cumulative; Months 1, 3, 5)	New	Both

Table 7-2. Summary of analyses to be conducted (continued)

Table/Figure (interview months)	Source	Sample
Breastfeeding Problems (continued)		
Table: Percentage of mothers reporting breastfeeding problems who received help by source of help (Cumulative; Months 1, 3, 5)	New	Both
Table: Percentage distribution of resolutions by type of breastfeeding problem (Cumulative; Months 1, 3, 5)	New	Both
Table: Percentage distribution of possible solutions to barriers (Cumulative, Months 1, 3,5)	New	Both
Table: Percentage of mothers receiving breastfeeding education/support (WIC vs. elsewhere) by breastfeeding decision (Cumulative, Months 1, 3)	New	Both
Figure: Median age of breastfeeding cessation, age when 25% and age when 75% of the infants are weaned from the breast (Cumulative: Months 1-13)	IFPS-1 p163	Both
Figure: Percentage of all WIC mothers breastfeeding, by age of the infant (Months 1-13)	IFPS-1 p164	Both
Continuation and Cessation of Breastfeeding		
Figure: Percentage of all WIC mothers still breastfeeding, by age of the infant and age of the mother (Months 1-13)	IFPS-1 p165	Both
Figure: Percentage of all WIC mothers still breast-feeding, by age of the infant and whether the mother reports knowing about the special WIC food package for breastfeeding women who do not accept infant formula for WIC (Months 1-13)	IFPS-1 p166	Both
Table: Frequency of top 10 reasons women stop breastfeeding within the first 2 and 6 weeks (Cumulative; Months 1, 3)	New	Both
Table: Frequency of top 5 reasons women stop breastfeeding within the first 6 weeks by infant health status and household demographics (Cumulative; Months 1, 3)	New	Both
Table: Frequency of top 5 reasons women stop breastfeeding by the magnitude of the difference between intended and actual breastfeeding duration	New	Both
Table: Percentage distribution of reasons for stopping breastfeeding between 2-3and 4-6 months (Months 3, 5,7)	New	Both
Table: Average Edinburgh Postpartum Depression Scale score by breastfeeding status (Month 3)	New	Both
Table: Characteristics and circumstances of mothers breastfeeding (Months 1, 7)	New	Both
Table: (Model) Relative risks estimated by the multivariate models of rates of breastfeeding cessation (survival analysis) (Months 1-13)	IFPS-1 p168p168	Both
Figure: Percentage of WIC mothers still breastfeeding by age of the infant and reported receipt of none, one, two, or three WIC program components that support breastfeeding (Months 1-13)	IFPS-1 p173	Both

Table 7-2. Summary of analyses to be conducted (continued)

Table/Figure (interview months)	Source	Sample
Initiation of Supplemental Foods: The Transitional Phase of Infant Feeding		
Table: Infant feeding patterns of WIC participants (by milk/food category) (Months 3-11)	FITSd S74	Both
Figure: Percentage of WIC mothers who have not yet initiated cereals, fruits, vegetables, and meats at each age of the infant (Months 1-13)	IFPS-1 p186	Both
Figure: Percentage of WIC mothers who have not yet initiated dairy foods, high-protein foods other than meats, and sweet/snack foods, at each age of the infant (Months 1-13)	IFPS-1 p188	Both
Table: Median age of the infant (in weeks) when specific supplemental foods are initiated by selected socio-demographic characteristics of the mother (Cumulative; Months 1-13)	IFPS-1 p189	Both
Table: Percentage of infants and toddlers consuming different types of milk and other beverages by age (Months 3-24)	FITS S40	Both
Table: Percentage distribution of combination feedings by age (Months 1-13)	New	Both
Figure: Percentage of WIC mothers who have not yet initiated cereals at each age of the infant, by maternal immigrant status (Months 1-13)	IFPS-1 p190	Both
Figure: Percentage of mothers initiating cereals, fruits, vegetables, and meats as the first, second, third or fourth type of supplemental food (Cumulative; Months 1-13)	IFPS-1 p192	Both
Table: Percentage distribution of the order of initiation of cereals, fruits, vegetables, and meats, by race/ethnicity of the mother (Cumulative; Months 1-13)	IFPS-1 p194	Both
Table: (Model) Relative risk of initiating cereals prior to four and six months of age (survival analysis) (Months 1-13)	IFPS-1 p196	Both
Table: (Model) Relative risk of initiating fruits prior to four and six months of age (survival analysis) (Months 1-13)	IFPS-1 p199	Both
Table: (Model) Relative risk of initiating vegetables prior to four and six months of age (survival analysis) (Months 1-13)	IFPS-1 p201	Both
Figure: Percentage of WIC mothers who have not yet initiated fruit juices, sweet drinks, and cow milk or other milk at each age of infant (Months 1-13)	IFPS-1 p207	Both
Table: Median age of the infant at the time of initiation of fruit juices or sweet drinks by selected socio-demographics (Cumulative; Months 1-13)	IFPS-1 p208	Both
Figure: Percentage of WIC mothers who have not yet introduced sweet drinks at each age of infant, by race/ethnicity of the mother(Months 1-13)	IFPS-1 p209	Both
Table: Average infant age mother previously introduced solid foods (cereal and other) to siblings (Baseline)	New	Both
Table: Transitions in infant and toddler feeding among toddlers 12 to 24 months (Cumulative; Months 11-24)	FITSd S74	Both

Table 7-2. Summary of analyses to be conducted (continued)

Table/Figure (interview months)	Source	Sample
Supplemental Foods and Feeding Practices		
Table: Percentage of distribution of food preparation methods used by caregivers (Months 7, 9, 11,13)	New	Both
Table: Percentage distribution of the impacts of food package choice on food child receives (Months 7, 15)	New	Both
Table: Percentage distribution of sources of baby food (Months 7-13)	New	Both
Table: Share of purchased baby food covered by WIC vouchers (Months 7-13)	New	Both
Table: Percentage distribution of food choices across feedings (morning, afternoon, evening) (Months 1-13)	New	Both
Table: Methods of feeding supplemental foods at interview months when data was elicited (Months 3-18)	IFPS-1 p215	Both
Figure: Percentage of WIC infants receiving supplemental foods using a spoon by race and ethnicity of the mother (Months 3-9)	IFPS-1 p216	Both
Figure: Percentage of WIC mothers who have used an infant feeder sometime during infancy by race and ethnicity of the mother (Cumulative, Months 3-11)	IFPS-1 p217	Both
Table: Percentage of WIC mothers who adopt supplemental food feeding practices that are generally not recommended (Cumulative; Months 1-5)	IFPS-1 p218	Both
Figure: Percentage of WIC mothers who feed supplemental foods before month 4prior to using a spoon, by race and ethnicity of the mother (Month 3)	IFPS-1 p220	Both
Table: Self feeding skills and the percentage of toddlers who were reported to show the self feeding skill by age (Months 9, 11, 13, 18)	FITSe S53	Both
Table: Average number of months using a bottle by socio-demographics(Cumulative; months7-24)	New	Both
Feeding Practices, Working, and Childcare		
Table: Number of caregivers who work or go to school (Months 3, 7, 13, 18, 24)	New	Both
Table: Percentage distribution of children in childcare by types of childcare (Months 3, 7, 13, 24)	New	Both
Table: Average age of child when they first started childcare by type of childcare (Cumulative; Months 3, 7, 13, 24)	New	Both
Table: Frequency of barriers to breastfeeding children in childcare (Cumulative; Months 3, 7,)	New	Both
Table: Percentage of mothers with children in childcare who go to facility to breastfeed during the day (Cumulative; Months 3, 7)	New	Both
Table: Percentage distribution of who provides the food for the child by type of childcare (Months 3, 7, 13, 24)	New	Both

Table 7-2. Summary of analyses to be conducted (continued)

Table/Figure (interview months)	Source	Sample
Feeding Practices, Working, and Childcare (continued)		
Table: Percentage of children in childcare getting human milk by age of infant and method of receipt (Months 3, 7)	New	Both
Table: Percentage distribution of accommodations available at work to assist with pumping milk (Month 3)	New	Both
Nutritional Intake		
Table: Percentage of WIC infants who receive each of the 13 groups of food at each age (Months 1-13)	IFPS-1 p225	Both
Table: Percentage of infants and toddlers consuming grains, vegetables, fruits, and meats/other protein sources, and desserts, sweets, sweetened beverages and salty snacks by age (Months 3-24)	New	Both
Table: Percentage of infants and toddlers consuming different types of grain products by age (Months 3-24)	FITSa S42	Both
Table: Percentage of infants and toddlers consuming different types of fruits products by age (Months 3-24)	FITSa S43	Both
Table: Top five fruits consumed by infants and toddlers by age (Months 3-24)	FITSa S44	Both
Table: Percentage of infants and toddlers consuming different types of vegetables by age (Months 3-24)	FITSa S45	Both
Table: Top five fruits vegetables consumed by infants and toddlers by age (Months 3-24)	FITSa S46	Both
Table: Percentage of infants and toddlers consuming meats or other protein sources by age (Months 3-24)	FITSa S47	Both
Table: Percentage of infants and toddlers consuming desserts, sweets, sweetened beverages, and salty snacks, by age (Months 3-24)	FITSa S48	Both
Table: Usual nutrient intake distributions of infants: Micronutrients (Months 3,5 & 7,11)	FITSb S16	Both
Table: Usual nutrient intake distributions of toddlers 12 to 24 months (Months 13-24)	FITSb S17	Both
Table: Estimated energy requirements and usual intake of food energy, infant and toddlers (Months 5-24)	FITSb S17	Both
Table: Usual nutrient intake distributions: Macronutrients (Months 5-24)	FITSb S18	Both
Table: Usual intake of dietary fiber (Months 5-24)	FITSb S19	Both
Table: Mean intakes of selected nutrients by source of milk (Month 5)	FITSb S20	Core
Table: Mean intakes of selected nutrients by source of milk (Month 5)	FITSb S20	Core
Figure: Percentage of infants and toddlers participating in nonmeal eating occasions (Months 7-24)	FITSc S66	Both

Table 7-2. Summary of analyses to be conducted (continued)

Table/Figure (interview months)	Source	Sample
Nutritional Intake (continued)		
Table: Percentage of total energy from each eating occasion by age category for infant and toddlers (Months 3-24)	FITSc S66	Both
Table: Macronutrient distributions at meals and snacks by age category (Months 7-24)	FITSc S67	Both
Table: Nutrient density: vitamin A, C, D, foliate, Ca, Fe per 1000 Kcals and fiber (Months 7-24)	FITSc S67 and new	Both
Table: Most frequently eaten foods at each eating occasion by age category (Months 3-24)	FITSc S68	Both
Child's Weight and Feeding Practices		
Table: Percentage of children in each weight/length quintile by breastfeeding experience for months 6, 12, and 24 (Months 1, 3 and clinical records 6, 12, 24)	New	Both
Table: Percentage of children (at 24 months) in each weight/length quintile by timing of the introduction of different types of solid foods (Cumulative; Months 1-13 & clinical records 24)	New	Both
Table: Child's weight/length quintile at 24 months by mothers average sweetened beverage and fruit and vegetable intake score (Month 24)	New	Both
Table: Percentage of children in top 20% and bottom 20% of the weight/length distribution at 12 and 24 months by breastfeeding experience and socio-demographics (Months 1, 3 and clinical records 12, 24)	New	Both
Table: Percentage of children in top 20% and bottom 20% of the weight/length distribution at 12 and 24 months by child's health, physical activity behavior, and rearing/feeding practices (Cumulative, Months 1-24 and clinical records 12, 24)	New	Both
Table: Average child weight/length gain in first 6 months by breastfeeding experience and gender (Months 1, 3 and clinical records 1, 6)	New	Both
Table: Average child weight/length gain in first 6-12 months by breastfeeding experience and gender (Months 1, 3 and clinical records 6, 12)	New	Both
Table: (Model) OLS regression estimates of the impact of the impact of socio-demographics and feeding practices on weight/length at 24 month (Cumulative; Months 1-24 and clinical records for 6, 12 24)	New	Both
Table: (Model) Quantile regression estimates of the impact of socio-demographics and feeding practices on weight/length at 6 month (Cumulative; Months 1-6 and clinical records for 6)	New	Both
Table: (Model) Quantile regression estimates of the impact of socio-demographics and feeding practices on weight/length at 12 month (Cumulative; Months 1-13 and clinical records for 6, 12)	New	Both
Table: (Model) Quantile regression estimates of the impact of socio-demographics and feeding practices on weight/length at 24 month (Cumulative; Months 1-24 and clinical records for 6, 12 24)	New	Both

Table 7-2. Summary of analyses to be conducted (continued)

Table/Figure (interview months)	Source	Sample
Child's Weight and Feeding Practices (continued)		
Table: (Model) Growth model estimates of the impact of socio- demographics and maternal health on weight gain trajectory of the child from birth to 2 years (Cumulative; Months 1-24 and clinical records for 0, 6, 12 24)	New	Both

We will also provide estimates of the measures used in the tables and figures listed above (in Table 7-2) by key subgroups. Some of the variables of interest are summary measures that are relevant to the entire population and therefore well suited to examining differences between subgroups. Key subgroups include:

- Race
- Ethnicity
- Age of mother
- Marital status
- Food security
- Participation in other benefit programs
- Parity
- Birthweight
- Birth complications
- Type of delivery
- Hospital length of stay
- Breastfeeding (history) group
- WIC prenatal (joined) WIC trimester (joined)
- Interpartum (<27 months, 27-68 months, > 69 months)[19]
- WIC exposure of the mother
- Weight status of mother

[19]Our data only allows us to measure the time between the last birth and current birth

- Income poverty
- Child's WIC participation status
- Continuity of WIC participation
- Nature/intensity of breastfeeding support at hospital
- Nature/intensity of breastfeeding support at home
- Nature/intensity of breastfeeding support at from WIC
- Nature/intensity of breastfeeding support at work
- Nature/intensity of breastfeeding support at childcare
- Nature/intensity of nutrition education and skills training

Not all the subgroups are applicable to every response measure of interest. Additionally, some measures of interest only apply to a subset of the population. Therefore, in selecting the subgroups to use for each table and figure, we will consider whether they are likely to be correlated with response measure of interest. In Appendix C, we provide example sets of table shells detailing how we would provide and display subgroup estimates for 3 of the tables listed in Table 7-2.
FITS studies as well as some additional analyses we believe are also important. In Appendix A, we provide a mapping of the relevant analyses to each research question to demonstrate that the study will answer all 60 questions.

Table 7-2 is a list of all the tables or figures by title. Following the title in parenthesis, we list the WIC participant survey interview months to be used in the analysis. Many tables are repeating the work of the IFPS-1 study or the FITS study and the specific publication and source page for the original table is provided to allow for cross-referencing[20].

[20] IFPS refers to Baydar, et al. Final Report: WIC Infant Feeding Practice Study, November 1997.

FITSa refers to Seiga-Riz, Anna Marie et al. Food Consumption Patterns of Infants and Toddlers: Where are we Now? in the *Supplement to the Journal of the American Dietetic Association,* 2010.

FITSb refers to Devaney, Barabara et al. Nutrient Intakes of Infants and Toddlers in the *Supplement to the Journal of the American Dietetic Association,* 2004.

FITSc refers to Skinner, Jean D. et al. Meal and Snack Patterns of Infants and Toddlers in the *Supplement to the Journal of the American Dietetic Association,* 2004.

FITSd refers to Ponza, Micheal et al. Nutrient Intakes and Food Choices of Infants and Toddlers and Toddlers Participating in WIC in the *Supplement to the Journal of the American Dietetic Association,* 2004.

FITSe refers to Carruth, Betty Ruthet al. Developmental Milestones and Self-Feeding Behaviors in Infants and Toddlers in the *Supplement to the Journal of the American Dietetic Association,* 2004.

Model Specifications

Several of the specific analyses shown in Table 7-2 involve estimating models. Table 7-3 provides the detailed specifications for these models. The first four models – the breastfeeding decision model, the formula supplementation model, the breastfeeding cessation model, and introduction of other foods model -- mirror models used in the previous IFPS-1 study. Initially, we will estimate these models primarily using the covariates that were used in the IFPS-1 study. This will facilitate the comparisons to the past research. We will also explore extending this work by making some improvements in the measurement of variables, the estimation method, and the covariates used. For these models, the additional covariates and estimation methods we propose to explore are noted in italics on Table 7-3. For many of the explanatory variables there are alternative proxy variables that we could use to measure the concept we are trying to capture. We will explore these alternative proxies if the initial variable proves to be insignificant. The weight and growth models shown in Table 7-3 are new.

Table 7-3. Proposed model specifications

Model	Dependent variable	Estimation methods	Minimum covariates to explore
Breastfeeding decision	■ Initiating breastfeeding ■ Breastfeeding at hospital discharge Measured dichotomously and *categorically (all breastfeeding, combination, all formula)*	■ Logistic regression (dichotomous) ■ *Multinomial logistic regression (categorical)*	■ Socio-demographics: Age, race/ethnicity, born in US, father in house, infant first born, income, poverty level, education, *worked during pregnancy* ■ Maternal and infant health: *Mother's post-delivery health status, infants health status (measured as in NICU or more than 6 weeks premature or very low birth weight)* ■ Prenatal attitudes, beliefs and knowledge: *Perceived benefits of breastfeeding, perceived barriers, breastfeeding intentions* ■ Prenatal experience and advice: breastfed previous children, receipt of advice to breastfeed from physician, receipt of advice to breastfeed from family, receipt of breastfeeding information from non-WIC sources ■ WIC program experience: Education, peer counseling, time in WIC ■ Hospital experience: Mom's length of stay, baby's length of stay, receipt of formula or bottle in gift package, *had baby friendly practices*

Table 7-3. Proposed model specifications (continued)

Model	Dependent variable	Estimation methods	Minimum covariates to explore
Formula Supplementation	■ Time until formula supplementation	■ Survival analysis	■ Socio-demographics: Age, race/ethnicity, born in US, infant first born, use of childcare, *education, worked during pregnancy* ■ Maternal and infant health: Mother's post-delivery health status, infants health status, birth weight, reported problems breastfeeding ■ Prenatal attitudes, beliefs and knowledge: Perceived benefits of breastfeeding, perceived barriers, *how long intend to breastfeed* ■ Prenatal experience and advice: Receipt of advice to breastfeed from physician, receipt of breastfeeding information from non-WIC sources ■ WIC program experience: Education, peer counseling, breast pumps, time in WIC
Breastfeeding cessation	■ Time until cessation	■ Survival analysis	■ Socio-demographics: Age, race/ethnicity, born in US, infant first born, education, use of child care ■ Maternal health: Reported breastfeeding problems ■ Breastfeeding practices: Current use of formula ■ Prenatal attitudes, beliefs and knowledge: Perceived benefits of breastfeeding, perceived barriers, how long intend to breastfeed ■ Prenatal experience and advice: Receipt of advice to breastfeed from physician, receipt of breastfeeding information from non-WIC sources ■ WIC program experience: *Education, peer counseling, breast pumps, time in WIC* ■ Return to work/school: *Returned to work/school within 2 months*
Introduction of other foods	■ Time until cereal ■ Time until fruits ■ Time until vegetables ■ Time until meats	■ Survival analysis	■ Socio-demographics: Age, race/ethnicity, born in US, household size, income, poverty level, use of child care, returned to work or school, education ■ Feeding practices: current use of formula ■ Attitudes, beliefs and knowledge: Belief formula provided from WIC is insufficient, parental assessment of baby's weight ■ Prenatal experience and advice: Receipt of breastfeeding information from non-WIC sources

Table 7-3. Proposed model specifications (continued)

Model	Dependent variable	Estimation methods	Minimum covariates to explore
	■	■	■ WIC program experience: Education, time in WIC ■ Return to work/school: *Returned to work/school within 2 months*
Weight	■ Child's weight/length (6, 12, and 24 months)	■ OLS ■ Quantile regression	■ Socio-demographics: Gender, race/ethnicity, income, born in US ■ Maternal/family health: Maternal BMI, paternal obesity, maternal diabetes, smoking during pregnancy, household food security (24 months only), maternal fruit and vegetable dietary intake (24 months only) ■ WIC program experience: Education, food package, time in WIC (and peer counseling for 6 month weight/length) ■ Child's health and physical activity: birth weight, premature, rapid early weight gain, physical activity indoors, physical outdoors (for 24 month measure) current sleep duration ■ Basic dietary intake: Breastfeeding duration, current intake of sweetened beverages ■ Feeding practices: Clean plate policy, track eating, careful not to feed too much
Growth	■ Repeated measures of child's weight/length	■ Growth model	■ Socio-demographics: Gender, race/ethnicity, income Maternal/family health: Maternal BMI, paternal obesity, maternal diabetes, smoking during pregnancy ■ WIC program experience: Education, food package, time in WIC ■ Child's health and physical activity: Birth weight, premature ■ Basic dietary intake: Breastfeeding duration

We will estimate several variants of the breastfeeding decision model. First, we will use two alternatives for the dependent variable: initiating breastfeeding and breastfeeding at hospital discharge. Similarly, we will explore using dichotomous measures (yes, no) for these variables as well using categorical measures that capture mixing breastfeeding and formula feeding from the start. Additionally, we will have mother's prenatal attitudes collected prior to delivery (rather than retrospectively) and can also explore how their breastfeeding intentions for initiation and duration affect actual initiation and exclusivity. Finally, for this model we will explore the viability of using a summary index to capture the mother's attitudes, beliefs, and knowledge on breastfeeding and her hospital experience in place of the individual covariates in these groups.

Our estimates of the formula supplementation model and time until the introduction of other foods models will closely parallel the past work with few extensions. In estimating the formula supplementation model we will explore how breastfeeding intentions regarding duration (which is typically not collected) affect the time until formula supplementation. The covariates we will examine for predicting the time until breastfeeding cessation and the introduction of cereals, fruits, and vegetables will parallel those used in the IFPS-1 study.

For the new weight model, we will run separate models estimating weight/length for the children at 6, 12, and 24 months. In addition to including direct measures of toddler feeding practices (such as family has a clean plate policy), we will explore the viability of using summary measures of a range of toddler feeding practices to predict weight outcomes.

Finally, in all these models we will capture the cross-sectional variation in the WIC program experience through the inclusion of WIC program composite measures which will be an enhancement over past studies. For breastfeeding initiation and duration decisions, we expect that the variation in educational programs, peer counseling and the provision and support for breast pumps will be factors affecting individuals' decision. For infant feeding transitions and toddler weight outcomes, we expect that variation in education and the food packages will be important factors. For all of these decisions and outcomes, we expect that the time the mother has spent in WIC will be an important predictor.

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8 Analysis Reports

Table 8-1 provides a summary of our proposed analytical report schedule and the content of each report. There are a few topic areas that draw solely from data collected during the first few interviews and these analyses can be completed prior to finishing all the data collection. Analyses of prenatal views, the study design and sample, breastfeeding decisions, hospital practices and neonatal circumstances, and breastfeeding problems can be completed prior to conducting the 13 months interview. Additionally, the analyses on formula supplementation, breastfeeding and formula feeding practice, and the continuation and cessation of breastfeeding can be completed using data through the month 13 interview. The analyses of all the other topic areas at least partially depend on data collected from later interviews. Therefore, as our report schedule shows, there are some topics for which we will provide preliminary analysis based on the currently available data and then update these analyses in final infant and final infant and toddler reports. Please note, that while we are contracted to deliver 4 interim reports on the toddler interviews, since FNS eliminated the 21 month interview, we have only 3 data collection interviews. We have some suggestions for the content of the 4th report we would like to discuss with FNS.

Table 8-1. List of analytical reports

Reports	Main topic	Content/ Data cutoff	Report
Infant interim 1	Intention to breastfeed	Prenatal views/ Results through prenatal interview	1/11/2014
Infant interim 2	Initiation of breastfeed	Study design and sample Breastfeeding decisions Hospital practices and neonatal circumstances/ Result through 3 month interview	10/10/2014
Infant interim 3	Breastfeeding and formula supplementation	Knowledge attitudes , and sources of information (initial data) Breastfeeding problems Formula supplementation (initial data) Breastfeeding and formula feeding practices (initial data)/ Results through 7 month interview	2/13/2015

Table 8-1. List of analytical reports (continued)

Reports	Main topic	Content/ Data cutoff	Report
Infant interim 4	Infant Feeding Practices, Introduction to Solid Foods	Mother/Caregivers WIC experience (initial data) Continuation and cessation of breastfeeding Initiation of supplemental foods: the transition phase of infant feeding (initial data)/ Results through 13 month interview	8/14/2015
Infant final	**1st Year Feeding Practices**	**All topics listed above (topics with initial data will be updated through 13 month interview)**	**10/9/2015**
Toddler interim 1	Nutrient Intake & Weight Gain	Nutritional intake (initial data) Child's weight and feeding practices (initial data)/ Results through 15 month interview	10/9/2015
Toddler interim 2	Supplemental foods and feeding practices	Supplemental foods feeding practices(initial data)/ Results through 18month interview	1/8/2016
Toddler interim 3	Feeding practices, working and childcare	Feeding practices, working, and childcare (initial data)/ Results through 24 month interview	4/1/2016
Toddler interim 4	Nutrient Intake & Weight Gain	Nutritional intake Child's weight and feeding practices Results through 24 month interview	4/1/2106
Infant/Toddler final	**1st & 2nd Year Feeding Practices**	**All topics (all topics with initial data will be updated through 24 month interview)**	**5/20/2016**

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Appendix A
Summary of WIC-IFPS-1 Analyses to be Repeated

Table A-1 provides a listed of all the tables and figures in the WIC-IFPS-1 final report in terms of the order in which they appear in the document. To facilitate cross-referencing to the WIC-IFPS-1 final report, we note the page on which the table or figure appears. We specify if we are repeating the analysis and note major deviations. In cases in which we will not repeat the analysis, we provide an explanation as to why.

Table A-1. List of WIC-IFPS-1 report tables and figures

Table/Figure	Page	Status
CHAPTER I: INTRODUCTION AND OVERIVIEW		
This chapter contains no tables or figures		
CHAPTER II: STUDY DESIGN AND SAMPLE		
Table II.1 Overall study participation counts and rates	20	Will repeat
Table II.2 Counts and percent of respondents by sample type and interview month	21	Will repeat
Table II.3 Percentage distribution of socio-demographic characteristics by maternal race and ethnicity	25	Will repeat
Table II.4 Percentage distribution of reported health-related characteristics by maternal race and ethnicity of the mother	26	Will repeat
Table II.5 Percentages of mothers reporting the receipt of WIC vouchers for formula and supplemental foods	27	Will not repeat. Replaced by table on food packages
Table II.6 Percentages of mothers reporting receipt of information about various aspects of infant feeding from WIC	28	Will repeat
CHAPTER III: CONCEPTUAL MODEL AND APPROACH TO ANALYSIS		
Table III.3 WIC-IFPS data on infant feeding practices in the nursing phase	31	Will not repeat but rather replace with a discussion of the variables we will collect
Table III.2 WIC-IFPS data on infant feeding practices in the transitional phase	33	Will not repeat but rather replace with a discussion of the variables we will collect
Figure III-1 A general model of infant feeding practices and the measures of predictors of infant feeding practices from WIC-IFPS	38	Will replace with graphics of updated model
CHAPTER IV: CHOICE BETWEEN BREATFEEDING AND FORMULA FEEDING		
Figure IV.1 A model of breastfeeding initiation and the measures of its predictors available from the WIC-IFPS	46	Will replace with graphics of updated breastfeeding decision model
Table IV.1 Breastfeeding initiation rates by selected socio-demographic and health-related characteristics	53	Will repeat
Figure IV.2 Breastfeeding initiation rates, by race and ethnicity of the mother	54	Will repeat
Table IV.2 Estimates of the relative odds estimated by the logistic regression model of breast feeding initiation	58	Will repeat similar content but models will differ

Table A-1. List of WIC-IFPS-1 report tables and figures (continued)

Table/Figure	Page	Status
Figure IV.3 Relative odds of initiating breastfeeding for WIC mothers who received breastfeeding information and advice from different sources	63	Will repeat similar content but specific categories for sources of information will differ
Table IV.3 Items that constitute the perceived benefits of breastfeeding and perceived barriers to breastfeeding scales (factor analysis)	71	Will repeat applying factor analysis but the items will differ
Table IV.4 Percentage of mothers agreeing with the nine statements about perceived benefits of breastfeeding	73	Will repeat but the items will differ
Table IV.5 Percentage of mothers agreeing with the 13 statements about perceived barriers to breastfeeding	74	Will repeat but the items will differ
Figure IV.4 A model of initiation of formula supplementation and the measures of the predictors available from the WIC-IFPS	82	Will replace with graphics of updated breastfeeding duration model
Figure IV.5 Percentages of only breastfeeding, combined breast-and formula feeding, and only formula-feeding WIC mothers at each month of interview	88	Will repeat
Table IV.6. Percentage distribution of the infants by nursing diets at the at the time of each interview month; by selected socio-demographic characteristics	90	Will repeat
Figure IV.6 Percentages of breastfeeding WIC mothers, by type of breastfeeding practice at each month of interview	92	Will repeat
Figure IV.7 Percentage of breastfeeding WIC mothers who have not yet initiated formula, by the age of the infant	94	Will repeat
Table IV.7 Median age in days of the infant at the time when formula supplementation is initiated, by selected socio-demographic characteristics	94	Will repeat but measure child's age in weeks not days
Table IV.8 Estimates of the relative risk estimated by the multivariate models of rates of formula supplementation (survival analysis)	96	Will repeat similar content but models will differ
CHAPTER V:HOSPITAL PRACTICES AND NEONATAL CIRCUMSTANCES EXPEREINCE BY MOTHERS		
Figure V.1 A model of feeding practices at hospital discharge and the measures of its predictors available from the WIC-IFPS	103	Will replace with graphics of updated breastfeeding decision model (for hospital)
Figure V.2Number of days of hospital stay for WIC mothers and infants	109	Will repeat
Figure V.3 Percentage of WIC infants who stayed in the nursery overnight	109	Will repeat
Table V. 1 The first feeding received by WIC infants in the hospital	110	Will repeat
Figure V. 4 The first feeding of WIC infants in the hospital, by race and ethnicity of the mother	111	Will repeat
Table V.2 Percentages of mothers reporting nursing problems while in the hospital	113	Will repeat
Figure V.5 Percentage of WIC mothers who did not receive help from the hospital staff among those who had common nursing problems	114	Will repeat
Figure V.6 Percentage of WIC mothers who reported receiving	115	Will repeat

Table A-1. List of WIC-IFPS-1 report tables and figures (continued)

Table/Figure	Page	Status
various items in their gift packages from the hospital		

Table A-1. List of WIC-IFPS-1 report tables and figures (continued)

Table/Figure	Page	Status
Table V.3 Percentage of type of feeding at hospital discharge by type of first feeding	116	Will repeat
Table V.4 Relative odds of formula feeding at hospital discharge for WIC mothers who breastfeed at the first feeding	118	Will repeat similar content but models will differ
Table V.5 Relative odds of breastfeeding at hospital discharge for WIC mothers who formula feed at the first feeding	120	Will repeat similar content but models will differ
CHAPTER VI: BREASTFEEDING AND FORMULA FEEDING PRACTICES		
Figure VI.1 A model of daily number of breastfeeds at Month 1 interview and its predictors available from the WIC-IFPS	126	Will not repeat as not deemed to be highly critical outcome
Table VI.1 Breastfeeding schedules of WIC mothers over the first five months of their infants' first year	128	Will repeat
Figure VI.2 Percentage of WIC mothers who breast feed on a set schedule, when the infant cries or seems hungry, and on a mixed schedule	130	Will repeat
Table VI. 2 Usual number of daily breastfeeds, by selected maternal socio-demographic characteristics	131	Will repeat
Table VI.2Percentage of WIC mothers who report expressing milk during the past week, by selected maternal socio-demographics	132	Will repeat
Figure VI.3 Percentage of breastfeeding WIC mothers expressing milk, using electric breast pumps, using manual breast pumps, and expressing milk by hand	133	Will repeat (excluding type of pump)
Table VI.4 Relative contribution of selected non-program and program factors to the usual number of daily breastfeeds reported at Month 1 interview	135	Will repeat similar content but models will differ
Table VI.5 Percentage of WIC mothers who add other foods or liquids into the bottle with the formula by selected socio-demographic characteristics	141	Will repeat
Figure VI.4 Percentage of mothers who report adding other foods or liquids in the bottle with the formula at Month 3	142	Will repeat
Figure VI.4 Percentage of mothers who report adding other foods in the bottle with formula at Month 1 among those who think that the amount of formula given by WIC is more than enough, the right amount, or not enough	143	Will repeat
Table VI.5 Percentage distribution of formula-feeding WIC mothers by brand name of formula	145	Will repeat
CHAPTER VII: FEEDING PROBLEMS, CONTINUATION AND CESSATION OF BREASTFEEDING		
Table VII.1 Reported nursing problems by WIC mothers at the time of the Month 1, Month 3 and Month 5 interviews	153	Will repeat
Figure VII.1 Percentage of breastfeeding WIC mothers who report experiencing nursing problems in Months 1,3 and 5	154	Will repeat
Table VII.2 Median age of breastfeeding cessation, age when 25% and age when 75% of the infants are weaned from the breast	163	Will not repeat; similar information can be better displayed in a graphic

Table A-1. List of WIC-IFPS-1 report tables and figures (continued)

Table/Figure	Page	Status
Figure VII.3 Percentage of all WIC mothers breastfeeding, by age of the infant	164	Will repeat But infant age will not be in days
Figure VII.4 Percentage of all WIC mothers still breastfeeding, by age of the infant and age of the mother	165	Will repeat But infant age will not be in days
Figure VII.5 Percentage of all WIC mothers still breast-feeding, by age of the infant and whether the mother reports knowing about the special WIC food package for breast-feeding women who do not accept intent formula for WIC	166	Will repeat But infant age will not be in days
Table VII.3 Relative risks estimated by the multivariate models of rates of breastfeeding cessation (survival analysis)	168	Will repeat similar content but models will differ
Figure VII.6 Percentage of WIC mothers still breastfeeding by age of the infant and reported receipt of none, one, two, or three WIC program components that support breastfeeding	173	Will repeat But infant age will not be in days
CHAPTER VIII: INITIATION OF SUPPLEMENTAL FOODS: THE TRANSITIONAL PHASE OF INFANT FEEDING		
Figure VIII.1 A model of early initiation of supplemental foods and the measures of its predictors from the WIC-IFPS	180	Will replace with graphics of updated introduction of other foods model
Figure VIII.2 Percentage of WIC mothers who have not yet initiated cereals, vegetables, and meats at each age of the infant	186	Will repeat But infant age will not be in days
Figure VIII.3 Percentage of WIC mothers who have not yet initiated dairy foods, high-protein foods other than meats, and sweet/snack foods, at each age of the infant	188	Will repeat (food categories may differ) But infant age will not be in days
Table VIII.1 Median age of the infant (in days) when specific supplemental foods are initiated by selected socio-demographic characteristics of the mother	189	Will repeat But infant age will not be in days
Figure VIII.4 Percentage of WIC mothers who have not yet initiated cereals at each age of the infant, by maternal immigrant status	190	Will repeat But infant age will not be in days
Figure VIII.5 Percentage of mothers initiating cereals, fruits, vegetables, and meats as the first, second, third or fourth type of supplemental food	192	Will repeat
Table VIII.2 Percentage distribution of the order of initiation of cereals, fruits, vegetables, and meats, by race/ethnicity of the mother	194	Will repeat
Table VIII.3 Relative risk of initiating cereals prior to four months of age	196	Will repeat similar content but models will differ
Table VIII.4 Relative risk of initiating fruits prior to four months of age	199	Will repeat similar content but models will differ
Table VIII.4 Relative risk of initiating fruits prior to four months of age	201	Will repeat similar content but models will differ
Figure VIII.6 Percentage of WIC mothers who have not yet initiated fruit juices, sweet drinks, and cow milk or other milk at each age of infant	207	Will repeat
Table VIII.6.Median age of the infant at the time of initiation of fruit juices or sweet drinks by selected socio-demographics	208	Will repeat
Figure VIII.7 Percentage of WIC mothers who have not yet sweet drinks at each age of infant, by race/ethnicity of the mother	209	Will repeat
CHAPTER IX SUPPLEMENTAL FOOD FEEDING PRACTICES		

Table A-1. List of WIC-IFPS-1 report tables and figures (continued)

Table/Figure	Page	Status
Table IX.1 WIC-IFPS interview months when questions on the method of feeding supplemental foods were elicited	214	Will not repeat as we focus on the dates changes occurred and not the timing of the interview to get behavioral changes information
Table IX.1 Methods of feeding supplemental foods at interview months when data was elicited	215	Will repeat
Figure IX.1 Percentage of WIC infants receiving supplemental foods using a spoon at interview months 2, 4, 5 and 9 by race and ethnicity of the mother	216	Will repeat
Figure IX.2 Percentage of WIC mothers who have used an infant feeder sometime during infancy by race and ethnicity of the mother	217	Will repeat
Table IX.3 Percentage of WIC mothers who adopt supplemental food feeding practices that are generally not recommended	218	Will repeat Rule changes?
Figure IX.3 Percentage of WIC mothers who feed supplemental foods before month 4, prior to using a spoon, by race and ethnicity of the mother	220	Will repeat

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Appendix B
Proposed Analyses for Answering Each Research Question

Table B-1 shows which analyses answer each research questions and whether the analysis is repeated from a past study or new. In cases in which the analyses repeats work from past studies we provide the study reference and page number for the relevant table or figure[21].

Table B-1. Tabular presentation of research design

Research question	Analysis and format	Repeated or new
1: What is the participant's practice on breastfeeding and formula feeding her infant?	Table: Breastfeeding initiation rates by selected socio-demographic and health-related characteristics (Cumulative, Months 1,3) Figure: Breastfeeding initiation rates, by race and ethnicity of the mother (Cumulative, Months 1, 3) Figure: Percentages of only breastfeeding, combined breast-and formula feeding, and only formula-feeding WIC mothers at each month of interview (Months 1-13) Table: Percentage distribution of the infants by initial diets at the at the time of each interview month; by selected socio-demographic characteristics (Months 1, 3) Table:(Model) Estimates of the relative odds estimated by the logistic regression model of breastfeeding initiation (Cumulative, Months 1,3) Table:(Model) Estimates of the relative risk estimated by the multivariate models of rates of formula supplementation (survival analysis) (Months 1-13) Table. (Model) Relative risks estimated by the multivariate models of rates of breastfeeding cessation (survival analysis) (Months 1-13)	Repeated from IFPS pages53, 54,88, 90, 58,96, 168

[21] IFPS refers to Baydar, et al. Final Report: WIC Infant Feeding Practice Study, November 1997.

FITSa refers to Seiga-Riz,Anna Marie et al. Food Consumption Patterns of Infants and Toddlers: Where are we Now? in the *Supplement to the Journal of the American Dietetic Association,* 2010.

FITSb refers to Devaney, Barabara et al. Nutrient Intakes of Infants and Toddlers in the *Supplement to the Journal of the American Dietetic Association,* 2004

FITSc refers to Skinner, Jean D. et al. Meal and Snack Patterns of Infants and Toddlers in the *Supplement to the Journal of the American Dietetic Association,* 2004

FITSd refers to Ponza, Michael et al. Nutrient Intakes and Food Choices of Infants and Toddlers and Toddlers Participating in WIC in the *Supplement to the Journal of the American Dietetic Association,* 20040

FITSe refers to Carruth, Betty Ruthet al. Developmental Milestones and Self-Feeding Behaviors in Infants and Toddlers in the *Supplement to the Journal of the American Dietetic Association,* 20040

Table B-1. Tabular presentation of research design (continued)

Research question	Analysis and format	Repeated or new
1a: Does the practice/behavior correspond to specific past feeding experiences (cultural norms, support received, personal feelings, barriers encountered, etc.)?	Table: Items that constitute the perceived benefits of breastfeeding and perceived barriers to breastfeeding scales (factor analysis) (Prenatal) Table: Percentage of mothers agreeing with statements about perceived benefits of breastfeeding by breastfeeding decision (Prenatal) Table Percentage of mothers agreeing with the statements (Prenatal) about perceived barriers to breastfeeding by breastfeeding decision Table Percentage of mothers receiving breastfeeding education/support (WIC vs. elsewhere) by breastfeeding decision (Cumulative; Months 1,3) Same as breastfeeding initiation model above	Repeated from IFPS pages 71, 73, and 74 Last table is new
1b: How does breastfeeding advice or support compare to rates of initiation, duration and exclusivity of breastfeeding?	Figure: (Model) Predicted relative odds of initiating breastfeeding for WIC mothers who received breastfeeding information and advice from different sources (Cumulative; Months 1,3) Same as last table above and formula supplementation and breastfeeding cessation models in question 1	Repeated from IFPS, page 63 but use different categories
1c: Are differences from one re-interview to the next statistically significant?	Figure :Percentages of breastfeeding WIC mothers, by type of breastfeeding practice at each month of interview (Month 1-9) Figure: Percentage of breastfeeding WIC mothers who have not yet initiated formula, by the age of the infant (Months 1-9)	Repeated from IFPS, pages 92 and 94
2: What is the frequency of breastfeeding or formula feedings and foods (total and by breast, formula, combinations, and foods) given?	Table : Usual number of daily breastfeeds, by selected maternal socio-demographic characteristics (Months 1, 3, 5) Table: Usual number of formula or combination feedings, by selected maternal socio-demographic characteristics (Months 1, 3, 5) Table: Usual number of solid food feedings , by selected maternal socio-demographic characteristics (Months 1, 3, 5)	Repeated from IFPS, pages 131 2nd and 3rd tables are new
2a: Do mothers/caregivers ever put anything other than human milk or formula in a bottle that is fed to their infant?	Table: Percentage of WIC mothers who add other foods or liquids into the bottle with the formula by selected socio-demographic characteristics (Months 1,3) Figure: Percentage of mothers who report adding other foods or liquids in the bottle with formula at months 3 (Month 3) Figure: Percentage of mothers who report adding other foods in the bottle with formula at Month 1 among those who think that the amount of formula given by WIC is more than enough, the right amount, or not enough (Month 1)	Repeated from IFPS, pages 141, 142, 143
3: What is the mean and range in the incidence, duration, and intensity of breastfeeding? *Not collecting duration of individual breastfeeds*	Table: Mean and standard deviation in the number of breastfeeds and intensity (% of feedings that are breast feedings) per day by month (Months 1-7)	New

Table B-1. Tabular presentation of research design (continued)

Research question	Analysis and format	Repeated or new
3a: Are differences from one re-interview to another statistically significant?	Same as above	Same as above
4: What are the breastfeeding history characteristics of postpartum women by level (e.g., quintile) of mean incidence, duration, and intensity?	Table: Median age in weeks/days of the infant at the time when formula supplementation is initiated, by selected socio-demographic characteristics and previous breastfeeding experience (Cumulative; Months 1-13) Table: Breastfeeding frequency, intensity, and duration by initial breastfeeding status (breastfeed only or with formula) (Months 1-7)	Repeated from IFPS, pages 94 2nd table is new
4a: Do these characteristics change from one interview to the next? If so, are the differences statistically significant?	Same as second table above	New
5: How does the mother/ caregiver determine the daily feeding schedule for the infant?	Table: Breastfeeding schedules of WIC mothers over the first five months of their infants' first year (Months 1,3, 5) Figure: Percentage of WIC mothers who breastfeed on a set schedule, when the infant cries or seems hungry, and on a mixed schedule (Months 1-13)	Repeated from IFPS-1, pages 128, 130
5a: How does this vary by day of the week, work schedule, and other factors? *Not collecting day of but rather typical pattern week*	Table: Breastfeeding schedules of WIC mothers over the first 13 months of their infants' first year by mother's work status and child care status (Months 1-13)	New
6: What are the feeding practices with pumping or expressing human milk?	Table: Percentage of WIC mothers who report expressing milk during the past week by selected maternal socio-demographics (Months 1-7) Figure: Percentage of breastfeeding WIC mothers expressing milk, using electric breast pumps, using manual breast pumps, and expressing milk by hand (Cumulative; Months 1-7)	Repeated from IFPS-1, pages 132, 133 with added months
6a: How does the mother/ caregiver determine these practices?	Table: Percentage distribution of reason for pumping (Cumulative; Months 1-7)	New
6b: How does this vary by day of the week, work schedule, healthcare support and other factors? *Not collecting day of week*	Table: Percentage of breastfeeding WIC mothers expressing milk, using electric breast pumps, using manual breast pumps, and expressing milk by hand by work status and receipt of WIC support services (Months 1-7)	New
7: How does the mother/ caregiver determine the specific time and duration of feeding?	Same table and figure as for question 5	Same as for question 5

Table B-1. Tabular presentation of research design (continued)

Research question	Analysis and format	Repeated or new
8: What are mothers reported breastfeeding problems?	Table: Reported breastfeeding problems by WIC mothers at the time of the month 1, month 3 and month 5 interviews (list of problems) (Months 1, 3, 5) Figure: Percentage of breastfeeding WIC mothers who report experiencing breastfeeding problems in months 1, 3 and 5 (main types of problems) (Months 1,3,5)	Repeated from IFPS-1, pages 153, 154 expanded to include environ-mental barriers
8a: Among those who had common breastfeeding problems, what are the number and percent receiving help from the WIC staff?	Table: Percentage of mothers reporting breastfeeding problems who received help by source of support (Cumulative; Months 1,3,5)	New
9: What is the distribution of caregiver understanding of appropriate feeding behaviors associated with infants' non verbal cues regarding satiety gestures and cry interpretations?	Table: Percentage of caregivers who respond to different infants cues with appropriate understanding (Month 3)	New
10: How are caregivers obtaining or preparing baby foods (e.g., making at home, buying, getting from WIC, etc.)?	Table: Percentage distribution of the sources for baby foods (Months 7-13) Table: Share of purchased baby food covered by WIC vouchers (Months 7-13)	New
11: How do caregivers' infant food choices vary across feedings (e.g., only human milk, only formula, mixture, alterations, or other drinks)?	Table: Percentage distribution of food choices across feedings (morning, afternoon, evening) (Months 1-13)	New
11a: Is the caregiver supplementing with food and/or other beverages besides formula and breast milk (e.g., soda, tea, juice)?	Table: Percentage of infants and toddlers consuming different types of milk and other beverages by age (Months 3-24) Table : Median age of the infant (in weeks/days) when specific supplemental foods are initiated by selected socio-demographic characteristics of the mother (Months 1-24) Table: Percentage of infants and toddlers consuming grains, vegetables, fruits, and meats/other protein sources, and desserts, sweets, sweetened beverages and salty snacks by age (Months 3-24)	Repeated from FITSa, page S40 with other beverages added and IFPS, page 189 with months added 3rd table is new

Table B-1. Tabular presentation of research design (continued)

Research question	Analysis and format	Repeated or new
11b: What is the percentage of combination feedings comparing human milk, formula, and/or foods (e.g., mom supplements in the evening to allow infant to sleep through the night being 90% human milk, 5% baby foods, and 5% formula per day)?	Table: Percentage distribution of combinations feedings by age (Months 1-13)	New
11c: How much food and/or cow's milk (i.e., whole, 2%, chocolate or 1% milk) is used?	Same tables as in question 11a	Same as for question 11a
12: What WIC Food Package is the caregiver/infant receiving (i.e., full breastfeeding or partial breastfeeding)?	Table: Percentage of caregivers and infants by type of food package received (Months 1, 7, 13)	New
13: What are the barriers (e.g., environmental) in breastfeeding practices and behaviors for infants?	Same tables as in question 8	Same as in question 8
13a: For those who identified barriers, what do they think would be the best possible solution to overcome the barriers?	Table: Percentage distribution of possible solutions to barriers (Cumulative; Months 1,3, 5)	New
14: What do mothers/caregivers perceive to be the impact of their food package choices on their breastfeeding behavior?	Table: Percentage distribution of the perceived impact of food package choices on the breastfeeding decision (Months 3, 7)	New
15: What do mothers/caregivers perceive to be the impact of their food package choices on the food their child receives?	Table: Percentage distribution of the impacts of food package choice on food child receives (Months 7, 15)	New
16: What is the nutrient intake of infants and (if option funded) toddlers?	Table: Usual nutrient intake distributions of infants: Micronutrients (Months 3,5 and 7-11) Table: Usual nutrient intake distributions of toddlers (Months 13 to 24) Table: Usual nutrient intake distributions of infants: Macronutrients (Months 5-24)	Repeated from FITSb, page S16, S17, and S18
16a: How does the nutrient intake vary by State food package choices?	Table: Estimates of the effect behaviors and demographics have on nutrient intake(Months 7, 13, 24)	New

Table B-1. Tabular presentation of research design (continued)

Research question	Analysis and format	Repeated or new
16b: How does the nutrient intake vary by age, primary milk source, and other factors?	Same table as above	Same as above
17: What is the frequency and nature of mothers' reported breastfeeding problems?	Same table as for question 8	Same as for question 8
17a: Did the mother receive support? For whom? If not, from whom would she have liked support (WIC, family, all the above, etc.)?	Same table as for question 8a	Same as for question 8a
17b: Are there group differences in the prevalence of breastfeeding problems by race/ethnicity, age, and education of the mother?	Table: Percentages of mothers reporting breastfeeding problems in the first 5 months by type of problem and socio-demographics (Cumulative; Months 1,3,5)	New
17c: How does the frequency of breastfeeding problems vary with other actors?	Same table as above	Same as above
17d: What are the resolutions of the problems?	Table: Percentage distribution of resolutions by type of breastfeeding problem (Cumulative; Months 1,3,5)	New
18: At each age, what percentages of WIC infants and/or toddlers use a cup (with and without assistance), a spoon, a Sippy cup or a pacifier throughout the first years of life? What percentage of WIC infants self-feed during mealtimes? How does this vary by eating location (e.g., home, childcare, away from home with primary caretaker)? *Not collecting by location*	Table: Self feeding skills and the percentage of toddlers who were reported to show the self feeding skill by age (Months 9, 11, 13, 18) Table. Methods of feeding supplemental foods at interview months when data was elicited (Months 3-9, 13, 18) Figure Percentage of WIC infants receiving supplemental foods using a spoon by race and ethnicity of the mother (Months 3-9, 13, 18)	Repeated from FITSe, page s53 and IFPS, page 215 and 216 3rd table in new
19: How well are caregivers who use formula following the standard or specialized formula dilutions prescribed by the doctor or nutritionist? What is the prescribed amount and is this over or under stand recommendations?	Table: Percentage of caregivers who deviate from formula dilution directions by type of deviation (Cumulative; Months 3, 7, 11) Table: Percentage if caregivers receiving doctor or nutritionist dilution guidance that deviate from recommendations by type of deviation (Cumulative; Months 1-13)	New

Table B-1. Tabular presentation of research design (continued)

Research question	Analysis and format	Repeated or new
20: What is the frequency of methods used by the caregiver to prepare foods (such as pureeing or mashing with utensils or by chewing up foods then giving to child)?	Table: Percentage distribution of food preparation methods used by caregivers (Months 7, 9, 11, 13)	New
21: When is pumping or expressing human milk done and how often? What are the storage practices? If using a breast pump where did mother receive the pump from? What is the distribution of the frequency of use of pumps?	Table: The average number of times a day women pump or express milk among those doing this (Months 1-13) Table: Percentage distribution of pumping/ expressing milk by location, time of day, and storage practices (Months 1-13) Table: Percentage distribution of sources for pumps (Cumulative; Months 1,3) Same table for question 6	New and same as for question 6
22: What non-program and program factors (i.e., supplies, policies, staff competencies, and actions) contribute to the likelihood of initiating breastfeeding, formula supplementation, baby foods, and cereals?	Same tables on breastfeeding decision and formula supplementation model estimates as for question 1 Table (Model) Relative risk of initiating cereals prior to four and six months of age (Cumulative; Months 1-13) Table: (Model) Relative risk of initiating fruits prior to four and six months of age (Cumulative; Months 1-13 Table: (Model) Relative risk of initiating vegetables prior to four and six months of age (Cumulative; Months 1-13)	Repeated from IFPS, pages 196,199, and 201
23: For women who chose a fully breastfeeding package yet also use formula, where do these women obtain formula?	Table: Percentage distribution of formula sources for women choosing the breastfeeding package(Cumulative; Months 1-13)	New
24: If formula is used, what type(s) of formula (i.e., exempt, soy, milk-based, ready to drink powdered or concentrated)?	Table: Percentage distribution of formula types (Cumulative; Months 1-13)	New
24a: Who provided formula?	Table: Percentage distribution of formula sources (Cumulative; Months 1-13)	New
24b: What was the reason for the formula?	Table: Percentage distribution of reasons for using formula by infant age (Months 1-13)	New
24c: How do these factors change in relation to the age of the infant?	Same as above	New

Table B-1. Tabular presentation of research design (continued)

Research question	Analysis and format	Repeated or new
25: Does the mother or child have any medical conditions? If so, what were the actions taken to rectify? *Are only asking about treatments that could affect feeding behaviors (e.g., hospitalization, medication, etc.)*	Table: Percentage of mothers with health problems during pregnancy and after birth by main treatment (Month 1) Table Percentage of children with health problems by main treatment (Month 1)	New
26: If child ever used a pacifier when was it introduced and who introduced it? For what reason was the pacifier introduced? How often is the pacifier used and are there specific times when it is used or not used? *Not asking when pacifier was introduced or frequency of use or times used as it is unlikely to provide useful information*	Table: Percentage of children using pacifiers and timing of introduction (Month 3) Table: Percentage distribution of pacifier use by reason (Month 3)	New
27: What is the overall prevalence of breastfeeding problems over the first half of infancy? What is the distribution of type of problem? How does this change over time?	Same as tables for question 8 and 17b	Same as for question 8 and 17b
28: How do the feeding practices of infants and children who continue WIC participation compare to those who leave the program or have non-continuous periods of participation?	Same tables as for question 22	Same as for question 22
29: What is the first feeding of WIC infants in the hospital?	Table: The first feeding received by WIC infants in the hospital (Month 1) Figure: The first feeding of WIC infants in the hospital, by race and ethnicity of the mother(Month 1)	Repeated from IFPS, page 110 , 111
29a: Was the mother encouraged to initiate breastfeeding?	Table: Percentage of mothers encouraged to breastfeed by family, WIC staff, or provider (Month 1)	New
29b: Did mother initiate breastfeeding in the hospital?	Table: Percentages of mothers who initiated breastfeeding in the hospital by time after birth (Month 1)	New

Table B-1. Tabular presentation of research design (continued)

Research question	Analysis and format	Repeated or new
29c: If so, how long after delivery was feeding initiated/ encouraged (such as within the first hour after birth)?	Same as above	New
29d: Did the infant receive anything other than human milk in the hospital? If so, what, when and how often?	Table: Percentage of infants who received something other than human milk in the hospital by product, day, and frequency (Month 1)	New
30: What are mothers' reported breastfeeding problems while in the hospital? Among those who had common breastfeeding problems, what are the number and percent receiving help from the hospital staff?	Table: Percentages of mothers reporting nursing problems while in the hospital (Month 1) Figure: Percentage of WIC mothers who did not receive help from the hospital staff among those who had common nursing problems (Month 1)	Repeated from IFPS, page 113 , 114
31: Did the mother/caregiver report receiving various items such as formula, pacifiers, bottles, breast pump; perhaps as part of a give package from inside the hospital? What is the distribution of the content of these items? How does this relate to breastfeeding and other infant feeding practices?	Figure: Percentage of WIC mothers who reported receiving various items in their gift packages from the hospital (Month 1) Table: Estimates of the relative odds of breastfeeding at hospital discharge (Month 1) Same tables on breastfeeding decision and formula supplementation model estimates and introduction of other foods (cereal) model as in question 22	Repeated from IFPS, page 115 2nd table is new Remaining tables are same as question 22
32: Did the mother use any of the following services in the hospital: Media campaign materials, Lactation consultant, Other trained specialist, Breastfeeding support groups or classes, Equipment for breastfeeding support, Peer counseling, Other counseling, 24-hr breastfeeding hotline, Designated staff members contact, Any other activities	Table: Percentage of WIC mothers who reported receiving various services from the hospital (infant in room, feeding on demand, referral for breastfeeding support, etc.)(Month 1)	New

Table B-1. Tabular presentation of research design (continued)

Research question	Analysis and format	Repeated or new
33: Did the mother birth multiples? If yes – vaginally or cesarean section?	Table: Percentage of multiple births and type of delivery (Month 1)	New
33a: Infants health status (such as height, weight, head circumference, blood tests; Apgar scoring, immunizations, amount of wet/soiled diapers, and food allergy)? *Not collecting data on food allergies*	Table: Percentage distribution of infants' health characteristics (Month 1)	New
34: When was mother discharged from hospital? Infant? How do these relate to infant feeding at discharge and later?	Figure : Number of days of hospital stay for WIC mothers and infants (Month 1) Table: Relative odds of formula feeding at hospital discharge for WIC mothers who breastfeed at the first feeding (Month 1) Table: Relative odds of breastfeeding at hospital discharge for WIC mothers who formula feed at the first feeding (Month 1) Same as second table for question 31 and last table for question 1	IFPS pages 109, 118, and 120
35: What was the type(s) of feeding at hospital discharge (e.g., breast, formula, or both)?	Table: Percentage of type of feeding at hospital discharge by type of first feeding (Month 1)	IFPS page 116
36: If applicable, what is the amount of expressed milk during the 1st 2 weeks after birth? What was done with the expressed milk? *Interview occurs at 1 month and not at 2 weeks*	Table: Average amount of expressed milk for breastfeeding mothers at 1 month in past 24 hours (Month 1) Table: Percentage distribution of what was done with the expressed milk (Month 1)	New
37: What are the reasons why mothers stop breastfeeding during the first few weeks of their infants' life? How often do these occur? Which pose the greatest risk to breastfeeding success and duration?	Table: Frequency of top 10 reasons women stop breast feeding within the first 2 and 6 weeks (Cumulative; Months 1,3) Same as breastfeeding cessation model in question 1	New

Table B-1. Tabular presentation of research design (continued)

Research question	Analysis and format	Repeated or new
38: What factors play into a mother being successful at breastfeeding her infant during the first few weeks of life and 4-6 months of life? What factors are associated with successful breastfeeding for the first 6 months of her infant's life?	Table: Characteristics and circumstances of mothers breastfeeding (Months 1, 3, 6) Same as breastfeeding initiation and cessation models in question 1	New
39: What is the distribution of reasons for mothers coming into WIC clinics at 4-6 month and in some cases stopping breastfeeding?	Table: Percentage distribution of reasons for stopping breastfeeding between 2-3 and4-6 months	New
40: What is the mothers Edinburgh Postpartum Depression Scale score? How does this relate to infant feeding practices?	Table: Average Edinburgh Postpartum Depression Scale score by breastfeeding status (Months 3 , 6) Same as the last 2 model tables for question 1	New and same as the last 2 model tables for question 1
41: How do the answers to all above listed research questions vary in relation to the infant's health status at birth (such as length, weight, etc.) and household demographic characteristics?	Table: Frequency of top 5 reasons women stop breast feeding within the first 6 weeks by infant health status and household demographics (Cumulative; Months 1,3) Same as breastfeeding decision and duration model tables for question 1 Same as breastfeeding cessation model table for question 37	New Same as for question 1 and 37
42: For working mothers, describe the distribution of characteristics of the place at work to pump human milk? Does the mother's employer have a workplace lactation program or provide any workplace accommodations (such as reasonable breaks, an appropriate place to store milk, a place other than the bathroom to pump/express human milk, etc.)?	Table: Percentage distribution of the accommodations available at work to assist with pumping milk (Month 3)	New

Table B-1. Tabular presentation of research design (continued)

Research question	Analysis and format	Repeated or new
43: Is the respondent's child participating in the CACFP? If yes, what is the transition of baby foods, table foods, cow's milk, and human milk in the CACFP and other facilities?	Table: Percentage distribution of children in childcare by type of childcare (Months 3,7,13,24) Table: Within CACFP facilities, the average month of key food transitions (Cumulative; Months 7,13)	New
44: If applicable, when did the child go into a childcare facility and what kind (i.e., child care center, family day care homes, early head start, homeless shelters, etc.)?	Same as table above Table: Average age of child when they first started childcare by type of childcare (Cumulative; Months 3, 7, 13, 24)	New
45: For infants in child care: What are the general barriers to breastfeeding in these facilities? Who provides the food to these facilities? Is human milk given by bottle or nipple when at facilities (e.g., may go to facility on break to breastfeed or some mothers only bottle feed human milk to infants)? If the mother providing expressed human milk or breastfeeding the infant at the facility? How does breastfeeding success relate to childcare policies and practices?	Table: Frequency of top 10 barriers to breastfeeding children in childcare (Cumulative; Months 3,7) Table: Percentage distribution of who provides the food for the child by type of childcare (Months 3, 7, 13, 24) Table: Percentage of mothers with children in childcare who go to facility to breastfeed during the day (Cumulative; Months 3,7) Table: Percentage of children in childcare getting human milk by age of infant and method of receipt (Months 3,7)	New
46: What are the caregivers socio-demographic characteristics (i.e., sex, birth order, age of mother at time of birth, US citizen, marital status, household size, poverty level, receipt of public assistance, education, employment prior WIC, drug history, healthcare, Medicaid, etc.) by maternal race and ethnicity? What is the Native language? *Not including drug history or native language. Will use*	Table: Percentage distribution of socio-demographic characteristics by maternal/caregiver race and ethnicity (Baseline)	Repeated from IFPS, page 25

Table B-1. Tabular presentation of research design (continued)

Research question	Analysis and format	Repeated or new
foreign born rather than citizenship.		
47: What are the distributions of caregivers and participants health-related characteristics by race and ethnicity of the mother?	Table: Percentage distribution of reported health-related characteristics by maternal race and ethnicity of the mother (month 1)	Repeated from IFPS-1, page 26
48: Is this the mother's first time breastfeeding or formula feeding?	Table: Percentage of WIC mothers by previous feeding practice experiences for siblings (Baseline)	New
49: Did the mother breastfeed siblings?	Same as above	New
49a: If so, when did she initiate and how long did she breastfeed?	Table: Average longest duration and number of years ago of previous breastfeeding experience (Baseline)	New
49b: When did she first give baby foods and table foods to siblings on WIC?	Table: Average infants age mother previously introduced solid foods (cereal and other table by type of food)to siblings(Baseline)	New
50: When did the mother/caregiver start participating in the WIC program?	Table: Percentage of mothers/caregivers who have previously participated in WIC and by the length of participation (Baseline) Table: For current child, percentage distribution of when the mother/caregiver joined WIC by infants age (screener)	New
51: What are mothers' influences to breastfeed or formula feed? What influences the mother to breastfeed or formula feed?	Same as model estimate tables for question 1a	Same as for question 1a
52: Does the mother intend to breastfeed?	Table: Mothers' intention to breastfeed by socio-demographics (Prenatal)	New
53: Did the mother receive counseling on infant feeding and care and by whom?	Table: Percentages of mothers reporting receipt of information about various aspects of infant feeding from WIC(Month 1) Table: Percentages of mothers reporting receipt of information about infant feeding from other professional sources (Month 1)	Repeated from IFPS, page 28and new with the addition of non-WIC sources of information
53a: Where did the mother receive her counseling on infant feeding and care (e.g., clinical dietitian from hospital, nurse practitioner or WIC nutritionist clinic)?	Same as above	Same as above

Table B-1. Tabular presentation of research design (continued)

Research question	Analysis and format	Repeated or new
54: What are staff and mothers/caregivers knowledge, attitudes, and beliefs about nutrition and behavior (e.g., following a kosher, vegan diet or other religious views affecting food consumption, etc.) for infants and toddlers?	Table: Percentage of mothers having certain knowledge and attitudes about nutrition and behavior (Month 13) Table: Percentage of WIC staff having certain knowledge and attitudes about infant and toddler nutrition (WIC staff survey)	New
55: What are the mothers/caregivers challenges in nutrition education involving feeding practices?	Table: Percentage of Top 5 nutrition challenges for mothers/caregivers reporting challenges getting nutrition information by source(Months 5, 15)	New
56: Where does the mother/caregiver get nutrition information (e.g., WIC, websites, social media, family, friends, social networks, healthcare providers, etc.)?	Table: Percentage distribution of mothers/caregivers sources of nutrition information (Months 5, 15)	New
57: What triggers mothers/caregivers behavior to get information (such as infant won't stop crying, desire to be good mother, etc.)?	Table: Triggers for seeking nutrition information (Months 5, 15)	New
58: What are the physicians' views and/or beliefs regarding breastfeeding a preemie vs. non-preemie (e.g., growth)? *Not interviewing providers. Instead asking mother/caregiver their perception of their provider's views*	Table: Percentage distribution of mother's perception of physician's views about breastfeeding preemies (Month 1)	New

Table B-1. Tabular presentation of research design (continued)

Research question	Analysis and format	Repeated or new
59: What is the relationship of infant and child feeding practices to infant and child growth and weight status (e.g., overweight/ underweight)?	Table: Percentage of children in each weight/length quintile at 6, 12 and 24 months by breastfeeding experience (Months 1, 3 and clinical records for 6, 12, 24) Table: Percentage of children in each weight/length quintile at 6, 12 and 24 months by timing of the introduction of different types of solid foods (Months 1-13 and clinical records for 24) Table. Percentage of children in top 20% and bottom 20% of the weight/length distribution at 12 and 24 months by breastfeeding experience and socio-demographics (Months 1, 3 and clinical records 12, 24) Table: Average child weight/length gain in first 6 months by breastfeeding experience (Months 1 ,3 and clinical records for 1, 5) Table: Average child weight/length gain between 6-12 months by breastfeeding experience (Months 1, 3 and clinical records for 6, 12) Table. (Model) OLS regression estimates of the impact of the impact of socio- demographics and feeding practices on weight/length at 24 month (Cumulative; Months 1-24 and clinical records for 6, 12 24) Table: (Model) Quantile regression estimates of the impact of socio- demographics and feeding practices on weight/length at 6 month (Cumulative; Months 1-6 and clinical records for 6) Table: (Model) Quantile regression estimates of the impact of socio- demographics and feeding practices on weight/length at 12 month (Cumulative; Months 1-13 and clinical records for 6, 12) Table: (Model) Quantile regression estimates of the impact of socio- demographics and feeding practices on weight/length at 24 month (Cumulative; Months 1-24 and clinical records for 6, 12 24) Table: (Model) Growth model estimates of the impact of socio- demographics and maternal health on weight gain trajectory of the child from birth to 2years (Cumulative; Months 1-24 and clinical records for 0, 6, 12 24)	New

Table B-1. Tabular presentation of research design (continued)

Research question	Analysis and format	Repeated or new
60: What are the mothers/caregivers and child's health care providers (OBGYN, pediatrician, etc.) views or beliefs regarding breastfeeding? What recommendations have mothers/caregivers received from their health care providers regarding breastfeeding? *Not interviewing providers Instead asking mother/caregiver their perception of their provider's views. As such perception of views and recommendations merge.*	Same as table for 1a <u>Table:</u> Percentage distribution of mother's perception of physician's views about breastfeeding (Month 1)	Same as table 1a 2nd table is new

Appendix C
Example Tables by Socio-Demographics

In this appendix we provide a few examples of how the tables will examine the measures of interest vary by key subpopulation groups.

TABLE EXAMPLE # 1

Table C-1 is an example of a new table that does not repeat work from a past study. The outcome measure is relatively simple and global in nature and therefore lends itself to making many subgroup comparisons. Below are the subgroups comparison we believe may prove meaningful for this measure.

Table C-1. Mother's Intention to breastfeed by socio-demographics

	Intend to breastfeed?			Total	
Subgroup	Yes	No	Undecided	n	Weighted n
Race*					
African American	%	%	%		
White					
All other					
Ethnicity*					
Hispanic					
Non-Hispanic					
Breastfeeding experience					
Never breastfed					
Breast fed					
WIC exposure					
Began prenatally in 1st trimester					
Began prenatally after 1st trimester					
Began postnatally					
Mother's weight status					
Overweight					
Obese					
Neither obese or overweight					

Table C-1. Mother's Intention to breastfeed by socio-demographics (continued)

	Intend to breastfeed?			Total	
Subgroup	Yes	No	Undecided	n	Weighted n
Poverty level					
0-75%	%	%	%		
76-130%					
>130%					
Mother's age					
<20					
20-25					
>25					
Marital status					
Married					
Not married					
Household food security					
Secure					
Not secure					
Total					
n					
Weighted n					

* Chi-square testing subgroup differences is significant at p ≤ .05
**Chi-square testing subgroup differences is significant at p ≤ .01

TABLE EXAMPLE # 2

Table C-2 is an example of a table that we are repeating from the IFPS-1 study. The first table below is a direct replication if the table as it appears in the IFPS-1 study. It includes two subgroup comparisons- race/ethnicity and breastfeeding status.

Table C-2. Percentage of mothers agreeing with statements about perceived benefits of breastfeeding by other background characteristics (repeats IFPS-I p 73)

Maternal attitude and belief	Race/ethnicity				Breastfeeding status		Total	
	White	African American	Hispanic	Other	Initiated breastfeeding	Did not breastfeed	n	Weighted n
Statement 1*	%	%	%	%	%	%		
Statement 2@								
…								
Statement n								
Total								
n								
Weighted n								

* Chi-square testing race/ethnicity differences is significant at p ≤ .05
**Chi-square testing race/ethnicity differences is significant at p ≤ .01
@ Chi-square testing breastfeeding status differences is significant at p ≤ .05,
@@ Chi-square testing breastfeeding status differences is significant at p ≤ .01
Etc.

We believe that it may prove meaningful to look at these responses by mothers' previous breastfeeding experience, marital status, and age as well as show a table shell (Tables C-3) for these subgroups below.

Table C-3. Percentage of mothers agreeing with statements about perceived benefits of breastfeeding by breastfeeding group

Maternal attitude and belief	Breastfeeding group		Marital status		Mother's age			Total	
	Never breastfed	Breastfed	Married	Not married	<20	20-25	>25	n	Weighted n
Statement 1*	%	%	%	%	%	%	%		
Statement 2@									
…									
Statement n									
Total									
n									
Weighted n									

* Chi-square testing breastfeeding group differences is significant at p ≤ .05,
**Chi-square testing breastfeeding group differences is significant at p ≤ .01,
@Chi-square testing marital status differences is significant at p ≤ .05
@@Chi-square testing marital status differences is significant at p ≤ .05
Etc.

TABLE EXAMPLE #3

Table C-4 is an example of a new table. The outcome measure is triggers mothers have for seeking nutrition information which does not lend itself to a single summary measure. Instead, we provide the percentage of women who agree with a list of potential triggers. We ask this question when the child is 5 months old and beginning to transition to solids as mothers are likely to be seeking nutrition information at this time. We repeat this question during the toddler period when the child is 15 months as we expect the triggers may change with older children.

Table C-4. Triggers for seeking nutrition information

Trigger	Percentages reporting trigger	
	At 5 months	At 15 months
Trigger 1	%	%
Trigger 2		
Trigger 3		
Trigger 4		
Total		
n		
Weighted n		

Although unlikely to vary greatly between subpopulations, we believe it may prove meaningful to look at these responses by race/ethnicity and mothers' age and show table shells (Tables C-5 and C-6) for these subgroups below.

Table C-5. Triggers for seeking nutrition information by race/ethnicity

Trigger	Percentages reporting trigger	
	At 5 months	At 15 months
White		
Trigger 1	%	%
Trigger 2		
Trigger 3		
Trigger 4		
Total		
n		
Weighted n		
African American		
Trigger 1	%	%
Trigger 2		
Trigger 3		
Trigger 4		
Total		
n		
Weighted n		
Other		
Trigger 1	%	%
Trigger 2		
Trigger 3		

Trigger	Percentages reporting trigger	
	At 5 months	At 15 months
Trigger 4		
Total		
n		
Weighted n		
Hispanic		
Trigger 1	%	%
Trigger 2		
Trigger 3		
Trigger 4		
Total		
n		
Weighted n		
Non-Hispanic		
Trigger 1	%	%
Trigger 2		
Trigger 3		
Trigger 4		
Total		
n		
Weighted n		

Table C-6. Triggers for seeking nutrition information by mother's age

Nutrition trigger	Percentages reporting trigger	
	At 5 months	At 15 months
< 20 year old		
Trigger 1	%	%
Trigger 2		
Trigger 3		
Trigger 4		
Total		
n		
Weighted n		
20-25 years old		
Trigger 1	%	%
Trigger 2		
Trigger 3		
Trigger 4		
Total		
n		
Weighted n		
➢> 25 years old		
Trigger 1	%	%
Trigger 2		
Trigger 3		
Trigger 4		
Total		
n		
Weighted n		