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WIC Breastfeeding Peer Counseling Study: Phase 2

Supporting Statement for Paperwork Reduction Act Submission

Part A: Justification

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A.1 EXPLAIN THE CIRCUMSTANCES THAT MAKE THE COLLECTION OF INFORMATION NECESSARY. IDENTIFY ANY LEGAL OR ADMINISTRATIVE REQUIREMENTS THAT NECESSITATE THE COLLECTION. ATTACH A COPY OF THE APPROPRIATE SECTION OF EACH STATUTE AND REGULATION MANDATING OR AUTHORIZING THE COLLECTION OF INFORMATION

This is a revision of a currently approved data collection (OMB# 0584-0548) which builds upon the first phase of this study. The Food and Nutrition Service (FNS) of the USDA requests clearance for a proposed impact study of the *Loving Support* Peer Counseling Program, an initiative designed to improve breastfeeding outcomes for WIC participants. This data collection is authorized by Section 203(e)(9) of Public Law 108-265 (“The Child Nutrition and WIC Reauthorization Act of 2004”). The impact study, building on findings from a recently-completed implementation study, will examine how specific variations in implementing peer counseling using the *Loving Support* model affect breastfeeding exclusivity and intensity among first-time mothers participating in WIC. Up to eight volunteer local WIC agencies (LWAs) with *Loving Support* Peer Counseling Programs will be selected to implement an enhanced model of the *Loving Support* Peer Counseling Program. First-time expectant mothers who opt to receive peer counseling at these volunteer LWAs will be invited to participate in the study. Study participants will be randomly assigned to a control group that will receive the LWA’s standard peer counseling services or to a treatment group that will receive an enhanced model of the *Loving Support* Peer Counseling Program. Accompanying data collection efforts will document the fidelity of implementation of the planned intervention.

To justify the data collection activities needed to conduct this study, we begin with an overview of the public health community’s recommendations for breastfeeding; WIC’s role in promoting breastfeeding; and the provision of breastfeeding peer counseling in WIC. We then describe the study’s objectives, research questions, data collection activities, analyses, and reporting proposed.

Breastfeeding Recommendations

According to the American Academy of Pediatrics (AAP), human milk is “uniquely superior for infant feeding” (AAP, 2005). The AAP’s 2005 policy statement titled “Breastfeeding and the Use of Human Milk” summarized a large body of research showing multiple benefits of breastfeeding, including “health, nutritional, immunologic, developmental, psychological, social, economic, and environmental benefits.” The Academy described exclusive breastfeeding as “the reference or normative model against which all alternative feeding methods must be measured with regard to growth, health, development, and all other short- and long-term outcomes.” They therefore recommend exclusive breastfeeding for 6 months postpartum and support for breastfeeding up to 12 months.

In the Healthy People 2010 initiative (U.S. Department of Health and Human Services, 2000), the federal government adopted measurable objectives for increasing the percentage of mother-infant pairs (or “dyads”) who are exclusively breastfeeding and breastfeeding at all by the year 2010:

- 75% breastfeeding shortly after birth;
- 50% breastfeeding at 6 months;
- 40% exclusively breastfeeding at 3 months; and
- 17% exclusively breastfeeding at 6 months.

The federal government’s Healthy People 2020 objectives (U.S. Department of Health and Human Services, 2010) renewed these Healthy People 2010 objectives.

Barriers to Breastfeeding

Although many new mothers find breastfeeding rewarding and a source of health advantages for their infant, many new mothers face significant barriers to breastfeeding (Racine, et al., 2008). Some mothers may have difficulty or pain with breastfeeding. For some, illness may prevent or discourage breastfeeding, although the medical contra-indications for breastfeeding are few and rare (AAP, 2005). Some mothers may not be aware of the health benefits associated with breastfeeding, or may perceive a social stigma against breastfeeding. Other mothers may find that work in the labor market presents insurmountable challenges.

Some mothers may be influenced by infant formula marketing practices, including the early provision of free infant formula, which deters continued breastfeeding (IOM, 2005), especially when formula is provided to breastfeeding mothers in the first month after an infants' birth (IOM, 2005). This early supplementation with formula is associated with shorter duration of breastfeeding, particularly exclusive breastfeeding (Bergevin et al., 1983; Feinstein et al., 1986; Frank et al., 1987; Snell et al., 1992; Caulfield et al., 1998; Chapman et al., 2004). Yet, hospital provision of such free formula samples are common in the United States. The Centers for Disease Control (CDC) reported that 70 percent of surveyed facilities gave discharge bags containing infant formula to breastfeeding mothers (CDC, 2008). A recent survey using a slightly broader question, which more clearly encompassed formula samples to any post-partum mothers, estimated that 91% of hospitals provide such samples (Merewood, 2008).

Breastfeeding Promotion in WIC

Breastfeeding promotion and support are central tenets of the WIC Program. States must provide training on the promotion and management of breastfeeding to staff at local agencies, which, in turn, provide information and assistance on this subject to WIC participants. States are responsible for identifying or developing resources and educational materials for use in local agencies, including breastfeeding promotion and instruction materials. In addition, they must ensure that local WIC agencies provide a positive clinic environment that endorses breastfeeding as the preferred method of infant feeding; train new WIC staff appropriately on breastfeeding promotion and support; and have a plan in place to guarantee that both pregnant and postpartum WIC participants have access to breastfeeding promotion and support activities.

In addition, FNS guidance to WIC emphasizes the importance of encouraging women to breastfeed exclusively, without formula supplementation, for as long as possible during the first year. To support this goal, WIC agencies are advised to limit the provision of infant formula. When a breastfeeding mother requests infant formula, WIC staff should first “troubleshoot” to find out the reason for the

request, FNS advises: “Care must be exercised to ensure that provision of formula does not interfere with or undermine the breastfeeding mother’s desire to maintain lactation” (USDA/FNS, 2009).

Breastfeeding Rates Among WIC Participants

Despite these efforts, breastfeeding rates for WIC participants continue to lag behind those of eligible non-participants. Data from the CDC’s 2007 National Immunization Survey show that:

- The percentage that ever breastfed was 67.5 percent for WIC participants, 77.5 percent for eligible nonparticipants, and 84.6 percent for ineligible nonparticipants. For comparison, the Healthy People 2010 goal was 75 percent.
- The percentage that breastfed for 6 months was 33.7 percent for WIC participants, 48.2 percent for eligible nonparticipants, and 54.2 percent for ineligible nonparticipants. The Healthy People 2010 goal was 50 percent.
- The percentage that exclusively breastfed for 3 months was 25.5 percent for WIC participants, 39.9 percent for eligible nonparticipants, and 41.9 percent for ineligible nonparticipants. The Healthy People 2010 goal was 40 percent.

While the breastfeeding rates for WIC participants were below the Healthy People 2010 goals, the breastfeeding rates for non-participants equaled or exceeded these goals. The CDC’s survey data also estimated the percentage of infants who had infant formula supplementation within the first two days of life: 31.0 percent for WIC participants, 19.7 percent for eligible nonparticipants, and 20.1 percent for ineligible nonparticipants.

In quasi-experimental studies comparing WIC nonparticipants to similar participants, the latter seem to be particular risk for lower rates of breastfeeding initiation and duration than the former. With data from the Ross Laboratories Mothers Survey for 1978 to 2003, Ryan and Zhou (2006) estimated higher rates of breastfeeding initiation for WIC nonparticipants compared to seemingly similar participants (*odds ratio* = 1.82), and likewise higher rates of breastfeeding at six months of age for WIC nonparticipants compared to seemingly similar participants (*odds ratio* = 2.11). In a multivariate hazard analysis of breastfeeding cessation, Racine et al. (2009) estimated that WIC participants had a significantly greater hazard of cessation (*hazard ratio* = 1.50) compared with seemingly similar nonparticipants. Although these studies

are more informative than simple unadjusted cross-sectional comparisons, unobservable factors are not controlled in these analyses, so these studies still do not necessarily demonstrate effects of WIC.

Breastfeeding Peer Counseling in WIC

Widespread adoption of breastfeeding peer counseling in WIC grew out of work that began in the late 1990s to improve breastfeeding rates among WIC participants. In 1997, as part of the WIC National Breastfeeding Promotion Project, FNS partnered with Best Start Social Marketing to develop a coordinated effort, called *Loving Support Makes Breastfeeding Work*, to provide breastfeeding support to the WIC community using social marketing techniques (mass media, participant education materials) and staff training. A follow-up effort in 2002, called *Using Loving Support to Build a Breastfeeding-Friendly Community*, provided training and technical assistance to selected WIC State Agencies to build State-specific breastfeeding promotion programs. WIC staff in each State worked to identify and address State-specific barriers to breastfeeding in an implementation plan for their state. The goal of this effort was to raise public awareness, acceptance and support of breastfeeding using social marketing techniques.

In 2004, FNS launched a national peer counseling initiative developed specifically for WIC: *Using Loving Support to Implement Best Practices in Peer Counseling*. The model provides a framework for State and LWAs either to develop new or enhance existing peer counseling programs. Since 2004, FNS has allocated funding to States and Indian Tribal Organizations and U.S. Territories (ITOTs) via non-competitive, two-year grants. To date, the *Loving Support* Peer Counseling Program model has been adopted by 50 States and the District of Columbia and 34 ITOTs. In FY2010, the Agriculture Appropriations bill increased funding to the *Loving Support* Peer Counseling Program from \$15 million to \$80 million annually.¹

The guidelines for implementing *Loving Support* are fairly broad and allow States and ITOTs flexibility in determining how to implement the program so that it meets unique local needs. An implementation

¹ Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act, 2010. Public Law 111-80, 111th Congress.

study conducted from fall 2008 through spring 2009 indicated that there is considerable variation in the implementation of the *Loving Support* Peer Counseling Program, but provided no information regarding the effectiveness of the various implementation models.²

FNS needs information on the relative effectiveness of the various implementation models to ensure that resources for *Loving Support* Peer Counseling are used in the most cost-effective manner. Information from this evaluation will provide FNS with the information necessary to fine-tune the program regulations and provide LWAs with better guidance on the implementation of *Loving Support* Peer Counseling.

Evaluation Objectives

Phase 1 of FNS's evaluation of the *Loving Support* Peer Counseling Program (OMB control number 0584-0548) developed a comprehensive and detailed picture of how the program was implemented in States and local WIC agencies (LWAs) throughout the country. The variation in the implementation of the *Loving Support* Peer Counseling model, documented in Final Implementation Report² published in the spring of 2010, provides FNS with an opportunity to test the impact of a relatively more intensive approach to *Loving Support* Peer Counseling that is practiced by some LWAs but is currently not being implemented in many. More specifically, the enhancement to be tested will entail contact (telephone or in-person) between peer counselors and WIC participants enrolled in *Loving Support* when the latter are in the hospital for delivery, and in-person contact (in the hospital, WIC clinic, or in the participant's own home) approximately one week after the infant's birth. Phase 2 of FNS's evaluation of the *Loving Support* Peer Counseling Program will test the impact of this enhanced approach on breastfeeding exclusivity and intensity among first-time mothers and document the fidelity with which the enhanced approach is implemented in participating LWAs.

² U.S. Department of Agriculture, Food and Nutrition Service, Office of Research and Analysis, WIC Breastfeeding Peer Counseling Study, Final Implementation Report, WIC-10-BPC, by Ann Collins, Catherine Dun Rappaport, and Nancy Burstein. Project Officer: Tracy K. Palmer, MPH. Alexandria, VA: June 2010

This submission requests clearance to conduct Phase 2 of FNS's *WIC Breastfeeding Peer Counseling Study*.

A.2 INDICATE HOW, BY WHOM, HOW FREQUENTLY, AND FOR WHAT PURPOSE THE INFORMATION IS TO BE USED. EXCEPT FOR A NEW COLLECTION, INDICATE THE ACTUAL USE THE AGENCY HAS MADE OF THE INFORMATION RECEIVED FROM THE CURRENT COLLECTION.

This section of the supporting statement provides an overview of the research design and data collection efforts planned to meet the overall objectives of Phase 2 of the *WIC Peer Counseling Study*.

OVERVIEW OF THE RESEARCH DESIGN

The evaluation will test the effects of an enhanced model of the *Loving Support Peer Counseling Program* on breastfeeding exclusivity and intensity among first-time mothers who certify to receive for WIC benefits during pregnancy and who sign-up to receive breastfeeding peer counseling. This enhanced *Loving Support* model entails the addition of two components to peer counseling offered to pregnant WIC participants who are first-time expectant mothers:

1. Peer counselor contact (by telephone or in-person) with the WIC peer counseling participant when she is in the hospital for delivery; and
2. Peer counselor in-person contact (in the hospital, the WIC clinic, or the participant's own home) with the WIC peer counseling participant during the first 10 days post-partum.

The implementation study revealed that, while a few LWAs allow in-person contacts in participant homes and hospitals, these were rarely part of the standard *Loving Support Peer Counseling* model. After the report from Phase 1 implementation study was released, FNS conferred with a group of experts who recommended that these components be tested to see if they had a positive impact on breastfeeding outcomes.

Phase 2 (the impact study) will estimate the impacts of the intervention in a small number of sites that volunteer to participate. Only those LWAs with *Loving Support Peer Counseling Programs* that do not

include the two enhanced components described above will be eligible to participate in this study. Volunteer LWAs will be recruited by the evaluation contractor (Abt Associates Inc.), who will administer a grant competition. The evaluation contractor will issue a Funding Opportunity Announcement, evaluate LWA applications, and select between four and eight LWAs to participate in the study. The selection process will exclude any LWAs that already routinely implement the two enhancements to the *Loving Support Peer Counseling Program* (i.e., the enhancements which form the intervention whose effectiveness is the purpose of this study). The exact number of LWAs selected will depend upon the nature and capacity of the LWAs who respond to the Funding Opportunity Announcement. Selected LWAs will sign a Memorandum of Understanding (MOU) in which they agree to implement the enhancements with WIC participants in the study who are randomly assigned to a treatment condition and not to provide the enhancements to C participants in the study who are randomly assigned to a control condition. After LWAs are selected, Phase 2 will consist of two stages or periods: a Demonstration Period and a Study Period. During the two-month Demonstration Period, each LWA will have a target number of WIC participants to which peer counselors will attempt to deliver the two components of the intervention –that is, the enhanced *Loving Support Peer Counseling Program*. Each LWA that successfully delivers the enhanced peer counseling services to its target number of WIC participants will be included in the Study Period.

During the Demonstration Period, no random assignment will be implemented, and no data collection from WIC participants will occur. Instead, each LWA will submit data biweekly using a Demonstration Period Progress Form (Appendix C1 to document: (a) the number of WIC participants whom peer counselors attempted to contact and successfully contacted in the hospital and in-person during the first 10 days post-partum; and (b) information abstracted from peer counselor contact logs. During the Demonstration Period, relevant LWA staff will participate in an interview about their existing *Loving Support Peer Counseling* services and their implementation of the enhanced peer counseling services (see LWA Staff Interview Guide 1, Appendix E1). At the end of two months, the evaluation contractor will

determine which LWAs will proceed to the Study Period, based on their success delivering the intervention (i.e., the two enhancements) to the target number of WIC participants. Each LWA that meets its target will proceed to the Study Period.

In the Study Period, WIC participants who enroll in peer counseling and in the study will be randomly assigned to receive either the agency’s pre-existing, “business-as-usual” model of the *Loving Support* Peer Counseling services or the enhanced model of the *Loving Support* Peer Counseling Program. LWAs that already offer hospital contact or early in-person post-partum contact will not be eligible for the study.³ Across the participating sites, approximately 1,800 WIC participants in breastfeeding peer counseling (hereafter, “WIC-BPC participants”) will be invited to enroll.⁴ Each participating LWA will receive resources to offset costs related to implementing the intervention and to participate in the evaluation. These resources will be administered as a grant to each participating LWA, with the exact amount based on the number of study participants the LWA enrolls.

Two telephone surveys with WIC-BPC participants in the study will provide data needed to estimate the impact of the intervention on breastfeeding outcomes (WIC Participant Baseline Survey and WIC Participant Follow-up Survey; see Appendices A1 and A2). The WIC Participant Baseline Survey (Appendix A1), conducted after enrollment but before random assignment, will be used to collect the mother’s due date, data on pre-existing attitudes towards and beliefs about breastfeeding, as well as employment and other demographic data needed to create covariates for impact analyses. These baseline covariates will be included in regression analysis models to increase the R-squared and reduce the size of the sample required for this evaluation. The WIC Participant Follow-up survey (Appendix A2), conducted approximately 8 to 12 weeks after each participant’s due date, will collect data on the two key outcomes, breastfeeding exclusivity and intensity, as well as experiences with the *Loving Support* Peer

³ Results of the implementation study show that these components are part of approximately 6 percent of LWAs’ *Loving Support* programs.

⁴ Individuals who are certified to receive WIC benefits by a local WIC agency are called “WIC participants” by WIC and FNS. For purposes of this study, we will refer to WIC participants who sign up to receive breastfeeding peer counseling (BPC) as “WIC-BPC participants.”

Counseling Program (including whether or not the participant received either of the two enhancements that constitute the intervention) and exposure to other breastfeeding promotional campaigns. These two surveys will be used to address the primary research question about the impact of the intervention.

Other data collection efforts will be used to describe participating LWAs' existing *Loving Support Peer Counseling* programs, the implementation of the intervention, and the implementation of study procedures, including ongoing monitoring of the peer counseling services delivered to WIC participants in the study to ensure compliance with random assignment). These data sources include a Peer Counselor Background Questionnaire, several tracking forms to document WIC participant enrollment and participation in the study, and interviews with LWA staff and peer counselors conducted during the Demonstration and Study Periods. (Details about these data collection activities are below; copies of instruments are in Appendices as indicated below.) These data sources will document the implementation of the intervention at each participating LWA to provide information on local contextual factors that may affect the impact study (e.g., high-visibility non-WIC breastfeeding promotion campaigns, changes in local hospital policies or practices regarding breastfeeding support and/or cooperative arrangements with the LWA). These interview data will be collected during each of two site visits, one to occur during LWAs' Demonstration Period (see LWA Staff Interview Guide 1, Appendix E1) and another during the Study Period (see LWA Staff Interview Guide 1 and Peer Counselor Interview Guide 3, Appendix E3). Research questions and data sources for the evaluation are presented below.

Research Questions and Data Sources

The guiding research question for the impact study is:

1. For first-time mothers in urban areas who participate in WIC *Loving Support Peer Counseling* (WIC-BPC participants), what is the impact on breastfeeding exclusivity and intensity of early and in-person post-partum contact between peer counselors and WIC participants enrolled in breastfeeding peer counseling compared to a less intense model of *Loving Support Peer Counseling* service delivery?

Additional research questions about the implementation of the intervention, include the following:

2. How is the “business as usual” *Loving Support* Peer Counseling Program implemented at participating WIC agencies (i.e., what is the control condition)?
3. How did the participating agency *plan* to implement the enhancement to the *Loving Support* Peer Counseling model and how did the *actual* implementation compare to what was planned?
4. Was the intervention implemented with fidelity?
5. What were the experiences of WIC-BPC participants in the treatment and control conditions with the peer counseling they received?

To address these five research questions, the study will use the following data sources:

- Extant administrative data from the WIC Participant and Program Characteristics 2010 (WIC PC 2010) (provided by FNS to the evaluation contractor)⁵
- WIC Participant Baseline and Follow-up Surveys of WIC-BPC participants in the study (English versions are found in Appendices A1 and A2; Spanish versions are found in Appendices A3 and A4);
- A Peer Counselor Background Questionnaire (Appendix B);
- Tracking forms, including:
 - Demonstration Progress Form to track delivery of the intervention during the Demonstration Period (Appendix C1);
 - Study Enrollment Form providing information for WIC-BPC participants who agree to participate in the study (Appendix C2);
 - Decline Form, completed by WIC-BPC participants who decline to participate in the study (Appendices C3 and C4; one version is English, a second is in Spanish);
 - An Identification Tracking Form, to track study enrollment rates and Peer Counselor staffing and caseloads (Appendix C5);
 - Peer Counseling Refusal/Withdrawal Form, completed by Peer Counselors to document any refused contact or withdrawal from peer counseling or the study by WIC-BPC participants (Appendix C6);
- Contact Log Abstraction Form (Appendix D), documenting Peer Counselors’ completed contacts with WIC-BPC participants;
- Interviews with *Loving Support* Peer Counseling Coordinators and other relevant LWA staff as needed, such as the LWA director and Breastfeeding Coordinator) during the Demonstration Period (LWA Staff Interview Guide 1; Appendix E1) and the Study Period (LWA Staff Interview Guide 2; Appendix E2); and
- Interviews with *Loving Support* Peer Counselors during the Study Period (Peer Counselor Interview Guide 3; Appendix E3).

Exhibit A2.1 illustrates how these data sources will be used to address the research questions.

Exhibit A2.2 provides an overview of the types of information to be collected with each data

⁵ Beginning with PC92, all WIC Participant and Program Characteristics biennial reports employ a reporting system developed by FNS that routinizes compilation of participant information from State WIC agencies. The system is an automated transfer of an agreed-upon set of data elements that are routinely downloaded by State WIC agencies. These data are downloaded from State WIC agencies’ existing automated client and management information systems used to certify applicant eligibility for WIC benefits and to issue food vouchers and checks.

source and how this information will be used. A brief description of each data source follows these two exhibits, and a copy of each of these measures is included in the Appendices listed above.

Exhibit A2.1 Research Questions and Data Sources

Research Question	WIC Participant Baseline Survey	WIC Participant Follow-up Survey	Peer Counselor Questionnaire	Contact Log Abstraction Form	Tracking Forms¹	LWA Staff Interview Guide 1: Demonstration Period	LWA Staff Interview Guide 2: Study Period	Peer Counselor Interview Guide 3
For first-time mothers in urban areas who participate in WIC <i>Loving Support</i> Peer Counseling, what is the impact on breastfeeding exclusivity and intensity of early and in-person post-partum contact with peer counselors, compared to a less intense model of <i>Loving Support</i> Peer Counseling service delivery?	✓	✓						
How is the standard, “business as usual” <i>Loving Support</i> Peer Counseling Program implemented at participating WIC agencies (i.e., what is the control condition)?				✓		✓	✓	✓
How did the participating agency plan to implement the enhancements to the <i>Loving Support</i> Peer Counseling model and how did the actual implementation compare to these plans?				✓		✓	✓	
Was the intervention (that is, the Enhanced <i>Loving Support</i> Peer Counseling Program) implemented with fidelity?		✓	✓	✓	✓		✓	✓
What were the experiences of WIC-BPC participants in the treatment and control conditions with the peer counseling they received?		✓	✓	✓				✓

¹ Tracking Forms include the Demonstration Period Progress Form, Study Enrollment Form, Study Decline Form, Invitation Tracking Form, and Peer Counseling Refusal/Withdrawal Form.

Exhibit A2.2: Data Sources, Type of Information Collected, and Uses of the Information

Data Source	Type of Information Collected	Uses of Information
WIC participant characteristics (WIC PC) 2010 data	Extant administrative data on LWA size (# of WIC participants served), location, demographic characteristics of WIC population served	<ul style="list-style-type: none"> • Evaluation team uses data to identify 250 largest local WIC agencies with available contact information for recruitment into the study • Needed for LWA recruitment and to provide descriptive data on participating LWAs
Study Enrollment Form	Enrollee contact information Due date Primary language if not English Assigned Peer Counselor	<ul style="list-style-type: none"> • LWA staff use form to enroll WIC peer counseling participants (WIC-BPC participants) in study • Needed to assign Study ID and conduct random assignment
Study Decline Form	Reasons for not participating Demographic characteristics (e.g., race, ethnicity, education, household income)	<ul style="list-style-type: none"> • LWA staff ask WIC-BPC participants who decline to enroll in the study to complete brief questionnaire • Needed for non-response bias analysis
Invitation Tracking Form	# invited to participate in study # who decline or agree to participate in study	<ul style="list-style-type: none"> • LWA staff use form to report enrollment rates (% of those women invited who agree to participate)
WIC Participant Baseline Survey	Demographic characteristics (e.g., race, ethnicity, education, household income) Employment status Breastfeeding knowledge and attitudes Breastfeeding attitudes and experiences of family members and friends	<ul style="list-style-type: none"> • Conducted with WIC peer counseling participants before random assignment • Needed to construct covariates for inclusion in impact analyses and inform descriptive analyses and examine baseline characteristics of treatment and control groups
WIC Participant Follow-up Survey	Exposure to/participation in breastfeeding promotion Receipt of formula at hospital Experience with <i>Loving Support</i> peer counseling Employment and breastfeeding support/resources at worksite Breastfeeding exclusivity Breastfeeding intensity	<ul style="list-style-type: none"> • Conducted with WIC peer counseling participants 8-12 weeks after due date • Needed to collect outcome data and covariates for descriptive and impact analyses

Exhibit A2.2: Data Sources, Type of Information Collected, and Uses of the Information

Data Source	Type of Information Collected	Uses of Information
Peer Counselor Background Questionnaire	Years of experience as a peer counselor Average # of hours worked per week Language(s) spoken Demographic characteristics (e.g., race, ethnicity, education, household income)	<ul style="list-style-type: none"> To provide data on the extent to which peer counselors are assigned to WIC peer counseling participants in the study who share common demographic characteristics
Contact Log Abstraction Form	Participant Study ID Peer Counselor name # months pregnant/post-partum Contact mode (phone, in-person, etc.), location, duration Topics discussed	<ul style="list-style-type: none"> LWA staff member (Peer Counseling Coordinator) collects information from peer counselor contact logs to document information about all contacts with WIC peer counseling participants Needed to monitor delivery of standard (control group) or enhanced (treatment group) <i>Loving Support</i> Peer Counseling services
Peer Counseling Refusal/Withdrawal Form	Participant Study ID Peer Counselor name # months pregnant/post-partum Reason for refusing contact or for withdrawing from peer counseling	<ul style="list-style-type: none"> Used by peer counselors to document any participant refusals for in-person contact or any peer counseling participant's withdrawal from the study and/or the peer counseling program Needed to track attrition from the study

Exhibit A2.2: Data Sources, Type of Information Collected, and Uses of the Information

Data Source	Type of Information Collected	Uses of Information
<p>LWA Staff Interview Guide 1: Demonstration Period</p>	<p>LWA staffing, budget, number of WIC participants served Breastfeeding promotion and peer counseling activities Partnerships with hospitals and other community organizations Training, supervision, and support given to peer counselors Characteristics of WIC participants who enroll in the standard peer counseling program Procedures for assigning peer counselors to participants and peer counselors' caseloads Frequency and mode of contacts peer counselors made with WIC-BPC participants and topics discussed</p>	<ul style="list-style-type: none"> • Used with Peer Counseling Coordinator and other LWA staff during the pilot test period to collect information on the implementation of the intervention • Needed for implementation analyses (i.e., to document the standard Loving Support peer counseling services and LWA ability to implement the enhanced Loving Support model with target number of WIC peer counseling participants)
<p>LWA Staff Interview Guide 2: Study Period</p>	<p>Staffing, especially any changes since the study began Partnerships with hospitals and other community organizations Training, supervision, and support for peer counselors participating in the study Peer counselors' caseloads and the process for assigning peer counselors to WIC-BPC participants in the treatment and control groups Procedures for tracking random assignment and Peer Counselor contacts with the different groups of WIC-BPC participants Relative ease/difficulty of contacting WIC-BPC participants in the hospital and conducting in-person contacts</p>	<ul style="list-style-type: none"> • Used with Peer Counseling Coordinator and other LWA staff during the impact study to collect information on the implementation of the intervention • Needed for implementation analyses (to document the implementation of all study procedures, local context and how it may affect the implementation of the intervention, delivery of peer counseling services to treatment and control groups)

Exhibit A2.2: Data Sources, Type of Information Collected, and Uses of the Information

Data Source	Type of Information Collected	Uses of Information
Peer Counselor Interview Guide 3:	Frequency, mode, duration, and topics discussed during contacts with WIC-BPC participants (including those assigned to the treatment and control conditions) during pregnancy, in the hospital, and post-partum Training received for implementing the enhancements to the Loving Support program Logistical challenges of implementing the enhancements How WIC-BPC participants in the treatment group reacted to the enhancements	<ul style="list-style-type: none">• Used with peer counselors during the impact study to collect ground-level data on implementation of the intervention• Needed to confirm data provided by LWA administrative staff and to describe both peer counselor perception of the enhanced Loving Support program and reaction of WIC peer counseling participants assigned to received it

WIC PC 2010 administrative data

WIC PC 2010 data will be used to provide general contextual information about the participating LWAs (age distribution, race/ethnicity, size, etc.). In addition, the evaluation contractor will use these data to identify the largest 250 LWAs for recruitment into the study. Should WIC PC 2010 data not be available at the time needed, the evaluation contractor will use WIC PC 2008 data.

WIC Participant Baseline Survey

After enrollment in the study, each WIC-BPC participant in the study will be contacted by telephone to complete a baseline survey. The baseline survey collects data on the following major topics:

- The participant's due date;
- Demographic characteristics (e.g., race, ethnicity, education, marital status, household income);
- Employment status;
- Breastfeeding knowledge and attitudes; and
- Breastfeeding experiences of family members and friends.

The baseline survey is largely based on a similar instrument used in FNS's *Evaluation of the Birth Month Breastfeeding Changes to the WIC Food Packages* (OMB control no. 0584-0551, expiration date: 2/29/2012). Data from the Baseline Survey will be included in analysis models as covariates to reduce the the R-squared, and thus the necessary sample size for the study. A Spanish version of the Baseline Survey will be used with Spanish-speaking study participants.

WIC Participant Follow-up Survey

Approximately eight to 12 weeks after a WIC-BPC participant's due date or known birth date of her infant, she will be contacted to participate in the Follow-up Survey. This survey contains the items that will be used to construct outcome measures of breastfeeding exclusivity and intensity, along with questions about the WIC participant's exposure to breastfeeding promotional materials or classes, experiences with the *Loving Support Peer Counseling Program*, any receipt of formula from hospital staff upon discharge after delivery, and if employed, the conditions at her worksite that may foster or hinder breastfeeding. The Follow-up Survey is largely based on a similar instrument used in FNS's *Evaluation of the Birth Month Breastfeeding Changes to the WIC Food Packages* (OMB control no. 0584-0551,

expiration date: 2/29/2012). A Spanish version of the Baseline Survey will be used with Spanish-speaking study participants.

Peer Counselor Background Questionnaire

Peer counselors at each LWA will be asked to complete a brief Peer Counselor Background Questionnaire on training relevant to providing breastfeeding support and demographic characteristics. Because the essence of “peer counseling” is the provision of counseling by a peer with whom the WIC participant is most likely to identify, this questionnaire will allow descriptive analysis of the similarities between WIC participants in peer counseling and the peer counselors assigned to them.

Study Enrollment Form

Prior to inviting a WIC peer counseling participant to the study, LWA staff will complete a two-part form. Part 1 includes four eligibility questions to ensure that all women enrolled in the study are first-time mothers, aged 18 or older, and expecting a baby within the impact study period. For each WIC breastfeeding peer counseling participant who agrees to participate in the study, LWA staff will record in Part 2 of this form her name, due date, contact information, alternate contact information, preferred language, and assigned peer counselor.

Decline Form

LWA staff will ask each WIC peer counseling participant who declines to take part in the study to complete a 10-item questionnaire that asks for the reasons she declined study enrollment and for basic demographic information. When necessary, LWA staff will ask study declines to complete a Spanish version of the Decline Form.

Invitation Tracking Form

On a rolling basis, during the enrollment period (i.e., after completion of the Demonstration Period), LWA staff who invite eligible WIC participants to the study will be asked to record the date of each invitation and its outcome (Enrolled, Declined) by completing one row of the Invitation Tracking Form. .

This form requests in close-ended form the following information:

- the date on which an eligible WIC participant was invited to participate in the study;
- The name of the LWA staff person who invited her);

- the first name of the WIC participant who was invited); and
- the WIC participant’s decision to decline study participation or enroll in the study .

Contact Log Abstraction Form

As part of ongoing operation of the *Loving Support* Peer Counseling Program at LWAs, each time a peer counselor speaks with a WIC-BPC participant, she completes a contact log documenting various aspects of the contact. During the study, designated LWA staff will review these contact logs and complete a Contact Log Abstraction Form (Appendix D), documenting for each WIC-BPC participant in the study, the peer counselor’s name, the date of the contact, the mother’s due date or infant’s data of birth (i.e., if post-partum) and the following information:

- Mode of contact (e.g., telephone, in-person, email, other)
- Location, if in-person contact (WIC clinic, hospital, participant’s home, other)
- Duration of the conversation or meeting
- Language(s) spoken by peer counselor and WIC-BPC participant
- Major topics to discuss
- Provision of a breastpump, referral to a lactation consultant or other professional; and
- An indication if the WIC-BPC participant’s contact information has changed.⁶

Names of WIC-BPC participants will be replaced with the participant’s unique study identification number to protect her privacy. By using a uniform Contact Log Abstraction Form across all participating LWAs, LWAs may continue to use their existing peer counselor contact logs (which vary across LWAs); in addition, the use of a Contact Log Abstraction Form limits the amount of data that must be shared with the evaluation contractor to the minimum amount necessary. The Contact Log Abstraction Form will be implemented electronically as an online web portal to ensure secure transmission of data (this web portal will be constructed after OMB clearance is obtained; no URL is available at this time).

Peer Counseling Refusal/Withdrawal Form

Peer counselors will complete a Peer Counseling Refusal/Withdrawal form for any WIC-BPC participant who refuses a peer counseling contact or withdraws altogether either from peer counseling or the study. This form will include the WIC-BPC participant’s study identification number, the date the form was completed, the name of the peer counselor completing it, and any reasons given for refusing a contact or

⁶ To maintain the privacy of the WIC-BPC participant, new contact information will be collected separately (i.e., not on the same form in which the content of the peer counseling session is described). LWA staff will be asked to provide updated contact information to the study site liaison by telephone or by completing an amended Study Enrollment Form for the WIC-BPC participant.

withdrawing from peer counseling altogether. This information is needed to track attrition from the study.

LWA Staff Interview Guide 1 : Demonstration Period

Adapted from OMB-approved interview guide used in the *WIC Breastfeeding Peer Counseling Study:*

Phase I (OMB control no. 0584-0548), this guide will be used to gather information from participating

LWAs about their breastfeeding promotion activities, the current *Loving Support* Peer Counseling

Program and about their implementation of the enhancements to the *Loving Support* program. Interviews

will take place with relevant staff with the knowledge to address particular questions. Such staff may

include, for example, the Peer Counseling Coordinator, the Breastfeeding Coordinator (some LWAs do

not have both of these position), the LWA director, and, if needed, a records clerk or database operator

who can retrieve information not readily answered from direct recall.

LWA Staff Interview Guide 2: Study Period.

The second guide (also adapted from a previously OMB-approved interview guide used in the *WIC*

Breastfeeding Peer Counseling Study: Phase I (OMB control no. 0584-0548) will be used to document

how the site is implementing study enrollment and keeping track of study participants' assignment status;

to assess how well the LWA is maintaining distinction between the peer counseling services offered to

women in the treatment and control groups; and to ascertain the fidelity with which the *enhanced Loving*

Support Peer Counseling Program is being implemented. Interviews will take place with relevant LWA

staff including the Peer Counseling Coordinator and/or the Breastfeeding Coordinator, the LWA director,

and, if needed, an executive assistant or other person familiar with administrative data at the LWA.

Major topics include:

- Changes in the implementation of the intervention since the pilot test;
- LWA's breastfeeding promotional activities, classes, and media campaigns;
- LWA's relationship with area hospitals serving WIC participants;
- LWA's partnership(s), if any, with other agencies or community organizations (e.g., public health department, *La Leche League*);
- Availability of lactation consultants and procedures for providing these services to WIC participants;
- Training, supervision, and support for peer counselors participating in the study;

- Peer counselors' caseloads and the process for assigning peer counselors to (a) study non-participants, (b) WIC-BPC participants assigned to the standard *Loving Support* Peer Counseling model (i.e., the control group), and (c) WIC-BPC participants assigned to the enhanced *Loving Support* Peer Counseling model (the treatment group);
- Procedures for tracking random assignment and peer counselor contacts with the different groups of WIC-BPC participants;
- Frequency and mode of contacts peer counselors have with the different groups of WIC-BPC participants and topics discussed; and
- Factors that facilitate or hinder the implementation of the *Loving Support* enhancements.

Peer Counselor Interview Guide 3: Study Period

The third guide will be used to understand how the enhancement worked from the peer counselors' perspectives. Site visitors will interview up to four peer counselors from each LWA about their role in the study and experiences implementing the intervention. These interviews are intended to validate LWA staff members' description of how study procedures are implemented and to document WIC-BPC participants' reaction to the peer counselors.

USE OF THE INFORMATION

FNS will use the information collected with these data collection activities to determine whether or not a more intensive model of the *Loving Support* Peer Counseling Program increases the percentage of WIC peer counseling participants who breastfeed their two- to three-month old infants exclusively, and/or increases the intensity with which WIC peer counseling participants breastfeed. (i.e., increases the proportion of WIC peer counseling participants feeding any breastmilk to greater levels of intensity)

A.3 DESCRIBE WHETHER, AND TO WHAT EXTENT, THE COLLECTION OF INFORMATION INVOLVES THE USE OF AUTOMATED, ELECTRONIC, MECHANICAL, OR OTHER TECHNOLOGICAL COLLECTION TECHNIQUES OR OTHER FORMS OF INFORMATION TECHNOLOGY, E.G., PERMITTING ELECTRONIC SUBMISSION OF RESPONSES, AND THE BASIS FOR THE DECISION FOR ADOPTING THIS MEANS OF COLLECTION. ALSO, DESCRIBE ANY CONSIDERATION OF USING INFORMATION TECHNOLOGY TO REDUCE BURDEN

The study strives to comply with the E-Government Act of 2002 (Public Law 107-347, 44 U.S.C. Ch 36) by taking advantage of information technology resources whenever possible and whenever the use of such technology reduces burden, rather than creating additional burden.

The use of electronic methods of data collection from local WIC agencies will depend upon each LWA's information technology resources and the skills of the individual who might be using such systems.

LWAs will submit Demonstration Period Progress Forms, Study Enrollment Forms, Invitation Tracking Forms, Contact Log Abstraction Forms, and Peer Counseling Refusal/Withdrawal Forms using electronic versions of these instruments via a secure study-dedicated web portal (this web portal will be constructed after OMB clearance is obtained; no URL is available at this time).

Both the WIC Participant Baseline and Follow-up surveys of WIC-BPC participants in the study will be implemented using computer-assisted telephone interviewing (CATI) technology. By including programmed skip patterns, consistency and data range checks, CATI reduces data entry error that often necessitate callbacks to respondents to clarify the responses recorded by an interviewer using pencil and paper to conduct an interview. The CATI system features sophisticated call management, recording of verbal consent and Spanish language interviewing capability. Spanish versions of the Baseline and Follow-up Surveys are included as Appendices A3 and A4.

Sample tracking of WIC-BPC participants in the study will be managed by our Field Management System (FMS), a major application composed of a set of interrelated applications that control all aspects of sampling, data collection, data cleaning, and delivery of survey data.

Protocols for interviews with LWA staff and peer counselors will be programmed into a CAPI system and loaded onto laptops for use by site visitors. The use of CAPI reduces the likelihood of incomplete interviews, thus minimizing any need for follow-up contact with respondents.

A.4 DESCRIBE EFFORTS TO IDENTIFY DUPLICATION. SHOW SPECIFICALLY WHY ANY SIMILAR INFORMATION ALREADY AVAILABLE CANNOT BE USED OR MODIFIED FOR USE FOR THE PURPOSE DESCRIBED IN ITEM 2 ABOVE

There are similar data collection efforts, but, none meet our needs. No existing data sources can provide data needed to answer the study's research questions. The data requirements for Phase 2 of the *WIC Breastfeeding Peer Counseling Study* have been carefully reviewed to determine whether the needed information is already available. Efforts to identify duplication included a review of published literature on breastfeeding peer counseling programs in WIC, FNS reporting requirements, State administrative agency reporting requirements, and special studies by government and private agencies.

A.5 IF THE COLLECTION OF INFORMATION IMPACTS SMALL BUSINESSES OR OTHER SMALL ENTITIES, DESCRIBE ANY METHODS USED TO MINIMIZE BURDEN

Information being requested has been held to the minimum required for the intended use. To minimize burden, the study will rely on data that local WIC agencies already collect whenever possible (e.g., information from contact logs already collected as part of the existing peer counseling program operations), and study data collection procedures will be designed to match the procedures that local agencies already use to collect their own data for program administration purposes. Interview guides for use with LWA staff were adapted from similar instruments used in FNS's *Evaluation of the Birth Month*

Breastfeeding Changes to the WIC Food Packages (OMB control no. 0584-0551), in which staff at 40 LWAs participated.

A.6 DESCRIBE THE CONSEQUENCE TO FEDERAL PROGRAM OR POLICY ACTIVITIES IF THE COLLECTION IS NOT CONDUCTED OR IS CONDUCTED LESS FREQUENTLY, AS WELL AS ANY TECHNICAL OR LEGAL OBSTACLES TO REDUCING BURDEN.

The data collection for the proposed study will be conducted in 2012 and January 2013 on a rolling basis as the study enrolls WIC-BPC participants in the study as shown below in Exhibit A16.1. Each survey (baseline and follow-up) is collected once per WIC participant; each Peer Counselor will complete the Peer Counselor Questionnaire one time (in 2012). LWA staff will participate in two interviews, both in 2012. Peer counselors will participate in one interview in 2012. LWA staff will complete enrollment forms for 1,800 WIC-BPC participants (225 per LWA) on a rolling basis from March through August 2012. Peer counselors will complete contact logs as needed in 2012 to document contact with WIC-BPC participants. They will also complete, on an as needed basis, and Refusal/Withdrawal forms for WIC-BPC participants who refuse peer counseling contact or withdraw altogether from the peer counseling program.

Without this data collection effort, FNS will not have the data necessary to estimate program impacts on breastfeeding intensity and exclusivity, or to examine how the demonstration sites implemented the enhanced *Loving Support* model.

A.7 EXPLAIN ANY SPECIAL CIRCUMSTANCES THAT WOULD CAUSE AN INFORMATION COLLECTION TO BE CONDUCTED IN A MANNER:

- requiring respondents to report information to the agency more often than quarterly;
- requiring respondents to prepare a written response to a collection of information in fewer than 30 days after receipt of it;
- requiring respondents to submit more than an original and two copies of any document;
- requiring respondents to retain records, other than health, medical, government contract, grant-in-aid, or tax records for more than three years;
- in connection with a statistical survey, that is not designed to produce valid and reliable results that can be generalized to the universe of study;
- requiring the use of a statistical data classification that has not been reviewed and approved by OMB;
- that includes a pledge of confidentiality that is not supported by authority established in statute or regulation, that is not supported by disclosure and data security policies that are consistent with the pledge, or which unnecessarily impedes sharing of data with other agencies for compatible confidential use; or
- requiring respondents to submit proprietary trade secret, or other confidential information unless the agency can demonstrate that it has instituted procedures to protect the information's confidentiality to the extent permitted by law.

There are no special circumstances. The collection of information is conducted in a manner consistent with guidelines in 5 CFR 1320.5.

A.8 IF APPLICABLE, PROVIDE A COPY AND IDENTIFY THE DATE AND PAGE NUMBER OF PUBLICATION IN THE FEDERAL REGISTER OF THE AGENCY'S NOTICE, SOLICITING COMMENTS ON THE INFORMATION COLLECTION PRIOR TO SUBMISSION TO OMB. SUMMARIZE PUBLIC COMMENTS RECEIVED IN RESPONSE TO THAT NOTICE AND DESCRIBE ACTIONS TAKEN BY THE AGENCY IN RESPONSE TO THESE COMMENTS.

DESCRIBE EFFORTS TO CONSULT WITH PERSONS OUTSIDE THE AGENCY TO OBTAIN THEIR VIEWS ON THE AVAILABILITY OF DATA, FREQUENCY OF COLLECTION, THE CLARITY OF INSTRUCTIONS AND RECORDKEEPING, DISCLOSURE, OR REPORTING FORM, AND ON THE DATA ELEMENTS TO BE RECORDED, DISCLOSED, OR REPORTED

An announcement was published in the *Federal Register* on Date, and specified a 60-day period for comment ending on March 11, 2011 (Federal Register Volume 76, No. 48, Pages 13340-13342). A copy

of the *Federal Register Notice* is provided in this package. Comments from consultants and public comments received by FNS are included in Appendix G.

Consultations Outside the Agency

FNS has consulted with the experts in maternal and family health and personnel at selected State WIC agencies. In addition, FNS has consulted with staff at the National Agricultural Statistical Service. All persons consulted for the design of the study are listed along with their contact information below.

Individuals consulted on design of the study		
Name	Title/Organization	Telephone number and email address
Cathy Carothers	Co-Director, Every Mother Inc	(877) 666-7226 cathy@everymother.org
Jewell Stremler	Peer Counselor Coordinator, Nutrition Services Section, Texas Department of State Health Services	(512) 341-4593 jewell.stremler@dshs.state.tx.us
Pat McKinney	Consultant and Former FNS Program Officer	(540) 868-9977 mpatmckinney@verizon.net
Julie A. Reeder	Research Analyst, Oregon Oregon Health Authority Nutrition and Health Screening Program - WIC	(971) 673-0051 julie.a.reeder@state.or.us
Yvonne Bronner	Morgan State University, School of Public Health	443-885-4035 ybronner@verizon.net
Susan Gross	Research Associate, Population, Family, and Reproductive Health Department, Bloomberg School of Public Health, Johns Hopkins University	(410) 585-4140 sgross@jhsph.edu
Beth Olsen	Associate Professor, School of Food Science and Human Nutrition, Michigan State University	(517) 355-7713, Ext. 113 olsonbe@msu.edu
Anne Merewood	Assistant Professor of Pediatrics, Boston University School of Medicine	(617) 414-6466 anne.merewood@bmc.org
Rafael Perez-Escamilla	Professor of Nutritional Sciences, University of Connecticut	(860) 486-5073 rafael.perez-escamilla@uconn.edu

A.9 EXPLAIN ANY DECISION TO PROVIDE ANY PAYMENT OR GIFT TO RESPONDENTS, OTHER THAN REMUNERATION OF CONTRACTORS OR GRANTEES

An incentive of \$20 will be made to respondents upon completion of both the baseline and follow-up surveys to improve response rates. An incentive of \$5 gift card will be made to all WIC-BPC participants

to call a toll-free number within two weeks of their delivery date to report the date of birth for their infant.

These incentives are justified by the following circumstances:

- There is a very short window of opportunity to conduct the baseline survey prior to random assignment (approximately 4 weeks), which makes it essential for respondents to complete the survey in a timely fashion without repeated call backs.
- The follow-up survey, despite efforts we have made to minimize its length, represents a burden for first-time mothers with a two- to three-month-old infant who may be easier to reach but who may find it burdensome to remain on the telephone for a 15 to 20 minute survey.
- Administration of the follow-up survey 8- to 12-weeks following the infant's birth depends on having accurate data on date-of-birth from mothers in the study and just as with the follow-up survey, obtaining this data presents a burden on first-time mothers that justifies a modest incentive to report their infant's date of birth.
- Respondents will be asked to report on sensitive information such as whether or not they are breastfeeding their infant, family members' attitudes toward breastfeeding, and experiences with the WIC breastfeeding peer counseling program.

We anticipate that offering these modest disbursements will increase the rate of response and therefore reduce overall cost as follow-up calls due to non-response should be reduced. These incentives are large enough to obtain the desired response rate, yet not so large that they will coerce women into responding.

No other gifts or incentives will be made to respondents.

A.10 DESCRIBE ANY ASSURANCE OF CONFIDENTIALITY PROVIDED TO RESPONDENTS AND THE BASIS FOR THE ASSURANCE IN STATUTE, REGULATION, OR AGENCY POLICY

The individuals participating in this study will be notified that the information they provide will not be released in a form that identifies them, except as otherwise required by law. No identifying information of individuals or local WIC agencies will be attached to any reports or data supplied to USDA or any other researchers. However, because of the small number of local WIC agencies expected to participate in the study, staff and peer counselors at these LWAs who participate in interviews will be notified before the interviews that of the possibility that they could be identified by others on the basis of what they say during the interviews, despite the researchers' use of such pseudonyms.

The evaluation contractor hired to conduct the study, Abt Associates Inc., has extensive experience in data collection efforts requiring procedures to maintain the confidentiality, security, and integrity of data. The following data handling and reporting procedures will be employed to maintain the privacy of survey participants and composite electronic files. In addition, the following procedures will be used to protect confidentiality of all participating LWAs and individuals:

- All project staff will be required to sign a Nondisclosure and Confidentiality Agreement (Appendix F4). In this agreement, staff pledges to maintain the confidentiality of all information collected from the respondents and will not disclose it to anyone other than authorized representatives of the evaluation.
- Documents containing personally identifiable information on respondents will be kept in locked files cabinets. At the close of the study, such documents are shredded.
- Data gathered from WIC-BPC participant survey respondents will be stored in a survey file that is assigned a unique study identification number (Study ID). A master respondent file containing study ID numbers and respondent personally identifiable information (PII) will be created and stored separately from respondent survey data. After creation of this master file, all PII will be removed from survey files. Individual respondents This master file linking Study IDs to PII will be stored in encrypted electronic form within a restricted drive to which only a limited number of project staff will have access.
- When information about a WIC-BPC participant must be exchanged between the LWA and the research team, such information will be identified with a Study ID only and no other PII whenever possible. If PII must be exchanged it will be uploaded to a secure ftp transfer site to which access is restricted via unique user-name and passwords allowing a log of all uploading and downloading of this data to be automatically recorded. All data on the secure ftp site is automatically deleted with 30 days.
- While in the field, site visitors are required to store interview notes, materials with identifying information and laptops containing any study-related data in a locked car trunk Site visitors are required to carry their signed pledge with them at all times while in the field and may be required to show it to respondents upon request. Procedures to protect respondent privacy and confidentiality are discussed during training sessions provided to all project staff.
- Each LWA will be assigned a unique Site Identification number (Site ID) and agency pseudonym and all LWA staff and peer counselors who participate in interviews will be assigned a pseudonym. Raw interview data collected from LWA staff and peer counselors will be removed from laptops used to collect the data in the field to secure servers at Abt Associates. Raw interview data files will be converted to analysis files with agency names, locations, and other identifying information (e.g., names of hospitals in the area) removed and replaced with pseudonyms and the Site ID. The master list of WIC agency names and Site IDs and staff/peer counselor names linked to pseudonyms will be stored separately from both raw and analysis interview data files.

In addition, the evaluation contractor has established a number of procedures to ensure the confidentiality and security of electronic data in their offices during the data collection and processing period. Standard backup procedures will be implemented for the central office computer system to protect project data from user error or disk or other system failure. Backups and inactive files will be maintained on tape or compact disks. The system servers will be maintained inside a secure locked area accessible only to authorized systems personnel. Files will be accessible only by authorized personnel who have been provided project logons and passwords. Access to any of the study files (active, backup, or inactive) on any network multi-user system will be under the central control of the database manager. The database manager will ensure that the appropriate network partitions used in the study are appropriately protected (by password access, decryption, or protected or hidden directory partitioning) from access by unauthorized users. Abt Associates will maintain security, virus, and firewall technology to monitor for any unauthorized access attempts and any other security breaches.

Institutional Review Board

Abt Associates maintains its own Institutional Review Board (IRB), which conducts prospective reviews of proposed research and monitors continuing research for the purpose of safeguarding research participants' rights and welfare (Appendix H). All research involving interactions or interventions with human subjects is within the purview of the Abt IRB. Abt Associates' IRB is the local agent responsible for ensuring that the organization's research: 1) meets only the highest ethical standards; and 2) receives fair, timely, and collegial review by an external panel. Abt Associates' IRB currently holds a federal-wide assurance (FWA) of compliance from the U.S. Department of Health and Human Services' Office of Human Research Protections (DHHS/OHRP). The FWA covers all federally supported or conducted research involving human subjects.

All study materials and instruments for the *WIC Breastfeeding Peer Counseling Study: Phase 2* will be submitted for approval by Abt's IRB prior to the start of participant recruitment and data collection. The IRB application will include the likely demographics of the study population, copies of all data collection

instruments and protocols for recruitment of local WIC agencies, their staff and peer counselors, and WIC-BPC participants. The IRB application will also include a data security plan detailing steps taken to protect personally identifiable information (PII) transmitted or stored. Confidentiality safeguards will be detailed in the IRB application. The IRB process at Abt takes approximately 2 to 3 weeks after an application has been filed, and we have factored this into our data collection timeline. Should OMB request revisions to the study materials or data collection instruments, these modified materials will be resubmitted to Abt's IRB for final approval before data collection begins.

A.11 PROVIDE ADDITIONAL JUSTIFICATION FOR ANY QUESTIONS OF A SENSITIVE NATURE, SUCH AS SEXUAL BEHAVIOR OR ATTITUDES, RELIGIOUS BELIEFS, AND OTHER MATTERS THAT ARE COMMONLY CONSIDERED PRIVATE. THIS JUSTIFICATION SHOULD INCLUDE THE REASONS WHY THE AGENCY CONSIDERS THE QUESTIONS NECESSARY, THE SPECIFIC USES TO BE MADE OF THE INFORMATION, THE EXPLANATION TO BE GIVEN TO PERSONS FROM WHOM THE INFORMATION IS REQUESTED, AND ANY STEPS TO BE TAKEN TO OBTAIN THEIR CONSENT

There are no personally sensitive questions contained in the interview guides to be conducted with LWA staff and peer counselors, nor in any other instrument except for the Baseline and Follow-up surveys.

These surveys are designed to describe infant feeding practices, including questions about attitudes toward breastfeeding and breastfeeding experiences, as well as experiences participating in the WIC breastfeeding peer counseling program. Some of these items refer to a woman's personal circumstances and behaviors that may be sensitive for some respondents. For example, to assess the key outcome measures for the study, items in the Follow-up survey ask women whether or not they gave their infants breastmilk in the last 24 hours to several days, and to what extent they are feeding both breastmilk and formula. Information to be collected using these items are the key outcomes and main purpose for conducting the study.

Other aspects about women’s circumstances that may be considered sensitive include questions about employment, education level, race and ethnicity, marital status, household income and receipt of any public assistance such as TANF or Medicaid. These demographic variables are important for conducting the data analysis; not collecting this information would omit variables that could confound the interpretation of study results (e.g., breastfeeding behaviors are known to differ among individuals with different employment status, educational levels, household incomes, and race/ethnicities). These same demographic questions were asked as part of FNS’s *Evaluation of the Birth Month Breastfeeding Changes to the WIC Food Packages* (OMB control no. 0584-0551; expiration date: 2/29/2012) and high item response rates were obtained, indicating that they may not be perceived as highly sensitive.

Interviewer training for the study will stress the importance of asking all questions that involve sensitive issues in a professional and non-judgmental manner. Finally, women will be assured that they do not have to respond to any questions that they do not want to answer.

A.12 PROVIDE ESTIMATES OF THE HOUR BURDEN OF THE COLLECTION OF INFORMATION. THE STATEMENT SHOULD

- **Indicate the number of respondents, frequency of response, annual hour burden, and an explanation of how the burden was estimated. If this request for approval covers more than one form, provide separate hour burden estimates for each form and aggregate the hour burdens in Item 13 of OMB Form 83-I.**
- **Provide estimates of annualized cost to respondents for the hour burdens for collections of information, identifying and using appropriate wage rate categories.**

Exhibit A12.1 shows sample sizes, estimated burden, and estimated annualized cost of respondent burden for each part of the data collection and total burden. Note that Exhibit A12.1 shows that the total burden per LWA is 2 hours, 40 minutes, or 2.67 hours (for each of two interviews), but this burden is allocated across different employees, as shown in a supporting exhibit, Exhibit A12.2. For example, the LWA Director is only asked to respond to interview questions for which she/he is the most knowledgeable respondent; those questions answered by the LWA Director are not repeated for other respondents. The interview requires 20 minutes (1/3 of an hour) of the LWA Director’s time. In contrast, the Peer

Counseling Coordinator is typically the most knowledgeable respondent for a greater number of questions; as a result, the interview requires 1 hour and 40 minutes of her time (1.67 hours), but items which the Peer Counseling Coordinator has answered are not repeated for other respondents. In this way, the burden per respondent is minimized.

Since roles vary greatly by WIC agency (for instance, in some cases the breastfeeding coordinator and peer counseling coordinator are the same person), it is not possible to split up the guide *a priori* by role. Instead, when scheduling the site visits during which interviews will be conducted, the evaluation contractor's research staff will ask who is the most knowledgeable about each module of the instrument and arrange to collect the information accordingly.

A.13 PROVIDE ESTIMATES OF THE TOTAL ANNUAL COST BURDEN TO RESPONDENTS OR RECORD KEEPERS RESULTING FROM THE COLLECTION OF INFORMATION, (DO NOT INCLUDE THE COST OF ANY HOUR BURDEN SHOWN IN ITEMS 12 AND 14). THE COST ESTIMATES SHOULD BE SPLIT INTO TWO COMPONENTS: (A) A TOTAL CAPITAL AND START-UP COST COMPONENT ANNUALIZED OVER ITS EXPECTED USEFUL LIFE; AND (B) A TOTAL OPERATION AND MAINTENANCE AND PURCHASE OF SERVICES COMPONENT.

There are no capital, start-up, or annualized maintenance costs associated with this data collection for respondents.

Exhibit A12.1: Estimated Burden in Hours and Cost

Respondent Type	Response Type	Number of respondents	Number of responses per respondent	Est. Total Annual Responses	Time Per Response (hours)	Total Time Burden (hours)	Hourly salary estimate	Estimated cost per respondent	Estimated overall cost
LWA director ¹	<i>Interview (Demo. Period)</i>	8	1	8	0.33	2.67	\$27.00	\$9.00	\$72.00
	<i>Interview (Study Period)</i>	8	1	8	0.33	2.67	\$27.00	\$9.00	\$72.00
Breastfeeding Coordinator ²	<i>Interview (Demo. Period)</i>	8	1	8	0.33	2.67	\$21.00	\$7.00	\$56.00
	<i>Interview (Study Period)</i>	8	1	8	0.33	2.67	\$21.00	\$7.00	\$56.00
	<i>Participant Enrollment Form</i>	8	225	1800	0.08	150.00	\$21.00	\$393.75	\$3,150.00
Peer Counseling Coordinator ²	<i>Interview (Demo. Period)</i>	8	1	8	1.67	13.33	\$21.00	\$35.00	\$280.00
	<i>Interview (Study Period)</i>	8	1	8	1.67	13.33	\$21.00	\$35.00	\$280.00
	<i>Demo. Period Progress Form</i>	8	4	32	1.00	32.00	\$21.00	\$84.00	\$672.00
	<i>Contact Log Abstraction Form</i>	8	43	344	2.10	722.40	\$21.00	\$1,896.30	\$15,170.40
Administrative Assistant ³	<i>Invitation Tracking Form</i>	8	335	2680	0.01	22.33	\$21.00	\$58.63	\$469.00
	<i>Interview (Demo. Period)</i>	8	1	8	0.33	2.67	\$20.00	\$6.67	\$53.33
	<i>Interview (Study Period)</i>	8	1	8	0.33	2.67	\$20.00	\$6.67	\$53.33
Peer Counselors ⁴	<i>Interview (Study Period)</i>	32	1	32	0.33	10.67	\$11.00	\$3.67	\$117.33
	<i>Questionnaire</i>	64	1	64	0.20	12.80	\$11.00	\$2.20	\$140.80
	<i>Refusal/Withdrawal Form</i>	64	4	256	0.05	12.80	\$11.00	\$2.20	\$140.80
WIC Participants ⁵	<i>Questionnaire</i>	1800	2	3600	0.33	1200.00	\$8.00	\$5.33	\$9,600.00
	<i>Decline Form</i>	300	1	300	0.05	15.00	\$8.00	\$0.40	\$120.00
total		1,864		9,172		2,221			\$30,503

Figures are round to the nearest whole dollar. Estimates of hourly wages based on:

¹ Bureau of Labor Statistics Occupational Employment Statistics (May 2009), 11-9151 Social and community service managers

² Bureau of Labor Statistics Occupational Employment Statistics (May 2009), 21-109 Health educators

³ Bureau of Labor Statistics Occupational Employment Statistics (May 2009), 43-611 Executive secretaries and administrative assistants

⁴ Data reported in U.S. Department of Agriculture, Food and Nutrition Service, Office of Research and Analysis, WIC Breastfeeding Peer Counseling Study, Final Implementation Report, WIC-10-BPC, by Ann Collins, Catherine Dun Rappaport, and Nancy Burstein. Project Officer: Tracy K. Palmer, MPH. Alexandria, VA: June 2010

⁵ Data for hourly salary estimate reported in WIC PC 2008 (URL: <http://www.fns.usda.gov/ora/menu/Published/WIC/FILES/pc2008.pdf>)

Exhibit A12.2: Distribution of Burden per Local WIC agency across LWA Respondents

	Interview during Demonstration Period	Interview during Study Period	Total per respondent
LWA Director	0.33 hours	0.33 hours	0.67 hours
Breastfeeding Coordinator	0.33 hours	0.33 hours	0.67 hours
Peer Counseling Coordinator	1.67 hours	1.67 hours	3.33 hours
Administrative Assistant	0.33 hours	0.33 hours	0.67 hours
Total per LWA	2.67 hours	2.67 hours	5.33 hours

A.14 PROVIDE ESTIMATES OF ANNUALIZED COST TO THE FEDERAL GOVERNMENT. ALSO, PROVIDE A DESCRIPTION OF THE METHOD USED TO ESTIMATE COST AND ANY OTHER EXPENSE THAT WOULD NOT HAVE BEEN INCURRED WITHOUT THIS COLLECTION OF INFORMATION.

This includes the costs associated with the contractor conducting the project and the salary of the assigned FNS project officer. The largest cost to the Federal government for the all tasks associated with *Phase 2 of the WIC Breastfeeding Peer Counseling Study* is \$1,560,547 to pay a contractor to conduct the study and deliver reports and data files. This contract cost includes all study tasks, including design, recruitment, sample selection, information collection, analysis and report writing, and overhead costs for computing, copying, supplies, postage, travel, shipping, and other miscellaneous items. This information collection also assumes a total of xx hours of a Federal employee time for a GS-XX, step X Social Science Research Analyst at \$xx.xx per hour for a total of \$x,xxx.xx and Federal staffing cost of \$xxx.xx on an annual basis. Federal employee pay rates are based on the General Schedule of the Office of Personnel Management (OPM) for 2011.

A.15 EXPLAIN THE REASONS FOR ANY PROGRAM CHANGES OR ADJUSTMENTS REPORTED IN ITEMS 13 OR 14 OF THE OMB FORM 83-1.

This is a revision of a currently approved collection of information. This program change will result in an increase of 2,221 burden hours. The changes are due to substantive revisions contained in this phase as well as changes to the instruments (adding and deleting questions). As a result of these changes the number of respondents and responses increased.

Note that the Terms of Clearance for Phase 1 (see Notice of OMB Action, Appendix I) stipulated the following:

1. Specific analysis of response patterns and/or response bias for all "check that apply" questions with more than 6 response options, as well as any web tables requiring horizontal scrolling on the survey instrument used in Part I.
2. A re-designed questionnaire that draws heavily on already validated instruments and adequately tests new questions. Adequate testing requires cognitive work beyond a simple pilot test. OMB recommends that FNS consult with survey methodologists at one of the two statistical agencies located within the Department of Agriculture for assistance. OMB will look for evidence of such consultation, as well as adequate testing with the submission of the Phase II collection request.”

Part I of the study included an online survey administered to 51 State WIC agencies and 34 WIC agencies in U.S. Territories or Indian Tribal Organizations (ITOs), the “State WIC Agency Survey.” The survey included some “check all that apply” items with more than 6 response options. In its implementation online, the survey did not include any items that required horizontal scrolling.

The stipulation in the Terms of Clearance for Phase 1 of the study do not apply to Phase 2: Phase 2 does not include any web surveys. Instead, as described in the supporting materials, the Baseline and Follow-up surveys of WIC participants (Appendices A1 and A2) will be conducted by telephone using Computer Assisted Telephone Interviewing (CATI) software and neither of these surveys includes any item with 6 or more response options. There are some items on these phone-administered surveys in which the interviewer categorizes an open-ended response from the respondent – but these items do not present the respondent with a list of 6 or more options (that is, the interviewer does not read aloud the categories she will use to classify the open-ended response).

A.16 FOR COLLECTIONS OF INFORMATION WHOSE RESULTS ARE PLANNED TO BE PUBLISHED, OUTLINE PLANS FOR TABULATION AND PUBLICATION

STUDY SCHEDULE

The schedule shown in Exhibit A16.1 lists the expected period of performance for the data collection and reporting. Data collection plans are designed to provide timely data for the evaluation reports, including:

- Draft report
- Revised report
- Final report, WIC Breastfeeding Peer Counseling Study: Phase 2
- Draft study brochure
- Revised study brochure
- Final study brochure
- Draft manuscript for submission to peer-reviewed journal
- Final manuscript for submission to peer-reviewed journal

ANALYSIS PLAN

The planned analyses includes descriptive analyses, estimation of impacts of the intervention on outcomes, and a process analysis. We first define the two key outcome measures and then describe each of the analyses to be conducted.

Analysis Methods

Tabulations and Cross-tabulations

We will use simple descriptive statistics to examine baseline characteristics of the sample both overall and in each participating LWA. In addition, data on the similarity of peer counselors to the WIC-BPC participants they serve will be examined to explore the degree to which peer counselors were “matched” to WIC-BPC participants based on racial, ethnic, and educational background, as well as on languages spoken. It is possible that WIC-BPC participants’ receptivity to breastfeeding counseling will be affected by the degree to which they perceive their peer counselor as similar to themselves. Although the impact estimates will not include any data on the degree of similarity between Peer counselors and WIC participants, these data will provide FNS with useful information about the extent to which peer

counselors are “matched” to WIC-BPC participants along these lines. No tests of the impact of the intervention on any subgroups are planned, as the sample sizes are too small to produce reliable estimates.

Exhibit A16.1: Timeline and Schedule of Deliverables Phase 2 of the WIC Peer Counseling Study				
Task	Deliverable	Month	Year	
Task 3.2 Revise & Expand Study Plan	Revised Study Plan, Draft	Dec	2010	
	Revised Study Plan, Final	Jun	2011	
	Request contract modification	May	2011	
Task 4.2 Data Collection Plan & Instruments	Draft Data Collection Plan	Jan	2011	
	Draft Study Instruments	Jan	2011	
	Final Data Collection Plan	Jun	2011	
Task 5.2 OMB Package & IRB Submission	Final Study Instruments	Mar	2011	
	60-day Notice for Federal Register	Feb	2011	
	Draft OMB Package	Mar	2011	
Task 6.2 Recruit & Work with LWAs	Revised OMB Package	May	2011	
	Final OMB Package	Jun	2011	
	Issue Preliminary Notice of Funding Opportunity to State, Local WIC Agencies	Aug	2011	
	Host Informational Webinars	Sep-Oct	2011	
	Issue Funding Opportunity Announcement (FOA)	Nov	2011 ¹	
	LWA Deadline for Response to FOA	Dec	2011	
	Evaluate Responses to FOA	Dec-Jan	2011	
	Memo: Recommended LWAs for Demonstration Period	Feb	2012	
	Notify LWAs Selected for Demonstration Period	Mar	2012	
	LWAs Prepare for Demonstration Period	Apr-May	2012	
Task 7.2 Collect Data	LWAs Conduct Demonstration	May-Jul	2012	
	Memo: Demonstration Period Results & First Round of Site Visits	Aug	2012	
	<i>(if needed) LWAs Continue Demonstration⁵</i>	Aug-Sep	2012	
	Begin Implementing Random Assignment	Aug	2012	
	7.2.1 Train Data Collectors	Clean Data and Prepare Analysis Data Files	Nov-Jan	2014
		Draft Training Materials for LWA Staff	Mar	2012
		Final Training Materials for LWA Staff	May	2012
		Draft Training Materials for Demo. Period Site Visitors	Mar	2012
		Final Training Materials for Demo. Period Site Visitors	Apr	2012
		Train Site Visitors (Demo. Period Site Visits)	May	2012
Draft Training Materials: Telephone Interviewers		May	2012	
Final Training Materials: Telephone Interviewers		Jul	2012	
Train Telephone Interviewers		Aug	2012	
Draft Training Materials for Study Period Site Visitors		Aug	2012	
7.2.2 Collect WIC Participant Data	Final Training Materials for Study Period Site Visitors	Oct	2012	
	Train Site Visitors (Study Period Site Visits)	Oct-Nov	2012	
	Biweekly progress reports on survey response rates	Sep-Nov	2012	
7.2.3 Collect LWA Data	Biweekly Progress Reports on Demo. Period	Jun-Jul	2012	
	Site Visits during Demo. Period	Jun-Jul	2012	
	Site Visits during Study Period	Nov-Feb	2013	
	Memo: Summary of Study Period Site Visits	Mar	2013	
Task 8.2 Prepare Data Files & Conduct Analyses	Analyze Data	Jan-Mar	2014	
	Prepare Analytic Tables and Summary of Findings	Jan-Mar	2014	
	Briefing Slides & Analysis Tables on Preliminary Findings	Apr	2014	
	Present Preliminary Findings to FNS	Apr	2014	
	Conduct New Analyses Requested	May	2014	
	Task 9.2 Phase 2 Report	Draft Outline of Phase 2 Report	Jun	2014
Final Outline of Phase 2 Report		Jul	2014	

Exhibit A16.1: Timeline and Schedule of Deliverables Phase 2 of the WIC Peer Counseling Study			
Task	Deliverable	Month	Year
	Draft Phase 2 Report	Aug	2014
	Revised Phase 2 Report	Oct	2014
	Final Phase 2 Report	Dec	2014
	De-identified Data Files	Dec	2014
Task 10.2 Monthly Progress Reports	Monthly Progress Reports	Once/month	
Task 11.2 Brochure & Journal Article	Draft Study Brochure	Jan	2014
	Revised Study Brochure	Jan	2014
	Final Study Brochure	Mar	2015
	Draft Journal Article Manuscript	Jan	2014
	Final Journal Article Manuscript	Mar	2015

¹ Assumes OMB clearance on 11/17/2011. FOA issuance and all subsequent study activities will be delayed if OMB clearance not received on that date.

Impact Estimates

The main impacts of enhanced *Loving Support Peer Counseling Program* on breastfeeding exclusivity and intensity will be estimated through multivariate logistic regression described in Part B of the Supporting Statement. Impacts will be estimated at the site-level and pooled across sites. These analyses will estimate the impact of *being offered* in-person peer counseling (effects of the intention-to-treat, ITT). However, some women in the treatment group will not avail themselves of the in-person counseling that is offered by the LWA. Such members of the treatment group in effect do not receive the treatment. In view of this the analysis will also estimate the impact of the treatment on those WIC-BPC participants who actually receive in-person peer counseling. That is, in addition to estimating the overall effects of making in-person peer counseling available, we will also estimate the impact of the treatment on those women who actually received in-person counseling—the effects of the treatment on the treated (ToT). No estimates of the impact on any other subgroups are planned.

PUBLICATION OF STUDY RESULTS

The study's findings will be published in a three forms: A final report; a study brochure; and a journal article which will undergo peer review. The projected dates for these reports are presented in Exhibit A16.1 (above).

A.17 DISPLAY OF EXPIRATION DATE FOR OMB APPROVAL

All data collection instruments for the Food and Nutrition Service *WIC Breastfeeding Peer Counseling Study: Phase 2* will display the OMB approval number and expiration date.

A.18 EXCEPTIONS TO CERTIFICATION STATEMENT

There are no exceptions to the Certification for Paperwork Reduction Act (5 CFR 1320.9) for this study.

Appendix A: REFERENCES

American Academy of Pediatrics. 2005. "Policy Statement: Breastfeeding and the Use of Human Milk," *Pediatrics* 115(2): 496.

Bergevin Y, Dougherty C, Kramer MS. 1983. Do infant formula samples shorten the duration of breastfeeding? *Lancet* 1(8334):1148–1151.

Caulfield LE, Gross SM, Bentley ME, Bronner Y, Kessler L, Jensen J, Weathers B, Paige DM. 1998. WIC-based interventions to promote breastfeeding among African-American women in Baltimore: Effects on breastfeeding initiation and continuation. *J Hum Lact* 14(1):15–22.

Centers for Disease Control and Prevention. 2008. Breastfeeding-related maternity practices at hospitals and birth centers — United States, 2007. *MMWR*. 57:621-625.

Chapman DJ, Damio G, Perez-Escamilla R. 2004. Differential response to breastfeeding peer counseling within a low-income, predominantly Latina population. *J Hum Lact* 20(4): 389–396.

Feinstein JM, Berkelhamer JE, Gruszka ME, Wong CA, Carey AE. 1986. Factors related to early termination of breast-feeding in an urban population. *Pediatrics* 78(2):210–215.

Frank DA, Wirtz SJ, Sorenson JR, Heeren T. 1987. Commercial discharge packs and breastfeeding counseling: Effects on infant-feeding practices in a randomized trial. *Pediatrics* 80(6): 845–854.

Merewood A, Fonrose R, Singleton M, et al 2008. From Maine to Mississippi: Hospital distribution of formula sample packs along the Eastern seaboard. *Arch Pediatr Adolesc Med*. 162: 823-827.

Racine, Elizabeth F., Kevin Frick, Joanne F. Guthrie, and Donna Strobino. 2009. Individual Net-Benefit Maximization: A Model for Understanding Breastfeeding Cessation among Low-Income Women. *Maternal and Child Health Journal* 13: 241-249.

Ryan, A. S, and W. Zhou. "Lower breastfeeding rates persist among the Special Supplemental Nutrition Program for Women, Infants, and Children participants, 1978-2003." *Pediatrics* 117, no. 4 (2006): 1136.

Snell BJ, Krantz M, Keeton R, Delgado K, Peckham C. 1992. The association of formula samples given at hospital discharge with the early duration of breastfeeding. *J Hum Lact* 8(2):67–72

U.S. Department of Agriculture, Food and Nutrition Service, Office of Research and Analysis (2010a). *WIC Participant and Program Characteristics 2008*, WIC-08-PC, by Patty Connor, Susan Bartlett, Michele Mendelson, Katherine Condon, James Sutcliffe, et al. Project Officer, Fred Lesnett. Alexandria, VA. <http://www.fns.usda.gov/ora/menu/Published/WIC/FILES/pc2008.pdf>, retrieved March 2, 2011

U.S. Department of Agriculture, Food and Nutrition Service, Office of Research and Analysis (2010b). *WIC Breastfeeding Peer Counseling Study, Final Implementation Report*, WIC-10-BPC, by Ann Collins, Catherine Dun Rappaport, and Nancy Burstein. Project Officer: Tracy K. Palmer, MPH. Alexandria, VA: June 2010

U.S. Department of Health and Human Services. *Healthy People 2010*. 2nd ed. With Understanding and Improving Health and Objectives for Improving Health. 2 vols. Washington, DC: U.S. Government Printing Office, November 2000.

U.S. Department of Health and Human Services (2010). Healthy People 2020. Retrieved February, 2011, from <http://www.healthypeople.gov/2020>.

Appendices: Data Collection Instruments and Supplementary Materials

The following data collection instruments are included in Appendices:

- A1. WIC Participant Baseline Survey (English)
- A2. WIC Participant Follow-up Survey (English)
- A3. WIC Participant Baseline Survey (Spanish)
- A4. WIC Participant Follow-up Survey (Spanish)
- B. Peer Counselor Background Questionnaire
- C1. Demonstration Period Progress Form
- C2. Study Enrollment Form
- C3. Decline Form (English)
- C4. Decline Form (Spanish)
- C5. Invitation Tracking Form
- C6. Peer Counseling Refusal/Withdrawal Form
- D. Contact Log Abstraction Form
- E1. LWA Staff Interview Guide 1: Demonstration Period
- E2. LWA Staff Interview Guide 2: Study Period
- E3. Peer Counselor Interview Guide 3: Study Period
- F1. Letter to State WIC agencies
- F2. Funding Opportunity Announcement
- F3. Memorandum of Understanding (Sample)
- F4. Nondisclosure and Confidentiality Agreement
- F5. Study Brochure
- F6. WIC Participant Consent Form
- G. Federal Register Notice, March 11, 2011
- H. Abt Associates' Institutional Review Board Policies and Procedures
- I. Notice of OMB Action: Terms of Clearance, WIC Peer Counseling Study, Phase 1