**Memorandum**

**Date: March 15, 2017**

**To: Stephanie Tatham, OMB Desk Officer, Food and Nutrition Service**

**Through: Christina Sandberg, Food and Nutrition Service, Information Collection Clearance Officer, Planning & Regulatory Affairs;**

**Ruth Brown, United States Department of Agriculture, Office of Chief Information Office, Department Clearance Officer**

**From: Alicia White, Chief, Nutrition Education and Promotion Branch, NETTA, Child Nutrition Programs, USDA – Food and Nutrition Service**

**Re: Under Approved Generic OMB Clearance No. 0584-0524 Request for Approval to Perform Formative Research to Revise Materials for Mothers and Child Care Providers of Infants**

The Food and Nutrition Service (FNS) of the United States Department of Agriculture (USDA) is requesting approval for formative research under Approved Generic OMB Clearance No. 0584-0524 Generic Clearance to Conduct Formative Research.

This request is to acquire clearance to conduct formative research with mothers of infants, expectant mothers, and Child and Adult Care Food Program (CACFP) child care directors and providers to inform the update, redesign, and revision of two existing materials: *Feeding Infants: A Guide for Use in the Child Nutrition Programs,* now titled, *Feeding Infants in the Child and Adult Care Food Program,* and *Breastfed Babies Welcome Here! A Mother’s Guide.* The research will collect feedback from the target audience to understand critical perceptions, attitudes, and preferences that can inform the revision of these resources and accompanying materials. Participation is voluntary and the following information is provided for your review:

1. **Title of the Project:** Formative Research to Revise Materials for Mothers and Child Care Providers of Infants
2. **Control Number:** 0584-0524, Expires 09/30/2019
3. **Public Affected by this Project:**

Individuals/Households

* Low-income mothers of infants who are breastfeeding or have breastfed in the past 18 months and have children enrolled in child care centers or family day care homes that participate in the CACFP
* Expectant mothers from low-income households who plan to enroll their children in child care centers or family day care homes that participate in the CACFP

State and Local/Tribal Employees

* Directors at CACFP child care centers
* Directors at CACFP family day care homes
* Providers/teachers in child care centers and family day care homes that are currently caring for an infant or infants (CACFP sites)

See section 7, *Project Purpose, Methodology & Formative Research Design,* for a description of the number of participants for each audience by research methodology.

1. **Number of Respondents:**

Table 4.1 – Site Recruitment & Approval\*

|  |  |
| --- | --- |
| Audience | # of Participants |
| Site Directors | 150 |
| Total | 150 |
| \*Includes non-responders, ineligible, and those choosing not to participate. We’re assuming an 8% success rate. | |

Table 4.2 – Consent Forms\*

|  |  |
| --- | --- |
| Audience | # of Participants |
| Breastfeeding Mothers1 | 288 |
| Expectant Mothers1 | 288 |
| Child Care Providers: Infant Classroom Providers2 | 32 |
| Child Care Providers: Site Directors2 | 16 |
| Total | 624 |
| \*Includes non-responders and those choosing not to participate.  1Calculated using an average of 24 qualifying moms per research site.  2Calculated attrition and eligibility would require consent from 400% of target sample. The 16 site directors listed here are counted as part of the 150 unique site directors that are counted as part of the total respondents for this collection. | |

Table 4.3 – Research Activities by Audience

|  |  |  |
| --- | --- | --- |
| Target Audience | Research Activity | # of Participants |
| Child Care Providers: Site Directors | Assisting Recruitment | 12 |
| In-Depth Interview | 4 |
| Child Care Providers: Infant Classroom Providers | Assisting Recruitment | 12 |
| In-Depth Interview | 8 |
| Breastfeeding Mothers | Focus Groups\* | 64 |
| Expectant Mothers | Focus Groups\* | 64 |
| Total |  | **164** |

\*Focus groups will invite 8 to 10 to seat 6 to 8

1. **Time Needed Per Response:**

|  |  |  |
| --- | --- | --- |
| Table 5.1 - Time Needed per Initial Recruitment & Consent Form\* | | |
| **Target Audience** | **Time (minutes)** | **Time (hours)** |
| Child Care Providers: Site Directors (Approval^) | 20 | 0.33 |
| Child Care Providers: Site Directors (Consent) | 15 | 0.25 |
| Child Care Providers: Infant Classroom Providers | 15 | 0.25 |
| Breastfeeding Mothers | 24 | 0.40 |
| Expectant Mothers | 24 | 0.40 |
| \*The time is an average response per respondent.  ^Approval for research to be conducted at the child care site; distinct from consent for the directors to participate in the research activities. | | |

Table 5.2 - Time Needed for Research Activities by Audience \*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Target Audience** | | **Research Activity** | **Time (minutes)** | **Time (hours)** |
| Child Care Providers: Site Directors | | Assisting Recruitment | 60 | 1.00 |
| Interviews | 45 | 0.75 |
| Child Care Providers: Infant Classroom Providers | | Assisting Recruitment | 60 | 1.00 |
| In-depth interviews | 45 | 0.75 |
| Breastfeeding Mothers | | Focus Group | 60 | 1.00 |
| Expectant Mothers | | Focus Group | 60 | 1.00 |
|  |  | | | |

1. **Total Burden Hours on Public:**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **(a) Affected Public** | | **(b) Screeners, Surveys** | **( c) Appendices** | **(d) No. Respon-dents^** | **(e) Frequency of Response** | **(f) Est. Total Annual Responses per Respondent (d x e)** | **(g) Hours per Response** | **Total Burden Hours (f x g)** |
| **State, Local/Tribal Employees** | Site Directors | Complete Site Approval Process | G | 150^ | 1 | 150 | 0.33 | 49.50 |
| Consent1 | B & BB | 16 | 1 | 16 | 0.25 | 4.00 |
| Assisting Recruitment2 | F | 12 | 1 | 12 | 1.00 | 12.00 |
| In-Depth Interview3 | E, EE, J & L | 4 | 1 | 4 | 0.75 | 3.00 |
| Classroom Care Providers | Consent Package4 | B & BB | 32^ | 1 | 32 | 0.25 | 8.00 |
| Assisting Recruitment2 | F | 12 | 1 | 12 | 1.00 | 12.00 |
| In-Depth Interview3 | E, EE, J & L | 8 | 1 | 8 | 0.75 | 6.00 |
| **Subtotal** |  |  |  | **182** |  | **234** |  | **94.50** |
| **Individuals & Households** | BreastFeeding Moms | Consent Package5 | A & AA | 288^ | 1 | 288 | 0.40 | 115.20 |
| Focus Group6 | C, CC, I & K | 64 | 1 | 64 | 1.00 | 64.00 |
| Expecting Moms | Consent Package5 | A & AA | 288^ | 1 | 288 | 0.40 | 115.20 |
| Focus Group6 | D, DD, I & K | 64 | 1 | 64 | 1.00 | 64.00 |
| **Subtotal** |  |  |  | **576** |  | **704** |  | **358.40** |
| **Total** |  |  |  | **758** |  | **938** |  | **452.90** |
| ^=Unique respondents affected by this data collection. All other numbers provided for tasks in *columns c* represent duplicate respondents. | | | | | | | | |
| 1=Burden Includes: Consent Cover Letter (2 minutes); Informed Consent Form (10 minutes); Questionnaire for Participation (3 minutes). | | | | | | | | |
| 2=Burden includes: Initial Recruitment Email (5 Minutes); Initial Recruitment Phone Call (8 Minutes); Follow Up Email to Interested Sites (5 Minutes); Follow Up Call with Interested Site Directors (12 Minutes). Also includes an estimated 30 minutes distributing and collecting flyers for parent focus groups, though there is no attachment for this task. | | | | | | | | |
| 3= Burden is inclusive of the 15 minutes required to review the materials during the interviews. | | | | | | | | |
| 4= Burden Includes: Child Care Director/Provider Consent Cover Letter (2 minutes); Informed Consent Form (10 minutes); Questionnaire for Participation (3 minutes).  5= Burden Includes: Focus Group Flyer (2 minutes); Consent Cover Letter (4 minutes); Informed Consent Form (10 minutes); Questionnaire for Participation (4 minutes); Focus Group Reminder Phone Script (4 Minutes)  6= Burden is inclusive of the 20 minutes required to review the materials during the focus groups. | | | | | | | | |

**Total burden hours on public: 452.90**

1. **Project Purpose, Methodology, and Formative Research Design:**

Background

The United States Department of Agriculture (USDA) Food and Nutrition Service (FNS) administers the nutrition assistance programs for the USDA. The mission of FNS is to provide students and low resource families better access to food and a more healthful diet through its nutrition assistance programs, which includes Child Nutrition Program’s Child and Adult Care Food Program (CACFP). The CACFP provides aid to child care institutions and family or group day care homes for the provision of nutritious foods that contribute to the wellness, healthy growth, and development of young children via reimbursement for meals and snacks that meet set nutrition standards.

As authorized under Section 6(a)(3) of the Richard B. Russell National School Lunch Act, 42 USC 1755(a)(3), FNS provides training and technical assistance for school foodservice, nutrition education for children and their caregivers, and encourages school and community support for healthy eating and physical activity. These activities are implemented under the Agency’s Team Nutrition initiative that is designed to improve children’s lifelong eating and physical activity habits by using the principles of the *Dietary Guidelines for Americans*.

In 2010, updates to the requirements of meals and snacks served in the CACFP were mandated, in order to reflect the science behind the nutritional needs of CACFP’s diverse participants, including infants. The updated meal standards for CACFP were published in the Federal Register in April 2016 as *7 CFR parts 210, 215, 220, et al Child and Adult Care Food Program: Meal Pattern Revisions Final Rule*, and hereby known as the “Final Rule.” CACFP child care centers and family day care homes must comply with the new meal standards by October 1, 2017. The Final Rule includes updates to the CACFP meal pattern requirements as well as guidelines related to breastfeeding in a manner consistent with the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) and other Child Nutrition Programs.

Under the Team Nutrition initiative, FNS is updating two publications, *Feeding Infants: A Guide for Use in the Child Nutrition Programs now titled Feeding Infants in the Child and Adult Care Food Program* and *Breastfed Babies Welcome Here! A Mother’s Guide* to reflect the updated CACFP meal pattern for infants and subsequent CACFP policy memos related to infant feeding. These materials were last updated in 2001 and 1993 respectively. As a result the materials are being redeveloped to reflect the child care environment today and to address barriers todays mothers face regarding breastfeeding, determining when a baby is developmentally ready for solid foods, and food safety for infants. These materials are also being developed in Spanish for the first time.

Purpose

The primary research objectives for this study are to:

* Ensure the information, images, and materials:
* Are clearly communicated, relevant, engaging, relatable, and reflective of the diversity of mothers of infants who attend or intend to attend CACFP sites;
* Foster a feeling of support and encouragement toward breastfeeding; and
* Engender a willingness to, and self-efficacy towards, breastfeeding.
* Understand if the *Feeding Infants: A Guide for use in the Child Nutrition Programs* now titled, *Feeding Infants in the Child and Adult Care Food Program* and *Breastfeed Babies Welcome Here! A Mother’s Guide (BBWH)* materials effectively communicate detailed information about preparing, storing, and feeding infants breastmilk, preparing formula, an infant’s developmental readiness for solid foods, and parent engagement;
* Identify and understand contextual, cultural, and attitudinal variables that may inhibit or engender the utilization of the *Feeding Infants in the CACFP* and *Breastfed Babies Welcome Here! A Mother’s Guide* materials and adoption of the communicated information;
* Understand how the guides, poster, and message graphic will be displayed and used by mothers and providers, the preferred format of the resources for the providers (i.e. digital vs. print copies), and the distribution methods providers intend to use; and
* Understand specific audience preferences towards select language (e.g. human milk vs. breastmilk), information, and layout.

Methodology/Research Design

To meet the objectives described above, we will conduct in-depth interviews (IDIs) with child care directors and providers (n=12) as well as focus groups (FGs) with expectant mothers (n=64) and current breastfeeding mothers (n=64). IDIs will allow researchers to structure interview questions for each unique context and are an effective means of data collection for a smaller sample size. FGs will allow for more informal dialog between parents (e.g. witticisms, anecdotes), which may uncover knowledge, attitudes, and perceptions more effectively than formal, direct questions.

IDIs and FGs will be conducted in both English and Spanish at child care centers and family child care homes that participate in the CACFP (hereby known as “sites”). Twelve CACFP sites, six sites in each of two FNS regions, will be selected as research sites to host research activities and provide access to eligible mothers. Table 4.3 details the total number of participants from each audience by research method.

**In-depth interviews.** A total of 12 in-depth interviews will be conducted with child care directors and providers at *Family Child Care Homes* (n=4) and *Child Care Centers* (n=8). Interviews will last 45 minutes and cover attitudes, beliefs, and perceptions around breastfeeding and infant feeding practices, perceptions of select materials, and their experience with the updated CACFP meal pattern. In addition, directors and providers will be asked to identify any terms or phrases that are unclear to them within the materials.

*Table 7.1 – Distribution of Interviews with Childcare Directors and Providers by Region*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | Mid Atlantic | | Southwest | | TOTAL |
|  | English | Spanish | English | Spanish |
| Child Care Centers  *Directors*  *Infant Classroom Providers* | 1  1 | 1  1 | 0  1 | 1  2 | **3**  **5** |
| Family Child Care Homes  *Directors*  *Infant Classroom Providers* | 0  2 | 0  0 | 0  1 | 1  0 | **1**  **3** |
| Total | **4** | **2** | **2** | **4** | **12** |

**Focus groups.** A total of 16 focus groups will be conducted with *Currently Breastfeeding Mothers* as well as *Expecting Mothers (*see *Table 7.2).* Eight to ten mothers will be invited to each 60-minute focus group to seat six to eight mothers in each group. Participating mothers will spend the first 15 minutes of the focus group discussing their attitudes, beliefs, and perceptions around breastfeeding. Following this conversation, mothers will review excerpts of the materials and information to provide feedback on the extent to which concepts, layouts, and language are relevant, clear, and engaging. Mothers will be asked to identify any terms or phrases within the materials that are unclear or unfamiliar. Research stimuli will be rotated to guard against any ordering bias.

*Table 7.2 – Distribution of Focus Groups with Mothers by Region*

|  |  |  |
| --- | --- | --- |
|  | Mid Atlantic  (# of parents) | Southwest  (# of parents) |
| Expectant Mothers  *English*  *Spanish* | 3 (16)  1 (16) | 1 (16)  3 (16) |
| Current Breastfeeding Mothers  *English*  *Spanish* | 3 (16)  1 (16) | 1 (16)  3 (16) |
| Total | **8 (64)** | **8 (64)** |

Design/Sampling Procedures

The sample of child care providers, directors, and mothers participating in formative research will be drawn from eight *Child Care Centers* and four *Family Day Care Homes* (FCCH) that participate in the CACFP. All research activities will take place in these eight research sites.

The research sites will be recruited from the Southwest and Mid-Atlantic FNS Regions (see Table 7.2). These regions were selected for a few reasons: [1] the breastfeeding rates in these regions provide some variability to capture differences in opinions, without deviating too far from the national average[[1]](#footnote-1); [2] both regions offer access to Hispanic communities, including rural Hispanic communities in the Southwest; and [3] each region offers a range of urban, suburban, small town, and rural communities as measured by NCES locale codes.

Six research sites will be sampled within each FNS region (total of 12 sites) from a diverse range of communities, as measured by *Population Density* (i.e. rural, suburban, urban) and race/ethnicity. The following data sources will be used to meet the following sampling targets:

* **Population density** (i.e. rural, suburban, urban): We will sample sites to represent the approximate national distribution of *Locale Codes,* a publicly available measure of rural-urban continuum developed by the *National Center for Educational Statistics* (NCES). We will intentionally under-sample suburban sites as these sites have the lowest levels of poverty (as measured by average school free/reduced price lunch).
* **Race/ethnicity**: We will use data available from the *U.S. Census* and the *Office of Civil Rights* to identify sites that serve diverse communities in these specific ways: Six sites > 50% Hispanic; Two sites > 40% African American; One site > 20% American Indian/Alaskan Native.

These measures of diversity were selected because the data is reliably available from trusted sources at the community level throughout the country, allowing for accurate sampling. These specific racial/ethnic groups were selected because: 1) the resources need to be reviewed by Spanish-speaking audiences; and 2) African-American and American Indian mothers report lower breast feeding rates than all other race/ethnicity groups (CDC, 2012[[2]](#footnote-2)) and represent a disproportionate percentage for WIC participation compared to their percentage of the US population (USDA, 2014[[3]](#footnote-3)). Using the parent screener (see Attachments A & B), we will also identify and invite mothers from additional race/ethnic groups without setting specific targets for sampling.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| *Table 7.3 Distribution of Research Sites by Select Sampling Variables* | | | | | |
| **Sampling Category** | | **Southwest Region** | **Mid-Atlantic Region** | **Total** | |
| Primary Language | |  |  | |  |
|  | Spanish | 4 | 2 | | **6** |
|  | English | 2 | 4 | | **6** |
| Locale Type (Locale Codes) | |  |  | |  |
|  | Urban (11-13) | 1 | 2 | | **3** |
|  | Suburban (21-23) | 1 | 2 | | **3** |
|  | Small Town (31-33) | 1 | 1 | | **2** |
|  | Rural (41-43) | 3 | 1 | | **4** |
| Race/Ethnicity Targets | |  |  | |  |
|  | > 40% African American | 0 | 2 | | **2** |
|  | > 50% Hispanic | 4 | 2 | | **6** |
|  | > 20% American Indian/Alaskan Native | 1 | 0 | | **1** |
| Site Types | |  |  | |  |
|  | Child Care Centers | 4 | 4 | | **8** |
|  | Family Day Care Homes | 2 | 2 | | **4** |

In addition, we will attempt to sample *male* site directors and providers, though sites will not be screened for male staff, as this data is not reliably available. To do so, we propose asking providers to identify their gender on the screener (see Attachment B & BB). While we have no specific targets based on gender, we intend to recruit participants that reflect a variety of diverse views. Identifying this information on the screener helps us describe the demographics of the formative research participants so there is a clear understanding of who participated. It is likely that male and female care providers may have different knowledge, attitudes, and concerns about promoting healthy feeding habits.

Table 7.3 details the sample by region. We intend to sample research sites from multiple states within each region to ensure the intended sample of diversity is achieved. The initial target states will include Pennsylvania, New Jersey, Maryland, New Mexico, and Texas.

Recruitment and Consent

Prior to recruitment, trained researchers will compile a database of potential research sites that fit the specifications described above using reliable data sources (e.g. child care councils, State and local agencies, community action groups, NCES) and relevant professional organizations (e.g. National CACFP Sponsors Association, National Association for the Education of Young Children). This database will include contact information (emails and phone numbers) and site characteristics that are relevant to the sampling plan. This database will be compiled to allow for expedient recruitment upon OMB approval.

The following procedures will be followed to recruit each research audiences:

*Research Sites.* Site directors will be contacted directly using both phone calls and emails and informed about the research project (see Attachment F). Before any research activities are conducted with directors, providers, or parents, the full scope of the project will be explained and approval will be obtained from the director (see Attachment G). Concurrent with OMB review, CNY will submit study protocols to an independent/external Institutional Review Board (IRB) - Chesapeake IRB - to ensure the protection of human subjects involved in this research. No information collection activities will begin until OMB and IRB approval is obtained.

*Site Directors and Infant Classroom Providers.* After director approval is obtained, directors and providers will receive a follow up call and email with detailed information about the responsibilities of the infant classroom provider in the research and parent. Those that are still interested will receive a consent form (see Attachment C & CC) that details their rights as research participants and their role in the study.

*Breastfeeding Mothers.* All mothers attending the research sites will receive flyers (Attachment A & AA) describing the study and posters will be displayed throughout the research sites describing the research opportunity. The flyer will include contact information for the research team and a link to the online screener so parents can sign up (via phone, email, text, and website link). If possible, digital flyers will be distributed via relevant social media platforms and influencers, with links to a digital screener. Interested mothers will complete a brief screener, available online and as a paper version. Site staff will collect paper versions of the screener to send back to the research team. The screener will collect key demographic variables (e.g. parents age, race/ethnicity, child’s age, breastfeeding practices, household income, and household size) that will be used to obtain a diverse sample of parents at or below 185% of the federal poverty level, and contact information for scheduling focus groups. All materials will also be made available in Spanish.

*Expectant Mothers* in communities served by the 12 selected research sites will be eligible to participate if they are beyond the first trimester of pregnancy and meet the federal poverty income guidelines. We will utilize all the methods described for *Current Breastfeeding Mothers* as well as referrals from mothers attending the research sites, contacting mothers on the waitlist at the research sites, and flyers (Attachment A & AA) distributed through local community organizations and support services. Digital flyers will be distributed via relevant social media platforms and influencers where available.

For all recruitment, we will utilize clear, engaging, and actionable communications, adopting strategies and templates that have been successful in recruiting similar participants in applied, community research for Federal agencies such as USDA-FNS, Center for Disease Control, and Food and Drug Administration. In addition, we will maintain regular communication with potential research participants, including confirmation calls within one day of the focus groups to encourage attendance (see Attachments A & AA).

Compensation

Each research site will receive a $150 facility fee to cover the cost of research staff using a conference room or classroom to conduct focus groups. This fee is based on conversations with a sample of six child care and community centers with which the trained research staff has recently conducted research. The average cost of community members renting a room in the space was $40 per hour. It is estimated that preparation, FGs, and IDIs will take approximately 3 hours per site, during which time the site may not be able to use and/or rent the rooms to other outside groups.

The populations for this research are mothers of infants enrolled in child care centers and family day care homes that participate in the CACFP and expectant mothers who meet the income eligibility criteria for the CACFP. This is a very specific and targeted group of individuals that are susceptible to non-participation for many reasons, including the financial burden of participation (e.g. arranging childcare and travel), existing and/or competing priorities for their time, and distrust of outside organizations. To achieve the required response rate and reduce non-response bias within this population, we believe it necessary that each FG participant be provided a monetary incentive to offset these costs and burdens to participation.

We expect $40 will cover the average mix of costs to be incurred by individual participants without coercing participants or providing undue influence on their decision (see Attachment J: Incentive Justification for Focus Group Participants for complete justification). This incentive will ensure that the potential burden of participation does not bias the final research sample. The incentive will be distributed in the form of a debit card with a PIN.

Mothers participating in the on-site FGs will also be provided with a meal, as the focus groups interfere with lunch and/or dinner (depending on site schedule). The meal will be arranged by the research staff and is valued at $8 per participant. Meals will be healthy and support the nutrition messages of the campaign.

Data Analysis

*Qualitative Data*. All focus groups will be audio-recorded (with respondent permission) and transcribed. Spanish transcripts will be translated into English by a native Spanish speaker. This text will become the data for qualitative analysis. Codes, representing new insights and relevant participant experiences and opinions, will be identified using Grounded Theory, by which codes and themes are allowed to emerge from the text (Corbin & Strauss, 1990; Glaser, 1992; Henwood & Pidgeon, 2003; Walker & Myrick, 2006) and entered into the NVivo software package in order to organize themes. In order to ensure that individuals did not bias findings, multiple researchers will code interview transcriptions, and themes will be compared and synthesized in Qualitative Debriefing Sessions. Findings will be considered descriptive and directional, but not definitive. No attempt will be made to generalize findings as nationally representative.

Outcomes/Findings

Information and formative input gathered from target audiences through the research will help refine materials so the materials are relevant, meaningful, and easy-to-use. Research summary findings may be published either electronically or in print, but such documents will not include information that personally identifies any of the research participants.

1. **Confidentiality:**

Participants completing focus groups and in-depth interviews will be informed of safeguards and privacy act provisions before the interviews (see Attachments A, AA, B, & BB). System of Record FNS-8, FNS Studies and Reports, published in the Federal Register on 4/25/1991 at 56 FR 19078, covers personal information collected under this research and identifies safeguards for the information collected. All research materials and protocols will also be reviewed by Chesapeake IRB, an independent Institutional Review Board approved by FDA and DHHS.

The research team will take several precautions to maintain the privacy of research participants, including de-identification of screener responses, notes, and transcripts. The research team will not disclose your name or any personally identifiable information in any report or presentation. Your information will be kept secure and only used for research purposes, except as otherwise required by law. All data will be identified only by an ID number assigned by the research team, not by any name. Only de-identified data will be shared with individuals outside of the immediate research team, unless it is necessary to protect participants, or if required by law.

All of the information collected will be kept for three years. The information, audio files, notes, and transcripts will be stored on a password-protected computer and/or in locked cabinets that only the research team can access. After three years, all of the collected information will be destroyed by securely shredding documents and/or permanently deleting electronic information.

As with all research, there is a chance that privacy could be breached. For example, despite the best efforts of the research team to keep the information we collect during the study private, a breach may occur as a result of accidental human error or hacking. In the event a breach occurs, it will be reported to Chesapeake IRB. If needed, participants will be contacted and notified as to the extent of the breach, any damages incurred, and future potential risks.

Results from this study may appear in professional journals or at scientific conferences. However, no individual participants will be identified or linked to the results. Results may also be used in future research or shared with other researchers. However, other researchers will not have access to any identifying information of participants.

**Federal Costs**: $95,309.65

1. **Research Tools/Instruments:**
   * **Attachment A:** Consent Package for Mothers and Expectant Mothers: Focus Group Flyer, Consent Cover Letter, Informed Consent Form, Questionnaire for Participation, and Focus Group Reminder Phone Call Script
   * **Attachment AA:** Consent Package for Mothers and Expectant Mothers: Focus Group Flyer, Consent Cover Letter, Informed Consent Form, Questionnaire for Participation, and Focus Group Reminder Phone Call Script (Spanish)
   * **Attachment B:** Consent Package for Directors and Providers**:** Consent Cover Letter, Informed Consent Form, and Questionnaire for Participation
   * **Attachment BB**: Consent Package for Directors and Providers**:** Consent Cover Letter, Informed Consent Form, and Questionnaire for Participation (Spanish)
   * **Attachment C**: Current Breastfeeding Mothers Focus Group Guideline
   * **Attachment CC:** Current Breastfeeding Mothers Focus Group Guideline (Spanish)
   * **Attachment D**: Expecting Mothers Focus Group Guideline
   * **Attachment DD**: Expecting Mothers Focus Group Guideline (Spanish)
   * **Attachment E:** Director and Provider Interview Guideline
   * **Attachment EE:** Director and Provider Interview Guideline (Spanish)
   * **Attachment F:** Director and Provider Recruitment Communications: Initial Recruitment Email, Initial Recruitment Phone Call, and Follow Up Email to Interested Sites, Follow Up Call with Interested Site Directors, Site Confirmation Letter
   * **Attachment G:** Site Confirmation Letter
   * **Attachment H**: Incentive Justification for Focus Group Participants
   * **Attachment I**: Research Stimuli for Parents - English
   * **Attachment J:** Research Stimuli for Child Care Providers - English
   * **Attachment K:** Research Stimuli for Parents - Spanish
   * **Attachment L:** Research Stimuli for Child Care Providers – Spanish

1. FY16 breastfeeding rates: national average 31.7%; Southwest 38.4%; Mid Atlantic 28.4%; United States Department of Agriculture FNS Supplemental Foods Programs Division, *WIC Breastfeeding Data: Local Agency Report FY2016*. Report released August 10, 2017, retrieved from https://fns-prod.azureedge.net/sites/default/files/wic/FY2016-BFDLA-Report.pdf [↑](#footnote-ref-1)
2. CDC (2012). Breastfeeding among U.S children born year 2002 – 2012, National immunization survey. Retrieved from: <http://www.cdc.gov/breastfeeding/data/NIS_data/index.htm> [↑](#footnote-ref-2)
3. Thorn, B., Tadler, C., Huret, N., Trippe, C., Ayo, E., Mendelson, M., Patlan, K. L., Schwartz, G., & Tran, V. (2015). WIC Participant and Program Characteristics 2014. Prepared by Insight Policy Research under Contract No. AG‐3198‐C‐ 11‐0010. Alexandria, VA: U.S. Department of Agriculture, Food and Nutrition Service [↑](#footnote-ref-3)