**APPENDIX O1**

**Study Extension Summary and Agreement -**

**Correspondence to State Agency with Copy to Site POC**

Date

Name

Title

Address

City, State, Zip

Dear [Name of State agency Director]:

Thank you for your ongoing participation in the WIC Infant and Toddler Feeding Practices Study II, called *“Feeding My Baby – A National WIC Study.”* We appreciate the cooperation and assistance from you, your staff, and the local WIC sites in the implementation of the study. The purpose of this letter is to provide information about the extension of the study for an additional year. This letter and the attachment(s) are an addendum to previous letters regarding the study.

**Study Background and Update**

The *Feeding My Baby* study is being conducted by Westat under contract to the U.S. Department of Agriculture, Food and Nutrition Service (FNS). Westat partners include Altarum, Public Health Foundation Enterprises, Inc. and the University of California Nutrition Policy Institute. The goals of the study are to document the feeding practices of WIC infants, toddlers and pre-school age children, and to assess WIC’s impact on those practices. Recruitment of the infants for the study occurred in 80 WIC sites nationwide in 2013. With assistance from State and local agencies and the sites, a total of 4,367 infants were enrolled in the study.

The study site(s) in your State include:

* [*insert Local Agency Name, Site Name]*
* *[insert Local Agency Name, Site Name]*
* *[insert Local Agency Name, Site Name]*

Since 2013, parents/caregivers of the infants enrolled in the study have participated in multiple phone interviews regarding infant and child feeding practices, dietary intake and other behaviors, and weight and length/height measurements have been collected periodically. The study has produced interim reports of findings which can be found on the FNS website at <http://www.fns.usda.gov/ops/wic-studies>.

According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB number. The valid OMB control number for this information collection is 0584-0580. The time required to complete this information collection is estimated to average 11 minutes (0.1833 hours) per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: U.S. Department of Agriculture, Food and Nutrition Services, Office of Policy Support, 3101 Park Center Drive, Room 1014, Alexandria, VA 22302, ATTN: PRA (0584-0580).  Do not return the completed form to this address.

Westat is staying in close contact with the parents/caregivers to keep them engaged in the study and participating in the interviews. To date, the retention of children in the study is meeting our expectations. When Westat Study Liaisons have a hard time contacting a parent/caregiver, they occasionally ask staff in the WIC sites or State agencies for assistance. We very much appreciate the help provided in response to these requests. Westat has also made requests to State agencies for specific WIC administrative data for children enrolled in the study and has asked sites to weigh and measure children in the study who are no longer WIC participants. Thank you for responding to these requests and providing critical data for the study.

**Study Extension to Age Six**

As noted above, FNS is extending the study for one additional year. The children who were enrolled as infants during 2013 will continue to be in the study until their sixth birthday even though they are no longer eligible for WIC. The parents/caregivers will be asked to complete one additional phone interview conducted when the children are 72 months (age six), and weight and height measurements will be collected around the time of the child’s sixth birthday. This extension will collect additional data regarding feeding practices, dietary intake, and other characteristics as the children mature, and it provides an opportunity to study the impact of WIC participation beyond the period of eligibility. This additional data collection will also allow the study team to explore food insecurity and other factors during the gap some children experience between participation in WIC and eligibility for school-based Federal food assistance programs. With this extension, the study will end in December 2021. Table 1 on page 4 provides an updated schedule of study activities.

**Implementation of Study Extension**

To extend the study, Westat will contact the parents/caregivers of the children, explain that the study is being continued through their child’s sixth birthday, and ask them to continue participating through that date. They will receive an informational letter with details regarding the additional phone interview and an explanation of the incentive amount they will receive for completing it. Westat Study Liaisons will continue to stay in contact with the parents/caregivers to encourage ongoing participation in the study, and they will assist them with obtaining weight and height measurements near the time of the sixth birthday. To obtain the measurements, Westat will provide the parents/caregivers with a *Feeding My Baby Study Measurement Card* and ask the parent/caregiver to take the child to a WIC site or to a healthcare provider to obtain the measurements and complete the measurement card. When parents/caregivers return the completed measurement card, Westat will provide a $60 incentive plus $10 transportation cost reimbursement.

**State Agency and WIC Site Assistance**

During the study extension period, your State Agency will:

* Assist Westat with identifying a WIC site where parents/caregivers can take their children to obtain height and weight measurements if the site where they were enrolled in the study is no longer operational or convenient for them. This assistance will be provided by [*insert description of what State agency agrees to do, e.g.* *a designated point-of-contact at the State agency to assist the Westat Study Liaison in identifying a WIC site in the vicinity of the parent/caregiver; providing Westat with information about WIC site locations or a way to access current information about WIC sites*].
* [*If State agency chooses to be contacted*: Occasionally provide Westat Study Liaisons with assistance in contacting parents/caregivers of children in the study who are enrolled in WIC when they cannot be located through other means.]

During the study extension period, the WIC sites in the study will:

* Conduct weight and height measurements for children in the study whose parents/caregivers choose to come to WIC for measurements, and record the measurements on a *Feeding My Baby Study Measurement Card*.
* [*If State agency chooses to have sites contacted*: Occasionally provide Westat Study Liaisons with assistance in contacting parents/caregivers of children in the study when they cannot be located through other means.]

The collection of height and weight measurements for study participants who are no longer on WIC is an authorized use of Nutrition Services and Administration funds under Federal regulations at 7 CFR 246.26(k), which require State and local agencies to cooperate in studies and evaluations conducted by or on behalf of the FNS. [*Insert when State agency agrees:* However, Westat will offer small grants to the study sites for their assistance in weighing and measuring the children who are no longer on WIC. The grants are available only for the 80 designated study sites.]

**Institutional Review Board (IRB) and Other Approvals**

The study extension has been reviewed and approved by the Westat Institutional Review Board (IRB). Westat will submit amendments for the study extension to the State and local IRBs that have previously approved the study. If requested, Westat will sign data use agreements or provide documentation of parent/guardian consent to obtain WIC administrative data.

**Table 1: Updated Summary of Data Collection Activities and Schedule**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Type of Data or** **Access Needed** | **Respondent** | **Who collects the data** | **Estimated Time** | **Timing** |
| Complete Referral Forms (with script) on 98 New WIC Enrollees | New WIC enrollee | WIC local site staff | 2 minutes | Completed |
| Recruit/Enroll Participants | New WIC enrollee | Westat recruiter | 20 minutes | Completed |
| State Agency Key Informant Interview | Identified by WIC State Agency Director  | Altarum staff person | 1 hour | Completed |
| Local Site Visit and Key Informant Interview  | Identified by WIC Local Agency Director or Site Supervisor  | Altarum staff person | 1 hour | Completed |
| Local WIC Staff Online Survey | All local site WIC staff working directly with participants | Altarum Institute receives and processes data | 30 minutes | Completed |
| WIC Participant Interviews  | WIC participants | Westat telephone interviewers | 30 minutes | July 2013-August 2020 |
| WIC Administrative Data (weight, length/height, date of measurements, and food package type for prenatal women and infants) | WIC State Agency data manager or designee  | Westat staff receive and abstract | 30 minutes | October 2014\*October 2015\*October 2016\*October 2017\*October 2018\* |

**\***Timing of the WIC administrative data request is based on the date when all children reach the target age for the data, with the final request in the fall/winter of 2018.

**Points of Contact**

If you have questions or concerns about this letter or your responsibilities in the study, please contact:

For State Agency questions:

Linnea Sallack, Study Coordinator, Altarum linnea.sallack@altarum.org

(734) 302-4925

For local agency/site questions:

Crystal MacAllum, Operations Director, Westat

crystalmacallum@westat.com

(301) 251-4232

The Study Contact we have for your State is: [*insert name of**State agency POC*].

If this changes, please let us know as soon as possible by contacting Carol Normand, Operations Manager at Altarum Institute, at carol.normand@altarum.org or (207) 358-2794.

We will provide a copy of this letter and Attachment A with information relevant to each site to the Study Contacts at the site(s) that are participating in the study.

Again, we are very grateful for your participation in the *Feeding My Baby Study* and appreciate all of the assistance provided by your State Agency and the local site(s).

Sincerely,

The *Feeding My Baby* *Study* Team



Linnea Sallack, Study Coordinator, Altarum



Crystal MacAllum, Operations Director, Westat

cc: [Site #1]

 [Site #2]