Appendix D4. Informed Consent for Observation and

OMB Control No: 0584-0663 Expiration Date: xx/xx/20xx



WIC Nutrition Assessment and Tailoring Study WIC Assessment Staff Informed Consent

Background

Westat, along with our partners at Insight Policy Research, is carrying out the *WIC Nutrition Assessment and Tailoring Study* for the Food and Nutrition Service of the U.S. Department of Agriculture. The purpose of this research study is to provide FNS with a comprehensive, detailed description of the WIC nutrition risk assessment process and the ways in which WIC sites tailor participant benefits to address the results of the assessment. We will use this information to identify best practices that promote efficient processes, effective identification of nutrition risks, and appropriate tailoring of participants' benefits. We are asking WIC staff who perform nutrition risk assessments in 30 WIC clinics across the country to take part in our study. We would like you to help by allowing us to observe your nutrition risk assessments and then participate in a follow-up interview about the nutrition risk assessment process in your clinic.

What Would I Do in the Study?

There are two things we would like you to do for this study:

1. Allow Us to Observe Your Nutrition Risk Assessments This Week

We will, with your permission, observe some or all of the nutrition risk assessments you conduct this week. (We will seek the informed consent of WIC participants for these observations as well.) The observer will sit in on the assessments, listen, and take notes. The notes will be about how the visit is conducted and the findings of each nutrition assessment. None of the notes will in any way identify you or record the private information you discuss with your client, and none of the information recorded during these observations will be shared with the site director or any clinic or LA staff. After the assessment is complete, the observer will ask you a few questions about the nutrition risks you identified for the participant during the assessment.

This information is being collected to assist the Food and Nutrition Service in obtaining a comprehensive and detailed description of the WIC nutrition risk assessment process and the ways in which participant benefits are tailored to address the assessment results. This is a voluntary collection and FNS will use the information to improve the delivery and tailoring of WIC services and increase satisfaction of both staff and participants. This collection does request personally identifiable information under the Privacy Act of 1974. 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 control number. The valid OMB control number for this information collection is 0584-0663. The time required to complete this information collection is estimated to average 5 minutes (0.08 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 Service, Office of Policy Support, 1320 Braddock Place, 5th Floor, Alexandria, VA 22314 ATTN: PRA (0584-0663). Do not return the completed form to this address.

2. Take Part in an Interview

If you agree to participate in this study, we will schedule an interview to be conducted this week at a time convenient for you, including during lunch hour or after work. The interview includes questions about how you conduct a nutrition risk assessment, how you use the assessment results to tailor benefits for WIC participants, and your satisfaction with the process and recommendations for improving it. The interview will take about an hour.

What Are the Risks of Being In This Study?

There is no known risk to you for participating in the observation conducted as part of this study, as we will collect no personal information about you for the observation. There is, however, a small risk to privacy for participating in the interview, should we conduct it by phone, since you are entrusting us with personal information (your phone number). We will take many steps and precautions to protect your privacy. While the final report will be available to the public, your name or any information that could be used to identify you will not be used in it. We may use quotes from you or other participants in our reports; however, participants' names will not be linked to any responses. Data in reports will be presented in summary form. We will assign a study ID to your information, and we will not share information linked to you with FNS, State or Local Agency WIC staff, or with anyone else who is not on the study staff, unless otherwise required by law.

What Are the Benefits of Being In This Study?

There are no direct benefits to you for taking part in this study. The information collected during the study will help the Food and Nutrition Service understand better how WIC meets the nutrition needs of its participants. They will then use this information to continue to improve WIC services for everyone.

What Are My Rights As a Participant In the Study?

Taking part in this study is completely voluntary. Giving consent means that you have heard or read the information about this study and that you agree to take part. You may still decide not to answer any questions we ask that you don't want to answer. If you decide to take part in the study and then change your mind, you can stop at any time. There is no penalty for stopping your participation in the study, and it won't affect your employment in any way.

Who Should I Call if I Have Questions?

If you have questions about the study itself and what we are doing, a member of our study team can help you. For those questions, please contact [NAME] at [XXX-XXX-XXXX].

If you have questions about your rights and welfare as a research participant, please call the Westat Human Subjects Protections office at 1-888-920-7631. Please leave a message with your

full name, the name of the research study that you are calling about (the WIC Nutrition Assessment and Tailoring Study), and a phone number beginning with the area code. Someone will return your call as soon as possible.

Visit Observation Consent

1) By signing below, I am saying that I have heard or read the information presented here, and I understand the information. I agree to take part in <u>visit observations</u> for the WIC Nutrition Risk Study.
Signature
Date
In-Person Interview Consent
2) By signing below, I am saying that I have heard or read the information presented here, and I understand the information. I agree to take part in an <u>in-person</u> <u>interview</u> for the WIC Nutrition Risk Study.
Signature
Date