

Appendix C-10. Site Visit Informed Consent Form

WIC Tribal Organizations and U.S. Territories Study: **Site Visit Informed Consent for WIC Staff**

Background

The U.S. Department of Agriculture's Food and Nutrition Service (FNS) has contracted with Westat to conduct a research study called *WIC Tribal Organizations and U.S. Territories*. Through this study, FNS aims to learn more about best practices, operational barriers and variations, and suggestions for improvement. FNS will use the study findings to consider future program or policy changes that may reduce operational barriers within Indian Tribal Organizations (ITOs; referred to as "Tribal Organizations" by this study) and U.S. territories, inform the development of customized ways to measure program reach, and ensure the best possible service to participants. To better understand best practices and challenges, study objectives include the following:

- › Comprehensively understanding program operations among Tribal Organizations and U.S. territories administering WIC
- › Understanding the facilitators and barriers to implementation of the WIC program
- › Examining reasons for differences in policy, service delivery, and operations
- › Improving data gathered for the FNS annual WIC Eligibility and Coverage Rates report

This study aims to include the following agencies: all 32 Tribal Organizations administering WIC as a State agency, all 5 U.S. territories administering WIC as a State agency, 5 Tribally operated local agencies, and approximately 15 geographic State agencies that share geography with a Tribal Organization.

What Is My Role in the Project?

Your agency is among 20 Tribal Organizations and U.S. territories operating as a WIC State agency invited to participate in a site visit as part of this study. Westat discussed the site visit with your agency in summer 2025 and has received (or is receiving) necessary approvals from your locality's institutional review board or other approval body. Site visits include the following activities:

- › WIC director interview (90 minutes)
- › Visits to one or two WIC clinics, each including:
 - Interviews with the clinic manager (60 minutes) and two frontline staff (30 minutes each)
 - Observations of the clinic(s) and two to eight appointments

Before the site visits, we ask the WIC director to participate in a 1-hour planning and clinic manager(s) to participate in a 30-minute planning meeting. Additional communication by phone or email may be needed to finalize site visit details. WIC staff involved in the study will also be invited to participate in an optional 90-minute virtual member checking session to discuss preliminary findings and help the study team accurately interpret the data.

Informed Consent

Participation in site visit activities is voluntary. We will request signed and verbal consent from each interview participant before the interview. We would like to audio record the interview to ensure we accurately capture the information you share with us. You may choose to skip any questions you do not wish to answer, answer questions off the record, or not be audio recorded. You may stop the interview at any time. There will be no penalties if you choose not to participate in a part or the entirety of this interview.

The interview recording will not be shared with FNS or anyone outside the study team. A de-identified transcript will be shared with FNS for its restricted use (i.e., internal Federal Government use). We will remove interviewees' names, FNS Region, name of your Tribal Organization or U.S. territory, and other direct identifiers from the transcripts. Your name will not be used in any direct quotes included in the final report or other dissemination materials. The information collected during site visits will be summarized in aggregate across all agencies visited. Names or other direct identifiers will not be used with any direct quotes included in the final report or other dissemination materials.

However, the name of your WIC agency may be used in the final report or dissemination materials (e.g., to highlight promising practices). Because of the small number of staff operating WIC in these agencies, we cannot guarantee the information you share will be completely anonymous.

How Will Participant Privacy Be Protected?

All data gathered as part of this study will be used for the purpose of meeting the stated objectives, which aim to better understand WIC program operations. The study team is required to take the following precautions:

- › Safeguard participant identities, including characteristics, contact, or sensitive information at the individual level.
- › Remove all direct identifiers as noted for the restricted use files and de-identify public use files for the purposes of statistical analyses, including removal or masking of all private and personally identifiable information.
- › Edit transcripts to remove personally identifying information, such as names, titles, agencies, or other direct identifiers throughout the document. No public use qualitative data files will be developed.

Your personally identifiable information will be kept private, except as otherwise required by law. We will not share the personally identifiable information you provide with anyone outside the study team. Your locality's institutional review board or other approval body and the study team may have agreed to additional data protections. The study team will honor all requirements described in any applicable memoranda of understanding, data-sharing or data use agreements, or other documentation. Study participants will be afforded safeguards as provided by the Privacy Act of 1974 (5 U.S.C. Sec. 552a), which requires the protection of individuals against invasion of privacy. Please contact the study team for more details about any data privacy agreements relevant to your agency.

What Are the Risks of Participating in This Study?

This study involves minimal risks to participants, though there is a time burden associated with participation. Study participants may feel uncomfortable answering some of the interview questions or being observed, and this study does not guarantee program or policy adjustments. To minimize discomfort, participants will be allowed to take breaks as needed, answer questions off the record, or skip any questions they do not wish to answer. A de-identified transcript of interviews and de-identified data collected during observations will be shared with FNS. Information will be summarized in aggregate for all agencies that participate in a final report and other dissemination

materials. Direct quotes included in the report will not include the speaker's name, title, or agency.

What Are the Benefits of Participating in This Study?

You can provide the on-the-ground perspective FNS needs to better understand how Tribal Organizations and U.S. territories administer WIC and your experiences doing so. This is also an opportunity for you to share the barriers your agency faces in administering WIC and potential solutions to those barriers. Your expertise is critical and will be at the center of what the study team learns and shares. The results of the study may inform revisions and enhancements to WIC policies that may reduce operational barriers and help ensure the best possible service to participants share interim findings with study participants during a member checking session to verify that WIC staff experiences are accurately reflected in the emerging findings. Agency staff may also have opportunities to author deliverables or present findings alongside the study team

Who Should I Contact With Questions?

If you have general questions about the study, please contact the study team (WICTTstudy@westat.com) or the FNS project officer, Dr. Karen Castellanos-Brown (karen.castellanos-brown@usda.gov).

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 first name, the name of the research study that you are calling about (*WIC Tribal Organizations and U.S. Territories*), and a phone number beginning with the area code. Someone will return your call as soon as possible.

Please sign below to acknowledge that you have read and agree with the contents of this form.

Signature: _____

Print name: _____

Date: _____

Public Burden Statement

This information is being collected to assist the Food and Nutrition Service in learning about variations in WIC operations between Tribal Organizations, U.S. territories, and geographic States. FNS will use the information to inform program or policy changes that may reduce operational barriers and enhance services for WIC participants. 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-XXX. The time required to complete this information collection is estimated to average 0.0835 hours (5 minutes).

Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the following address: U.S. Department of Agriculture, Food and Nutrition Service, Evidence, Analysis, and Regulatory Affairs Office, 1320 Braddock Place, Alexandria, VA 22314, ATTN: PRA (0584-XXXX). Do not return the completed form to this address.