

ATTACHMENT D1: URBAN INSTITUTE IRB PACKAGE

TO: Everett Madden, IRB Administrator
THRU: Rolf Pendall, METRO Center Director
FROM: Nancy Pindus, Principal Investigator
DATE: 11/1/2012
SUBJ: Request for IRB Review

PD/Project (Name & No.): Study of the Food Distribution Program on Indian Reservations (08322-20-000)

Type of Review Requested:

1. Initial IRB Review:

Full Review: attach six copies of materials, or

Expedited Review: attach two copies of materials.

or

2. Annual Review or When There Has Been a Change to a Previously Approved Project:

No changes. I certify that there have been no changes in the following since the last IRB review: purpose, methods and procedures, including study population and what is required of the subjects to include —

Potential risks and benefits
Consent procedures to be followed
Data security plan
Survey instrument

There have been changes in the project since the last IRB review. **Provide narrative summary of changes and attach revised materials, highlighting the changed sections, as appropriate.**

PI Signature

Date

Center Director Signature

Date

Request for Expedited IRB review

STUDY OF THE FOOD DISTRIBUTION PROGRAM ON INDIAN RESERVATIONS: PRETEST OF DATA COLLECTION INSTRUMENTS UI # 08322-020-00

This is a request for an expedited review for pretesting the data collection instruments of a 3-year study of the Food Distribution Program on Indian Reservations that the Urban Institute is undertaking between November 2011 and October 2014. The evaluation is being done under contract to the U.S. Department of Agriculture, Food and Nutrition Service.

The Principal Investigator is Nancy Pindus, the Project Manager is Diane Levy, and Urban Institute staff includes Doug Wissoker, Chris Narducci, Sophie Litschwartz, and Jennifer Biess. Subcontractors involved in pretesting will be NORC at the University of Chicago, whose staff includes Carol Hafford and Suzanne Bard; and Support Services International, Inc., whose staff includes Walter Hillabrant and Judy Earp.

The pretest will be conducted in 2-3 FDPIR sites. Pretest participants will be recruited by contacting tribes with whom NORC, UI, or SSI has an established relationship through prior work. These tribes have indicated a willingness to assist in the pretest process and they are not part of the sample selected for the study of the Food Distribution Program on Indian Reservations. NORC will make the initial contacts with tribes for the pretest. While a full IRB review will be requested prior to beginning primary data collection activities associated with these surveys and interview guides, at this time we are requesting an expedited IRB review to allow us to pretest the following data collection protocols (see attached table for a summary of data collection instruments and respondents):

1. Case Record Review Form

The purpose of the case record review is to obtain information that will describe current program participants and their characteristics. Information will be abstracted from individual case records of several FDPIR programs. NORC will take the lead in testing procedures for accessing case records and extracting data, as well as pre-testing the case record review form itself. We plan to obtain and review 5 case records at up to 3 FDPIR pretest sites.

Our working assumption is that the majority of FDPIR programs do not have automated case record files. Therefore, the pretesting of the case record review form will be conducted on-site at tribal FDPIR offices. The existing records that will be examined for the case record review are the eligibility forms that are filled out by program applicants in order to participate in the FDPIR program. Each tribe or Indian Tribal Organization (ITO) maintains the records as part of its federally-approved program and according to strict program implementation guidance issued by USDA/FNS.

Appendix 1 includes the Case Record Review Form and a sample FDPIR case record.

2. FDPIR Participant Survey

NORC will take the lead in testing this primarily close-ended questionnaire designed to assess household food needs and satisfaction with the FDPIR program. Topics covered in the survey are food storage and preparation, FDPIR contribution to the household's food supply, access to the FDPIR program and access barriers, food costs, participation in FDPIR and other food assistance programs, nutrition education and other health-related services, and satisfaction with the program. The length of the survey interview is estimated to be 45 minutes. For the pretest, a total of up to 8 interviews will be conducted in 2-3 FDPIR sites. The respondents will be a convenience sample from the list of participants provided by the Food Distribution Program on each of the reservations in the pretest.

Pretest respondents will receive an incentive of \$25 for their time and cooperation. With the subject's permission, we do plan to audio-tape pretest interviews to hear how the question wording works and what questions the subjects have a difficult time understanding. The Informed Consent form for the pretest of the Participant Survey also includes a request for permission to audio-tape. The audio tapes will be destroyed when OMB clearance has been received.

Upon completion of the pretest field work, a telephone debriefing session will take place with the interviewers. A debriefing report will be produced and shared with FNS and the Urban Institute in order to make revisions to the instrument.

The Participant Survey instrument is included in Appendix 2.

3. Participant/Eligible Nonparticipant Discussion Group Guide

NORC will take the lead in testing the discussion group guide designed for current FDPIR participants and eligible nonparticipants. The discussion aims to collect information from eligible FDPIR candidates on how they choose between different food assistance programs and what they think about the food and related services offered in FDPIR. For the pretest, 2 individuals (FDPIR participants and/or eligible nonparticipants) will be selected to pretest the discussion guide in an interview format. The discussion group pretest respondents will receive an incentive of \$25 for their time and cooperation. Pretest participants will be recruited as part of the process for recruiting for the Participant Survey pretest. The interviews held to pretest the discussion guide will be audio-taped (with the consent of the participant) and audio tapes will be destroyed after the instruments have been revised and approved by OMB.

The contacts with tribes will also pretest their ability to identify nonparticipants as well as participants and any concerns they may have about including nonparticipants and participants in the same group. A debriefing will be held to discuss the pretest experience, followed by a written report covering any suggested improvements and suggestions.

The discussion group guide is included in Appendix 3.

4. On-Site Interview Guides

On-site interview guides will be pretested either on-site by NORC staff or over the telephone by UI and SSI staff. This will maximize our flexibility in accommodating respondent schedules in the compressed time frame available for the pretest. On-site interview guides are semi-structured and will be pretested with two Tribal leaders, two FDPIR representatives, and two representatives of other programs that work with FDPIR or serve FDPIR participants, such as IHS, WIC, and TANF (a total of 6 interviews). Pretest respondents may vary at each site depending on staff availability and the organization of the FDPIR program. Pretest participants will be recruited as part of the process described above for obtaining agreement from 2-3 non-sampled tribes to participate in the pretest.

A debriefing will be held to discuss the pretest experience, followed by a written report covering any suggested improvements and suggestions.

The on-site interview guides are included in Appendix 4.

HUMAN SUBJECTS AND DATA SECURITY ISSUES

This section identifies human subjects and data security issues that pertain to the pretests.

A. Pretest of Case Record Review Procedures and Form

Study populations. The Case Record Form will be tested with 5 case records in each of 2-3 sites. No new data collection will be involved; rather, we will be using the site's existing participant case files.

How data will be collected. For the pretest, NORC staff will extract case file data on-site. A NORC researcher trained in the data abstraction procedures will conduct the case record review. Data abstraction will be conducted manually using a pre-formatted template that has been installed on a secure NORC laptop computer. NORC staff will conduct the case review in a secure area of the FDPIR Program's offices during working hours (typically 8.00 AM to 4.30 PM). It is advisable to have a member of the FDPIR staff available to answer questions (e.g., to decipher handwriting on a form).

Use of Records Linked to Individuals. There will be no direct or indirect identifiers linked to the subjects for the case record review. Although there is identifying information in the case files to be reviewed, this information will not be abstracted, nor will it be linked to the subjects for the case file reviews. Nor is there any linkage between the participant files reviewed in the case record review and responses to the participant survey (i.e., they are mutually exclusive). FDPIR eligibility forms/case records are usually maintained as paper files only. It would impose a considerable burden on the tribe or Indian Tribal Organization (ITO) to duplicate the case records and redact names, addresses, etc. in order to obscure this information

from the researchers abstracting the information. We will not be abstracting any of the following information that is present on the case record:

- Name, phone, mailing address, city, county
- Household members (name, birthday, SSN)
- Prior application for or receipt of food stamps (SNAP)
- Disqualification

Potential Risks. The information extracted from the case files will include sensitive information, such as household characteristics and composition, and income and employment. Although the risk is minimal, this information could compromise the privacy and integrity of FDPIR participants if shared with the wrong party. Our data protection plan explains how we will address these potential risks.

Informed consent procedures. NORC has received a Waiver/Alteration of Consent for the Case Record Review from its IRB, as this component of the study meets the criteria as specified: “Collection of data from records where the investigator will not directly interact with the participants.” NORC’s request and approval are included in Appendix 5. If UI’s IRB agrees with this decision, informed consent for the case record review will not be obtained from individuals but from the Tribal leaders or Tribal Council through a tribal resolution. This document will serve as a data sharing agreement with NORC to conduct the case record review. A sample data sharing agreement is included in Appendix 6.

B. Pretest of Participant Survey and Participant Discussion Group Guide

Study populations. The Participant Survey will be tested on up to 8 individual households in 2-3 different FDPIR service areas that have not been selected for the study sample. The group discussion guide will be tested with 2 heads of Tribal households in FDPIR sites that are not in the sample.

How data will be collected. For both the survey and discussion guide, data collection will be conducted by staff from NORC and done in-person. Survey interviews and discussion guide interviews will be audio-taped contingent upon permission of the subject in order to inform question wording and probing. Notes will also be taken during the survey with paper and pencil. The Data Security Plan discusses how such records will be handled. Following on-site data collection, a debriefing will occur and a report produced of the findings from conducting the test.

Use of Records Linked to Individuals. NORC staff will never record identifying information on the same forms as any forms containing survey data. Respondents will be assigned code numbers (e.g., “Participant Pretest 1”) and these will be stored separately from the respondent contact/identifying information. All recorded information will be stored in locked file cabinets. Survey data will never be stored in the same place as identifying information. All pretest surveys, notes, and recordings will be destroyed upon OMB approval of the data collection plan and instruments.

Potential Risks. Much of the information collected in the Participant Survey and Group Discussion will involve sensitive information, such as participants’ health and nutrition and

needs, household characteristics and composition, and income and employment. Although the risk is minimal, the survey and group discussion guide will contain sensitive information that could compromise the privacy and integrity of interviewees if shared with the wrong party. Our data protection plan explains how we will address these potential risks.

Informed consent procedures. Materials for gaining cooperation include an advance letter, phone script, and brochure. Each household will be mailed an advance letter that will include a description of the study and contact information for the Urban Institute Principal Investigator and the NORC Project Director. It will be clearly stated that the household will be contacted by a NORC interviewer. Also included will be the time commitment required. Respondents will also have an opportunity to learn about the study at most sites through tribally-organized informational meetings, radio announcements, newspaper articles, word of mouth, tribal websites, and advance letters for all sites. They will receive additional information and clarifications from the interviewer or through calls they make to project and/or tribal officials.

With this outreach and advance notice, participants should be expecting a call or visit from the NORC field interviewer. The main purpose of the first call or visit will be to inform the respondent about the study, answer any questions they may have, be given time to make an informed decision, and set up an appointment at a time convenient to the respondent. Interviewers will also accept refusal during this call or visit. The phone script is integrated into page 1 of the Participant Survey (Appendix 2). If the respondent agrees, the interview will take place at the decided time. Any additional questions or concerns may be answered at this time. The respondent will be read the informed consent statement on page 1 of the instrument and, after agreeing, the 45 minute interview will begin. Proxies may also be requested for elders and those who are unable to participate, but wish for someone else to answer for them. In such cases, respondents will be asked to sign a form (integrated into the informed consent) giving permission for the proxy to answer the questions of his or her behalf. The proxy permission is provided on page 3 of Appendix 2.

The gaining of cooperation, informed consent, and interview procedures described above for the study will be conducted for the pretest. Selection of participants will occur at the discretion of the tribe, as will disclosure about the pretest. (We do not anticipate use of proxies for the pretest). The Informed Consent form for the pretest of the Participant Survey also includes a request for permission to audio-tape.

Specifically, the study's informed consent procedures will include the following information:

- The purpose of the study, who is conducting it, and how the data will be used;
- That participation is voluntary;
- That the interview will be recorded;
- That respondents can refuse to answer any question and/or quit the survey at any point without penalty;
- That respondents' privacy will be protected; that the information collected will be reported without identifying the individual interviewee;
- That the identity of all households participating in the study will be kept confidential.

In addition to these informed consent procedures planned for the evaluation, pretest participants will be informed that their responses on the pretest will NOT be included in the evaluation and that the information will be destroyed after the pretest. The research team will not disclose to FNS, or to any others outside of the research staff indicated above, the individuals, or tribal or program officials that have been selected for the pretest. Nor will we tell respondents who else was selected for the pretest or who responded.

C. Pretest of in-person interview guides

Interview population. There will be 6 program-related pretest interviews with tribal area administrators and officials. The guide, which is organized into topic-specific modules, will be tested on two Tribal leaders, two FDPIR program directors, and two related-service program directors in FDPIR program sites that are not part of study sample.

How data will be collected. For the pretest of the interview guide, data collection will be conducted on-site by staff from NORC and over the telephone by Urban Institute and SSI staff. Notes will be taken during the interview, but it will not be audio recorded. Following the pretest, a debriefing will occur and a report produced of the findings from conducting the test.

Use of Records Linked to Individuals. Urban Institute, NORC, and SSI staff will never record identifying information on the same forms as any forms containing interview data. Respondents will be assigned code numbers (e.g., “Tribal Interview Pretest 1”) and these will be stored separately from the respondent contact/identifying information. All recorded information will be stored in locked file cabinets until it is no longer needed. Interview data will never be stored in the same place as identifying information and interview data will be destroyed after the pretest is complete.

Potential Risks. Some of the information collected in the guides will involve sensitive information, such as perceptions of other federal, state, and local agencies, local populations, and socioeconomic conditions. While the risk is minimal, these interviews will contain sensitive information that could compromise the privacy and integrity interviewees if shared with the wrong party.

Informed consent procedures. Introductory letters will be sent to interviewees prior to scheduling the interview. See the introductory scripts to the guide in Appendix 3. Specifically, the study’s informed consent procedures will include the following information:

- The purpose of the study, who is conducting it, and how the data will be used;
- That participation is voluntary;
- That respondents can refuse to answer any question and/or quit the survey at any point without penalty;
- Taping of interviews will be done only with the permission of the respondent and the respondent can request that the tape recorder be turned off at any time.
- That respondents’ privacy will be protected; that the information collected will be reported without identifying any individual interviewee.

In addition to these informed consent procedures planned for the evaluation, pretest participants will be informed that their responses on the pretest will NOT be included in the evaluation and that the information will be destroyed after the pretest.

Pre-test Instrument	Population Definition	Recruitment	Consent	Interview Length	Method of Recording	Incentive Payments	Data Security	Risk
1. Case Record Review	5 FDPIR case records in each of 2- 3 FDPIR pretest sites that are NOT part of study sample.	The method of contacting and selecting the pretest sites will follow Tribal research protocols. We have established relationships and contacts with many Tribal areas nationally that would be good candidates for pre-testing, as well as a cohort of AI/AN interviewers currently on NORC staff to facilitate pretesting.	Informed consent required of each pre-test respondent. Consent precedes each pre-test. See Instruments in Appendix for exact language.	NA	Written notes	NA	All written and recorded information collected during the pre-tests will be subject to the same data security procedures described in the Data Security Plan section of the IRB request. In addition, information collected for the pretest will be destroyed upon OMB clearance.	Much of the information collected in the Case record, Participant survey, and Discussion guide will involve sensitive information, such as participants' health and nutrition and needs, household characteristics and composition, and income and employment. This survey will contain sensitive information that could compromise the privacy and integrity of interviewees if shared with the wrong party.
2. Participant Survey	8 Heads of tribal households within 2-3 FDPIR service areas that are NOT part of study sample.			45 minutes	Audio tape and written notes	\$25 cash or gift card incentive		
3. Discussion group discussion guide	2 Heads of tribal households within FDPIR service areas that are NOT part of study sample.			1 hour	Audio tape and written notes	\$25 cash or gift card incentive		
4. On-site Interview Guide for: a) FDPIR managers and staff; b) other service providers; c) Tribal leaders	2 Tribal Leaders; 2 FDPIR Program Directors; and 2 Other Program Directors in FDPIR program sites that are NOT part of study sample.			1.5 hours	Audio tape and written notes	No incentive		Some of the information collected in the guides will involve sensitive information, such as perceptions of other federal, state, and local agencies, local populations, and socioeconomic conditions. This information could compromise the privacy and integrity interviewees if shared with the wrong party.

DATA SECURITY PLAN

This section describes how we will store, handle, report, and dispose of the data collected through the pretest of the case record review form, participant survey, group discussion guide, and guides for on-site discussions with program administrators and staff.

Data Identifiers. We will not be collecting any additional identifying information from the pretest respondents. There will be no direct or indirect identifiers linked to the subjects for the case record review. Also, there is no linkage between the subject files reviewed in the case record review and responses to the participant survey.

In order to preserve the anonymity of any private persons and entities identified in the surveys or interviews, unique case numbers will be assigned to Tribal organizations, service organizations, and respondents, with respondent identification information kept in a separate file. The sensitive information will be saved in a locked file cabinet in Chris Narducci's office until the end of the pretest, at which time all data from the pretest will be destroyed, as described below. NORC will follow the same procedures for preserving anonymity of respondents and storing sensitive information.

Data Storage at UI. While the pretest is underway, interview tapes will be uploaded to a confidential drive on the computer network set up for this purpose and erased from the digital recorder. Access to the confidential drive will be limited to UI research staff working on the project who have signed the confidentiality pledge. Hard copies of interview notes will be stored in a locked file cabinet when not in use. The locked file cabinet will be in Metro and Chris Narducci, a UI Research Associate will be in possession of the key. Electronic files of interview notes may also be prepared by researchers by typing notes after interviews. These notes will be stored on the confidential drive using the assigned identifiers. Hardcopies of any necessary printouts of sensitive data or electronic media will be kept in locked cabinets in Chris Narducci's office. All storage media that hold sensitive data will be marked "CONFIDENTIAL." Any printouts of sensitive data that are no longer needed will be shredded. At the end of the pretest, we will follow the data destruction procedures described below. NORC will follow the same data storage and destruction procedures.

Data Reporting. There will be no data reporting for the pretest. Reporting is limited to a memo summarizing the pretest experiences and resulting modifications in data collection instruments and procedures.

Printing. When confidential data are being printed, the pause feature in printing will be employed so that the printout does not actually print until the sender is present at the printer to retrieve the copies.

Destruction of other hardcopy documents and electronic media. At the conclusion of the pretest, hardcopy documents will be shredded and electronic files, including backups, will be securely deleted using PGP software.

Staff Confidentiality. All Urban Institute staff, NORC staff, and SSI staff will receive training on the study's confidentiality procedures. All of these individuals will sign a confidentiality pledge agreeing not to divulge any information obtained as part of the data collection activities.

A copy of the confidentiality pledge is included as Attachment A.

Since staff of other organizations will also be involved in pretest data collection, additional procedures will be implemented to assure data security in the sharing of information. NORC and SSI staff will be required to keep their notes and survey documents in a locked file cabinet when not in use until the summary pretest report is completed. When pretest surveys/interviews are completed, they will be asked to send all notes to Chris Narducci at the Urban Institute via FedEx. Electronic copies of notes will be required to be kept secure either on a confidential drive or a password-protected computer disk. When electronic copies of site reports or any other material containing site visit information is transmitted to the Urban Institute, a password-protected computer disk or CD will be sent to Chris Narducci via FedEx. NORC has its own institutional IRB and the pretest activities in which NORC staff are involved will require approval from their IRB as well.

Attachments

A. Confidentiality Pledge

APPENDICES

- 1. Case Record Review Form and sample FDPIR case record**
- 2. Participant Survey**
- 3. Group Discussion Guide**
- 4. In-person Interview Guide**
- 5. NORC's Request for Waiver/Alteration of Informed Consent and Approval Notice**
- 6. Sample data sharing agreement**

STAFF CONFIDENTIALITY PLEDGE

Study of Food Distribution Programs on Indian Reservations (FDPIR)

Assurance of Confidentiality

The Urban Institute assures all respondents and participating organizations that the information they release to this study will be held in the strictest confidence by the contracting organization, and that no information obtained in the course of this study will be disclosed in such a way as to identify individuals or organizations. Access to the data in this study is by consent of the respondents who have been guaranteed confidentiality, except when the intent to commit a crime or harm themselves is revealed to the researcher. Their right to privacy is protected under law.

I have carefully read and understand this assurance that pertains to the confidential nature of all information and records to be handled in this study. I have read a copy of the *Confidential Data at the Urban Institute – Guidelines for Data Security*. I understand that I must comply with all of data security requirements adapted from those Guidelines for this project as approved by the Urban Institute Institutional Review Board. As an employee of, or consultant to, the Urban Institute, I understand that I am prohibited from disclosing any such confidential information that has been obtained under the terms of this contract to anyone other than authorized contractor staff and, if I am an Urban Institute employee, I agree to follow the procedures outlined to me during training. I understand that any willful and knowing disclosure of information released to this study may subject an Urban Institute employee to disciplinary action, up to and including termination of employment.

(Print Your Name)

(Signature)

(Date)

(Witness signature)

(Date)

APPENDICES



INSTITUTIONAL REVIEW BOARD NOTICE OF APPROVAL
(Federalwide Assurance Number #0189)

PROJECT DIRECTOR: Nancy Pindus

TITLE: "Study of the Food Distribution Program on Indian Reservations"

SPONSOR AGENCY: US Dept of Agriculture PROTOCOL DATE: November 2012

UI PROJECT NUMBER: 08322-020-00 PROPOSAL NUMBER: -

NATURE OF REVIEW:
(Check One) FULL _____ EXPEDITED X EXEMPT _____

MEETING DATE: N/A

TYPE OF APPROVAL

- PRELIMINARY
- PRETEST/PILOT TEST. SCHEDULE NEXT REVIEW PRIOR TO FULL IMPLEMENTATION
- FULL IMPLEMENTATION
- ANNUAL RENEWAL
- AMENDMENT

Please note the following requirements:

PROBLEMS OR ADVERSE REACTIONS: If any problems in treatment of human subjects or unexpected adverse reactions occur as a result of this study, you must notify the IRB Chairperson immediately.

CHANGES IN PROTOCOL: If there are significant changes in procedures or study protocol, you must notify the IRB Chairperson before they are implemented.

RENEWAL: You are required to apply for renewal of approval at least annually for as long as the study is active. Your next review date should be on or before 11/1/2013.

IRB Chairman
Martin D. Abravanel
Print or Type Name

November 2, 2012
Date

Copy: PI