APPENDIX DDDD:
IRB APPROVAL LETTERS

IRB ID Number: 13338

RESEARCH TRIANGLE INSTITUTE
COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS
Request for Exemption from IRB Review

To request approval for exemption from Institutional Review Board (IRB) review, the Project Manager (includes Project Director or Leader, Principal Investigator, or Survey Manager) must complete this form and deliver the request to an IRB Administrator. The Project Manager will be notified if more information is necessary and the results of the determination.

Date: 02/21/14 **RTI Project/Proposal No.:** 0213523

Project Title: WIC Nutrition Education Study

Project Manager: Sheri Cates (APD) **Sponsor:** U.S. Department of Agriculture, Food and Nutrition Service

Date Participation of Human Subjects Scheduled to Begin: 09/01/14

A. Brief Description of Study Procedures and Participant Population: FNS contracted with RTI International and its team members at Altarum Institute and researchers from the Atkins Center for Weight and Health, University of California at Berkeley to conduct a nationally representative study of Women, Infants, and Children (WIC) nutrition education processes. As part of this large study, in Phase I, RTI and its partners will conduct (a) a nationally representative web-based survey of local agencies (LAs) and WIC sites and (b) in-depth telephone interviews with a subset of sites. In Phase II, we will conduct (c) interviews with staff and (d) a web-survey of nutrition educators at six WIC sites selected for the Phase II pilot study.

a. **Phase I Web-based survey of LAs and WIC sites** – this survey will provide the data needed to develop a broad description of WIC nutrition education. Our target population is all LAs and their affiliated sites in 50 geographic States, 5 U.S. territories, the District of Columbia, and 34 ITOs.

Prior to the survey, we will establish early and ongoing communication about the web-based survey with WIC State agencies (SAs) and LAs to promote awareness of the survey; gain buy-in for it; and ultimately achieve the desired response rate. We initially send to all SAs a **study brochure (attachment 1)** that describes both phases of the study and **a letter from FNS (attachment 2)** that describes the study objectives and approach, including what will be asked of them and their LAs and associated WIC sites as part of the study. After the two samples for the web-based surveys are drawn, we will send an email to each SA, which will provide them with a list of the LAs and WIC sites selected to complete the survey. The letter will ask the SA to notify their LAs and WIC sites about the study and to encourage survey participation **(see attachment 3 for SA letter)**. We will include with the letter a **"frequently asked questions" (attachment 4)** document and the study brochure. FNS Regional Offices will receive advance copies of all communications with SAs and LAs to enable them to assist with questions and to support the study activities.

Our sample will include 1,000 randomly selected LAs and 2,000 randomly selected sites associated with the selected LAs. We expect 800 and 1,600 completed surveys from LAs and WIC sites, respectively. Upon receiving OMB approval, **an e-mail (attachment 5) with the link to the web-based survey** and instructions for completing it will be sent to the contacts at selected LAs. In the e-mail, we will include contact information for requesting assistance with accessing the survey and/or answering questions. At the end of the LA survey, the LA will be asked to provide contact information for selected WIC sites, and the survey will then be sent to the **WIC sites (attachment 6)** via an email request. For both selected

LAs and WIC sites, a paper version of the survey will be available if a respondent does not have Internet access. **Attachment 7 provides the LA Survey** which is expected to take 45 minutes to complete. There are two versions of the **Site Survey**; half of the sites will randomly receive **Version 1 (Attachment 8),** and half will receive **Version 2 (Attachment 9).** The estimated burden for the Site Survey is 45 minutes.

One week after the launch of the LA Survey, RTI will send a thank you/reminder email to all LA survey respondents. Three and five weeks after launch of LA Survey, RTI will send a second and third thank you/reminder email to LA survey nonrespondents (i.e., no LA or Site Surveys received). Two weeks before the end of data collection, RTI will send final emails to LAs that have not submitted a LA Survey or whose sites have not submitted Site Surveys. During the last two weeks of data collection, RTI will make follow-up calls to 100 LAs that have not submitted any LA or Site Surveys.

b. **Phase I in-depth telephone interviews** -- Based on responses to the LAs and site web-based surveys, we will select a subset of 80 WIC sites to conduct in-depth telephone interviews. These interviews will help us gather qualitative information on nutrition education practices, coordination of nutrition messages, and other topics. We will schedule the phone interviews with the selected WIC sites at a time that is mutually agreeable. We anticipate that each interview will take about 30 minutes to complete. The interviews will be conducted by a trained and experienced interviewer **(see attachment 10 for interview guide)**, and a note taker will document responses. If the site agrees, the interview will be recorded. The interviewer will review the notes using the recordings and make any additions and/or corrections before data analysis.

c. **Phase II Site Staff Interviews** -- Based on the results of Phase I, in consultation with FNS, we will select six WIC sites that demonstrated a considerable variability among them in terms of nutrition education exposure. The director of each WIC site will be interviewed in person at baseline (45 minutes) and by phone at interim, and again at the end of the 12-month pilot study period. The purpose of these interviews is to verify and update the information obtained in the LA and sites web-surveys **(see Attachment 11 for interview guides).**

d. **Phase II Nutrition Educator Survey** -- For each of the six pilot sites, we will conduct a brief web-based survey of nutrition educators to collect information about how they implement nutrition education; what they feel are effective strategies and challenges in providing nutrition education; and self-efficacy (e.g., confidence in using skills learned in training sessions) **(see attachment 12 for nutrition educator web-survey).** The survey will take 20 minutes to complete. If a respondent does not have Internet access, we will provide him/her with a hard copy of the survey.

B. Description of Physical, Psychological, Social or Legal Risks to Participants: There are no physical risks to participating in this study. There are minimal psychological, social, or legal risks to participating in this study. No study participant will be asked questions that are sensitive in nature. Respondents can choose not to answer any survey questions. In addition, study participants will be assured that their responses will be kept completely private.

Completion of the LA and Site Surveys is "required by the Healthy, Hunger-Free Kids Act of 2010 (P.L. 111-296, Sec. 305), which requires WIC State and local agencies to cooperate in studies or evaluations conducted by or on behalf of USDA." This language is included in the information that is sent to LA and WIC sites. There is not a similar requirement to complete the Phase I and Phase II interviews or the Phase II nutrition educator survey. Participation in these study components is voluntary.

C1. For educational tests (cognitive, diagnostic, aptitude, achievement), survey or interview research with adults:

1. Is information recorded in such a manner that human subjects can be identified, directly *or through identifiers linked to the subjects?*

☐ Yes ☒ No ☐ NA

If yes, explain: Altarum will collect the data and deliver the survey and interview data files to RTI. Responses are de-identified through the process of creating a link file containing respondent information (name, telephone number, and address) to a unique survey identification number. Information will be encrypted when transmitted between Altarum and RTI or placed on a secure, password protected FTP site. Access to Altarum's and RTI network is restricted to system users and devices that are correctly identified and authenticated; access to a project folder on a shared drive is restricted to specific project personnel. All paper files will be stored in locked cabinets. Paper and electronic information will be destroyed at the conclusion of the project after the final report has been submitted to FNS. Destruction of paper files will be placed in a proprietary waste bin designated for collection of documents requiring destruction. Electronic files will be deleted.

2. Would any disclosure of the human subjects' responses outside the research reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing employability or reputation?

☐ Yes ☒ No ☐ NA

C2. For research with existing data, documents, records, pathological or diagnostic specimens:

1. Are the sources of the data publicly available?

☐ Yes ☐ No ☒ NA

2. Is information recorded in such a manner that human subjects can be identified, directly *or through identifiers linked to the subjects?*

☐ Yes ☐ No ☒ NA

D. Describe other categories of exempt research[1] here: NA

[1] Note: Categories C1 and C2 above are the most common types of research conducted at RTI that may be exempt from IRB review. For a complete list of exemption criteria, please see below.

----------Space below this line for IRB use only.----------

Decision of IRB Coordinator or Chair

Name of IRB Coordinator or Chair making exemption determination: Ina Wallace, Ph. D.

Please check appropriate answer(s):

I agree that this study is exempt [45CFR46.101(b)] from IRB review based upon the information provided by the Project Manager above. (Check applicable category below.)

__(1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

__X__(2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

__(3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if: (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

__(4) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

__5) Research and demonstration projects which are conducted by or subject to the approval of Department or Agency heads, and which are designed to study, evaluate, or otherwise examine: (i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

__(6) Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

Ira J Wallace

Signature of IRB Coordinator or Chair named above

February 25, 2014

Date

Version 11-30-00

RTI INTERNATIONAL

IRB ID Number: 13338

Office of Research Protection
Institutional Review Board Notice of Approval
Federalwide Assurance No. 3331

Title of Study: Nationally Representative Study of WIC Nutrition Education Process
RTI Project Number: 0213523 **RTI Proposal Number** (if no Project Number)
Project Leader: Sheri Cates
Project Team Member Contact (if different from Project Leader): Kathy Kosa
Source of Funding for this Study: USDA
Date Submitted to IRB: February 20, 2014
Level of Review *(check one)*:
Full ☐, IRB Meeting Date: _____
Expedited ☒, category: **7: Behavioral - surveys, focus groups, etc.**

Type of Review *(check one)*:
☐Preliminary review (For DHHS grants where RTI is prime, the grant application/contract proposal and protocol submitted to the IRB are in concordance (45 CFR 46.103(f)). **Do not involve human subjects or data until pretest or full study is approved.**)
☐Amendment, describe:
☐Add study site(s): _____
☐Pretest/Pilot Test _____
☒Full Implementation: surveys, data collection, focus groups and observations
☐Renewal
☐Study Closure

IRB Approval of Special Conditions *(check all that apply to this review)*:
☒ Waiver of Signed Informed Consent/Parental Permission
☐ Waiver of elements of Informed Consent or requirement for Informed Consent/Parental Permission
☒ Participation of Pregnant Women (**Worksheet B** submitted by project team)
☐ Participation of Prisoners (**Worksheet C** submitted by project team)
☐ Participation of Prisoners in DHHS-funded studies (OHRP acknowledgement required)
☐ Participation of Minors (**Worksheet D** submitted by project team)
☐ IRB Agreement of Nonsignificant Risk Device Study Determination
☐ HIPAA Waiver of Authorization

Please note the following requirements:
- If **unexpected problems** or **adverse events** occur, the project team must notify the IRB.
- If there are **changes** in study procedures or protocol or any data collection materials (brochures, letters, questionnaires, etc.) the project team must notify the IRB before they are implemented.
- The project team is required to apply for **continuing review** as long as the study is active, which includes participation of human subjects or possession of human data or specimens.

Expiration Date of IRB Approval: May 15, 2014
(No human subjects research can occur after this date without continuing review and approval.)

Ina Wallace

Signature - IRB Member or Chair

February 24, 2014
Date of IRB Approval

Ina Wallace, PhD
Name - IRB Member or Chair (print or type)

☒Copy sent to project leader on: February 24, 2014
☐Entered into MIS
☐ OHRP acknowledgement received for participation of prisoners in DHHS-funded studies on:_____

Office of Research Protection and Ethics, Institutional Review Board
3040 Cornwallis Road, Research Triangle Park, NC 27709-2194, USA
Telephone: 919-316-3358 Fax: 919-316-3897 orpe@rti.org

RTI INTERNATIONAL

IRB ID Number: 13338

Office of Research Protection
Institutional Review Board Notice of Approval
Federalwide Assurance No. 3331

Title of Study: Nationally Representative Study of WIC Nutrition Education Process
RTI Project Number: 0213523 **RTI Proposal Number** (if no Project Number)
Project Leader: Sheri Cates
Project Team Member Contact (if different from Project Leader): Kathy Kosa
Source of Funding for this Study: USDA
Date Submitted to IRB: March 25, 2014
Level of Review *(check one)*:
Full ☐, IRB Meeting Date: _____
Expedited ☒, category: **9: Cont. Rev. minimal risk research**
Type of Review *(check one)*:
☐Preliminary review (For DHHS grants where RTI is prime, the grant application/contract proposal and protocol submitted to the IRB are in concordance (45 CFR 46.103(f)). **Do not involve human subjects or data until pretest or full study is approved.)**
☐Amendment, describe:
☐Add study site(s): _____
☐Pretest/Pilot Test _____
☐Full Implementation:
☒Renewal
☐Study Closure

IRB Approval of Special Conditions *(check all that apply to this review)*:
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Expiration Date of IRB Approval: **May 15, 2015**
(No human subjects research can occur after this date without continuing review and approval.)

Juesta M. Caddell
Signature - IRB Member or Chair

5/14/2014
Date of IRB Approval

Juesta Caddell, Ph.D.
Name - IRB Member or Chair (print or type)

☒Copy sent to project leader
☒Entered into MIS
☐ OHRP acknowledgement received for participation of prisoners in DHHS-funded studies on:_____

Office of Research Protection and Ethics, Institutional Review Board
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