APPENDIX D:
IRB APPROVAL FORM

SEE PAGE 2.

IRB ID Number: 13700

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 the IRB Administrator. The Project Manager will be notified if more information is necessary and the results of the determination.

Date: 12/17/14 **RTI Project No.:** 0214016.004.000.002

Project Title: Professional Services to Support Requirements Gathering Sessions for Safe Food Handling Instructions

Project Manager: Sheri Cates

Sponsor: U.S. Department of Agriculture, Food Safety Inspection Services (USDA, FSIS)

Date Participation of Human Subjects Scheduled to Begin: February 10, 2015

A. Brief Description of Study Procedures and Participant Population: To gather consumers' understanding and use of the current Safe Handling Instructions (SHI) found on raw and partially-cooked meat and poultry products and responses to possible revisions to the SHI, RTI will conduct six focus groups with 48 adults who cook and prepare meals at home at least four times a week. The groups will be segmented by at-risk and general population groups (see Table 1). To provide geographic diversity, we will conduct two focus groups in Raleigh, NC and each of two other to be determined locations in the Midwest and West regions of the United States. In each location, we will conduct one focus group with English-speaking adults and one focus group with Spanish-speaking adults. RTI will subcontract with a local market research company in each of the three locations to recruit participants and provide the facilities for hosting the focus group discussions. The market research companies will over-recruit to ensure 8 to 10 eligible individuals to participate in each focus group discussion. Each group will include a mix of genders, ages, races, and education if not specifically characterized by subpopulation. Using convenience sampling, the market research companies will recruit from their databases potential participants who meet the eligibility criteria defined by the screening questionnaire (see attachment). To encourage recruited individuals to not only attend but to arrive on time for the focus group discussions, the market research companies will add all those who sign in 15 minutes prior to each group to a drawing for a chance to win $50.

Upon arrival to the focus group facility, participants will read and sign an informed consent form (see attachment) and answer a few short questions to confirm eligibility. Next, participants will complete a short pre-discussion questionnaire to record their current awareness and use of the SHI label (see attachment). RTI will conduct the focus group discussions using a moderator guide (see attachment). At the end of each focus group, participants will be asked to complete a short post-discussion questionnaire (see Appendix C) to record the likelihood they would change their behaviors if the SHI label is revised.

Focus group participants will receive a $75 incentive for their participation in a 90-minute focus group. Each focus group discussion will be professionally and digitally recorded by the local market research companies, and the audio-recordings will be professionally transcribed.

Prior to the full-scale study, we will conduct a pilot focus group with 8 RTI employees who will be recruited via word-of-mouth and Staffnet. Participants will receive $30 for their time and opinions.

B. Description of Physical, Psychological, Social or Legal Risks to Participants: There are minimal psychological, social, or legal risks to participating in this study. Participants will be sharing their thoughts and opinions in a group setting, but no sensitive information will be asked of participants. Participation is voluntary, and respondents can choose not to answer any questions. Participants will be addressed by their first name only; they will not provide any identifying information during the focus groups. The market research facility will not share any identifying information with RTI or USDA.

Although no sensitive questions will be asked during the focus group discussions, during the recruitment of individuals to participate in the "immunocompromised focus group," individuals will be asked whether they have or have a household member who has been diagnosed with cancer, diabetes, or a condition that weakens the immune system. Individuals will not be asked for a specific diagnosis. Immunocompromised individuals are considered at risk for foodborne illness; thus, it is important to include them and/or their caregivers to capture their understanding and use of the SHI for raw meat and poultry.

Table 1. Proposed Focus Group Subpopulations and Locations

Group	Subpopulation	Language	Location
1	Parents of young children/Any education level[a]	Spanish	Raleigh, NC
2	Immunocompromised[b]	English	Raleigh, NC
3	Older adults[c]	Spanish	Oklahoma City, OK
4	General population/Less educated[d]	English	Oklahoma City, OK
5	General population/Less educated[d]	Spanish	Portland, OR
6	Parents of young children/More educated[e]	English	Portland, OR

[a] Parents/caregivers of children aged 5 years old or younger, including pregnant women; no restriction on education
[b] Adults and/or caregivers of those diagnosed with cancer, diabetes, or other condition that weakens the immune system
[c] Adults aged 60 years or older
[d] Adults aged 26 to 59 years old with a high school education or less
[e] Parents/caregivers of children aged 5 years old or younger with a 4-year college degree or higher

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?

[x] Yes [ ] No [ ] NA

If yes, explain: The focus groups will be audio- and video-recorded; however, participants will be addressed by their first name only. At the end of the study, the tapes will be destroyed.

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 [x] 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 [x] NA

If no, explain:_____

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

[ ] Yes [ ] No [x] NA

If yes, explain:_____

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

[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: Jamia Bachrach, JD

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.

Jam I Bachrach

_____ December 31, 2014

Signature of IRB Coordinator or Chair named above Date

Version 11-30-00