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## PRELIMINARY VALIDATION OF A NATIVE AMERICAN FOOD SAFETY KNOWLEDGE SURVEY

by

# MARGARET MARKHAM SIEBERT BACHELOR OF ART, CULTURAL ANTHROPOLOGY, 2003

#### **THESIS**

Submitted in Partial Fulfillment of the Requirements for the Degree of

**Masters of Science Health Education** 

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#### **Dedication**

In loving memory of my mother, Joan Markham Siebert.

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# PRELIMINARY VALIDATION OF A NATIVE AMERICAN FOOD SAFETY KNOWLEDGE SURVEY

by

#### **Margaret Markham Siebert**

B.A., Cultural Anthropology, University of New Mexico, 2003M.S., Health Education, University of New Mexico, 2012

#### **ABSTRACT**

The objective of this study was to develop and validate a food safety knowledge survey culturally appropriate for Native American Populations. A reiterative three-phased approach (survey generation and item construction, survey item review, and statistical item analysis) to survey validation was employed to collect both quantitative and qualitative data.

Surveys were given to 28 individuals fitting the demographic criteria: Native American adults who are primary food handlers with children under the age of 10. Surveys were analyzed statistically using item difficulty, item discrimination, and internal consistency. Key informant interviews were conducted with six participants who fit the inclusionary criteria. Key informant interviews were used to assess the cultural appropriateness of the survey as it pertains to level of difficulty, format, wording and language, length, and content. Additionally, five experts in the field of nutrition and dietetics assessed item construct domain, essentialness, clarity, and representativeness. Subject-matter expert data was

analyzed using inter-rater agreement, content validity index, and factorial validity index. A culturally appropriate, content valid, and reliable survey for Native American primary food handlers with children under the age of ten was created to collect national data on food safety knowledge of Native Americans.

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#### **Chapter One: Introduction**

The purpose of this chapter is to provide a general overview of the area of study to be investigated, describe how this topic is important to the field of community health education, and introduce the research questions of interest. A brief list of pertinent definitions and key terms is also provided.

#### **Statement of the Problem**

Foodborne illness is a preventable health challenge and continues to be a persistent threat in the 21<sup>st</sup> century (Centers for Disease Control and Prevention, 2007a). It is estimated that foodborne pathogens account for more than 48 million illnesses, 128,000 hospitalizations, and 3,000 deaths each year in the United States (Centers for Disease Control and Prevention, 2011; Scallan, Hoekstra, et al., 2011). Food safety and the reduction of foodborne illness have been identified as priority areas in the Healthy People 2020 initiative (U.S. Department of Health and Human Services, 2010).

Although 31 pathogens have been identified, a large proportion are unspecified agents (Centers for Disease Control and Prevention, 2011a; Scallan, Griffin, et al., 2011). Regardless of identification, many foodborne illnesses go unreported for a variety of reasons including: not being seen by a physician, lack of diagnostic testing, improper classification of symptoms and illness, failure of the hospital to report the case to appropriate health surveillance systems, milder cases not being detected, pathogens can be transmitted through secondary sources (such as person to person), or certain pathogens are not yet identified as being foodborne (Scallan, Griffin, et al., 2011; Mead et al., 1999). Underreporting of foodborne illness

may mean that the reported figures are an inadequate representation of the actual magnitude of foodborne illness (Scallan, Griffin, et al., 2011).

Certain populations are more at risk for contracting foodborne illness such as children, the elderly, and persons with weakened immune systems (Buzby, 2001). Of these groups, children under the age of 15 are of particular importance because they amount to roughly 50% of all cases of foodborne illness (Centers for Disease Control and Prevention, 2007a) and almost 33% of the cost accrued to treat foodborne illnesses, an estimated \$2.3 billion (Buzby, 2001). Notably, the reported cases of foodborne illness are more accurate in child populations because medical care is sought out quickly (Buzby, 2001). This more accurate accounting may cause appeared inflation of statistics when compared to other populations. However, most experts argue that children's immune systems are not fully developed, they have a lower bodyweight, reduced stomach acid production, and limited control over food preparation, and therefore are more susceptible to contracting foodborne illness (Buzby, 2001; Haffejee, 1995). Another risk factor specific to children is their limited access and ability to prepare foods. Children are reliant on an adult or family member to provide and prepare their food (Buzby, 2001). Foodborne illness is preventable using proper food safety practices. This implies that primary food handlers must be aware of correct food safety practices in order to protect themselves and their families from contracting foodborne illness (Pew Health Group & Center for Foodborne Illness and Prevention, 2009; Buzby, 2001).

Additionally, when segmented by age bracket and pathogen, children have much higher rates of certain foodborne illnesses. Infants under one year of age have

the highest reported rates of campylobacteriosis (Buzby, 2001) and children under the age of four are almost three times as likely to contract campylobacteriosis than any other age group below 50 (Pew Health Group & Center for Foodborne Illness and Prevention, 2009). Although foodborne illnesses are typically acute and short in duration the U.S. Food and Drug Administration (FDA) estimates that 2-3% of cases will develop subsequent problems, or secondary complications, some of which are chronic (Buzby, 2001). Some secondary complications relating to the campylobacteriosis pathogen are reactive arthritis and Guillain-Barre Syndrome, an autoimmune nervous disorder with potentially debilitating consequences (Buzby, 2001).

Foodborne illness inordinately effects minority populations. New Mexico represents a unique cultural milieu with high percentages of minority populations. According to the 2010 United States Census, when compared with the average demographic composition of the United States, New Mexico has a significantly higher Hispanic population (46.3% to 16.3%) and American Indian/Alaskan Native population (9.4% to 0.9%). In 2004, the CDC's Foodborne Diseases Active Surveillance Network, FoodNet, began surveillance of New Mexico. The rates of foodborne illness in New Mexico are significant (Centers for Disease Control and Prevention, 2011b) and are higher in Hispanic and Native American populations when compared to white populations (Khanlian, 2011).

Rates of foodborne illnesses differ between ethnic groups. According to the CDC Hispanics are at an increased risk of contracting foodborne illness due to certain common food preferences such as the consumption of unpasteurized milk

Products (Centers for Disease Control and Prevention, 2007b). For instance Hispanic infants have 12 times greater incidence of listeriosis and Hispanic women ages 30-34 are 13 times more likely to contract listeriosis (Lay et al., 2002). Similarly, incidence rates of salmonella were highest among Hispanic populations from 1997-2001 (Voetsh, Angulo, & Jones, 2007). One possible reason for the considerably higher rates of certain foodborne illnesses in Hispanic populations is attributable to traditional food handling practices or a lack of knowledge of proper food safety practices. Numerous studies indicate that a knowledge gap exists between the Hispanic population's knowledge of food safety and proper food handling practices when compared to other groups (Palmeri, Auld, Taylor, Kendall, & Anderson, 1998; Taylor, Serrano, Anderson, & Kendall, 2000; Yang et al., 1998).

There is insufficient data at present to fully understand the food safety knowledge and practices of Native American populations. New Mexico has a large Native American population constituting 9.4% of the demographic data (U.S. Census Bureau, 2010). The New Mexico Department of Health, Epidemiology and Response Division reported that Native American populations are at a significantly higher risk of contracting campylobacteriosis (41.7/100,000)—a rate more than three times greater than white New Mexican residents (13.1/100,000) (Racz et al., 2009). A meta-analysis of food handling behaviors that segmented respondents by ethnicity proposed that the heightened rates between ethnicities could be derivative of a variance in socio-economics and cultural practices (Patil, Cates, & Morales, 2005). However, socio-economics and culture cannot account for all behavior surrounding food choice and preparation. For instance, access to clean potable water can be

difficult in rural New Mexico, especially on the 22 sovereign Indian nations in rural New Mexico (Racz et al., 2009). Animal husbandry practices of Native Americans (including slaughter and milk production) incorporate sheep, cattle, and other farm animals known to be vectors of campylobacteriosis (Racz et al., 2009). If understood, the specific cultural practices surrounding food and water preparation and acquisition may explain the heightened rates of campylobacteriosis in New Mexican Native American populations. More research targeting the culture of food in Native American populations could reveal information relevant to knowledge, behaviors, and attitudes regarding food safety within this population.

Despite the increased rates of foodborne illness in Hispanic and Native

American populations, surveys developed to examine food safety knowledge and/or

practices do not specifically address the varying food practices of these cultures.

Food safety knowledge and practices must be better understood in families of

diverse cultural backgrounds, such as Hispanic and Native American. However,

differences between Hispanic and Native American food practices exist. Food safety

measurement instruments such as surveys must be tailored to each. In order to

determine the food safety knowledge of these diverse populations a survey

instrument will be validated and tailored to each specific cultural background. To

begin this process, this study, "Preliminary Validation of a Native American Food

Safety Knowledge Survey", will test a food safety knowledge survey for validity,

reliability, and cultural appropriateness specifically among the Native American

population living in New Mexico.

#### **Purpose of the Study**

The purpose of this research study is to develop a comprehensive, valid, and reliable food safety knowledge questionnaire that is culturally appropriate for Native American populations. This study is part of a larger study funded by the USDA, "Food Safety for Diverse Families with Young Children". The larger project will assess food safety knowledge and practices in both Hispanic and Native American families with children under the age of ten. The knowledge survey validated through this study will be used in this larger study.

#### **Research Questions**

- 1. To what extent is this survey a valid measure of food safety knowledge among Native Americans?
- 2. To what extent is this survey a reliable measure of food safety knowledge among Native Americans?
- 3. To what extent is this survey appropriate and compatible to Native American culture?

#### **Significance of the Study**

Numerous studies are available to estimate consumer food safety attitudes, knowledge, and practices but all have limited demographic segmentation (Angelillo, Viggiani, Rizzo, & Bianco, 2000; Brewer & Prestat, 2002). A search for a valid and reliable instrument to measure the knowledge and food safety practices of Native American populations was unable to yield any results. Without appropriate, valid, and reliable measures it is difficult to develop and implement food safety education efforts for this population (Contento, Randell, & Basch, 2002).

#### **Definition of Terms**

Foodborne illness refers to an infectious or toxic disease resulting from the consumption of contaminated food (World Health Organization, 2007).

Native American refers to a subpopulation within the state of New Mexico who self report their ethnicity/race as Native American on a demographic form.

#### **Chapter Two: Review of the Literature**

This chapter describes the findings from a review of the scientific literature on those variables and concepts that are key to this study. An epidemiological description of foodborne illness in the U.S. is reviewed followed by a more specific focus on risk factors associated with this health problem. In addition, the specific impact of foodborne illness on children and minority populations, and the role of food safety knowledge and practices as risk and protective factors are explored. Concepts from the Fight BAC Food Safety campaign are introduced as they apply to the construction of the knowledge survey to be studied.

#### **Epidemiology of Foodborne Illness**

Foodborne illness unequally effects populations when segmented by age (Buzby, 2001; Centers for Disease Control and Prevention, 2007a; Haffejee, 1995; Pew Health Group & Center for Foodborne Illness and Prevention, 2009) and by ethnicity (Centers for Disease Control and Prevention, 2007a; Lay et al., 2002; Palmeri et al., 1998; Patil et al., 2005; Racz et al., 2009; Taylor et al., 2000; Voetsh et al., 2007). Health disparities exist among the rates of foodborne illness within the Hispanic and Native American populations when compared to majority populations (Centers for Disease Control, 2004; Lay et al., 2002; Palmeri et al., 1998; Patil et al., 2005; Racz et al., 2009; Taylor et al., 2000; Voetsh et al., 2007). In New Mexico, these inequities are even greater due to the unique cultural diversity represented in the population (Racz et al., 2009; U.S. Census Bureau, 2010). Certain predisposing and reinforcing behavioral patterns exist within cultural food practices that may perpetuate foodborne illness (Patil et al., 2005; Racz et al., 2009). Various food

safety knowledge surveys (Albrecht, 1995; Angelillo et al., 2000; Boone et al., 2005; Brewer and Prestat, 2002; Bruhn & Schutz, 1999; Cates, Carter-Young, Conley, & O'Brien, 2004; Johnson et al., 1998; Kennedy et al., 2005; Li-Cohen & Bruhn, 2002; Raab & Woodburn, 1997; Redmond & Griffith, 2004; Unklesbay, Sneed, & Ramses, 1998; Wenrich, Cason, Lv, & Kassab, 2003) and interventions (Fight BAC, Be Food Safe, & Thermy) have been developed and implemented but with little demographic segmentation and/or cultural sensitivity.

Foodborne illness remains a persistent yet preventable health problem. There are 31 known major pathogens in food causing around 9.4 million illnesses a year (Scallan, Hoekstra et al., 2011). However, there are many unknown or unspecified foodborne pathogens. These pathogens contribute to an estimated 38.4 million episodes of domestically acquired foodborne illness (Scallan, Griffin et al., 2011). Together known and unknown foodborne pathogens caused almost 50 million illnesses, 130,000 hospitalizations, and 3,000 deaths. Many foodborne illnesses go unreported suggesting that these figures could be much larger (Mead et al., 1999; Scallan, Griffin et al., 2011).

Of the known pathogens: 58% of reported cases of foodborne illness were caused by norovirus, 11% by nontyphoidal Salmonella spp., 10% by Clostridium perfringens, and 9% by Campylobacter spp.; 35% of hospitalizations were caused by nontyphoidal Salmonella spp., 26% from norovirus, 15% from Campylobacter spp. and 8% from Toxoplasma gondii; and 28% of deaths due to foodborne illness were caused by nontyphoidal Salmonella, 24% from Toxoplasma gondii, 19% from Listeria monocytogenes, and 11% from norovirus (Scallan, Hoekstra et al., 2011).

FoodNet, the Center for Disease Control's (CDC) Foodborne Active Surveillance Network, provides surveillance data for infections in ten states nationwide for foodborne illness including the pathogens Salmonella, Shigella, Campylobacter, Escherichia coli O157, Listeria monocytogenes, Yersinia enterocolitica, and Vibrio, and parasites such as Cryptosporidium and Cyclospora. FoodNet's final report in 2004 reported that Salmonella and Campylobacter have the highest incidence. The CDC reported in 2007 that nine pathogens (Campylobacter, Salmonella, Shigella, Yersinia, Escherichia coli (E. coli) 0157:H7, Cryptosporidium, Cyclospora, Vibrio, and Listeria) are the cause of most foodborne illness (Centers for Disease Control, 2007a).

#### **Risk Factors**

Foodborne illness disproportionately effects populations when stratified by age, health status, and ethnicity. Many risk factors such as lower immunity, food safety knowledge, and practices impact the risk of contracting a foodborne illness and its severity. Children, the elderly, and persons with suppressed immune systems are at a heightened risk for contracting foodborne illness (Buzby, 2001). Children are at an increased risk not only because they are smaller in body size and have not fully developed their immune systems but also because they are not in control of food choices or preparation (Buzby, 2001).

Children account for nearly 50% of all reported foodborne illnesses (Centers for Disease Control, 2007a) and children are at an increased risk for contracting many foodborne illnesses (Buzby, 2001). For instance, the incidence of Campylobacter (26.98/100,000) and Salmonella (121.57/100,000) for children

under the age of one is significantly higher than any other age group (Centers for Disease Control, 2007a). For Campylobacter, children under the age of four are three times as likely (28.54/100,000) to contract the illness than any other age group under 50 (Centers for Disease Control, 2009). The incidence of E. coli 0157:H7 infection in children under the age of four is 4.24/100,000 and 2.57/100,000 for children between four and 11 years of age (Centers for Disease Control, 2009). Similar statistics are found for the incidence of Listeria monocytogenes (0.76/100,000), Salmonella (74.65/100,000), and Shigella (27.86/100,000 for children under four and 25.67/100,000 in children between four and eleven) (Centers for Disease Control, 2009; Pew Health Group & Center for Foodborne Illness and Prevention, 2009).

Children are disproportionately affected by foodborne illnesses, sometimes contracting chronic and severe secondary conditions. Campylobacter can result in Guillain-Barre syndrome, an autoimmune nervous disorder, and reactive arthritis (Buzby, 2001). E. coli O157:H7 can cause kidney disorders and hemolytic uremic syndrome (HUS) (Buzby, 2001). Almost one-third of Listeria monocytogenes cases occur in pregnant women (Pew Health Group & Center for Foodborne Illness and Prevention, 2009). Congenital infections of Listeria monocytogenes can lead to varying birth complications including stillbirth, premature birth, miscarriage, death and mental retardation (Buzby, 2001; Pew Health Group & Center for Foodborne Illness and Prevention, 2009).

Foodborne illness also disproportionately affects certain ethnicities including
Hispanic populations and Native American populations. Hispanic populations are

12 times more likely to contract listeriosis (Lay et al., 2002). Hispanic populations also are at a higher risk of contracting invasive Salmonella when compared to white populations (Voetchet et al., 2007). Native American populations are almost three times more likely to contract campylobacteriosis than white New Mexican residents (Khanlian, 2011; Racz et al., 2009).

#### **Food Safety Education Campaigns**

Many surveys of food safety have been conducted concerning consumer food safety knowledge, attitudes, and practices (Albrecht, 1995; Angelillo et al., 2000; Brewer & Prestat, 2002; Bruhn & Schutz, 1999; Kennedy et al., 2005; Raab & Woodburn, 1997; Redmond & Griffith, 2004). Surveys have been conducted to determine food safety knowledge and practices among specific populations such as college students (Unklesbay et al., 1998), low-income adults (Wenrich et al., 2003), mature/elderly people (Boone et al., 2005; Johnson et al., 1998), pregnant women (Cates et al., 2004), and specific commodity practices, such as fresh produce handling (Li-Cohen & Bruhn, 2002). However, researchers were unable to find a food safety knowledge survey targeting Native American primary food handlers with children under the age of ten.

Various food safety educational and social marketing programs exist and are currently being implemented and developed by the USDA and FDA to increase proper food safety practices (Fight BAC, Be Food Safe, and Thermy). Again there is very little audience segmentation to educate specific minority populations such as Native Americans. Some educational components target specific audiences such as the Coloring Book (USDA) for young children and "To Your Health! Food Safety for

Seniors" (USDA) a video and booklet for older adults. Both the Fight BAC and Be Food Safe campaigns simplify food safety into four categories: clean, cook, chill and separate. Community interventions and campaigns educate audiences about these four topics.

With greater audience segmentation and cultural appropriateness, food safety knowledge may improve and rates of foodborne illness may decline among minority and at risk populations.

#### **Chapter Three: Methods**

This methodology chapter describes the three-phased reiterative approach taken to conduct this research study. Each phase is described in detail including the purpose of each phase and a review of the methods used for data collection and analysis. Study assumptions and delimitations are also addressed.

The purpose of this study was to construct and validate a food safety knowledge survey that is culturally appropriate for Native American families in New Mexico. This study (HRPO# 11-386) was approved by the University of New Mexico Institutional Review Board on July 27, 2011 (Appendix F).

#### A Three-Phased Approach

The validation process used in this study was implemented in three phases in order to conduct the study in a systematic and comprehensive manner.

Phase 1: Item generation and survey construction. The objectives for Phase 1, item generation and survey construction, were to first develop a pool of items based on the food safety literature and previously established and validated food safety surveys and to construct a psychometrically sound survey (Byrd-Bredbenner et al., 2007; Haapala & Probart, 2004; Medeiros et al., 2004; Meysenburg, 2009; Unklesbay et al., 1998; Wenrich et al., 2003). The second objective required the consultation of an independent psychometric evaluator, the Buros Institute for Assessment Consultation and Outreach (BIACO), at the University of Nebraska-Lincoln. The survey was evaluated based on item format, survey construction, and language complexity.

Phase 2: Survey item review. Phase 2, survey item review, included two critical steps. The first step included a series of key informant interviews with members of the subpopulation to determine the cultural appropriateness of all survey items as they relate to length, wording, language, and content. The second step established content–related validity of survey items. This was obtained by a careful item analysis based on the professional judgment of subject-matter experts. Each survey item was evaluated based on content domain match, construct relevance, representativeness, and clarity.

*Key informant procedures.* Snowball sampling, a non-probability sampling technique, was used to recruit the key informants. Participants identified as eligible were asked to recommend additional possible participants whom they knew fit the eligibility criteria (Berg, 1988; Van Meter, 1990). Each additional participant was asked to identify an additional potential participant and so forth until an adequate sample size (n=5-8) was met. Snowball sampling, or chain of referrals sampling, is often used in the social sciences when the population is relatively inaccessible (Berg, 1988).

Key informants were either called on the phone or met in person. Interviews were recorded on an audio recording device and transcribed verbatim (Krueger & Casey, 2009). Audio files and written transcriptions were stored electronically on a computer and an external hard drive.

Content validity procedures. Subject-matter experts in the field of Nutrition Sciences and Dietetics were recruited to individually assess each survey item across four validity criteria: content domain match, construct relevance,

representativeness, and clarity. The experts were selected by their tenure in the field (minimum 5 years experience) and academic credentials (Registered Dietician). Experts were mailed a study packet that included a letter of invitation, instructions for completing the validity questionnaire, and a copy of the final version of the food safety knowledge survey that had been reformatted to include the four validity criteria, see Figure 1 (Rubio et al., 2003).

Figure 1. Sample Format for Content Validity Questionnaire Item

Please <u>circle</u> the number that best corresponds with your answer.

- 1. Which food(s) will likely cause food poisoning? (Check all that apply)
  - a. Rare hamburgers
  - b. Grilled steak served on the same plate that held raw steak without washing the plate
  - c. Meat cooked medium-well
  - d. Frozen foods with frost built up in the package

Content Domain	1 Cook	2 Clean	3 Chill	4 Separate
Construct Relevance	1 Item is not essential or useful	2 Item is useful but not essential	3 Item somewhat useful & somewhat essential	4 Item is essential and useful
Representativeness	1 Item not representative	2 Major revisions needed	3 Minor revisions needed	4 Item is representative
Clarity	1 Item is not clear	2 Major revisions needed	3 Minor revisions needed	4 Item is clear

Survey items were jumbled to decrease the likelihood that experts may group items by their association to surrounding items measuring the same content domain. Each item was then copied and pasted into the questionnaire with content assessment scales. Experts were asked to mail the questionnaire in a return-stamped envelope within two weeks of receipt. Once received, questionnaires were entered into two excel files, one for quantitative data and one for qualitative data. All electronic files were stored on a computer and on an external hard drive.

Phase 3: Statistical item analysis procedures. A convenience sample of Native American adults who matched the study criteria for inclusion completed the food safety knowledge survey for the purpose of conducting the necessary preliminary statistical analyses to determine item difficulty, item discrimination, and internal consistency.

Survey respondents were recruited from University of New Mexico Health Education courses and Gallup, NM using a Snowball sampling method (Berg, 1988; Van Meter, 1990). The demographic section of the survey verified that participants met selection criteria.

Before the participant completed the survey, they were given the informed consent letter (Appendix D) to read. The researcher answered all questions prior to participants filling out the survey. No signature was required. Completing the survey implied consent. Willing participants were then asked to fill out the survey and make comments in the margins. Upon completion of the survey participants were asked to place their survey in an unmarked envelope. There were no identifiers collected on the survey. Participation in this study was voluntary and

anonymous. Data collected from the survey was stored in a locked file cabinet in the faculty member's office and shredded after two years. There was no follow-up with these participants.

In summary, three phases were conducted to validate the Food Safety

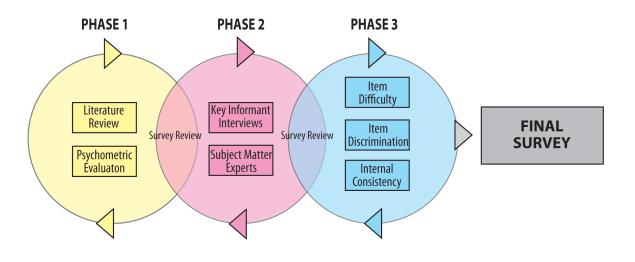
Knowledge survey. Table 1 outlines the critical steps conducted in each phase.

Table 1. Steps taken for each phase of the validation process

Phase 1: Item Generation and Survey Construction	Phase 2: Survey Item Review	Phase 3: Statistical Item Analysis
1. Review of the scientific literature	<ol> <li>Key informant interviews</li> </ol>	1. Item difficulty
2. Psychometric evaluation	2. Establish content validity	2. Item discrimination
	Ž	3. Internal consistency

Figure two graphically illustrates the flow of project implementation demonstrating the reiterative process where each stage informs the next and also reflects back to previous stages.

Figure 2. Project Implementation Flow Chart



#### **Data Analysis**

All quantitative data were entered onto excel spreadsheets and imported into SPSS for analyses (version 19.0, SPSS Inc., Chicago, IL, 2010). A transcript based analysis approach was used to analyze the qualitative data (Krueger & Casey, 2009). Interviews were transcribed verbatim. Resultant themes were analyzed using an intra-case analysis, first examining each case individually, and then using a cross-case analysis, summarizing intra-case themes for differences, similarities, and/or unexpected results (Ryan & Bernard, 2003).

The data collected from the content validity questionnaire were analyzed quantitatively using Factorial Validity Index (FVI), Content Validity Index (CVI) and

Inter-rater Agreement (IRA). FVI was used to determine whether experts were able to correctly identify the content domain of each survey item. CVI was used to assess expert estimation of the essentialness and usefulness of each item to measure food safety knowledge of respondents. IRA was used to measure expert agreement of the representativeness and clarity of each survey item. A 4-point Likert scale was used to estimate level of essentialness, representativeness, and clarity.

Factorial Validity Index (FVI) was calculated by adding the total number of experts who correctly chose the content domain (CD) of the item (Cook, Clean, Chill or Separate) divided by the total number of experts (N). (FVI=Total CD Correct/N)

Content Validity Index (CVI) was calculated by dichotomizing the scale (1-4) into two variables, high (3+4) and low (1+2). The total number of experts identifying the item as either "3" (Item is somewhat useful and somewhat essential) or "4" (Item is essential and useful) divided by the total number of experts (N).  $(CVI=(Construct\ Relevance\ of\ 3+4)/N)$ 

Inter-Rater Agreement-Representativeness/Clarity (IRA-R/C) was calculated by dichotomizing the scale (1-4) into two variables, high (3+4) and low (1+2) agreement. The high agreement was used in the calculation indicating how many experts agree that the item is highly representative or clear.

(IRA-R/C=(# of items 75% agreement or higher)/Total number of items (n=41))

Expert's feedback written in the margins was used as a qualitative method to triangulate the quantitative data. For example, if an item was identified as having low clarity expert feedback was used to reword the item.

Various statistical analyses were conducted to determine item difficulty, item discrimination, and item consistency. Frequencies and descriptive statistics were used to describe the demography of the total sample of participants. The knowledge items were coded such that higher scores reflect favorable answers. Knowledge questions for all domains were coded one for the correct answer and zero for the wrong answer. For questions that have multiple correct answers, individuals scoring 80% or higher received a point for mastery of the item content; below 80% received a zero for not mastering item content. All missing data was coded as a zero because an unanswered question cannot receive a knowledge score. The knowledge survey used in this process and a more detailed discussion of the results is in appendices B and E respectively.

Item difficulty. Frequencies were used to determine survey items to be deleted if the item was too difficult (less than 20%) or too easy (greater than 80%) (Kline, 1993). Every effort was made to retain the integrity of the scale in measuring knowledge when deleting items. In these cases the question stem and/or the response choices were revised to improve the item.

**Item discrimination.** An item-to-total-score correlation of 0.2 was the cutoff point below which items were discarded from the survey (Streiner & Norman, 1992). This was adhered to except in circumstances where an item was critical to the content validity of the scale.

**Internal consistency.** The Kuder-Richardson Formula 20 was used to measure the internal consistency of each of the six content domains in the survey. The minimum requirement for internal consistency was 0.7 (Kline, 1993).

Respondents' comments. In the survey instructions participants were encouraged to use specific notations to indicate survey questions that were confusing or offensive. Question marks were drawn next to unclear or confusing items or words. Offensive items or words were crossed out. Participants were also encouraged to use the margins to comment on why a question or word was confusing or offensive. These written comments provided by the survey respondents were transcribed verbatim and used to modify wording and questions to enhance clarity and cultural appropriateness.

#### **Assumptions**

This study is based on the assumption that Native Americans have higher rates of foodborne illness nationally. Currently the only data available for foodborne illness in Native Americans populations nationally is from FoodNet the Center for Disease Control's foodborne illness active surveillance network (Centers for Disease Control, 2011b). Additionally the study is predicated on the fact that foodborne illness rates are higher in children under the age of ten nationally. The New Mexico data from FoodNet confirms that this is true in New Mexican Native American children under the age of five (Khanlian, 2011) but other national data was not found for this population.

This study assumes that foodborne illness rates will be reduced if food safety knowledge is improved. It remains unproven whether or not persons with increased knowledge about food safety are implementing their knowledge in practice and thus reducing foodborne illness risk.

The results of this study are limited by the methodology's inability to quantify food safety practices. Additional research is recommended to qualitatively address food safety knowledge and its translation into home practice of food handling behaviors in Native American families.

#### **Delimitations**

This study is delimited to self-identified Native American adults, English speaking, and primary food handlers of children under 10 years of age.

#### **Chapter Four: Results**

The purpose of this chapter is to present the results of each phase conducted in this study: Item Generation and Survey Construction, Survey Item Review, and Statistical Item Analysis.

#### Phase 1: Item Generation and Survey Construction

The objectives of Phase 1 were to first generate knowledge items derived from the scientific literature and to solicit advice from a panel of psychometric experts regarding item format, survey construction, and language complexity.

**Review of the scientific literature**. To generate survey items, researchers consulted the relevant food safety literature including validated food safety knowledge surveys (Byrd-Bredbenner et al., 2007; Haapala & Probart, 2004; Medeiros et al., 2004; Meysenburg, 2009; Unklesbay et al., 1998; Wenrich et al., 2003). Food safety experts and registered dieticians extracted survey items fitting within the conceptual framework of the national "Fight BAC" campaign (Partnership for Food Safety Education, 2010). The conceptual framework included four-domain areas: Chill, Separate, Cook and Clean. Two additional categories were added: Foods that Increase Risk of Foodborne Disease and Groups Most at Risk for Foodborne Disease. The SMOG Readability Formula (US Department of Health and Human Services, 1992) was conducted on the survey yielding a 7th grade reading level (Daley, Cowan, Nollen, Greiner, & Choi, 2009; Davis, Michielutte, Askov, Williams, & Weiss, 1998). Certain words and foods were changed to enhance cultural appropriateness. The first iteration of the food safety knowledge survey contained 56 items (Appendix A). Table 2 presents examples of final survey items and the

three different types of response items used: multiple choice questions with one correct answer, multiple choice questions with multiple correct answers, and true or false questions.

Table 2. Examples of knowledge survey items and response options Item Item Item Question **Response Options** Number Domain Multiple Choice (One Correct Answer) 6 Chill b. 3-4 c. 5-7 How long can you store a. 1-2 d. More days \* days than a days raw hamburger and week chicken in the refrigerator to eat later? Multiple Choice (Multiple Correct Answers) 22 Clean a. Soak c. Wash b. c. How should dishes be and dry them in Hand Hand washed to prevent food them in a the wash wash and dishwasher sink for them poisoning? right rinse several hours after them and the right then meal after wash and the them in then meal the let and same them then air-dry water dry them with a dish towel True or False 39 Cook True False Your TV dinner will be cooked properly in your microwave when you follow the package directions.

\* = Correct Answer

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Psychometric Evaluation. The Buros Institute for Assessment Consultation and Outreach (BIACO), an independent psychometric evaluation organization, reviewed the Knowledge Survey for Food Safety for Diverse Families. The review assessed item format, survey construction, and language complexity of the instrument. The review did not assess content, but recommended that an additional review be conducted by experts in the field regarding content. Table 3 outlines the recommendations made by BIACO and changes made to the knowledge survey.

Table 3. Buros Institute for Assessment Consultation and Outreach,

# Recommendations Matrix

Suggested Revisions	Revisions Implemented	Purpose
Directions  *Context - To orient respondents by providing context at beginning of the survey or sections  *Definitions - Define words that respondents may be unfamiliar with at the beginning of the survey	None.	To assist in comprehension of survey instructions and terms.
*Reading-level - Revise language of the question stems and response items to reflect intended population's reading level *Potential revisions are shorter stems and/or response items and simplifying terminology of both stems and responses	Some wording was changed to enhance comprehension.	To reduce cognitive load of respondent and increase validity.  To reduce tendency for respondent to acquiesce (choosing "true" regardless of content), satisfice (to decrease efforts to generate correct answers) and/or suffer fatigue.
Item Format  *The survey uses three types of item formats (multiple choice with 1 correct answer, multiple choice with multiple correct answers, and true or false) *Potential revisions are to group items by their format type, give instructions for each item format and changing items to fit one format style	Items were regrouped by format and instructions were provided at the beginning of each section.	To reduce cognitive load of respondent, increase clarity of the items and decrease the risk of respondent misinterpretation.

Table 3. Buros Institute for Assessment Consultation and Outreach, Recommendations Matrix, continued						
Item Stems *Revise item stems to avoid vague phrasing such as "may" *Use direct questions for item stems whenever possible	"May" was changed to "will likely" in item stems.	To increase clarity and comprehension of items and ensure the item clearly represents the question being asked.				
Response Options  *The response option "I don't know" could elicit a high response rate and become a source of measurement error  *Some items have increasingly complex response options which could indicate a correct response and be too identifiable *Some response items are too close making it difficult to distinguish the correct response *Some response options are clues to other items on the survey and/or are logical subsets of other responses *Some responses are too easy implying a high correct response and will not contribute to the construct measured	Response option "I don't know" was removed in all items, items with response options with above average difficulty (questions about the correct temperature of cooked meats) were removed, additionally certain response options were changed to clearly delineate between answer choices.	To reduce measurement error and correctly measure the construct.				
*Several survey items seemed redundant, reduce redundant items	Some redundant items were deleted, however some remained for further validity testing.	Reducing redundant items reduces cognitive load and time commitment of respondent. Reducing cognitive load and time commitment may increase validity.				

## **Phase 2: Survey Item Review**

The objectives of Phase 2 were to first determine the cultural appropriateness of the knowledge survey for Native American populations through key informant interviews and then to establish content validity using subject-matter

experts in the field of nutrition science and dietetics. The results of the key informant interviews and content validation process are presented.

**Key informant interviews.** Six key informants who fit the demographic criteria for inclusion (English-speaking and literate adults who self-identify as Native American, a primary food-handler in their family with at least one child under ten years of age living in their home) participated in in-depth interviews with the researcher. Table 4 summarizes the demographic data of the participants.

Table 4. Demographic Description of Key Informant Participants

Demographic Identifier	P1	P2	Р3	P4	P5	P6
Gender	Female	Female	Female	Female	Female	Female
Race/ Ethnicity Tribal Affiliation Birth Date/Age	Native American Diné/ Navajo 03/1978 33 yrs.	Native American Diné/ Navajo 10/1975 36 yrs.	Native American Diné/ Navajo 03/1984 27 yrs.	Native American Diné/ Navajo 12/1981 29 yrs.	Native American Diné/ Navajo 06/1980 31 yrs.	Native American Diné/ Navajo 09/1960 51 yrs.
Education Level	Post- College Graduate	College Graduate	Some College	Some College	College Graduate	Less than High School
Food Service	Y	Y	N	Y	NA	Y
Experience	<5 yrs.	3 yrs.		<1 yr.		2-3 mos.
Children Under 10	2	1	3	3	1	1
Meals Prepared a Week	15	14	35	25	18	21
Employment	Volunteer	Part-time	Part-time student	Part-time	Part-time	Not employed

Participants were asked to respond to questions related to cultural appropriateness, survey format, length, wording, language, and content. Table 5 illustrates the interview questions and provides a brief summary of the participants' responses.

Table 5. Key Informant Interview Questions and Summary

Table 5. Key informant interview Questions and Summary						
Category: Question:	Level of Difficulty Overall rate the level of difficulty of the survey. (Were the questions too complex, too hard, or too easy?)	Survey Format Was the survey format appropriate? Did the flow of questions make sense?	Wording and Language Was the wording and language appropriate? Did it make sense? Was anything offensive?			
Summary:	Overall respondents found the survey to be average difficulty appropriate for most individuals.	Participants agreed that the survey format was appropriate and made sense.	Overall the wording and language of the survey was perceived as logical and inoffensive. Many participants felt that the survey would become more culturally appropriate for Native American individuals if certain words were changed or added.			
Category:	Survey Length	Content	Cultural			
Question:	Was the survey length appropriate? How long did it take you to complete? Did you feel like you rushed or did you thoughtfully address each question?	Overall, how did you feel about the content of the survey?	Appropriateness Was the survey culturally appropriate? In your opinion, in gearing this survey towards a Native American population, would you change anything (such as the inclusion of "Feast Days" or certain foods such as beans)?			
Summary:	The majority of participants agreed the survey was an appropriate length. The survey takes from 10 to 30 minutes to complete, the average time to complete the survey is 17 minutes. The majority of participants did not rush.	The majority of participants found the survey informative and suggested that taking the survey influenced or increased awareness of behaviors surrounding food safety when preparing meals.	The survey may not reflect cultural traditions of all Southwestern Native Americans and may not be culturally appropriate. The survey may be more appropriate for Native Americans dwelling off the reservation as opposed to on the reservation.			

Item difficulty. One respondent felt that the survey needed clarification because some of the questions could be trick questions and required a lot of thought. Specifically the respondent mentioned that questions 13 and 20 required more time and thought and needed clarification. Question 13 has lengthy response options that specify the correct hand washing procedure. Question 20 asks about the types of people who can prepare food and it is unclear whether these individuals have taken proper precautions, such as hand washing, to prevent the spread of foodborne illness.

Survey format. Two of the respondents took the survey before it was reformatted based on the psychometric evaluation. These two respondents both felt that the survey was too lengthy and time consuming. The remaining four respondents did not agree that the survey was too lengthy but thought that it was appropriate. The reformatting of the survey by grouping the questions by their item type (multiple choice question with one correct answer, multiple choice question with multiple correct answers, and true or false questions) appears to reduce perceived respondent burden.

Cultural appropriateness. Participants agreed that the inclusion of traditional foods such as beans and corn would make the survey more culturally appropriate. However, respondents cautioned that regional variability of Native American food preferences should be taken into account. The respondents agreed that "stew" is a more culturally appropriate word than "soup". Respondents also agreed that most southwestern Native Americans do not eat seafood and therefore

do not know the likelihood of it causing foodborne illness. For example, most respondents did not know what "ceviche" was.

When asked if the inclusion of "feast days" or "powwows" would improve cultural appropriateness respondents cautioned that all Native American tribes have different cultural celebrations. It may be more appropriate to use a more generic term such as "traditional gathering" or "traditional celebration".

One respondent was offended by the demographic questions D5 and D6 that ask, "What United States generation are you" and "how long you have been living in the United States". These questions were intended for the Hispanic population and do not provide any useable data for Native American respondents. These questions will be removed for further testing of the survey instrument.

Many respondents did not feel that the survey would be culturally appropriate, and could potentially be offensive, for Native Americans living on "the reservation". Respondents elaborated saying that on the reservation access to resources are limited. Many residents on the reservation do not have access to running water or electricity in the home. Much of the survey assumes that survey respondents are living in average American living conditions. Additionally respondents added that many residents on the reservation are impoverished and also have limited access to education, technology, grocery stores (where they can buy fresh grocery products), and may have limited ability to store their leftover food. Many Native Americans living on the reservation still raise and butcher their own meat. Further discussion of cultural appropriateness is in the discussion chapter and appendix E for more detailed results.

Content validity. Six subject-matter experts in the field of Nutrition

Sciences and Dietetics completed the content validity food safety questionnaire.

Experts rated survey items across four validity factors: content domain match,

construct relevance, representativeness, and clarity. A 4-point Likert scale with

varied anchors was provided. Three types of analyses were conducted to determine

degree of content validity: factorial validity index, content validity ratios, and inter
rater agreement. Results of these analyses were used to inform decisions whether

to retain, delete, or revise each survey item.

*Factorial validity index.* Factorial Validity Index (FVI) measures expert ability to correctly associate a survey item with the correct content domain (Cook, Clean, Chill, or Separate). FVI is calculated by adding the total number of experts who correctly identified the content domain divided by the total number of experts: FVI=Total CD Correct/N. An FVI of at lease 0.8 is recommended (Rubio et al., 2003). The mean FVI, 0.81, was high among all survey items (n=41) indicating that most experts correctly identified each item's content domain (Cook, Clean, Chill, or Separate). Of the 41 survey items experts correctly identified 35 with the appropriate domain match. Only six survey items (survey questions: 7, 11, 20, 21, 40, & 41) scored a low FVI indicating that these survey items may not accurately measure the content domain they were constructed to measure. FVI was not calculated for items from the Foods that Increase Risk of Foodborne Disease and the Groups at Greatest Risk for Foodborne Disease content domains because these were not content domain match options. When survey items were analyzed within their respective content domains the FVI remains high in all domains excluding Separate.

Cook FVI=0.97, Clean FVI=0.93, Chill FVI=0.87 and Separate FVI=0.37. See appendix E for more detailed results.

each item's relevance and essential quality to measure food safety knowledge. In other words, how necessary is each item to measuring food safety knowledge (Lawshe, 1975). CVI was calculated by dichotomizing the 4-point Likert scale into high and low values and then dividing the total number of experts who identified the item as highly essential by the total number of experts: *CVI=(Construct Relevance of 3+4)/N.* A CVI of 0.8 is recommended to establish the item's content validity (Rubio et al., 2003). CVI ranged from 0.5 to 1.0. The majority of items (37/41) scored high CVI, above 0.8. The remaining four items (26, 29, 30, 39) scored a low CVI and will be either revised or omitted. See appendix E for more detailed results and information.

**Representativeness.** Representativeness refers to an item's ability to represent the content domain it was designed to measure. Some content domains were not answer choices so they have been eliminated from all calculations for representativeness. Inter-Rater Agreement (IRA) for representativeness was calculated by first dichotomizing the 4-point Likert scale into high (3+4) and low (1+2) representativeness and then dividing the highly representative items by the total number of experts. Then the number of items scoring above 75% were added together and divided by the total amount of survey items that were used to analyze representativeness: IRA=(# of items 75% agreement or higher)/Total number of items (n=27) (Rubio et al., 2003). An IRA of 0.75 was used to establish

representativeness. The mean IRA for representativeness of all survey items was 0.93. The majority of survey items (25/27), scored high representative values. The two survey items that scored low representativeness (22 & 41) will be revised or omitted. See appendix E for more detailed results and information.

Clarity. Clarity refers to how clearly an item is worded. Inter-Rater Agreement (IRA) for clarity was calculated by first dichotomizing the 4-point Likert scale into high (3+4) and low (1+2) clarity and then dividing the high clarity sum by the total number of experts. The number of items scoring above 75% were then added together and divided by the total number of survey items: IRA=(# of items 75% agreement or higher)/Total number of items (n=41) (Rubio et al., 2003). An IRA of 0.75 was used to establish clarity. The IRA for clarity of all survey items was 0.88. The majority of survey items (36/41) scored high IRA for clarity. The survey items scoring low IRA for clarity (19, 22, 25, 28, & 30) will be revised using expert comments to enhance clarity. See appendix E for more detailed results and information.

Table 6 lists all survey items that scored low factorial validity index (below 0.8), low content validity index (below 0.8), and low inter-rater agreement (below 0.75) for representativeness and clarity. The remaining survey items all scored high across all four validity criteria.

Table 6. Identifying Survey Items for Review

Item	Factorial	Content	Inter-rater	Inter-rater
	Validity	Validity	Agreement-	Agreement-
	Index	Index	Representativeness	Clarity
7	0			
11	0.5			
19				0.66
20	0			
21	0			
22			0.66	0.66
25				0.5
26		0.66		
28				0.5
29		0.66		
30		0.66		0.5
39		0.5		
40	0.66			
41	0.66		0.66	

### **Phase 3: Statistical Item Analysis**

The objectives for phase 3 are to quantitatively analyze item difficulty, item discrimination, and internal consistency. The results will be used to determine items to retain, revise, or omit.

**Scale refinement.** Descriptive statistics and frequencies were used to construct the demographic data. The table below lists the demographic data of the 28 survey respondents used in phase 3 of survey validation: statistical item analysis.

Table 7. Demographic Data of Survey Respondents

Gender	Male	Female	Un-				
denuei	Male	remate	known				
	2.60/	02.00/	3.6%				
	3.6%	92.8%	3.6%				
	T	1		T	T	1	ı
Race/	Native	Navajo	Other				
Ethnicity	Amer.		Tribes				
	100%	82%	18%				
Mean Age	38.8						
Education	<1 yr.	Some	High	Additional	Some	College	Post
	High	High	School/	Training	College	Grad.	College
	School	School	GED	J			
	7.1%	7.1%	25%	3.6%	35.7%	21.4%	0%
	11270	11270		0.070	70		- 70
Food Exp.	Yes	No					
Toou Exp.	165	110	Un-				
			known				
	39.3%	57.1%	3.6%				
	03.070	071270	0.070				
Average Amt.	1.86						
of Children	1.00						
or children	<u> </u>						
Average Meals	19.9						
Prepped a Wk.	19.9						
rieppeu a wk.							
Employers	1	E 0	1		1	I	1
Employment	F 0	Emp. &				F 0	
	Emp. &	Work	П 0	П 0		Emp. &	
	Work	Outside	Emp. &	Emp. &		Work	
	Outside	of Home	Work at	Work at		Outside	
	of Home	Part-	Home	Home Part-	Not	of Home	
	Full-Time	Time	Full-Time	Time	Emp.	Full-Time	
	32.10%	14.30%	7.10%	3.60%	42.90%	32.10%	

Descriptive statistics were used to analyze average knowledge scores for the entire survey and across each content domain. Table 8 illustrates the average knowledge scores across each content domain.

Table 8. Mean Knowledge Scores (% Respondents Answered Correctly)

Knowledge	Total	Chill	Separate	Clean	Cook	Groups*	Foods*
Mean	49%	57%	54%	59%	40%	13%	46%

<sup>\*</sup>Groups Most at Risk for Foodborne Disease

<sup>\*</sup>Foods that Increase Risk of Foodborne Disease

Item difficulty. Test construction recommendations suggest that items should be correctly answered by respondents 20-80% of the time (Kline, 1993). Using frequencies, items were analyzed to determine item difficulty, or the percentage of the respondents who correctly answered each question. Any item identified as either too easy (greater than 80% of respondents correctly answered the item) or too hard (less than 20% of respondents correctly answered the item) was reassessed. First, the Content Validity Index (CVI) of each item was referenced to determine the item's relevance to the construct being measured, food safety. If an item was determined to be essential to the measurement of food safety knowledge the item was retained and revised. If an item scored a low CVI it was considered for omission.

If a multiple-choice question was marked as either too easy (a frequency of 80% or above) or too hard (a frequency of 20% or below) then the answer choices, distracters, were also examined for frequency of choice, a process known as distracter analysis. Distracters, or answer choices, identified as either too easy or too hard were considered for omission or revision.

Table 9 presents the items that were identified as either too easy or too hard in the frequency analysis. The "correct" and "incorrect" columns show the percentages of respondents who either answered the item correctly or incorrectly. If a frequency was above 0.8 or below 0.2 it was marked as either too easy or too hard. All of the multiple choice questions were additionally analyzed using the distracter analysis. If an answer choice, distracter, was identified as being either too

easy or too hard it was further examined for revision or omission. The distracter analysis and further explanation can be found in appendix E.

Table 9. Item Difficulty

			Too	Too
Item	Correct	Incorrect	Easy	Hard
1	64.3	35.7		
2	85.7	14.3	X*	
3	75	25		
4	14.3	85.7		X*
5	14.3	85.7		Х*
6	78.6	21.4		
7	75	25		
8	28.6	71.4		
9	92.9	7.1	X*	
10	82.1	17.9	X*	
11	89.3	10.7	X*	
12	53.6	46.4		
13	60.7	39.3		
14	57.1	42.9		
15	78.6	21.4		
16	39.3	60.7		
17	25	75		
18	42.9	57.1		
19	39.3	60.7		
20	14.3	85.7		X*
21	57.1	42.9		
22	17.9	82.1		X*
23	32.1	67.9		
24	35.7	64.3		
25	7.1	92.9		X*
26	17.9	82.1		X*
27	42.9	57.1		
28	28.6	71.4		
29	21.4	78.6		
30	3.6	96.4		X*
31	71.4	28.6		
32	17.9	82.1		X*
33	17.9	82.1		X*
34	71.4	28.6		

Table 9. Item Difficulty, Continued						
35	92.9	7.1	X			
36	64.3	35.7				
37	78.6	21.4				
38	35.7	64.3				
39	57.1	42.9				
40	82.1	17.9	X			
41	60.7	39.3				

<sup>\* =</sup> Analyzed using the distracter analysis

Item discrimination. An item-to-total-score correlation was performed to identify items that negatively impacted a respondent's total score. Items receiving a 0.2 or below were either revised or discarded from the survey (Streiner & Norman, 1992). Table 10 depicts each survey item, their item-to-total score, and the internal consistency of the survey if the item is deleted. Items with an item-to-total score, below 0.2, are marked with an "X" for being too low. Each of these items will be compared to the expert assigned content validity index to determine the essentialness of each item.

Table 10. Item Discrimination

	I-total-		Rif
Item	score	Too Low	deleted
S1	-0.134	X	0.793
S2	0.074	X	0.793
S3	0.233		0.793
S4	-0.312	X	0.793
S5	0.106	X	0.793
S6	0.394		0.793
S7	-0.023	X	0.793
S8	0.208		0.793
S9	0.076	X	0.793
S10	-0.198	X	0.793
S11	-0.144	X	0.793

Table 10. Item Discrimination, Continued					
S12	0.038	X	0.793		
S13	-0.023	X	0.793		
S14	-0.033	X	0.793		
S15	-0.163	X	0.793		
S16	0.199		0.793		
S17	0.083	X	0.793		
S19	-0.062	X	0.793		
S20	-0.098	X	0.793		
S21	-0.039	X	0.793		
S22	-0.24	X	0.793		
S23	-0.074	X	0.793		
S24	-0.183	X	0.793		
S25	0.029	X	0.793		
S26	0.196		0.793		
S27	0.269		0.793		
S28	0.162	X	0.793		
S29	0.225		0.793		
S30	0.084	X	0.793		
S31	0.507		0.792		
S32	0.135	X	0.793		
S33	0.196		0.793		
S34	0.603		0.779		
S35	0.514		0.775		
S36	0.78		0.761		
S37	0.783		0.761		
S38	0.733		0.757		
S39	0.596		0.774		
S40	0.785		0.761		
S41	0.826		0.75		

Internal consistency. Internal consistency of the entire survey and each content domain was measured using the Kuder-Richardson Formula 20. An internal consistency of 0.7 is recommended (Cronbach, 1951). When respective content domains were measured, the reliability for all constructs is low (Chill=0.45, Separate=0.222, Clean=-0.12, Cook=0.014, and Groups=-0.272) except for the Foods

category (0.704). However, when the items are grouped together as one construct, measuring food safety knowledge, the internal consistency was high at 0.793. Reliability of measuring instruments is higher when there are more test items (cite textbook). It may be that items are not accurately measuring the construct they were designed to measure. The Factorial Validity Index (FVI) for each item was referenced to determine whether subject-matter experts could correctly identified each item's content domain. Tables presenting the internal consistency of each content domain are contained in appendix E.

Table 11 synthesizes the items identified in the content validity and scale refinement processes that were either revised or omitted. Items that scored low in factorial validity index (below 0.8), content validity index (below 0.8), inter-rater agreement (below 75%, for reliability or clarity), and item-to-total-score correlation (below 0.2) are marked with an "X" to indicate the item's specific weakness.

Table 11. Synthesized Results Table

Item	Factorial Validity Index	Content Validity Index	Inter- Rater Agg Rep.	Inter- Rater Agg Clarity	Frequenci es	Item- total score
1						X
2					X	X
3						
4					X	X
5					X	X
6						
7	X					X
8						
9					X	X

	1			T		1
10					X	X
Table 11. Synthesized Results Table, Continued						
11	X				X	X
12						X
13						X
14						X
15						X
16						
17						X
18						X
19				X		X
20	X				X	X
21	X					X
22			X	X	X	X
23						X
24						X
25				X	X	X
26		X			X	
27						
28				X		X
29		X				
30		X		X	X	X
31						
32					X	X
33					X	
34						
35					X	
36						
37						
38						
39		X				
40	X				X	
41	X		X			

#### **Chapter Five: Discussion**

The purpose of this chapter is to discuss and synthesize the results of this study.

This study established a content valid, reliable, and culturally appropriate survey for Native American populations. To date, surveys have been validated and tailored for other populations from college students and young adults (Byrd-Bredbenner et al., 2003; Unklesbay et al., 1998) to pregnant women (Cates et al., 2004) but surveys targeting diverse populations, such as Hispanic and Native American, in which rates of foodborne illness exceed those of ethnic majority populations were not found in the literature. Previous research has indicated an increased risk of foodborne illness in these populations (Centers for Disease Control, 2007a; Lay et al., 2002; Palmeri et al., 1998; Patil et al., 2005; Racz et al., 2009; Taylor et al., 2000; Voetsh et al., 2007) but to date no study was found that tried uncover the possible causes. This validated knowledge survey can now be used to assess whether these heightened rates are due to an existent knowledge gap.

Each phase of survey validation provided the research team with valuable insight into modifications and revisions to the survey. The phases followed an organic process that constantly reflected back on other phases to triangulate data and affirm survey modifications. In Phase 1, researchers were able to construct a survey based on the research literature (Albrecht, 1995; Angelillo et al., 2000; Boone et al., 2005; Brewer and Prestat, 2002; Bruhn & Schutz, 1999; Cates et al., 2004; Johnson et al., 1998; Kennedy et al., 2005; Li-Cohen & Bruhn, 2002;

Partnership for Food Safety Education, 2010; Raab & Woodburn, 1997; Redmond & Griffith, 2004; Unklesbay et al., 1998; Wenrich et al., 2003) and then parse it down based on recommendations from an independent psychometric evaluator. These recommendations allowed researchers to remove survey response items that would not contribute to measurable results and reformat the survey to reduce perceived respondent cognitive burden. The survey was initially constructed with 56 items but after the psychometric evaluation was parsed down to 41. This 41-item food safety knowledge survey was used in Phases 2 and 3 of survey validation.

In Phase 2 researchers assessed cultural appropriateness using key informant interviews with individuals from the population subset and content validity with subject-matter experts from the field of nutrition science and dietetics. The key informant interview process of Phase 2 allowed researchers to subjectively assess the survey from the eyes of the intended population, Native American. Demographic items 5 and 6 were perceived as offensive and were removed from the survey. Without the subjective cultural perspective of the key informants interviewed such clear recommendations may not have been implemented and could have contributed to invalidation due to respondent bias.

Subject-matter experts also proved essential to evaluating each question's ability to measure the appropriate content domain, it's essential relevance to measuring food safety knowledge, each item's clarity, and representativeness.

Previous research (Lawshe, 1975; Rubio et al., 2003; Rungtusanatham, 1998) indicates that similar processes have been used to validate survey content objectively. Survey items averaged high content validity across all four content

criteria. Weak survey items were identified and marked for revision or deletion. The factorial validity index (FVI) was used to identify survey items that did not accurately measure the designed construct. Without this objective vantage researchers may have been confounded when the internal consistency of each content domain scored low reliability. With this measure (FVI) quantified, researchers can now answer why.

This step, establishing content validity with subject-matter experts, additionally allowed researchers to quantitatively and qualitatively assess items identified as having low content validity. Researchers were also able to return to the qualitative data and rework items to enhance clarity based on the objective perspective of the expert third party. This step in Phase 2 was used to identify survey items that may pose threats to validity and reliability of the survey instrument. This information was used to triangulate the data collected in Phase 3 and provide a framework to base the retention, deletion, or omission of survey items.

In Phase 3 the survey underwent a preliminary statistical analysis assessing item difficulty, item discrimination, and internal consistency. This process yielded additional quantitative measures supporting the processes used in the second step of Phase 2, subject-matter expert content validation. This process assisted researchers in determining items that were statistically unsound (Tables 9 & 10). These items were then compared to the data from subject-matter experts (Table 11) to assist researchers in retaining, revising, or deleting survey items. Researchers used the distracter analysis to omit answer choices that did not yield measureable

results. After deleting distracters researchers were able to combine questions 27-33 into one item, condensing the survey from 41 items to 34. Overall, the survey was internally consistent at 0.793. The Separate content domain was confirmed to be a weak link in measuring the content domain. Surveys designed with fewer items may decrease respondent burden but will score lower reliability. This is another reason why the individual content domains should be viewed collectively as one construct, food safety knowledge.

Cultural appropriateness is difficult to generalize in Native American populations nationally due to high regional variability. All key informants interviewed in this process were from the Dine or Navajo Nation located in the four corners area where New Mexico, Arizona, Utah and Colorado intersect. One key informant pointed out that there are differences in food consumption between the Pueblo and Tribal Native Americans living in New Mexico. For instance the pueblo cultures eat buffalo but the Navajo do not. One respondent thought adding traditional foods such as beans and corn would improve cultural relevance but certain foods that are considered traditional, such as "fry bread" are not traditional and would only serve to promote and perpetuate unhealthy cultural food practices.

There is considerable discrepancy of beliefs and practices among Native

Americans living on and off the reservation or tribal land. Most key informants

agreed that this survey would be culturally inappropriate and even offensive if given
to a Native American living on the reservation. One reason is the limited access and

availability of resources on the reservation such as water or grocery stores—

questions about how fresh the water you wash your dishes in become irrelevant and

in some cases offensive. One key informant grew up on the Navajo reservation.

When she left the reservation she was behind educationally and technologically.

This lack of education could also be a factor. If the resulting food safety knowledge survey were to be administered on the reservation it would need additional pilot testing and more key informant interviews to address the differences in environment and culture of Native Americans living on and off the reservation.

# Chapter 6: Conclusions, Limitations, Recommendations, and Implications Conclusion

The process of determining content validity used in this study is recommended for future research. Although the process is initially time consuming and lengthy it will reduce the amount of time spent on future revisions. Key informant interviews proved valuable in enhancing cultural relevance within Native American populations. The Expert Content Validity Questionnaire provided both quantitative and qualitative data that can be used to revise the survey to enhance content validity. The statistical analyses further identified weak items that could be revised or omitted without reducing reliability of the survey instrument.

#### Limitations

This study is limited by regional proximity to Southwestern Native American cultures. Regional variability among American Indian nations and tribes exists but this study only encompasses the views of Native American residents living in New Mexico.

All data collected from Native American respondents, including the key informants and survey respondents came from Native Americans living off reservations in New Mexico. Native Americans living off reservations have differing access to resources, food handling practices, and food choices. The data collected and results generated are not intended to reflect the beliefs and practices of Native American populations living on reservations or tribal lands.

The data collected and results generated in Phase 3, Statistical Item Analysis, are to be considered preliminary. Final analysis will be conducted when the sample size reaches at least 50 respondents.

#### **Recommendations for the Food Safety Knowledge Survey**

#### Key informant interview recommendations.

- Key Informant Interviews should be conducted in the other regions of the United States to assess cultural appropriateness of survey wording and language. Interviews should focus specifically on traditional foods and gatherings.
- 2. Survey wording should remain generic and inclusive. Native American festivals such as Feast Days and Powwows are specific to each tribe or nation. Gathering or festival would be more regionally inclusive.
- 3. Key informants expressed their desire to know their knowledge scores and asked for resources to affirm their food safety home practices. Respondents participating in further phases of study implementation should be given a quick home reference of correct food safety practices to implement at home. A website or additional resource that contains more detailed information should also be given to all respondents in case they want more information.
- 4. An additional question should be considered addressing roadside food vending. Key informants suspected this practice as a possible avenue for foodborne disease transmission in Native American communities in New Mexico. Although food vendors are supposed to be food safety certified in the state of New Mexico, key informants questioned whether they were.

- 5. Reformat survey questions 13 and 20 to enhance clarity and reduce respondent cognitive burden. Key informant interviews identified these two questions as requiring more time and thought.
- 6. The cultural validity of the survey may be additionally enhanced if the survey is back translated into the language of each tribal nation. This would reinforce validity by reducing the possibility for misinterpretation due to cultural linguistic phrasing.
- 7. Once the scale has been modified in any way it should be tested in focus groups to reassess cultural appropriateness.

#### Content validity recommendations.

- 8. Survey items 7, 20 and 21 were all designed to measure the content domain Separate. Experts agreed these numbers measured the construct Clean. It is recommended that these three items be moved to the construct Clean or be revised to more accurately measure the food safety construct Separate.
- 9. Experts identified repetitive or redundant questions. These items should be either combined or revised. Experts found items 11, 12 and 23 redundant. These items address correct counter or cutting board sterilization to prevent food poisoning. Experts identified items 15 and 21 as redundant. Both address hand-washing behavior after changing a dirty diaper. Survey items 16 and 17 address the proper way to tell if meat is cooked. The two questions ask about different types of meat (chicken and hamburger) but may be measuring the same construct.
- 10. Expert comments should be used to enhance clarity of survey items.

#### Statistical item analysis recommendations.

- 11. Once adequate sample size has been met (n=50) all statistical analyses should be re-run to determine survey items and response options that should be revised or omitted.
- 12. Items should be grouped together and analyzed as one scale, measuring food safety knowledge, instead of being separated into content domains.
- 13. Items or response choices identified as too easy or too hard are to be revised or omitted.
- 14. After survey revisions are made, additional surveys should be distributed and statistical analyses should be re-run to determine if validity and reliability of the survey instrument is stable, worsens, or improves.
- 15. A confidence scale should be added each survey item and at the end of the survey to assess the respondent's level of confidence and perception of their knowledge level of food safety.

#### **Recommendations for Future Research**

Future research should be conducted comparing food safety knowledge and behaviors of Native American populations living both on and off tribal land or reservations. Rates of foodborne illness of Native Americans living on and off tribal lands should be collected so that researchers can assess whether the heightened rates of foodborne illness are similar among both populations. Additionally each population should be analyzed for their readiness and ability to change behaviors.

It is inconclusive as to why rates of foodborne illness are higher among

Native American populations living in New Mexico. A knowledge survey can help to

determine individuals' knowledge of food safety but is insufficient to determine whether that knowledge is being used in home practice of food preparation. More qualitative research must be conducted to determine the risk factors, behaviors and practices that may contribute to increased rates of foodborne illness.

Regional variability may exist between Native American rates of foodborne illness and food safety knowledge and practices. Future research should focus on first on establishing rates of foodborne illness in Native American populations. If it is confirmed that these rates are indeed heightened then further investigation is required to determine the causal relationship between knowledge of food safety, cultural food practices, and increased risk of foodborne illness.

The purpose of this study was to create a valid, reliable and culturally appropriate survey not to generate knowledge scores of respondents. This validated survey should now be distributed to a larger group of Native American respondents to determine if there are knowledge gaps that may be related to food safety practices.

#### **Implications**

This study established a valid, reliable, and culturally appropriate survey for Native American populations. To date, surveys have been validated and tailored for other populations from college students and young adults (Byrd-Bredbenner et al., 2003; Unklesbay et al., 1998) to pregnant women (Cates et al., 2004) but diverse populations, such as Hispanic and Native American, in which rates of foodborne illness exceed those of ethnic majority populations, have not been addressed. Previous research has indicated an increased risk of foodborne illness in these

populations (Centers for Disease Control, 2007a; Lay et al., 2002; Palmeri et al., 1998; Patil et al., 2005; Racz et al., 2009; Taylor et al., 2000; Voetsh et al., 2007) but to date no study was found in the research literature that has sought to uncover the possible causes. This validated knowledge survey can now be used to assess whether these heightened rates are due to an existent knowledge gap.

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## Appendices

### Appendix A: Food Safety Knowledge Survey (Phase 1)

# **Knowledge Survey for Food Safety for Diverse Families**1. Gender:

1. Gender:	
□ Male	□ Female
2. Race/Ethnicity:	
<ul> <li>Caucasian</li> </ul>	or White
□ Native Am	nerican (Tribe/Pueblo name)
□ African A₁	nerican or Black
□ Hispanic,	Latino or Spanish origin
□ Asian	
□ Other, ple	ase specify
3. What is your bir	th date (month/year)?
4. City, State, Count	try of birth
5. How long have y	ou been living in the U.S.?
6. What United Sta	tes generation are you (if known/applicable)?
<ul> <li>□ Less than</li> <li>□ Some high</li> <li>□ High scho</li> <li>□ Additiona</li> <li>□ Some coll</li> <li>□ College gr</li> <li>□ Post-Colle</li> </ul>	n school ol (graduate or GED) l training beyond high school (not college) ege raduate ege graduate
related job? (Th: □ I have nev	llowing best describes your experience in a food or nutrition is includes working in a restaurant or fast food) wer worked in a food or nutrition related job; <i>Go to question 9</i> wy work or did work in a food or nutrition related job; <i>Go to</i>
9. How many child household?	r(s) did you work in a food or nutrition related job?Year(s) ren aged 10 years or younger are currently living in your
_	ıls a <u>week</u> do you make for your children (include snacks and

#### 11. Are you:

□ Employed and work outside of the home full-time
 □ Employed and work outside of the home part-time
 □ Employed and work at home full-time
 □ Employed and work at home part-time
 □ Not employed

#### **Survey Directions:**

- Choose 1 answer for each question. Unless the question states otherwise.
- If you do not know the answer, choose "I don't know." Please do not guess.
- If you do not understand the question, please put a question mark (?) If possible, make comments on why it is confusing.
- If you find the question offensive, please cross it out and comment on why it offends you.
- Please feel free to write any other comments or opinions about this survey in the margins.

## Please <u>circle</u> your answer.

#### **CHILL**

- 1. What is a safe freezer temperature for preventing food poisoning?
  - a.  $0^{0}F$  (-18 $^{0}C$ )
  - b. 18<sup>0</sup>F (-8<sup>0</sup>C)
  - c.  $24^{0}F(-4^{0}C)$
  - d.  $32^{0}F(0^{0}C)$
  - e. I don't know
- 2. Your electricity went off in your freezer and the meat, chicken, and fish thawed and felt warm. What should you do to prevent food poisoning?
  - a. Throw them away
  - b. Cook them right away
  - c. See how they smell or look before deciding what to do  $% \left\{ \mathbf{r}_{i}^{\mathbf{r}_{i}}\right\} =\mathbf{r}_{i}^{\mathbf{r}_{i}}$
  - d. Immediately re-freeze until solidly frozen, then cook it
  - e. I don't know

- 3. What is the highest temperature your refrigerator should be to prevent your food from getting spoiled?
  - a.  $0^{0}$ F (-18 $^{0}$ C)
  - b. 25°F (-4°C)
  - c.  $40^{0}$ F ( $4^{0}$ C)
  - d. 45°F (7°C)
  - e.  $60^{\circ}$ F ( $16^{\circ}$ C)
  - f. I don't know
- 4. Your child is going to be eating 2 hours after you cook a meal. How should you keep the meal safe before your child eats it?
  - a. Store it in the refrigerator and reheat it when the child is ready to eat it
  - b. Place it on the kitchen counter until the child is ready to eat it
  - c. Store it in a cool oven until the child is ready to eat it
  - d. Store it in a warm oven until the child is ready to eat it
  - e. I don't know
- 5. Which food needs to be refrigerated to prevent food poisoning?
  - a. Apples
  - b. Dried corn
  - c. Open box of raisins
  - d. Corn bread
  - e. An open can of beans
  - f. I don't know
- 6. Circle the safe way(s) to thaw frozen meat? (Circle <u>all</u> that apply)
  - a. In the refrigerator
  - b. In the microwave
  - c. On the countertop
  - d. Under running water
  - e. Put in a sink filled with water
- 7. What is the safest way to cool a large pot of hot soup?
  - a. Put the soup in a clean shallow pan and refrigerate it right away
  - b. Place the cooking pot filled with soup in the refrigerator right away
  - c. Transfer the soup to a clean, deep pot before refrigerating it
  - d. Leave it on the counter until it cools to room temperature, then refrigerate
  - e. I don't know
- 8. If a leftover food looks and smells good, it is still safe to eat.
  - a. True
  - b. False
  - c. I don't know

- 9. How long can you store <u>cooked</u> hamburger and chicken in the refrigerator to eat later?
  - a. 1-2 days
  - b. 3-4 days
  - c. 5-7 days
  - d. More than a week
  - e. I don't know
- 10. How long can you store <u>raw</u> hamburger and chicken in the refrigerator to eat later?
  - a. 1-2 days
  - b. 3-4 days
  - c. 5-7 days
  - d. More than a week
  - e. I don't know
- 11. Deli foods or luncheon meat kept beyond the expiration date are safe.
  - a. True
  - b. False
  - c. I don't know

#### **SEPARATE**

- 1. If you have a cut or sore on your hand, what should you do before you prepare food for your family?
- a. Nothing, if it is not infected
- b. Put a bandage on the cut or sore
- c. Wash hands
- d. Put a bandage on the sore and wear a glove
- e. I don't know
- 2. Where is the best place to store raw meat in the refrigerator
- a. On the top shelf
- b. Where there is space
- c. Below ready-to-eat foods, like salad
- d. It does not matter
- e. I don't know

- 3. To prevent food poisoning, which of these individuals should not prepare food for other people? (Circle <u>all</u> that apply)
- a. A person with diarrhea
- b. A person with sores or pimples on face
- c. A person with a fever
- d. A person with a rash
- e. A person who smokes
- f. A person with a sore throat
- g. A person with allergies
- h. A person who has just vomited
- i. A person with a runny nose
- 4. When preparing food, you should wash your hands after touching which of these?

#### (Circle all that apply)

- a. Your face
- b. Dirty pots and pans
- c. Fresh fruit
- d. Dishes that came out of the dishwasher
- e. Clean countertop
- f. Cell phone or home telephone
- g. Tissue after blowing nose
- h. Dirty diaper
- 5. Putting raw meat in a separate bag (away from other food items) before placing it in the grocery cart:
- a. Increases the chance of food poisoning
- b. Decreases the chance of food poisoning
- c. Makes no difference

#### **CLEAN**

- 1. How should you wash fresh fruits and vegetables to keep you from getting food poisoning?
  - a. Wash with regular soap
  - b. Wash with hot water
  - c. Wash with anti-bacterial soap
  - d. Hold under cool running water
  - e. I don't know

- **2.** After you have used a cutting board to slice raw meat or chicken, or fish and need to cut other foods, which of these is the best way to prevent food poisoning?
  - a. Wipe the cutting board off with a paper towel
  - b. Rinse the cutting board under very hot water
  - c. Turn the cutting board over and use the other side
  - d. Wash the cutting board with hot soapy water and rinse
  - e. I don't know

## 3. How should dishes be washed to prevent food poisoning? (Circle <u>all</u> that apply)

- a. Soak them in the sink for several hours and then wash them in the same water
- b. Hand wash them right after the meal and then let them air-dry
- c. Hand wash and rinse them right after the meal and then dry them with a dish towel
- d. Wash and dry them in a dishwasher
- e. I don't know
- 4. How should kitchen counters be cleaned to prevent food poisoning?
  - a. Spray with a strong bleach solution
  - b. Wash with hot soapy water, rinse and wipe with a bleach solution, or Lysol™
  - c. Wash with hot soapy water and wipe dry
  - d. Brush off any dirt or food, then wipe with a bleach solution
  - e. I don't know
- 5. What is the best way to wash your hands?
  - a. Apply sanitizer, run water, rub hands together for 20 seconds, rinse hands, dry hands, rub on an antiseptic hand lotion
  - b. Apply soap, rub hands together for 20 seconds, rinse hands under water, dry hands, apply sanitizer
  - c. Run water, moisten hands, apply soap, rub hands together for 20 seconds, rinse hands, dry hands
  - d. Run water, moisten hands, apply sanitizer, rub hands together for 20 seconds, rise hands, dry hands, rub on antiseptic hand lotion
  - e. I don't know
- 6. Which is an acceptable way to clean a cutting board or counter after it is used for raw meat? (Circle all that apply)
  - a. Rinse well with water
  - b. Wipe with a dishrag
  - c. Wash with hot soapy water only
  - d. Wash with hot soapy water, rinse with water, then rinse with bleach

- e. Clean with a disinfectant (example: Lysol, Clorox, bleach)
- f. Wash cutting board in a dishwasher
- g. I don't know
- 7. Washing hands after changing a diaper:
  - a. Increases the chance of food poisoning
  - b. Decreases the chance of food poisoning
  - c. Makes no difference

#### СООК

- 1. For hamburger to be safe to eat, it needs to be cooked until its internal temperature reaches
  - a.  $90^{0}$ F ( $32^{0}$ C)
  - b. 125°F (52°C)
  - c. 160°F (71°C)
  - d. 250°F (121°C)
  - e. I don't know
- 2. All foods are considered safe when cooked to an internal temperature of
  - a.  $130^{\circ}$ F ( $54^{\circ}$ C)
  - b. 140°F (60°C)
  - c. 150°F (66°C)
  - d. 165°F (74°C)
  - e. I don't know
- 3. What is the **best** way to tell if hamburgers are cooked enough to prevent food poisoning?
  - a. Cut one to Circle the color of the meat inside
  - b. Circle the color of the juice to be sure that it is not pink
  - c. Measure the temperature with a food thermometer
  - d. Circle the texture or firmness of the meat
  - e. I don't know
- **4.** What is the **best** way to tell when chicken has cooked long enough?
  - a. The juices run clear
  - b. The meat is not pink in the center
  - c. The meat falls off the bone
  - d. Test with a meat thermometer
  - e. I don't know

- 5. When cooking in a microwave, you should know your microwave wattage.
  - a. True
  - b. False
  - c. I don't know
- 6. Your TV dinner will be cooked properly in your microwave when you follow the package directions.
  - a. True
  - b. False
  - c. I don't know
- 7. A food is properly cooked in a microwave oven when (Circle all that apply)
  - a. The food looks done
  - b. You follow directions on the package
  - c. You stir the food about half way through cooking
  - d. You use a turntable in the microwave
  - e. The food feels hot
  - f. You test the food with a thermometer
  - g. I don't know
- 8. To prevent food poisoning, how long should leftover soup be heated?
  - a. Until it is boiling hot
  - b. Just until it is hot, but not too hot to eat right away
  - c. When it is at least room temperature
  - d. Reheating isn't necessary
  - e. I don't know

#### GROUPS AT GREATEST RISK FOR FOODBORNE DISEASE

- **1.** Which foods may cause food poisoning for pregnant women, infants, and children? (Circle all that apply)
  - a. Soft cheeses
  - b. Cold smoked fish
  - c. Cold deli salads
  - d. Hot dogs that have not been heated
  - e. Raw eggs
  - f. Undercooked eggs
  - g. Canned vegetables
  - h. Canned fruit juice

- 2. Which of these people may get sick from harmful germs in food? (Circle <u>all</u> that apply)
  - a. Preschool children
  - b. Teenagers
  - c. Pregnant women
  - d. Older people (age 60 and over)
  - e. People with type II diabetes
  - f. Cancer patients
  - g. People who frequently eat at restaurants or get take-out food often
  - h. None of these individuals

#### FOODS THAT INCREASE RISK OF FOODBORNE DISEASE

- 1. Chilling or freezing eliminates harmful germs in food.
  - a. True
  - b. False
  - c. I don't know
- 2. Which food(s) may cause food poisoning? (Circle all that apply)
  - a. Slices of cantaloupe left on the counter overnight
  - b. Baked potato that was left on the counter overnight
  - c. Leftover turkey eaten cold
  - d. Chocolate cake that was left on the counter overnight
  - e. Refried beans cooled on the counter
- 3. Which food(s) may cause food poisoning? (Circle all that apply)
  - a. Fried eggs with a runny or soft yolk
  - b. Purchased cookie dough
  - c. Raw homemade cookie dough or cake batter
  - d. Soft scrambled eggs
  - e. Hard cooked (boiled) eggs
- 4. Which food(s) may cause food poisoning? (Circle <u>all</u> that apply)
  - a. Raw oysters, clams, or mussels
  - b. Sushi
  - c. Cooked shellfish
  - d. Ceviche

- 5. Which food(s) may cause food poisoning? (Circle <u>all</u> that apply)
  - a. Home canned beans, carrots, peas or potatoes right from the jar
  - b. Commercially canned vegetables right out the can without re-heating them
  - c. Unpasteurized fruit juice
  - d. Sliced melon
  - e. Raw sprouts (alfalfa, bean, clover, radish)
  - f. Fresh homemade salsa
- **6.** Which food(s) may cause food poisoning? **(Circle all that apply)** 
  - a. Leftover soup reheated until warm but not boiling
  - b. Potato salad that was left at room temperature for more than 2 hours
  - c. Soft food like cream cheese after scraping off mold
  - d. Box of rice
  - e. Food stored in a cabinet beside oven
- 7. Which food(s) may cause food poisoning? (Circle all that apply)
  - a. Raw milk (not pasteurized)
  - b. Fresh cheese made with raw milk
  - c. Infant milk or formula with honey added
  - d. Milk with raw egg added
- **8.** Which food(s) may cause food poisoning? (Circle <u>all</u> that apply)
  - a. Rare hamburgers
  - b. Grilled steak served on the same plate that held raw steak without washing the plate
  - c. Meat cooked medium-well
  - d. Frozen foods with frost built up in the package
- 9. *E. coli* (a harmful germ) in undercooked hamburger can cause kidney failure in children
  - a. True
  - b. False
  - c. I don't know
- 10. Undercooked chicken and raw eggs can carry Salmonella (a harmful germ).
  - a. True
  - b. False
  - c. I don't know
- 11. It is safe to use raw eggs in recipes that will not be cooked.
  - a. True
  - b. False
  - c. I don't know

the
d.

### Appendix B: Food Safety Knowledge Survey (Phases 2 & 3)

### **Knowledge Survey for Food Safety for Diverse Families**

1. Ge	
2 Do	□ Male □ Female
2. Ka	ce/Ethnicity:    Caucasian or White
	□ Native American (Tribe/Pueblo name )
	□ African American or Black
	□ Hispanic, Latino or Spanish origin
	□ Asian
	□ Other, please specify
3. Wh	☐ Other, please specifyat is your birth date (month/year)?
4. Cit	y, State, Country of birth
5. Ho	w long have you been living in the U.S.?
6. Wł	at United States generation are you (if known/applicable)?
7. W	nat is the last grade or year of school that you have <b>completed</b> ?  □ Less than high school  □ Some high school  □ High school (graduate or GED)
	<ul> <li>□ Additional training beyond high school (not college)</li> <li>□ Some college</li> <li>□ College graduate</li> <li>□ Post-College graduate</li> </ul>
8a. W job?	hich of the following best describes your experience in a food or nutrition related (This includes working in a restaurant or fast food)  □ I have never worked in a food or nutrition related job; Go to question 9  □ I currently work or did work in a food or nutrition related job; Go to question 8b
	ow many year(s) did you work in a food or nutrition related job?Year(s) w many children aged 10 years or younger are currently living in your household?
10. H lunch	ow many meals a <u>week</u> do you make for your children (include snacks and schooles)?
11. A	re you:
	☐ Employed and work outside of the home full-time
	□ Employed and work outside of the home part-time □ Employed and work at home full-time

□ Employed and	work at ho	me part-time
□ Not employed		

#### **Directions:**

- Choose 1 answer for each question. Unless the question states otherwise.
- If you do not know the answer, choose "I don't know." Please do not guess.
- If you do not understand the question, please put a question mark (?) If possible, make comments on why it is confusing.
- If you find the question offensive, please cross it out and comment on why it offends you.
- Please feel free to write any other comments or opinions about this survey in the margins.

#### MULTIPLE CHOICE – PLEASE CHOOSE 1 ANSWER FOR EACH OUESTION

- 1. Your electricity went off in your freezer and the meat, chicken, and fish thawed and felt warm. What should you do to prevent food poisoning?
  - a. Throw them away
  - b. Cook them right away
  - c. See how they smell or look before deciding what to do
  - d. Immediately re-freeze until solidly frozen, then cook it
- 2. Your child is going to be eating 2 hours after you cook a meal. How should you keep the meal safe before your child eats it?
  - a. Store it in the refrigerator and reheat it when the child is ready to eat it
  - b. Place it on the kitchen counter until the child is ready to eat it
  - c. Store it in a cool oven until the child is ready to eat it
  - d. Store it in a warm oven until the child is ready to eat it
- 3. Which food needs to be refrigerated to prevent food poisoning?
  - a. Apples
  - b. Dried corn
  - c. Open box of raisins
  - d. Corn bread
  - e. An open can of beans
- 4. What is the safest way to cool a large pot of hot soup?
  - a. Put the soup in a clean shallow pan and refrigerate right away
  - b. Keep the soup in the cooking pot and refrigerate right away
  - c. Put the soup in a clean, deep pot before and refrigerate right away
  - d. Cool the soup to room temperature on the counter, then refrigerate it

- 5. How long can you store <u>cooked</u> hamburger and chicken in the refrigerator to eat later?
  - a. 1-2 days
  - b. 3-4 days
  - c. 5-7 days
  - d. More than a week
- 6. How long can you store <u>raw</u> hamburger and chicken in the refrigerator to eat later?
  - a. 1-2 days
  - b. 3-4 days
  - c. 5-7 days
  - d. More than a week
- 7. If you have a cut or sore on your hand, what should you do before you prepare food for your family?
  - a. Nothing, if it is not infected
  - b. Put a bandage on the cut or sore
  - c. Wash hands
  - d. Put a bandage on the sore and wear a glove
- **8.** Where is the best place to store raw meat in the refrigerator
  - a. On the top shelf
  - b. Where there is space
  - c. Below ready-to-eat foods, like salad
- 9. Putting raw meat in a separate bag (away from other food items) before placing it in the grocery cart:
  - a. Increases the chance of food poisoning
  - b. Decreases the chance of food poisoning
  - c. Makes no difference
- 10. How should you wash fresh fruits and vegetables to keep you from getting food poisoning?
  - a. Wash with regular soap
  - b. Wash with hot water
  - c. Wash with anti-bacterial soap
  - d. Hold under cool running water

- 11. After you have used a cutting board to slice raw meat or chicken, or fish and need to cut other foods, which of these is the best way to prevent food poisoning?
  - a. Wipe the cutting board off with a paper towel
  - b. Rinse the cutting board under very hot water
  - c. Turn the cutting board over and use the other side
  - d. Wash the cutting board with hot soapy water and rinse
- 12. How should kitchen counters be cleaned to prevent food poisoning?
  - a. Spray with a strong bleach solution, rinse and wipe dry
  - b. Wash with hot soapy water, rinse and wipe with a bleach solution
  - c. Wash with hot soapy water and let air dry
  - d. Brush off any dirt or food, wipe with a bleach solution and let air dry
- 13. What is the best way to wash your hands?
  - a. Apply sanitizer, run water, rub hands together for 20 seconds, rinse hands, dry hands, rub on an antiseptic hand lotion
  - b. Apply soap, rub hands together for 20 seconds, rinse hands under water, dry hands, apply sanitizer
  - c. Run water, moisten hands, apply soap, rub hands together for 20 seconds, rinse hands, dry hands
  - d. Run water, moisten hands, apply sanitizer, rub hands together for 20 seconds, rise hands, dry hands, rub on antiseptic hand lotion.
- 14. Before you begin preparing food, how often do you wash your hands with soap?
  - a. All of the time
  - b. Most of the time
  - c. Some of the time
  - d. Rarely
- 15. Washing hands after changing a diaper:
  - a. Increases the chance of food poisoning
  - b. Decreases the chance of food poisoning
  - c. Makes no difference
- 16. What is the **best** way to tell if hamburgers are cooked enough to prevent food poisoning?
  - a. Cut one to check the color of the meat inside
  - b. Check the color of the juice to be sure that it is not pink
  - c. Measure the temperature with a food thermometer
  - d. Check the texture or firmness of the meat
- 17. What is the **best** way to tell when chicken has cooked long enough?
  - a. The juices run clear
  - b. The meat is not pink in the center
  - c. The meat falls off the bone
  - d. Test with a meat thermometer

- 18. To prevent food poisoning, how long should leftover soup be heated?
  - a. Until it is boiling hot
  - b. Just until it is hot, but not too hot to eat right away
  - c. When it is at least room temperature
  - d. Reheating isn't necessary

## IN THIS SECTION, EACH QUESTION MAY HAVE MORE THAN ONE CORRECT ANSWER. PLEASE SELECT <u>ALL</u> OF THE CORRECT ANSWERS.

- 19. Check the safe way(s) to thaw frozen meat? (Check all that apply)
  - a. In the refrigerator
  - b. In the microwave
  - c. On the countertop
  - d. Under running water
  - e. Put in a sink filled with water
- **20.** To prevent food poisoning, which of these individuals should not prepare food for other people? (Check <u>all</u> that apply)
  - a. A person with diarrhea
  - b. A person with sores or pimples on face
  - c. A person with a fever
  - d. A person with a rash
  - e. A person who smokes
  - f. A person with a sore throat
  - g. A person with allergies
  - h. A person who has just vomited
  - i. A person with a runny nose
- 21. When preparing food, you should wash your hands after touching which of these?

#### (Check <u>all</u> that apply)

- a. Your face
- b. Dirty pots and pans
- c. Fresh fruit
- d. Dishes that came out of the dishwasher
- e. Clean countertop
- f. Cell phone or home telephone
- g. Tissue after blowing nose
- h. Dirty diaper

- 22. How should dishes be washed to prevent food poisoning? (Check all that apply)
  - a. Soak them in the sink for several hours and then wash them in the same water
  - b. Hand wash them right after the meal and then let them air-dry
  - c. Hand wash and rinse them right after the meal and then dry them with a dish towel
  - d. Wash and dry them in a dishwasher
- 23. Which is an acceptable way to clean a cutting board or counter after it is used for raw meat? (Check <u>all that apply</u>)
  - a. Rinse well with water
  - b. Wipe with a dishrag
  - c. Wash with hot soapy water only
  - d. Wash with hot soapy water, rinse with water, then rinse with bleach
  - e. Clean with a disinfectant (example: Lysol, Clorox, bleach)
  - f. Wash cutting board in a dishwasher
- 24. A food is properly cooked in a microwave oven when (Check all that apply)
  - a. The food looks done
  - b. You follow directions on the package
  - c. You stir the food about half way through cooking
  - d. You use a turntable in the microwave
  - e. The food feels hot
  - f. You test the food with a thermometer
- 25. Which foods will likely cause food poisoning for pregnant women, infants, and children? (Check all that apply)
  - a. Soft cheeses
  - b. Cold smoked fish
  - c. Cold deli salads
  - d. Hot dogs that have not been heated
  - e. Raw eggs
  - f. Undercooked eggs
  - g. Canned vegetables
  - h. Canned fruit juice
- 26. Which of these people will likely get sick from harmful germs in food?

#### (Check <u>all</u> that apply)

- a. Preschool children
- b. Teenagers
- c. Pregnant women
- d. Older people (age 60 and over)
- e. People with type II diabetes
- f. Cancer patients
- g. People who frequently eat at restaurants or get take-out food often
- h. None of these individuals

- 27. Which food(s) will likely cause food poisoning? (Check <u>all</u> that apply)
  - a. Slices of cantaloupe left on the counter overnight
  - b. Baked potato that was left on the counter overnight
  - c. Leftover turkey eaten cold
  - d. Chocolate cake that was left on the counter overnight
  - e. Refried beans cooled on the counter
- 28. Which food(s) will likely cause food poisoning? (Check <u>all</u> that apply)
  - a. Fried eggs with a runny or soft yolk
  - b. Purchased cookie dough
  - c. Raw homemade cookie dough or cake batter
  - d. Soft scrambled eggs
  - e. Hard cooked (boiled) eggs
- 29. Which food(s) will likely cause food poisoning? (Check all that apply)
  - a. Raw oysters, clams, or mussels
  - b. Sushi
  - c. Cooked shellfish
  - d. Ceviche
- 30. Which food(s) will likely cause food poisoning? (Check all that apply)
  - a. Home canned beans, carrots, peas or potatoes right from the jar
  - b. Commercially canned vegetables right out the can without re-heating them
  - c. Unpasteurized fruit juice
  - d. Sliced melon
  - e. Raw sprouts (alfalfa, bean, clover, radish)
  - f Fresh homemade salsa
- 31. Which food(s) will likely cause food poisoning? (Check all that apply)
  - a. Leftover soup reheated until warm but not boiling
  - b. Potato salad that was left at room temperature for more than 2 hours
  - c. Soft food like cream cheese after scraping off mold
  - d. Box of rice
  - e. Food stored in a cabinet beside oven
- **32.** Which food(s) will likely cause food poisoning? (Check all that apply)
  - a. Raw milk (not pasteurized)
  - b. Fresh cheese made with raw milk
  - c. Infant milk or formula with honey added
  - d. Milk with raw egg added

- 33. Which food(s) will likely cause food poisoning? (Check all that apply)
  - a. Rare hamburgers
  - b. Grilled steak served on the same plate that held raw steak without washing the plate
  - c. Meat cooked medium-well
  - d. Frozen foods with frost built up in the package

## TRUE/FALSE - PLEASE CHOOSE TRUE OR FALSE FOR THE FOLLOWING STATEMENTS

34. E. coli (a harmful germ) in undercooked hamburger can cause kidney failu	re in
children	
a. True	

- 35. Undercooked chicken and raw eggs can carry Salmonella (a harmful germ).
  - a. True

b. False

- b. False
- 36. It is safe to use raw eggs in recipes that will not be cooked.
  - a. True
  - b. False
- 37. It is safe to give an infant a bottle of baby formula that has been out of the refrigerator for longer than 2 hours?
  - a. True
  - b. False
- 38. Chilling or freezing eliminates harmful germs in food.
  - a. True
  - b. False
- 39. Your TV dinner will be cooked properly in your microwave when you follow the package directions.
  - a. True
  - b. False
- 40. Deli foods or luncheon meat kept beyond the expiration date are safe.
  - a. True
  - b. False
- 41. If a leftover food looks and smells good, it is still safe to eat.
  - a. True
  - b. False

#### Appendix C: Food Safety Knowledge Survey (Final)

#### **Directions:**

- Choose 1 answer for each question. Unless the question states otherwise.
- If you do not understand the question, please put a question mark (?) If possible, make comments on why it is confusing.
- If you find the question offensive, please cross it out and comment on why it offends you.
- Please feel free to write any other comments or opinions about this survey in the margins.

#### MULTIPLE CHOICE - PLEASE CHOOSE 1 ANSWER FOR EACH QUESTION

- 1. Your electricity went off in your freezer and the meat, chicken, and fish thawed and felt warm. What should you do to prevent food poisoning?
  - a. Throw them away
  - b. Cook them right away
  - c. See how they smell or look before deciding what to do
  - d. Immediately re-freeze until solidly frozen, then cook it
- 2. Your child is going to be eating 2 hours after you cook a meal. How should you keep the meal safe before your child eats it?
  - a. Store it in the refrigerator and reheat it when the child is ready to eat it
  - b. Place it on the kitchen counter until the child is ready to eat it
  - c. Store it in a cool oven until the child is ready to eat it
  - d. Store it in a warm oven until the child is ready to eat it
- 3. Which food needs to be refrigerated to prevent food poisoning?
  - a. Apples
  - b. Dried corn
  - c. Open box of raisins
  - d. Corn bread
  - e. An open can of beans
- 4. What is the safest way to cool a large pot of hot soup?
  - a. Put the soup in a clean shallow pan and refrigerate right away
  - b. Keep the soup in the cooking pot and refrigerate right away
  - c. Put the soup in a clean, deep pot before and refrigerate right away
  - d. Cool the soup to room temperature on the counter, then refrigerate it

- 5. How long can you store <u>cooked</u> hamburger and chicken in the refrigerator to eat later?
  - a. 1-2 days
  - b. 3-4 days
  - c. 5-7 days
  - d. More than a week
- 6. How long can you store <u>raw</u> hamburger and chicken in the refrigerator to eat later?
  - a. 1-2 days
  - b. 3-4 days
  - c. 5-7 days
  - d. More than a week
- 7. If you have a cut or sore on your hand, what should you do before you prepare food for your family?
  - a. Nothing, if it is not infected
  - b. Put a bandage on the cut or sore
  - c. Wash hands
  - d. Put a bandage on the sore and wear a glove
- **8.** Where is the best place to store raw meat in the refrigerator
  - a. On the top shelf
  - b. Where there is space
  - c. Below foods that are ready to eat
- 9. Putting raw meat in a separate bag (away from other food items) before placing it in the grocery cart:
  - a. Increases the chance of food poisoning
  - b. Decreases the chance of food poisoning
  - c. Makes no difference
- 10. How should you wash fresh fruits and vegetables to keep you from getting food poisoning?
  - a. Wash with regular soap
  - b. Wash with hot water
  - c. Wash with anti-bacterial soap
  - d. Hold under cool running water

- 11. After you have used a cutting board to slice raw meat or chicken, or fish and need to cut other foods, which of these is the best way to prevent food poisoning?
  - a. Wipe the cutting board off with a paper towel
  - b. Rinse the cutting board under very hot water
  - c. Turn the cutting board over and use the other side
  - d. Wash the cutting board with hot soapy water and rinse
- 12. How should kitchen counters be cleaned to prevent food poisoning?
  - a. Spray with a strong bleach solution, rinse and wipe dry
  - b. Wash with hot soapy water, rinse and wipe with a bleach solution
  - c. Wash with hot soapy water and let air dry
  - d. Brush off any dirt or food, wipe with a bleach solution and let air dry
- 13. What is the best way to wash your hands?
  - a. Apply sanitizer, run water, rub hands together for 20 seconds, rinse hands, dry hands, rub on an antiseptic hand lotion
  - b. Apply soap, rub hands together for 20 seconds, rinse hands under water, dry hands, apply sanitizer
  - c. Run water, moisten hands, apply soap, rub hands together for 20 seconds, rinse hands, dry hands
  - d. Run water, moisten hands, apply sanitizer, rub hands together for 20 seconds, rise hands, dry hands, rub on antiseptic hand lotion.
- 14. Washing hands after changing a diaper:
  - a. Increases the chance of food poisoning
  - b. Decreases the chance of food poisoning
  - c Makes no difference
- 15. What is the **best** way to tell if hamburgers are cooked enough to prevent food poisoning?
  - a. Cut one to check the color of the meat inside
  - b. Check the color of the juice to be sure that it is not pink
  - c. Measure the temperature with a food thermometer
  - d. Check the texture or firmness of the meat
- **16.** What is the **best** way to tell when chicken has cooked long enough?
  - a. The juices run clear
  - b. The meat is not pink in the center
  - c. The meat falls off the bone
  - d Test with a meat thermometer
- 17. To prevent food poisoning, how long should leftover soup be heated?
  - a. Until it is boiling hot
  - b. Just until it is hot, but not too hot to eat right away
  - c. When it is at least room temperature
  - d. Reheating isn't necessary

## IN THIS SECTION, EACH QUESTION MAY HAVE MORE THAN ONE CORRECT ANSWER. PLEASE SELECT <u>ALL</u> OF THE CORRECT ANSWERS.

- 18. Check the safe way(s) to thaw frozen meat? (Check all that apply)
  - a. In the refrigerator
  - b. In the microwave
  - c. On the countertop
  - d. Under running water
  - e. Put in a sink filled with water
- 19. To prevent food poisoning, which of these individuals should not prepare food for other people? (Check all that apply)
  - a. A person with diarrhea
  - b. A person with sores or pimples on face
  - c. A person with a fever
  - d. A person with a rash
  - e. A person who smokes
  - f. A person with a sore throat
  - g. A person with allergies
  - h. A person who has just vomited
  - i. A person with a runny nose
- **20.** When preparing food, you should wash your hands after touching which of these? (Check all that apply)
  - a. Dirty pots and pans
  - b. Fresh fruit
  - c. Dishes that came out of the dishwasher
  - d. Clean countertop
  - e. Cell phone or home telephone
- 21. How should dishes be washed to prevent food poisoning? (Check all that apply)
  - a. Hand wash and rinse them right after the meal and then let them air-dry
    - b. Hand wash and rinse them right after the meal and then dry them with a dish towel
    - c. Wash and dry them in a dishwasher
- 22. Which is an acceptable way to clean a cutting board or counter after it is used for raw meat? (Check <u>all that apply</u>)
  - a. Wash with hot soapy water only
  - b. Wash with hot soapy water, rinse with water, then rinse with bleach
  - c. Clean with a disinfectant (example: Lysol, Clorox, bleach)
  - d. Wash cutting board in a dishwasher

- 23. A food is properly cooked in a microwave oven when (Check all that apply)
  - a. You follow directions on the package
  - b. You stir the food about half way through cooking
  - c. You use a turntable in the microwave
  - d. The food feels hot
  - e. You test the food with a thermometer
- **24.** Which foods will likely cause food poisoning for pregnant women, infants, and children? (Check <u>all</u> that apply)
  - a. Soft cheeses
  - b. Cold smoked fish
  - c. Cold deli salads
  - d. Hot dogs that have not been heated
  - e. Undercooked eggs
  - f. Canned fruit juice
- 25. Which of these people will likely get sick from harmful germs in food?

#### (Check <u>all</u> that apply)

- a. Preschool children
- b. Teenagers
- c. Pregnant women
- d. Older people (age 60 and over)
- e. People with type 2 diabetes
- f. Cancer patients
- g. People who frequently eat at restaurants or get take-out food often
- h. None of these individuals

26.	Eating which of these foods will increase a person's risk of food poisoning?  (Check <u>all</u> that apply)
	<ul> <li>a Baked potato that was left on the counter overnight</li> <li>b Leftover turkey eaten cold</li> </ul>
	c Cake that was left on the counter overnight d Refried beans cooled on the counter e Fried eggs with a runny or soft yoke
	f Purchased cookie dough g Raw homemade cookie dough or cake batter
	h Sushi i Raw shellfish
	j Ceviche k Unpasteurized fruit juice l Sliced melon
	m Raw sprouts (alfalfa, bean, clover, radish) n Fresh homemade salsa
	<ul> <li>o Leftover soup reheated until warm but not boiling</li> <li>p Raw milk (not pasteurized) or fresh cheese made with raw milk</li> <li>q Infant milk or formula with honey added</li> <li>r Meat cooked medium-well</li> </ul>
	s Milk with raw egg added t Hamburger cooked rare
	FALSE - PLEASE CHOOSE TRUE OR FALSE FOR THE FOLLOWING EMENTS
27	E. coli (a harmful germ) in undercooked hamburger can cause kidney failure in children a. True b. False
28.	Undercooked chicken and raw eggs can carry <i>Salmonella</i> (a harmful germ).  a. True  b. False
29.	It is safe to use raw eggs in recipes that will not be cooked.  a. True  b. False
30.	It is safe to give an infant a bottle of baby formula that has been out of the refrigerator for longer than 2 hours?  a. True  b. False

- 31. Chilling or freezing eliminates harmful germs in food.
  - a. True
  - b. False
- 32. Your TV dinner will be cooked properly in your microwave when you follow the package directions.
  - a. True
  - b. False
- 33. Deli foods or luncheon meat kept beyond the expiration date are safe.
  - a. True
  - b. False
- 34. If a leftover food looks and smells good, it is still safe to eat.
  - a. True
  - b. False

## Food Safety for Diverse Families with Young Children Demographic Survey

1. Gender:	
☐ Male ☐ Female	
2. Race/Ethnicity:	
☐ Caucasian or White	
☐ Native American (Tribe/Pueblo name	_)
☐ African American or Black	
☐ Hispanic, Latino or Spanish origin	
□ Asian	
☐ Other, please list	
3. How old are you?	
4. City, State, Country of birth	
5. How long have you been living in the U.S.?	
6. Who was the first member of your family to live in the U.S.?	
☐ You	
☐ Parents	
$\square$ Grandparents	
☐ Other, please list	
7. What is the last grade or year of school that you have <b>completed</b> ?	
$\square$ Less than high school	
$\square$ Some high school	
☐ High school (graduate or GED)	
$\square$ Additional training beyond high school (not college)	
$\square$ Some college	
☐ College graduate	
☐ Post-College graduate	

8. Have you worked in a food or nutrition related job?	
□ no	
□ yes	
9. Have you ever had training in food safety or nutrition? (Ch	oose all that apply)
$\square$ I have not had any education/training in food or nut	rition
$\square$ I have had education/training in nutrition	
$\square$ I have had education/training in food preparation	
$\square$ I have had education/training in food safety	
10. Please list the ages of the children you make food for:	
First Child age: Second Child age: Third Child age: Fourth Child age: Fifth Child age: Sixth Child age:	
11. Are you:	
☐ Employed full-time	
☐ Employed part-time	
☐ Not employed	
12. Please check how you would like to get food and nutrition	information.
Print (example: mail, brochure, poster, materials f Media (example: TV, radio) Electronic (example: email, internet, text message People (example: family/community member, doc Education (example: classes, workshops)	, blogs)

#### **Appendix D: Consent Form**

### The University of New Mexico Consent to Participate in Research Validating a Food Safety Knowledge Survey

#### Introduction

You are being asked to complete a survey as part of a research study. This study is led by Dr. Christina Perry, a faculty member at UNM and her graduate student Maggie Siebert. The purpose of this project is to create a survey about food safety. You are being asked to participate in this study because you have at least one child in your household under 10 years of age or younger. Filling out this survey means you agree to participate. No signatures are required on this form or the survey.

We would like to explain the research study to you, including possible risks and benefits. If you have any questions, please ask one of the study leaders.

#### What will happen if I decide to participate?

If you agree to participate this is what will happen:

- You will be asked to fill out a survey about food safety which will take about 35 minutes.
- You will NOT have to give your name on the survey.
- You will be asked to write comments on the survey so we can make it better.

#### What are the risks and benefits of being in this study?

The risks in this study are not considered to be any greater than those experienced in everyday life. You may withdraw from the study at any time, for any reason and without any effect on you. The results of this project will help us develop a culturally sensitive survey about food safety. This survey could help communities understand how to keep families from getting sick from food.

What other choices do I have if I do not want to be in this study? This study is voluntary, so you can choose not to participate.

#### How will my information be kept confidential?

Your name will **not** be used in any reports or publications. Everyone's survey will be kept safe in a locked cabinet in Dr. Perry's office at the University of New Mexico. The compiled information from all surveys may be presented at scientific meetings and/or published.

What are the costs of taking part in this study?

There are no costs to participate in this study.

Will I be paid for taking part in this study? Snacks and refreshments will be provided.

#### Whom can I call with questions or complaints about this study?

If you have any questions, concerns or complaints at any time about the research study, Dr. Christina Perry or her graduate student will be glad to answer them at 505-277-5151.

If you need to contact someone after business hours or on weekends, please call and leave a message at 505-277-5151 and someone will return your call as soon as possible.

If you would like to speak with someone other than the research team, you may call the UNM Human Research Protections Office at (505) 272-1129.

Whom can I call with questions about my rights as a research subject? If you have questions regarding your rights as a research subject, you may call the UNM Human Research Protections Office at (505) 272-1129. The HRRC is a group of people from UNM and the community who provide independent oversight of safety and ethical issues related to research involving human subjects. For more information, you may also access the HRRC website at <a href="http://hsc.unm.edu/som/research/hrrc/">http://hsc.unm.edu/som/research/hrrc/</a>.

#### **Appendix E: Detailed Results**

#### **Key Informant Interviews**

#### Key informant interview questions.

- 1. Overall rate the **level of difficulty** of the survey. (Were the questions too complex, too hard, too easy, or obvious?).
- 2. Was the **survey format** appropriate? Did the flow of questions make sense?
- 3. Was the **wording and language** appropriate? Did it make sense? Was anything offensive?
- 4. Was the **survey length** appropriate? (Too long, too short?) How long did it take you to complete? Did you feel like you rushed or did you thoughtfully address each question?
- 5. Overall, how did you feel about the **content** of the survey?
- 6. Was the survey **culturally appropriate**? In your opinion, in gearing this survey towards a Native American population, would you change anything (such as the inclusion of "Feast Days" or certain foods such as beans)?

#### Key informant interview response summary tables.

Responses to Question 1 - Level of Difficulty

P1	P2	Р3	P4	P5	Р6
NA	Medium/ Average "Suited for most individuals"	"Pretty straightforward" "Some of the questions are trick questions" "Depends on the level of education" "(Tailored more for) Higher education"	"Medium, Neutral"	"Average difficulty" "Straightforward"	NA
Question 1 Summary	Overall responding most individu		rvey to be ave	rage difficulty appro	priate for

Responses to Question 2 - Survey Format

P1	P2	Р3	P4	P5	P6
Fine, flows	NA	"Pretty	"Yes"	"There was	"Yeah it
nicely		much"		a flow"	did"
Organized					
Question 2	Participants a	agreed that the	survey format	was appropri	ate and made
Summary	sense.				

Responses to Question 3 - Wording and Language

P1	P2	Р3	P4	P5	P6	
Include	"Overall,	"depending	"Made sense"	Everything	"it was	
"Feast Days"	yeah"	on your level		made sense	good"	
and		of language	Did not take			
traditional	Offended by	skills or	offense to	Did not take		
foods like	questions 5	education"	anything	offense to		
beans, corn	& 6 in the			anything		
and squash	demographic					
	section					
<b>Question 3</b> Overall the wording and language of the survey was perceived as logical and						
Summary						
	culturally appropriate for Native American individuals if certain words were					
	changed or added.					
(See Question 6: Cultural Relevance for further elaboration on language,						
wording and question items pertaining to culture.)						

Responses to Question 4 - Survey Length

P1	P2	P3	P4	P5	Р6		
4.1: Too lengthy	4.1: "a little bit long"	4.1: "didn't have a problemthought it was going to be longer"	4.1: "it's appropriate."	4.1: "just about right."	4.1: NA		
4.2: NA	4.2: "Too long, cut it down"	4.2: "it wasn't too long or it wasn't too short."	4.2: NA	4.2: "I don't think it was too long"	4.2: "It was average."		
4.3: 10 minutes	4.3: 15 minutes	4.3: 15 minutes	4.3: 20-25 minutes	4.3: 10 minutes	4.3: 30 minutes		
4.4: NA	4.4: "I was in a rushI don't think I answered some of them accurately"	4.4: "I don't think I rushed…"	4.4: "No" (did not rush)	4.4: "I don't think I rushed"	4.4: "Thoughtfully"		
Question							

4	survey takes from 10 to 30 minutes to complete, the average time to complete					
Summary	the survey is 17 minutes. The majority of participants did not rush.					

Responses to Question 5 - Content

P1	P2	Р3	P4	P5	Р6			
"getting	"Informative"	"Informative"	"It kind of	NA	"it was			
information	"it allowed	"to make	makes you		good."			
about	me to	you think	realize and					
nutritional	become	about your	take a					
information	aware and to	food	second look					
was helpful."	become	practices"	on how food					
	more		is handled					
	cautious"		and					
			cooked"					
Question 5	The majority of participants found the survey informative and suggested							
Summary	that the act of taking the survey influenced or increased awareness of							
	behaviors surrounding food safety when preparing meals.							

#### Responses to Question 6 - Cultural Appropriateness

P1	P2	P3	P4	P5	P6			
Need to	"on the	"it's hard to say	"it could	"if you're	"Not			
"reflect	reservation	becausegrowin	be not	doing a big	really."			
certain	it probably	g upI was	appropriate	spectrum of	"there's a			
traditional	wouldn't	really into	because I	peopleout	lot of			
foods or	be	culture and	would say	on the res	traditions			
practices	appropriat	traditional	some of my	and urban	"			
oridentifyin	e but now	whatever but	familythe	settings	"every			
g feast days	that I live	starting like four	y would	then I don't	tribeit's			
or	in the	years ago like I'm	think that it	think it's	kind of			
powwows."	city"	a Christian	would be	culturally	different"			
		now"	ridiculous	appropriate.				
			"	"				
Question 6	The survey may not reflect cultural traditions of all Southwestern Native							
Summary	Americans and may not be culturally appropriate. The survey may be more							
	appropriate for Native Americans dwelling off the reservation as opposed							
	to on the reservation.							

#### Additional key comments.

Level of Difficulty. Participant 3 (P3) felt that overall the survey was straightforward but that certain questions would be tricky for those without a "college student perspective". Participant 3 specifically referenced questions 20 (individuals who should not prepare food) and 13 (correct hand washing procedure). Participant 3 thought that if "A person with a runny nose" (answer

choice "i") were to wash their hands it would be all right for them to prepare food. It is unclear by the question if the different types of individuals in the answer choices have washed their hands. Question number 13 about the correct sequence and procedure to wash ones hands did not specify the way that she was taught to wash her hands, "...you have to wet your hands, put soap, and from what I learned at school is you really have to like get under your nails you know, really rub your hands together, all the way up to your wrists."

Participant 3, admitted to being "kind of stumped" on some of the questions in the survey. She thought that "...you're so used to doing things...a couple of times I got stumped because I was like, 'Well that answer sounds right but that's not what I do in my house'...you don't want to be wrong, so you're trying to listen for the correct answer even though in your mind you might think, Uh-oh! That's not what I do." When asked if she looked for the correct answer regardless of home practice, P3 answered in the affirmative.

Survey Format. The Buros Institute recommended grouping survey items by format within their respective sections and to provide instructions for each item type (multiple choice questions with one correct answer, multiple choice questions with multiple correct answers, and true or false questions). This suggestion was implemented and items were grouped by type and additional instructions for each item type were added. (e.g. IN THIS SECTION, EACH QUESTION MAY HAVE MORE THAN ONE CORRECT ANSWER. PLEASE SELECT ALL OF THE CORRECT ANSWERS.) Participants 1 and 2 both took the survey before modifications and saw the modified survey after taking the first version. Both P1 and P2 felt the survey was too lengthy, whereas P3, P4, P5 and P6 felt the survey was an appropriate length. This difference in opinion may be due to decreasing respondent cognitive load after reformatting the survey.

**Wording and Language.** Participant 1 suggested adding beans, corn and squash and including feast days however, added that this would only be culturally relevant to Southwest Native American culture.

Participant 2 was offended by questions numbers 5 & 6 in the demographic section that precedes the survey.

- 5. How long have you been living in the U.S.?
- 6. What United States generation are you (if known/applicable)?

Participant 2 expressed that these questions were particularly offensive at the beginning of the interview before the question was posed, "Was anything on the survey offensive?" This suggests that P2 remembered these questions as offensive and did not want to forget to mention them to the interviewer. Participant 2 asked if the survey was for, "...just Native Americans or is it for all different groups?" because "...if we're Native Americans a lot of them were born here, it just doesn't make sense." Participant 2 went on to say, "I never, ever came across anything that was so awkward to me".

An additional question regarding the offensiveness of questions D5 & D6 in the demographic section of the survey was added to the interview questions after interviewing Participant 2. Participants 3 & 4 did not find the questions offensive but Participant 5 agreed that the questions did not pertain to Native Americans. It is recommended that questions 5 & 6 in the demographic section of the survey be deleted. Potentially offensive or controversial questions could increase respondent bias and invalidate survey results.

The word "soup" was used in the survey but Participant 2 commented that Native Americans more frequently use "stew". To quote P2, "...I appreciate the fact that you guys put soup, I don't know if you guys should make it stew instead because they are

actually a little bit different." When Participant 6 was asked if stew would be a more appropriate word than soup she responded, "...the Native would turn around and say, 'Soup? We have no chicken noodle soup here. (laughs)"

*Survey Length.* Before implementing the interview process, Participant 1 was quick to express emphatically that the survey was too long. In addition, Participant 1 suggested to make the survey shorter as she thought many Native Americans would be intimidated and would not complete it. Participant 2 concurred that the survey length was "...way too long". However, Participants 1 and 2 both took the survey before it was reformatted to decrease respondent burden and reduce cognitive load as recommended by the Buros Institute for Assessment Consultation and Outreach (BIACO). Although both participants viewed the subsequent iteration, their first impression may have tainted their experience of the second iteration of the survey. Participants 3, 4, 5 and 6 all received the second iteration of the survey further supporting the recommendation from BIACO to classify survey items by type (Multiple choice questions with one correct answer, multiple choice questions with multiple correct answers, and true or false questions) and to insert instructions before each item type (e.g. IN THIS SECTION, EACH QUESTION MAY HAVE MORE THAN ONE CORRECT ANSWER. PLEASE SELECT ALL OF THE CORRECT ANSWERS).

Additionally, Participant 2 admitted that she rushed through the survey (e.g. "...I just started guessing...I don't think I answered some of them accurately. I just wanted to fill it out."). This presents a threat to validity because it threatens the accuracy of the survey. However, Participant 2 took the survey before it was reformatted. After reformatting no participant said they rushed. Further supporting the reformatting of the survey reduced respondent burden and cognitive load.

**Additional Comments.** An unexpected result from the act of taking the survey was an increase in awareness of food safety and potentially a change of behaviors regarding food safety practices. Although Participant 1 did not mention

this when asked about the content of the survey, she did when asked if she had any additional comments, "...how should things be prepared and just being able to talk about nutrition, I kind of have to remember and like refresh my own memory even though I'm considered educated." All of the first four participants mentioned this facet. Participant 5 did not express this result and when prompted to respond to whether taking the survey had, "...increased awareness about your own behaviors and practices or perhaps even changed some of your behaviors and practices?" Participant 5 acknowledged that taking the survey, "...made me think about my knowledge of safe food practices..." When prompted Participant 6 agreed that, "...it's awareness."

Additionally Participant 3 and 4 asked for resources to affirm their home food safety behaviors. Specifically, Participant 3 wanted to know after taking the survey what she got wrong. Participant 4 asked if there were a website she could visit that would list the correct information regarding food safety practices. These two comments enforce the previous unexpected result that from the act of taking the survey, food safety awareness and practices may be influenced positively.

Table 9: Theme Matrix - Food

Theme: Food	P1	P2	Р3	P4	P5	P6
Soup/Stew		* (-)				* ( - )
Seafood/Fish		* (-)	* (-)			
Beans	* (+)	* (+)		* (+)	* (-)	* ( ≈ )
Traditional	* (+)	* (+)	* ( ≈ )	* (+)	* (-)	* (+)
Foods						
Microwave		* ( ≈ )				* (-)
Canned		* ( ≈ )	* ( ≈ )			* (-)
Milk					* ( -,≈ )	
Butchering					* ( -,≈ )	* ( ≈ )
Vendors	* ( + )		* (+,-)			
Gatherings	* ( + )	* ( + )	* ( ≈ )		* ( - )	* ( ≈ )

Key: \*=mentioned

+=Positively

-=Negatively

≈=unclear or unsure

Table 10: Theme Matrix - Access to Resources

Theme:	P1	P2	Р3	P4	P5	P6
Access to						
Resources						
Water			* ( - )	* ( - )	* ( - )	* ( ≈ )
Refrigeration			* ( - )	* ( - )		* ( - )
Electricity			* ( - )	* ( - )	* ( - )	* ( ≈ )
Grocery					* ( - )	
Stores						
Storage			* ( - )			* ( ≈ )
Canned		* ( ≈ )	* ( ≈ )			* ( - )
Goods						
Education	* (NA; + )	* (NA; + )	* (NA; + )	* ( - ; + )	* (NA; ≈ )	* (NA; ≈ )
(access to;						
FS programs)						
Technology				* ( - )		
Poverty		* ( - )	* ( - )			
General					* ( - )	

Key: \*=mentioned

+=Positively

-=Negatively

≈=unclear or unsure

### **Content Validity**

Experts were asked to determine each item's appropriate content domain, construct relevance, representativeness, and clarity. Content domain match refers to the expert's ability to correctly identify each item's factorial category (Cook, Clean, Chill or Separate). Some items belong to content domains that were not answer choices (Groups at Greatest Risk of Foodborne Illness, & Foods that Increase Risk of Foodborne Illness); these items are meant to foil the experts. These items were used to ensure that experts are correctly identifying survey items that do not belong to any of the four given factorial indexes. Construct relevance refers to the expert's rating of an item's essentialness and usefulness in measuring a respondent's food safety knowledge. Representativeness refers to how representative an item is to the

expert assigned content domain. Clarity refers to how clearly an item is worded. Additionally, experts were asked to comment in the margins to further assist in enhancing each survey item.

**Factorial validity index.** In three of the five survey items representing the content domain Separate (20, 21 & 7) none of the experts chose Separate as the domain match (FVI=0). However, experts did agree on the content domain of these items: item 20 experts agreed represented Clean (FVI=1), item 21 experts agreed represented Clean (FVI=1), and item 7 experts agreed represented Clean (FVI=1). The inability of the experts to correctly match the survey item with the correct content domain, Separate, may indicate that these items are not representative of the Separate content domain. In addition, all of the experts agreed that these items are better classified in another content domain, Clean. Each of the FVIs were high for the alternatively chose content domain, Clean. In further phases of analyses this should be considered.

The following are the three questions experts incorrectly identified as Clean instead of Separate.

#### Item 20:

To prevent food poisoning, which of these individuals should not prepare food for other people (Check <u>all</u> that apply)

- a. A person with diarrhea
- b. A person with sores or pimples on face
- c. A person with a fever
- d. A person with a rash
- e. A person who smokes
- f. A person with a sore throat
- g. A person with allergies
- h. A person who has just vomited
- i. A person with a runny nose

# **Expert Comment**

E6: "Hard to apply if you are a single parent Mom with small children. A Mom is not an employee you can tell to stay home."

#### Item 21:

When preparing food, you should wash your hands after touching which of these?

# (Check all that apply)

- a. Your face
- b. Dirty pots and pans
- c. Fresh fruit
- d. Dishes that came out of the dishwasher
- e. Clean countertop
- f. Cell phone or home telephone
- g. Tissue after blowing nose
- h. Dirty diaper

### **Expert Comment**

E1: "Seems repetitive with question 19 – intentional?"

#### Item 7:

If you have a cut or sore on your hand, what should you do before you prepare food for your family?

- a. Nothing, if it is not infected
- b. Put a bandage on the cut or sore
- c. Wash hands
- d. Put a bandage on the sore and wear a glove

### **Expert Comments**

E4: Expert commented on answer choice "d", "Specify type of glove."

E5: Expert chose "b", "c" & "d" and commented, "All three". Expert chose clarity-minor revisions needed and then asked, "Is this check all that apply or one answer?" E6: "People don't have gloves at home."

Additional Items with Low Factorial Validity Index (FVI):

Additionally in each of the other content domains (Cook, Clean and Chill) there were items with low FVI indicating that experts could not correctly identify the content domain. Anything below 0.8 is identified as a low FVI and the question is flagged as not accurately representing the content domain and threatening validity. Items with an FVI below 0.8 are: item 40 (Cook, FVI=0.66), item 11 (Clean, FVI=0.5, the remaining 0.5 experts matched this item with Separate), and item 41 (Chill, FVI=0.66).

#### Item 40:

Deli foods or luncheon meat kept beyond the expiration date are safe.

- a True
- b. False

#### **Expert Comment**

E1: Added "refrigerated" in front of question.

E2: Circled expiration and commented, "Or sell by?" and further elaborated that the answer would be "False for expiration; unopened vacuum packed are OK two weeks after sell by date." Expert chose "Separate" as the content domain but added a question mark after circling it. Expert also added a question mark after circling "Item is somewhat useful and somewhat essential".

#### Item 11:

After you have used a cutting board to slice raw meat or chicken, or fish and need to cut other foods, which of these is the best way to prevent food poisoning?

- a. Wipe the cutting board off with a paper towel
- b. Rinse the cutting board under very hot water
- c. Turn the cutting board over and use the other side
- d. Wash the cutting board with hot soapy water and rinse

#### **Expert Comment**

E1: "Seems repetitive with #14 (Intentional?)"; expert drew an arrow from the word "foods" from the item stem that reads "to cut other foods..." and wrote, "...that will be eaten raw? Maybe give specifics such as 'salad to eat raw' to question."

E2: Chose answer choice "d" but added, "spray with bleach and air dry" and added an answer choice "e. Use a different cutting board."

E6: "None good answer"; "get new cutting board and knife"; additionally expert added "and sanitize bleach" to the end of answer choice "d".

#### Item 41:

If a leftover food looks and smells good, it is still safe to eat.

- a. True
- b False

# **Expert Comment**

E2: Expert wrote question marks after the following content domains instead of choosing one: Cook, Chill, and Separate. The expert also drew a question mark after "Item is representative".

E6: Expert circled "still" in item stem and wrote "leave out".

The remaining survey items all scored above a 0.8 FVI indicating that these items accurately represent their respective content domains.

Content validity index. The Content Validity Index (CVI) measures how essential or useful an item is to assessing food safety knowledge within the selected domain. Experts used a 4-point Likert scale to assess item relevance (1=Item is not essential or useful, 2=Item is useful but not essential, 3=Item somewhat essential & somewhat useful, or 4=Item is essential and useful). Items scoring a "3" or higher were dichotomized into high relevance, items scoring a "2" or below were dichotomized into low relevance. An average CVI of 0.8 is recommended (Lawshe, 1975; Rubio et al., 2003). Survey items averaged a 0.93. Survey items with a low CVI (below 0.8) were

survey item 30 (Foods, CVI=0.66), item 39 (Cook, CVI=0.5), item 26 (Groups, CVI=0.66), and item 29 (Foods, CVI=0.66). It is recommended that these items be reviewed for omission or revision from the final survey as experts do not find them essential or useful to assessing food safety knowledge.

The following are items identified as having low CVI:

#### Item 30

Which food(s) will likely cause food poisoning? (Check <u>all</u> that apply)

- a. Home canned beans, carrots, peas or potatoes right from the jar
- b. Commercially canned vegetables right out the can without re-heating them
- c. Unpasteurized fruit juice
- d. Sliced melon
- e. Raw sprouts (alfalfa, bean, clover, radish)
- f. Fresh homemade salsa

# **Expert Comments**

E1: Expert commented on answer choice "d", "Washed? Clean knife and cutting board used?"; on answer choice "f", "Washed? Clean knife and cutting board used?".

Representative – "Several potential domains" and "I may be over thinking the question but seems like you would need more info to determine if some of these would cause food poisoning".

E2: Expert circled "likely" and put a question mark. Expert chose "a", "c" and "e" but commented, "All have been known to cause food poisoning but not frequently".

E5: Expert commented on answer choice "b", "Can cause, not sure if likely" and on answer choice "d", "Fresh sliced? Washed?".

E6: Expert wrote "Too many to check" before "Content Domain", "Cook" after answer choices "a" and "c" and "2/3" after answer choice "d".

#### Item 39

Your TV dinner will be cooked properly in your microwave when you follow the package directions.

- a. True
- b. False

### **Expert Comments**

E4: Expert commented, "Also addressed in Q39 (consider eliminating?)"

E5: Expert changed "will" to "may" and commented that it "depends on micro power, frozen? (illegible writing) handling". Expert chose "a" but then wrote "unsure".

#### Item 26

Which of these people will likely get sick from harmful germs in food?

# (Check all that apply)

- a. Preschool children
- b. Teenagers
- c. Pregnant women
- d. Older people (age 60 and over)
- e. People with type II diabetes
- f. Cancer patients
- g. People who frequently eat at restaurants or get take-out food often
- h. None of these individuals

#### **Expert Comments**

E1: Expert commented, "Are you looking for people who are MOST likely to get sick from harmful germs in food? This question is tricky because of multiple response options."

E2: Expert underlined "harmful germs" and wrote "how harmful/how many germs?" Additionally the expert was unsure of content domain and wrote, "Cook? Chill? Separate? Item is representative?"

E3: Expert added a question mark after answer choice "d" and also after choosing content domain Clean.

E6: Expert crossed out "will likely" from the item stem and wrote, "are most likely to get sick."

#### Item 29

Which food(s) will likely cause food poisoning? (Check <u>all</u> that apply)

- a. Raw oysters, clams, or mussels
- b. Sushi
- c. Cooked shellfish
- d. Ceviche

#### **Expert Comment**

E2: "What is objective? To see if they know cooked fish is usually safer or if both raw and cooked fish can possibly be unsafe?" After answer choice "c" expert added, "Might cause (illegible) toxin if not handled properly before cooking or toxin if shellfish consumed certain algae". Expert added a question mark after choosing content domain Cook, after choosing "Item somewhat useful and somewhat essential", and after choosing "Major revisions needed" under Representativeness. Expert also added that, "Maybe two questions?".

E3: Expert commented after answer choice "b", "Not raw".

E4: Expert commented after answer choice "d", "Ceviche needs definition/clarification"

E5: Expert commented after answer choice "b", "Raw?" and after answer choice "d", "Had to look up, didn't know what it was."

E6: Expert circled "will likely" in the item stem and wrote a question mark above it.

**Representativeness.** Experts were asked to rate all survey items on a 4-point Likert scale (1=Item not representative, 2=Major revisions needed, 3=Minor revisions needed and 4=Item is representative). Items were first dichotomized into high (3+4) and low representativeness (1+2). High representativeness was calculated for each item based on the percentage of experts in agreement that the item was highly representative of the content domain. Inter-rater reliability was

assessed by adding all items with 75% or higher agreement that the item was highly representative and dividing that by the total number of survey items (n=41). Interrater reliability for representativeness of all survey items was 0.83.

Survey items with low representativeness were flagged. It is recommended that these items are either omitted or revised to more accurately represent their content domain. All survey items were included in this analysis but only four of the six content domains were choices (Cook, Clean, Chill and Separate). The other two content domains (Foods that Increase Risk of Foodborne Illness (Foods) and Groups at Greatest Risk of Foodborne Disease (Groups)) were not answer choices and are intended to foil experts and assure that reliability of expert feedback is high. This must be considered when items score low in representativeness when the correct content domain was not a possible choice. Items flagged for low representativeness are item 22 (Clean, Rep=0.66), item 30 (Foods, Rep=0.66), item 25 (Groups, Rep=0.66), item 32 (Foods, Rep=0.66).

The following survey items are to be considered for either omission or revision based on low representativeness of the expert identified content domain (Cook, Clean, Chill, and Separate). The foils from the Foods and Groups categories are not included as they are expected to receive low representativeness from expert raters.

### Item 22 (Clean)

How should dishes be washed to prevent food poisoning? (Check <u>all</u> that apply)

- a. Soak them in the sink for several hours and then wash them in the same water
- b. Hand wash them right after the meal and then let them air-dry
- c. Hand wash and rinse them right after the meal and then dry them with a dishtowel
- d. Wash and dry them in a dishwasher

### **Expert Comments**

E2: Expert commented after answer choice "b", "Rinse and dip into light bleach solution" and after answer choice "d", "Address hot/cold water".

E6: Expert underlined "and rinse" in answer choice "c" and wrote in margin, "If c is going to say 'and rinse' then b should also."

#### Item 41 (Chill)

If a leftover food looks and smells good, it is still safe to eat.

- a. True
- b. False

### **Expert Comments**

E2: Expert placed question marks after content domains Cook, Chill, and Separate and also after "Item is representative".

E6: Expert circled "still" in item stem and wrote "leave out."

Clarity. Experts were asked to rate all survey items on a 4-point Likert scale (1=Item is not clear, 2=Major revisions needed, 3=Minor revisions needed and 4=Item is clear). Items were first dichotomized into high (3+4) and low clarity (1+2). High clarity was calculated for each item based on the percentage of experts in agreement that the item exhibited high clarity. Inter-rater reliability was assessed by adding all items with 75% or higher agreement that the item was high clarity divided by the total number of survey items (n=41). Inter-rater reliability for clarity of all survey items was 0.878.

Survey items with low clarity are identified to be considered for rewording to clarify the survey item. Items identified as low clarity (below 0.8) are identified to rework to enhance item clarity. Items identified as low clarity are: item 22 (Clean, Clarity=0.66), item 30 (Foods, Clarity=0.5), item 25 (Groups, Clarity=0.5), item 28 (Foods, Clarity=0.5), and item 19 (Chill, Clarity=0.66). Expert feedback in the margins will be used to reword survey items to enhance clarity.

The following items were the items experts identified as low clarity:

### Item 22

How should dishes be washed to prevent food poisoning? (Check all that apply)

- a. Soak them in the sink for several hours and then wash them in the same water
- b. Hand wash them right after the meal and then let them air-dry
- c. Hand wash and rinse them right after the meal and then dry them with a dishtowel
- d. Wash and dry them in a dishwasher

### **Expert Comments**

E2: Expert commented after answer choice "b", "Rinse and dip into light bleach solution" and after answer choice "d", "Address hot/cold water".

E6: Expert underlined "and rinse" in answer choice "c" and wrote in margin, "If c is going to say 'and rinse' then b should also."

#### Item 30

Which food(s) will likely cause food poisoning? (Check <u>all</u> that apply)

- a. Home canned beans, carrots, peas or potatoes right from the jar
- b. Commercially canned vegetables right out the can without re-heating them
- c. Unpasteurized fruit juice
- d. Sliced melon
- e. Raw sprouts (alfalfa, bean, clover, radish)
- f. Fresh homemade salsa

# **Expert Comments**

E1: Expert commented on answer choice "d", "Washed? Clean knife and cutting board used?"; on answer choice "f", "Washed? Clean knife and cutting board used?".

Representative – "Several potential domains" and "I may be over thinking the question but seems like you would need more info to determine if some of these would cause food poisoning".

- E2: Expert circled "likely" and put a question mark. Expert chose "a", "c" and "e" but commented on all, "All have been known to cause food poisoning but not frequently".
- E5: Expert commented on answer choice "b", "Can cause, not sure if likely" and on answer choice "d", "Fresh sliced? Washed?".
- E6: Expert wrote "Too many to check" before "Content Domain", "Cook" after answer choices "a" and "c" and "2/3" after answer choice "d".

#### Item 25

Which foods will likely cause food poisoning for pregnant women, infants, and children? (Check all that apply)

- a. Soft cheeses
- b. Cold smoked fish
- c. Cold deli salads
- d. Hot dogs that have not been heated
- e. Raw eggs
- f. Undercooked eggs
- g. Canned vegetables
- h. Canned fruit juice

# **Expert Comments**

E1: Expert added "young" in front of children. Expert commented that, "Some of these would potentially cause food poisoning in other population groups as well (e.g. raw eggs), do you want them to select those that are particularly/esp. harmful for infants/pregnant women/young children?"

E5: Expert commented on answer choice "b", "Certain kinds?"

E6: Expert wrote "cook" after answer choices "a", "d", "e", and "f" and added "(or chill)" after answer choice "d".

#### Item 28

Which food(s) will likely cause food poisoning? (Check <u>all</u> that apply)

a. Fried eggs with a runny or soft yolk

- b. Purchased cookie dough
- c. Raw homemade cookie dough or cake batter
- d. Soft scrambled eggs
- e. Hard cooked (boiled) eggs

#### **Expert Comments**

E1: Expert commented after answer choice "a", "Runny or soft? Which option?" and after answer choice "d", "Not clear what this means".

E2: Expert commented after answer choice "b", "Eaten raw?"

E5: Expert commented after answer choice "d", "Not sure what 'soft' scrambled means".

E6: Expert underlined "will likely cause food poisoning" and wrote an arrow off of the end of answer choice "a" to say, "People eat these all the time and do not get food poisoning. Is it recommended? –No. Likely cause food poisoning? –No."

#### **Scale Refinement**

Items identified as too easy were 2, 9, 10, 11, 35 and 40. Items identified as too hard were 4, 5, 20, 22, 25, 26, 30, 32, and 33. Of those items 2, 4, 5, 9, 10, 11, 20, 22, 25, 26, 30, 32 and 33 are multiple choice questions and will be examined using the distracter analysis.

**Distracter analysis**. Below are listed the multiple choice questions with only one correct answer and the frequency of each answer choice.

Item 2

a (correct)	85.7
b	3.6
С	3.6
-99	7.2

Your child is going to be eating 2 hours after you cook a meal. How should you keep the meal safe before your child eats it?

a. Store it in the refrigerator and reheat it when the child is ready to eat it

- b. Place it on the kitchen counter until the child is ready to eat it
- c. Store it in a cool oven until the child is ready to eat it
- d. Store it in a warm oven until the child is ready to eat it

The correct answer to S2 is "a. Store it in the refrigerator and reheat it when the child is ready to eat it" indicating S2 is too easy and should be considered for omission or revision.

Item 4

a (correct)	14.3
b	0
С	14.3
d	64.3
-99	7.1

What is the safest way to cool a large pot of hot soup?

- a. Put the soup in a clean shallow pan and refrigerate right away
- b. Keep the soup in the cooking pot and refrigerate right away
- c. Put the soup in a clean, deep pot before and refrigerate right away
- d. Cool the soup to room temperature on the counter, then refrigerate it

The correct answer to S4 is "a. Put the soup in a clean shallow pan and refrigerate right away" indicating S4 is too hard. Answer choice "b" was never chosen indicating that it is too easy or obvious. Answer choice "d" was chosen the most frequently indicating a practice or behavior that is common or viewed as correct.

Item 5

a	78.6
b (correct)	14.3
С	3.6
d	0
-99	3.6

How long can you store <u>cooked</u> hamburger and chicken in the refrigerator to eat later?

- a. 1-2 days
- b. 3-4 days
- c. 5-7 days
- d. More than a week

The correct answer choice is "b. 3-4 days" indicating that the question is too hard and that the majority of respondents believe cooked hamburger should be disposed of in 1-2 days.

Item 9

а	3.6
b (correct)	92.9
С	3.6

Putting raw meat in a separate bag (away from other food items) before placing it in the grocery cart:

- a. Increases the chance of food poisoning
- b. Decreases the chance of food poisoning
- c. Makes no difference

Most respondents correctly chose answer choice "b. Decreases the chance of food poisoning" indicating that this question is too easy or that the distracters are weak.

Item 10

а	3.6
b	14.3
С	0
d (correct)	82.1

How should you wash fresh fruits and vegetables to keep you from getting food poisoning?

a. Wash with regular soap

- b Wash with hot water
- c. Wash with anti-bacterial soap
- d. Hold under cool running water

Most respondents correctly chose answer choice "d. Hold under cool running water" indicating the question is too easy or that the distracters are weak.

Item 11

а	3.6
b	0
С	7.2
d (correct)	89.3

After you have used a cutting board to slice raw meat or chicken, or fish and need to cut other foods, which of these is the best way to prevent food poisoning?

- a. Wipe the cutting board off with a paper towel
- b. Rinse the cutting board under very hot water
- c. Turn the cutting board over and use the other side
- d. Wash the cutting board with hot soapy water and rinse

Most respondents correctly chose answer choice "d. Wash the cutting board with hot soapy water and rinse" indicating the question is too easy.

Below are the frequency tables for the multiple choice questions with multiple correct answers. Each answer choice (a-x) was coded using: -99=missing data, 0=incorrect answer or 1=correct answer. All answer choices were coded as individual questions. If the respondent correctly chose "a" when that was correct the respondent scored a one. If the respondent correctly did not choose "b" when the answer choice was not "b" then the respondent scored a one. Their total score was calculated by adding all correct answers and dividing that by the total possible correct answers giving the respondent a percentage total score. The maximum possible total score being a one.

For example, S20 below has "a" through "i" answer choices. Each respondent can get a maximum of nine points out of nine total points. If the respondent were to answer all of the items correctly they would receive a one for getting 100% of the item correct. If the respondent were to have only gotten seven out of nine of the answer choices correct they would have received a 0.77 for getting 77% correct, and so forth.

Item 20

S20	-99	Incorrect	Correct
a (correct)	3.6	7.1	89.3
b	3.6	10.7	85.7
c (correct)	3.6	25	71.4
d	3.6	67.9	28.6
е	3.6	25	71.4
f (correct)	3.6	17.9	78.6
g	3.6	32.1	64.3
h (correct)	3.6	17.9	78.6
i	3.6	82.1	14.3

To prevent food poisoning, which of these individuals should not prepare food for other people? (Check all that apply)

- a. A person with diarrhea
- b. A person with sores or pimples on face
- c. A person with a fever
- d. A person with a rash
- e. A person who smokes
- f. A person with a sore throat
- g. A person with allergies
- h. A person who has just vomited
- i. A person with a runny nose

The correct answers to S20 were "a", "c", "f", and "h". Most respondents knew to choose "a" and not to choose answer choice "b" indicating they are too easy. Answer

choices "f" and "h" are bordering 0.8 indicating they are almost too easy. Answer choice "i" is too hard as most people chose it as correct when it was incorrect.

Item 22

S22	-99	0	1
а	3.6	0	96.4
b (correct)	3.6	28.6	67.9
С	3.6	53.6	42.9
d (correct)	3.6	50	46.4

How should dishes be washed to prevent food poisoning? (Check all that apply)

- a. Soak them in the sink for several hours and then wash them in the same water
- b. Hand wash them right after the meal and then let them air-dry
- c. Hand wash and rinse them right after the meal and then dry them with a dishtowel
- d. Wash and dry them in a dishwasher

Answer choices "b" and "d" were correct. Most respondents correctly identified answer choice "a" as incorrect indicating the answer choice is too easy or obvious.

Item 25

S25	-99	Incorrect	Correct
a (correct)	10.7	50	39.3
b	10.7	57.1	32.1
c (correct)	10.7	71.4	17.9
d (correct)	10.7	35.7	53.6
e (correct)	10.7	3.6	85.7
f (correct)	10.7	17.9	71.4
g	10.7	3.6	85.7
h	10.7	3.6	85.7

Which foods will likely cause food poisoning for pregnant women, infants, and children?

# (Check <u>all</u> that apply)

a. Soft cheeses

- b. Cold smoked fish
- c. Cold deli salads
- d. Hot dogs that have not been heated
- e. Raw eggs
- f. Undercooked eggs
- g. Canned vegetables
- h. Canned fruit juice

Answer choices "a", "c", "d", "e", and "f" are correct. Most respondents correctly chose answer choice "e" indicating that it is too easy or obvious. Also, most respondents did not choose answer choices "g" and "h" indicating that they too are also too easy or obvious.

Item 26

S26	-99	0	1
a (correct)	10.7	7.1	82.1
b	10.7	42.9	46.4
c (correct)	10.7	3.6	85.7
d (correct)	10.7	0	89.3
e (correct)	10.7	32.1	57.1
f (correct)	10.7	46.4	42.9
g	10.7	32.1	57.1
h	10.7	3.6	85.7

Which of these people will likely get sick from harmful germs in food?

# (Check all that apply)

- a. Preschool children
- b. Teenagers
- c. Pregnant women
- d. Older people (age 60 and over)
- e. People with type II diabetes
- f. Cancer patients
- g. People who frequently eat at restaurants or get take-out food often

#### h. None of these individuals

The correct answer choices are "a", "c", "d", "e", and "f". The frequency table indicates that answer choices "a" and "d" are too easy or obvious. Additionally respondents did not choose answer choices "c" and "h" indicating they are also too easy or obvious.

Item 30

S30	-99	0	1
a (correct)	17.9	53.6	28.6
b	17.9	42.9	39.3
c (correct)	17.9	28.6	53.6
d (correct)	17.9	71.4	10.7
e (correct)	17.9	50	32.1
f	17.9	10.7	71.4

Which food(s) will likely cause food poisoning? (Check <u>all</u> that apply)

- a. Home canned beans, carrots, peas or potatoes right from the jar
- b. Commercially canned vegetables right out the can without re-heating them
- c. Unpasteurized fruit juice
- d. Sliced melon
- e. Raw sprouts (alfalfa, bean, clover, radish)
- f. Fresh homemade salsa

Answer choices "a", "c", "d", and "e" are correct. When the number of respondents who did not choose answer choice "d" are added to the missing data total, as is done in the final coding for reliability, it is too hard. However, it is observable that with such a high missing data total and the high scores of incorrect answers that this item is generally too hard.

Item 32

S32	-99	0	1
a (correct)	7.1	25	67.9

b (correct)	7.1	42.9	50
c (correct)	7.1	46.4	46.4
d (correct)	7.1	10.7	82.1

Which food(s) will likely cause food poisoning? (Check all that apply)

- a. Raw milk (not pasteurized)
- b. Fresh cheese made with raw milk
- c. Infant milk or formula with honey added
- d. Milk with raw egg added

Answer choices "a", "b", "c", and "d" were correct. Most respondents also correctly chose "d" indicating that the answer choice is too easy or obvious.

Item 33

S33	-99	0	1
a (correct)	7.1	10.7	82.1
b (correct)	7.1	14.3	78.6
С	7.1	42.9	50
d	7.1	42.9	50

Which food(s) will likely cause food poisoning? (Check <u>all</u> that apply)

- a. Rare hamburgers
- b. Grilled steak served on the same plate that held raw steak without washing the plate
- c. Meat cooked medium-well
- d. Frozen foods with frost built up in the package

Answer choices "a" and "b" were correct. Both choices have high frequencies although "a" is the only choice above 0.8. This question should be considered for omission or revision.

The remaining questions (S35 & S40) should also be considered for omission or revision. Both questions were frequently correct indicating they are too easy. Below are listed questions S35 & S40.

# S35

Undercooked chicken and raw eggs can carry Salmonella (a harmful germ).

- a. True
- b. False

### S40

Deli foods or luncheon meat kept beyond the expiration date are safe.

- a. True
- b. False

# Internal consistency.

Table 11: Internal Consistency of the Chill Construct

Chill: .450	Item-total	Reliability
	score	if deleted
S1	-0.019	0.457
S2	0.153	0.455
S3	0.049	0.456
S4	-0.039	0.462
S5	0.144	0.455
S6	0.507	0.449
S19	-0.131	0.459
S40	0.671	0.034
S41	0.722	-0.034

Table 12: Internal Consistency of the Separate Construct

Sep: .222	Item-total	Reliability
	score	if deleted
S7	-0.045	0.335
S8	0.18	0.092
S9	0.398	-9.41
S20	-0.119	0.36

S21 0.	214 0.034
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Table 13: Internal Consistency of the Clean Construct

Clean: -1.2	Item-total	Reliability
	score	if deleted
S10	-0.171	-1.13
S11	-0.313	-0.837
S12	-0.36	-0.624
S13	-0.292	-0.829
S15	-0.307	-0.795
S22	0.024	-1.69
S23	-0.396	-0.546

Table 14: Internal Consistency of the Cook Construct

Cook: .014	Item-total	Reliability
	score	if deleted
S16	0.12	0.01
S17	-0.012	0.015
S18	0.169	0.008
S24	0.108	0.01
S39	0.148	0.468

Table 15: Internal Consistency of the Groups Construct

Groups:	Item-total	Reliability
272	score	if deleted
S25	-0.129	
S26	-0.129	

Table 16: Internal Consistency of the Foods Construct

Foods:	Item-total	Reliability
.704	score	if deleted
S27	0.219	0.709
S28	0.182	0.709
S29	0.221	0.709
S30	0.082	0.71
S31	0.497	0.708
S32	0.096	0.71
S33	0.196	0.709
S34	0.537	0.684

S35	0.49	0.659
S36	0.742	0.623
S37	0.745	0.622
S38	0.711	0.602

### **Survey Description**

The food safety knowledge survey (Appendix TBD) used in the study's validation process contains 11 demographic questions and 41 knowledge items. The demographic questions include age, ethnicity, gender, location of residence, citizenship, level of education, experience in the food industry, amount of children under the age of ten living in the household, and current employment.

The knowledge survey items were developed to measure the following food safety constructs: Chill, Separate, Clean, Cook, Groups at Greater Risk for Foodborne Disease, and Foods that Increase the Risk of Foodborne Disease. The first four (Chill, Separate, Clean and Cook) derive from the national food safety campaign "Fight BAC" (Fight BAC, retrieved on September 5, 2011) that condenses food safety awareness, knowledge and practices into these four categories in order to promote education, safe food handling and reduce foodborne illness. The questions in all six categories derive from measures used in previously reported studies (FDA, 2009; Haapala & Probart, 2004; Medeiros et al., 2004; Unklesbay et al., 1998; Wenrich et al., 2003; Meysenburg, 2009, Byrd-Bredbenner et al., 2007). Questions were modified to be understood at a 7th grade level to augment comprehension and accuracy. Certain words and foods were changed to enhance cultural appropriateness.

The Chill construct contained 9 questions (survey items 1, 2, 3, 4, 5, 6, 19, 40, & 41): six were multiple choice, one was multiple choice with multiple correct answers, and two were true or false. The Separate construct had five questions (survey items 7, 8, 9, 20, & 21): three of which were multiple choice, the remaining two were multiple choice with multiple correct answers. The Clean construct had seven

questions (survey items 10, 11, 12, 13, 15, 22, & 23): five were multiple choice, the remaining two were multiple choice with multiple correct answers. The Cook construct had five questions (survey items 16, 17, 18, 24, & 39): three were multiple choice, one was multiple choice with multiple correct answers, and one true or false. The construct Groups at Greater Risk of Foodborne Disease contained two questions (25 & 26): both were multiple choice with multiple correct answers. The final section, Foods that Increase Risk of Foodborne Disease, contained 12 questions (27, 28, 29, 30, 31, 32, 33, 34, 35, 36, 37, & 38): seven were multiple choice with multiple correct answers and five were true or false.

Sample questions from the food safety knowledge survey in each question type include:

### **Example 1: Multiple Choice Question**

Your child is going to be eating 2 hours after you cook a meal. How should you keep the meal safe before your child eats it?

- a. Store it in the refrigerator and reheat it when the child is ready to eat it
- b. Place it on the kitchen counter until the child is ready to eat it
- c. Store it in a cool oven until the child is ready to eat it
- d. Store it in a warm oven until the child is ready to eat it

(Example one excerpted from Chill construct, item 2.)

# **Example 2: Multiple Choice Question with Multiple Correct Answers**

To prevent food poisoning, which of these individuals should not prepare food for other people? (Circle <u>all</u> that apply)

- a. A person with diarrhea
- b. A person with sores or pimples on face
- c. A person with a fever
- d. A person with a rash
- e. A person who smokes
- f. A person with a sore throat
- g. A person with allergies

- h. A person who has just vomited
- i. A person with a runny nose

(Example two excerpted from Separate, item 20.)

# **Example 3: True or False Question**

Undercooked chicken and raw eggs can carry Salmonella (a harmful germ).

- a. True
- b. False

(Example three excerpted from Foods that Increase Risk of Foodborne Illness, item 35.)

### **Appendix F: IRB Approval Letter**



Main Campus Institutional Review Board Human Research Protections Office MSC08 4560 1 University of New Mexico~Albuquerque, NM 8

1 University of New Mexico~Albuquerque, NM 87131-0001 http://hsc.unm.edu/som/research/HRRC/

27-Jul-2011

Responsible Faculty: Christina Perry Investigator: Maggie Siebert

Dept/College: Health Exercise & Sports Science

SUBJECT: IRB Approval of Research - Initial Review - Modification

Protocol #: 11-386

Project Title: Validation of a Food Safety Knowledge Survey

Type of Review: Expedited Review Approval Date: 27-Jul-2011 Expiration Date: 26-Jul-2012

The Main Campus Institutional Review Board has reviewed and approved the above referenced protocol. It has been approved based on the review of the following:

- 1. Expedited Review Application submitted to the HRPO on 07/26/2011;
- 2. Investigator's Protocol version 07/19/2011;
- 3. UNM Consent Document version 07/11/2011;
- 4. Phone Interview Script submitted 07/19/2011;
- 5. Volunteers Needed Tear-Off Flyer submitted 07/19/2011;
- 6. Demographic Survey submitted 07/19/2011;
- 7. Knowledge Survey submitted 07/19/2011.

#### Consent Decision:

Signature waived; requires written statement about research

HIPAA Authorization Addendum not applicable

If a consent is required, we have attached a date stamped consent that must be used for consenting participants during the above noted approval period.

If HIPAA authorization is required, the HIPAA authorization version noted above should be signed in conjunction with the consent form.

As the principal investigator of this study, you assume the following responsibilities:

- CONSENT: To ensure that ethical and legal informed consent has been obtained from all research participants.
- RENEWAL: To submit a progress report to the IRB at least 45 days prior to the end of the approval period in order for this study to be considered for continuation.
- ADVERSE EVENTS: To report any adverse events or reactions to the IRB immediately.

- MODIFICATIONS: To submit any changes to the protocol, such as procedures, consent/assent forms, addition of subjects, or study design to the IRB as an Amendment for review and approval.
- COMPLETION: To close your study when the study is concluded and all data has been de-identified (with no link to identifiers) by submiting a Closure Report.

Please reference the protocol number and study title in all documents and correspondence related to this protocol.

Sincerely,

J. Scott Tonigan, PhD

Jewn B

Chair

Main Campus IRB

<sup>\*</sup> Under the provisions of this institution's Federal Wide Assurance (FWA00004690), the Main Campus IRB has determined that this proposal provides adequate safeguards for protecting the rights and welfare of the subjects involved in the study and is in compliance with HHS Regulations (45 CFR 46).