Appendix K:
IRB Approval Form

NORTH CAROLINA STATE UNIVERSITY

INSTITUTIONAL REVIEW BOARD FOR THE USE OF HUMAN SUBJECTS IN RESEARCH

SUBMISSION FOR NEW STUDIES

Protocol Number 10599

Project Title

Evaluating Consumer Behaviors and Responses to Risk Messaging

IRB File Number:

Original Approval Date:

05/05/2017

Approval Period

05/05/2017 - 05/05/2018

Source of funding (if externally funded, enter PINS or RADAR number of funding proposal via 'Add New Sponsored Project Record' button below):

PINS 75222

NCSU Faculty point of contact for this protocol:NB: only this person has authority to submit the protocol

Chapman, Benjamin James: Agricultural & Human Sciences

Does any investigator associated with this project have a significant financial interest in, or other conflict of interest involving, the sponsor of this project? (Answer No if this project is not sponsored)

No

Is this conflict managed with a written management plan, and is the management plan being properly followed?

No

Preliminary Review Determination

Category:

Full Board

In lay language, provide a brief synopsis of the study (limit text to 1500 characters)

The objective of this study is to determine consumers' adherence to four recommended food safety behaviors of clean, cook, separate, and chill, when preparing food. Additionally the research will attempt to determine whether food messaging affects consumer food safety handling behaviors and whether consumers introduce cross-contamination during food preparation. These questions will be answered through a mixed-methods approach of observation of practices coupled with microbiological data collection and supplemented with a post-observation interview. A full description of the study can be found as an attachment (Chapman 10599 -Observation-study-design)

Briefly describe in lay language the purpose of the proposed research and why it is important.

This research fills a large gap in the literature as it relates to how food is handled by consumers. Actual practices, and their impacts, are needed for specific intervention development and risk assessment calculations. Much of the food safety communication and interventions to date have been built on non-systematic research leaving efforts not risk- or science-based. This work will come the most robust approach to actual consumer food handling to date.

My research qualifies for Exemption. Exempt research is minimal risk and must fit into the categories b.1 - b.6 found here: http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html

0

Is this research being conducted by a student?

Yes

Is this research for a thesis?

Yes

Is this research for a dissertatiion?

No

Is this independent research?

No

Is this research for a course?

No

Do you currently intend to use the data for any purpose beyond the fulfillment of the class assignment?

No

Please explain

If so, please explain

If you anticipate additional NCSU-affiliated investigators (other than those listed on the Title tab) may be involved in this research, list them here indicating their name and department.

Rebecca Goulter (FBNS)

Will the investigators be collaborating with researchers at any institutions or organizations outside of NC State?

Yes

List collaborating institutions and describe the nature of the collaboration

RTI International

RTI will aid in the analysis of already coded, de-identifed and anonymous data. They will not have access to video, raw transcript or written data. We state that video information will be shared with RTI we do not mean actual videos or any visuals, just the data that is coded and de-identified.

What is NCSU's role in this research?

We are the lead institute for the research.

Describe funding flow, if any (e.g. subcontractors)

USDA Food Safety Inspection Services contract with RTI International, we are subcontractors

Is this international research?

No

Identify the countries involved in this research

An IRB equivalent review for local and cultural context may be necessary for this study. Can you recommend consultants with cultural expertise who may be willing to provide this review?

Adults 18 - 64 in the general population?

Yes

NCSU students, faculty or staff?

No

Adults age 65 and older?

Yes

Minors (under age 18--be sure to include provision for parental consent and/or child assent)?

No

List ages or age range:

Could any of the children be "Wards of the State" (a child whose welfare is the responsibility of the state or other agency, institution, or entity)?

No

Please explain:

Prisoners (any individual involuntarily confined or detained in a penal institution -- can be detained pending arraignment, trial or sentencing)?

No

Pregnant women?

No

Are pregnant women the primary population or focus for this research?

No

Provide rationale for why they are the focus population and describe the risks associated with their involvment as participants

Fetuses?

No

Students?

No

Does the research involve normal educational practices?

No

Is the research being conducted in an accepted educational setting?

No

Are participants in a class taught by the principal investigator?

No

Are the research activities part of the required course requirements?

No

Will course credit be offered to participants?

No

Amount of credit?

No

If class credit will be given, list the amount and alternative ways to earn the same amount of credit.Note: the time it takes to gain the same amount of credit by the alternate means should be commensurate with the study task(s)

How will permission to conduct research be obtained from the school or district?

Will you utilize private academic records?

No

Explain the procedures and document permission for accessing these records.

Employees?

No

Describe where (in the workplace, out of the workplace) activities will be conducted.

From whom and how will permission to conduct research on the employees be obtained?

How will potential participants be approached and informed about the research so as to reduce any perceived coercion to participate?

Is the employer involved in the research activities in any way?

No

Please explain:

Will the employer receive any results from the research activities (i.e. reports, recommendations, etc.)?

No

Please explain. How will employee identities be protected in reports provided to employers?

Impaired decision making capacity/Legally incompetent?

No

How will competency be assessed and from whom will you obtain consent?

Mental/emotional/developmental/psychiatric challenges?

No

Identify the challenge and explain the unique risks for this population.

Describe any special provisions necessary for consent and other study activities (e.g., legal guardian for those unable to consent).

People with physical challenges?

No

Identify the challenge and explain the unique risks for this population.

Describe any special provisions necessary for working with this population (e.g., witnesses for the visually impaired).

Economically or educationally disadvantaged?

Yes

Racial, ethnic, religious and/or other minorities?

Yes

Non-English speakers?

No

Describe the procedures used to overcome any language barrier.

Will a translator be used?

No

Provide information about the translator (who they are, relation to the community, why you have selected them for use, confidentiality measures being utilized).

Explain the necessity for the use of the vulnerable populations listed.

Please see the study design document (Chapman 10599 -Observation-study-design) Table 1 for proposed sample demographics. All observation studies to dates have not been structured to collect data from a representative population, leaving grave limitations to develop interventions across different populations. In short, there is not good data on these populations as primary meal preparers (lay individuals, which is our target, not professional chefs) and this work will fill that gap.

State how, where, when, and by whom consent will be obtained from each participant group. Identify the type of consent (e.g., written, verbal, electronic, etc.). Label and submit all consent forms.

Consent will be obtained in two ways, in written form (10599-fscrp_consent form_final-5-3-17.docx) and orally during the post observation debrief and interview (Chapman 10599 Post-observation-interview-guide_5-3-17)

verbal consent script below (adjusted per comments):

Introduction script:
Thank you so much for your time today and allowing us to record your actions while you prepared a meal just like you would in your home. If it is okay with you, Iâ€™m going to ask you a few follow-up questions that will focus on some of the activities you participated in while in the model kitchen.
Is it okay with you if I record your answers? The recording is confidential and will only be used to accurately capture our conversation (allowed recording y/n).

We mentioned in our recruiting materials that we were interested in cooking practices and how you evaluate recipes. However, the specific focus of our study is on food safety and how to prevent food poisoning. The aim of this study is to measure handling and preparation practices and investigate the movement of bacteria from raw foods, so we can better understand exactly how contamination can spread. In addition, a biological tracking agent was in the food to help us track where contamination might occur. This biological tracking agent is a bacteriophage called MS2, and it does not pose any health hazard to you. We purposely did not tell you exactly what our specific research objectives were in advance to capture your behaviors in a natural way. You can request to be removed from the study at any time, and if you decide to exit the study at this point, we will destroy the recordings of your actions, and you will not be included in the data set.

We want to confirm with you now that you understand the focus of our study and that you wish to remain as a participant.

If no: Thank you so much for your time, your participation in our study is now complete, and we will remove your data from our dataset and destroy any records.

If yes: Thank you for your consent.
If it is okay with you, Iâ€™d like to begin this interview, which will take about 15 minutes.

If any participants are minors, describe the process for obtaining parental consent and minor's assent (minor's agreement to participate).

n/a

Are you applying for a waiver of the requirement for consent (no consent information of any kind provided to participants) for any participant group(s) in

your study?

No

Describe the procedures and/or participant group for which you are applying for a waiver, and justify why this waiver is needed and consent is not feasible.

Are you applying for an alteration (exclusion of one or more of the specific required elements) of consent for any participant group(s) in your study?

No

Identify which required elements of consent you are altering, describe the participant group(s) for which this waiver will apply, and justify why this waiver is needed.

Are you applying for a waiver of signed consent (consent information is provided, but participant signatures are not collected)? A waiver of signed consent may be granted only if: The research involves no more than minimal riskThe research involves no procedures for which consent is normally required outside of the research context.

No

Would a signed consent document be the only document or record linking the participant to the research?

No

Is there any deception of the human subjects involved in this study?

Yes

Describe why deception is necessary and describe the debriefing procedures.Does the deception require a waiver or alteration of informed consent information?Describe debriefing and/or disclosure procedures and submit materials for review.Are participants given the option to destroy their data if they do not want to be a part the study after disclosure?

Deception is necessary for this project as we want to collect data in the most natural way. There is a lack of data in the published literature specific to actual food handling behaviors (thermometer usage, cross-contamination) with the vast majority of studies focusing on self-reported data which is fraught with problems when it comes to socially acceptable behaviors like cleanliness and hygiene (people are more likely to report behavior that is more positive than their actual practices).

While we are aware of the Hawthone effect (observing/data collection impacting behaviors) we feel that by not sharing the true nature of data collection (food safety practices) until after the observation data collection is the best way to collect the closest to real practices.

During the post-observation debrief and interview we will explain the full objectives (see Chapman 10599 Post-observation-interview-guide-5-3-17 for full script) and will ask for additional oral consent (audio recorded). Participants are provided the option to destroy their data if they wish to be removed from the study.

For each participant group please indicate how many individuals from that group will be involved in the research. Estimates or ranges of the numbers of participants are acceptable. Please be aware that participant numbers may affect study risk. If your participation totals differ by 10% from what was originally approved, notify the IRB.

Primary meal preparers are the only participant group in this study. We are targeting 400 participants.

How will potential participants be be found and selected for inclusion in the study?

Recruiting will be completed through a mix of passive posters at retail stores, community gathering locations and restaurants (see Chapman 10599 observation-study-poster-11-22-16) and through social media (Facebook and Twitter using the same poster elements).

Participants responding to the ads/fliers wlll be screened through an online screener (text found in chapman-10599-FSCRP_Screening_Questionnaire_Revised_11_7_16)

For each participant group, how will potential participants be approached about the research and invited to participate? Please upload necessary scripts, templates, talking points, flyers, blurbs, and announcements.

See Chapman 10599 observation-study-poster-11-22-16, and chapman-10599-FSCRP_Screening_Questionnaire_Revised_11_7_16

Email reminder script:

Welcome to the NCSU kitchen study and thank you for your participation.

My name is Dr. Ben Chapman and Iâ€™ll be walking you through what youâ€™ll be doing as part of our study when you arrive on (x date at x time) You will be preparing two recipes to test a new product formulation: a salad and turkey burgers. The recipes are will be provided to you when you arrive. You will be asked to prepare the foods in the order that you would usually do so at home.
After preparing the recipes, please clean up the kitchen as you normally would at home.
We will interview you after you are finished cooking. The cooking and interview will last no more than 2 hours total.

Please view this video for more information on the study expectations. (Intervention group will also get: Please also review this video from USDA:https://www.youtube.com/watch?v=-2KkV2yFiN0

If you have any questions please contact me at benjamin_chapman@ncsu.edu or 919 515 8099.

Expectations video script:

My name is Dr. Ben Chapman and Iâ€™ll be walking you through what youâ€™ll be doing as part of our study when you arrive. You will be preparing two recipes to test a new product formulation: a salad and turkey burgers. The recipes are will be provided to you when you arrive. You will be asked to prepare the foods in the order that you would usually do so at home. Please do not eat the food you are preparing.
After preparing the recipes, please clean up the kitchen as you normally would at home.
We will interview you after you are finished cooking. Please do not eat the food you are preparing. The cooking and interview will last no more than 2 hours total.

This is the area where you will be cooking (show kitchen). All the available utensils and dishes are in these drawers/cabinets (indicate). Feel free to use whatever you need. Please make yourself at home, you are welcome to use your phone to listen to music, or whatever you usually do when cooking at home. If you have any questions please contact me at benjamin_chapman@ncsu.edu or 919 515 8099.

Describe any inclusion and exclusion criteria for your participants and describe why those criteria are necessary (If your study concentrates on a particular population, you do not need to repeat your description of that population here.)

See chapman-10599-FSCRP_Screening_Questionnaire_Revised_11_7_16 for all inclusion/exclusion criteria

Is there any relationship between researcher and participants - such as teacher/student; employer/employee?

No

What is the justification for using this participant group instead of an unrelated participant group? Please outline the steps taken to mitigate this relationship.

Describe any risks associated with conducting your research with a related participant group.

Describe how this relationship will be managed to reduce risk during the research.

How will risks to confidentiality be managed?

Address any concerns regarding data quality (e.g. non-candid responses) that could result from this relationship.

In the following questions describe in lay terms all study procedures that will be experienced by each group of participants in this study.For each group of participants in your study, provide a step-by-step description of what they will experience from beginning to end of the study activities.

1. A 5 minute, 10 question screening questionnaire conducted online (chapman-10599-FSCRP_Screening_Questionnaire_Revised_11_7_16)

2. A follow-up email or phone call to schedule observation event
Prior to the observation event, each participant will receive a reminder email (and if receipt is not confirmed, will be followed up via phone) with a confirmation of location, time, and check-in procedures.

The study will also assess pathogen transfer during meal preparation through observed actions (captured by video) as well as by using a tracer in the meat, a harmless bacteriophage named MS2, which does not require biosafety approval (naturally occurring, only infects E. coli). Also included in this email will be a link to a short YouTube video explaining what participants can expect to take place during the study and the meal we are asking them to prepare with some visuals on raw and finished meals (video not yet developed but will be less than 30 seconds, script below).

The treatment group will receive a link via email prior to the study and asked to watch the USDA YouTube video â€œThe Importance of Cooking to a Safe Internal Temperature and How to Use a Food Thermometerâ€• which will serve as the test intervention. The video intervention they are watching is found at: https://www.youtube.com/watch?v=-2KkV2yFiN0

3. A 1 hr observation event

To ensure exposure to the intervention, participants in the treatment and control groups will be provided iPads upon entering the observation waiting area and will be asked to view the expectation video. The treatment group will also be asked to view the thermometer safety videos intervention.

We will observe whether participants use a food thermometer to check doneness of the meat or poultry product and the product is cooked to the recommended temperature. Participants will prepare a ground turkey burger , followed by a ready-to-eat salad. They will inform researchers when their meal is complete. No food will be eaten.

4. A 15 min post-observation event interview will be conducted (script found here: 10599-post-interview guide-3-20-17-final.docx), this will also contain a second consent (due to deception). Interview will be audio recorded.

Email script for participants:

Welcome to the NCSU kitchen study and thank you for your participation.

My name is Dr. Ben Chapman and Iâ€™ll be walking you through what youâ€™ll be doing as part of our study when you arrive on (x date at x time) You will be preparing two recipes to test a new product formulation: a salad and turkey burgers. The recipes are will be provided to you when you arrive. You will be asked to prepare the foods in the order that you would usually do so at home.

After preparing the recipes, please clean up the kitchen as you normally would at home.
We will interview you after you are finished cooking. The cooking and interview will last no more than 2 hours total.

Please view this video for more information on the study expectations. (Intervention group will also get: Please also review this video from USDA:https://www.youtube.com/watch?v=-2KkV2yFiN0

If you have any questions please contact me at benjamin_chapman@ncsu.edu or 919 515 8099.

Video script:

My name is Dr. Ben Chapman and Iâ€™ll be walking you through what youâ€™ll be doing as part of our study when you arrive. You will be preparing two recipes to test a new product formulation: a salad and turkey burgers. The recipes are will be provided to you when you arrive. You will be asked to prepare the foods in the order that you would usually do so at home. Please do not eat the food you are preparing.

After preparing the recipes, please clean up the kitchen as you normally would at home.
We will interview you after you are finished cooking. Please do not eat the food you are preparing. The cooking and interview will last no more than 2 hours total.

This is the area where you will be cooking (show kitchen). All the available utensils and dishes are in these drawers/cabinets (indicate). Feel free to use whatever you need. Please make yourself at home, you are welcome to use your phone to listen to music, or whatever you usually do when cooking at home. If you have any questions please contact me at benjamin_chapman@ncsu.edu or 919 515 8099.

Questions from Jennie (all incorporated above):
Is this the video intervention they are watching? https://www.youtube.com/watch?v=-2KkV2yFiN0
Yes

Is the "the thermometer safety videos intervention." the video referenced above via youtube?
Yes

Is anyone eating the food?
No. Instructed not to.

Describe how, where, when, and by whom data will be collected.

Observation (video) and interview (audio recording) data will be collected at test kitchens, to be located at 512 Brickhaven Dr.,in Fall 2017 by two graduate students and two undergraduate research assistants.

Social?

No

Psychological?

No

Financial/Employability?

No

Legal?

No

Physical?

Yes

Academic?

No

Employment?

No

Financial?

No

Medical?

No

Private Behavior?

No

Economic Status?

No

Sexual Issues?

No

Religious Issues/Beliefs?

No

Describe the nature and degree of risk that this study poses. Describe the steps taken to minimize these risks. You CANNOT leave this blank, say 'N/A', none' or 'no risks'. You can say "There is minimal risk associated with this research."

There is minimal risk associated with this research, participants will not be exposed to any risks that are greater or different from what they would be exposed to in their own home as a primary meal preparer. There are heat sources (stove, oven, counter top grill) and sharp objects that may result in cuts (knives, forks, slicers).

The items and appliances are common home kitchen equipment. Each study kitchen is equipped with a first aid kit and fire extinguisher. Researchers will be available just outside of the kitchen to assist in case of injury by providing the first aid kits and alerting medical staff if needed.

If you are accessing private records, describe how you are gaining access to these records, what information you need from the records, and how you will receive/record data.

We are not accessing private records.

Are you asking participants to disclose information about other individuals (e.g., friends, family, co-workers, etc.)?

No

You have indicated that you will ask participants to disclose information about other individuals (see Populations tab). Describe the data you will collect and discuss how you will protect confidentiality and the privacy of these third-party individuals.

If you are collecting information that participants might consider personal or sensitive or that if revealed might cause embarrassment, harm to reputation or could reasonably place the subjects at risk of criminal or civil liability, what measures will you take to protect participants from those risks?

We are not collecting sensitive data.

If any of the study procedures could be considered risky in and of themselves (e.g. study procedures involving upsetting questions, stressful situations, physical risks, etc.) what measures will you take to protect participants from those risks?

There is minimal risk associated with this research, no further risks than handling foods that they are familiar with (based on inclusion criteria) that they would encounter in their home kitchens. Knives and heat will be available to prepare and cook foods, so there is a risk of cuts/burns. We will ensure that all equipment is in working condition.

Describe the anticipated direct benefits to be gained by each group of participants in this study (compensation is not a direct benefit).

There are no direct benefits for participants.

If no direct benefit is expected for participants describe any indirect benefits that may be expected, such as to the scientific community or to society.

The scientific community has very little data on the actual food handling practices of consumers in home environments. Only a handful of studies have been performed and many current risk messages are based on this small existing data set. This study will be used to evaluate new risk messages and have a greater understanding of practices so further interventions can be designed and implemented, resulting in better food safety and impacting public health.

Will you be receiving already existing data without identifiers for this study?

No

Will you be receiving already existing data which includes identifiers for this study?

No

Describe how the benefits balance out the risks of this study.

Will data be collected anonymously (meaning that you do not ever collect data in a way that would allow you to link any identifying information to a participant)?

No

Will any identifying information be recorded with the data (ex: name, phone number, IDs, e-mails, etc.)?

Yes

Will you use a master list, crosswalk, or other means of linking a participant's identity to the data?

No

Will it be possible to identify a participant indirectly from the data collected (i.e. indirect identification from demographic information)?

Yes

Audio recordings?

Yes

Video recordings?

Yes

Images?

No

Digital/electronic files?

Yes

Paper documents (including notes and journals)?

Yes

Physiological Responses?

No

Online survey?

Yes

Restricted Computer?

Yes

Password Protected files?

Yes

Firewall System?

Yes

Locked Private Office?

Yes

Locked Filing Cabinets?

Yes

Encrypted Files?

No

Describe all participant identifiers that will be collected (whether they will be retained or not) and explain why they are necessary.

Email addresses, phone numbers and names will be collected during the screening process. They are necessary to schedule observation times. Once scheduled, screening data will be discarded. An observation event schedule will be provided from the screener to the observation kitchen manager, however only first names and last initials will be shared from screener to manager. Identifiers will not be retained, and will not be connected to observation data collection process.

Following the observation events, recorded video filenames will not contain names (i.e. Observation-1.mp4) and observation coders will not receive schedule. Videos will contain visuals of faces, but only viewed by researchers and observation scheduling/screener information will not be provided to coders (so connection between names and faces will not be provided). If a coder recognizes a participant from their video, they will be instructed to stop coding that video and pass it to another coder and required to not discuss or disclose identities.

If any links between data and participants are to be retained, how will you protect the confidentiality of the data?

Video links will exist. but recorded video filenames will not contain names (i.e. Observation-1.mp4) and observation coders will not receive schedules (with names).Videos will contain visuals of faces, but only viewed by researchers and observation scheduling/screener information will not be provided to coders (so connection between names and faces will not be provided). If a coder recognizes a participant from their video, they will be instructed to stop coding that video and pass it to another coder and required to not discuss or disclose identities.

If you are collecting data electronically, what (if any) identifiable information will be collected by the host site (such as email and/or IP address) and will this information be reported to you?

Email and phone numbers only. Videos will contain faces. Needed for scheduling events only, not retained.

Describe any ways that participants themselves or third parties discussed by participants could be identified indirectly from the data collected, and describe measures taken to protect identities.

Screening data (name/phone number , schedule and video recording time stamps, if accessible by one person might be used to unlock the keys). Screener, schedule and observation recordings will all be controlled by three different individuals. Also, the nature of video will include face recording, videos will be stored safely (see below).

For all recordings of any type:Describe the type of recording(s) to be made Describe the safe storage of recordings Who will have access to the recordings? Will recordings be used in publications or data reporting? Will images be altered to de-identify?Will recordings be transcribed and by whom?

Video recordings will be made of observations. Audio recordings will be made of post observation interviews.
Audio and video recordings will be stored on computers that are password protected, using two factor authentication. Computers wifi will also not be enabled (so the computers will not be on any sort of network). Computers will be stored in locked filling cabinets, in locked offices in 512 Brickhaven Dr.

Two graduate students and two biweekly undergraduate research assistants will have access to the recordings and will code the videos on site, in closed offices during the coding process. They will also transcribe the audio recordings.
Recordings will not be used in publications or data reporting, just the de-idenfied, coded aggregate data.
Images will not be altered to de-identify.

Audio recordings will be transcribed by two graduate students and two biweekly undergraduate research assistants

Describe how data will be reported (aggregate, individual responses, use of direct quotes) and describe how identities will be protected in study

reports.

Data will be reported in aggregate for video observation, no individual data will be reported from observations. Identities for audio recordings will be full protected as participants will be assigned a participant number. Direct quotes an may be used in audio recordings. (i.e. Participant 267 said "I chose to use the thermometer to see whether the turkey burger was done").

Will anyone besides the PI or the research team have access to the data (including completed surveys) from the moment they are collected until they are destroyed?

Video information will be shared with the RTI and NCSU study team. Because videos include visual information about participants, they are not considered to be de-identified. Names will not be connected to the recordings or interview responses. All data will be identified by a unique identification number and stored securely with only one student holding the code key. This code key will be stored on a At the completion of this study, the recordings will be destroyed.

Describe any compensation that participants will be eligible to receive, including what the compensation is, any eligibility requirements, and how it will be delivered.

Participants will receive $75 as well as digital food thermometer for completing the study (observation and interview components). It will be provided at the observation site following the completion of the individuals' session.

Explain compensation provisions if the participant withdraws prior to completion of the study.

Participants will not be provided with compensation if they withdraw.