

Appendix K

IRB Approval

Letter to IRB Requesting in Person Interactions

Faculty Point of Contact Name: Benjamin Chapman

Additional Personnel Name(s): Lisa Shelley

eIRB Number: 10599

Study Title: Evaluating Consumer Behaviors and Responses to Risk Messaging
(Phased Research, 5 Phases)

Funding: USDA Food Safety Inspection Service

The target population for this study are participants who are between the ages of 18 and 64 with grilling (hamburgers) experience within the last six months. Because the focus of this study is on the home consumer, the target population excludes people with previous work experience in the food industry and who have had food safety training within the last five years.

To achieve the goals of this research, the following activities that must take place in person include meal preparation with meat items containing surrogate and sampling of bacterial load after meal preparation. I have explored alternative options and they will not suffice because purpose of the observational study is to evaluate adherence to the key behaviors of clean, separate, cook, and chill following exposure to food safety messaging and to assess the extent of cross-contamination in the kitchen due to failure to follow recommended practices. In Phase 4, we will evaluate adherence to the key behavior of “cook” when grilling hamburgers and bratwursts or Italian sausages (i.e., whether a food thermometer is used and, if so, whether cooked to proper temperature) following exposure to direct messaging of food safety information on thermometer use, handwashing, and other safe handling behaviors in the form of a recipe formatted using the Safe Recipe Style Guide. We will also examine whether participants follow recommended practices for repackaging leftover ground beef from a “chub”-style package. Furthermore, we will assess adherence to other food safety behaviors including handwashing, cleaning and sanitation, and produce washing. We will collect microbiological samples to assess the extent of cross-contamination in the kitchen due to failure to follow recommended cleaning and sanitation practices when grilling, preparing a side salad, and handling the leftover ground beef. A subsample of participants will prepare guacamole (using avocados and fresh cilantro) in addition to the side salad and grilled burgers/brats to provide information on how consumers handle avocados and cilantro.

This data will be used to shape best-practice guidance and safe food handling materials to reduce the incidence of foodborne illness and increase safe food handling practices in the home environment.

To mitigate risks to Covid-19 for participants and to aid in participant safety during all in person research activities, the following safety precautions will be implemented:

- Access to the kitchens will be controlled by key card.
- Participants will be scheduled at times that do not overlap.
- Waiting room furniture will be spaced six feet apart.
- Floor markers will be placed in the test kitchens to ensure six feet distance between researcher and observer during introduction to the kitchen equipment and location of supplies.
- Researchers and participants will wear face masks during the entire observation.
- Researchers will wear gloves when swabbing and sampling participant hands and any surfaces in the kitchen.
- Kitchen equipment and surfaces will be sanitized with Clorox Clean-Up Cleaner and Bleach spray and Clorox Disinfecting Wipes before each observation (three rounds of sanitizing per study design).
- High touch surfaces in the observation room will be wiped down with Clorox Disinfecting Wipes after each observation.
- Researchers will adhere to strict personal hygiene guidelines including washing hands following CDC guidelines and use of hand sanitizer while in the observation room.

I have received the following approvals and permissions from NC State University:

- Department of Agricultural and Human Sciences
- Use of the Dinah E. Gore Teaching and Research Kitchens
- USDA Food Safety and Inspection Services (sponsor)
- Division of Environmental Health and Safety (approved use of surrogate from Phase 2)

All research team members who will interact with participants in person during the Covid-19 pandemic have completed necessary CITI training modules for working with Human Subjects:

- Group 2: Social-Behavioral-Educational Researchers - HSR Basic
- CITI Responsible Conduct of Research

This research is essential, and it must take place immediately because the risk of contracting Covid-19 from kitchen materials or team members is minimal due to the cleaning and sanitizing procedures involved with the use of a bacterial surrogate. Additionally, because of the screening of both participants and members of the research team, social distancing, and the use of protective personal equipment by both participants and team members, the risk of person to person infection is low. This project does have a direct benefit to the public because this study begins to address and the efficacy of alcohol-based sanitizers to prevent the spread of pathogenic organisms in the food preparation/restaurant setting.

Though this letter outlines information about the safety, I have detailed all Covid-19 additional procedures in the Covid-19 Additional Procedures packet and uploaded all the supplemental documents into the eIRB application for this study.

From: IRB Administrative Office <pins_notifications@ncsu.edu>

Date: July 8, 2020 at 3:16:53 PM EDT

To: bjchapma@ncsu.edu

Subject: Chapman - 10599 - IRB Protocol renewal/amendment approved
Reply-To: ncsuirboffice@ncsu.edu

Dear Benjamin Chapman:

Date: 07/08/2020

Project Title: Evaluating Consumer Behaviors and Responses to Risk Messaging (Phased Research, 5 phases)

IRB#: 10599

PI: Chapman, Benjamin James

Approval period ends: 07/07/2021

The renewal/amendment request for the project listed above has been approved in accordance with policy under 45 CFR 46. If your application was to amend your study protocol, and your study received expedited or full board review, this letter does NOT change the expiration date for your study. If you applied to renew your expedited or full board protocol, your new expiration date is shown above.

1. This board complies with requirements found in Title 45 part 46 of The Code of Federal Regulations. For NCSU the Assurance Number is: FWA00003429.
2. You must use the approved documents which have the status "approved" in the document viewer in the eIRB for your study.
3. Any changes to the protocol and supporting documents must be submitted and approved by the IRB prior to implementation via amendment request.
4. If any unanticipated problems or adverse events occur, they must be reported to the IRB office within 5 business days by completing and submitting the unanticipated problem form on the IRB website: <http://research.ncsu.edu/sparcs/compliance/irb/irb-forms/>
5. Any unapproved departure from your approved IRB protocol results in non-compliance. Please find information regarding how to avoid non-compliance here: http://research.ncsu.edu/sparcs-docs/irb/non-compliance_faq_sheet.pdf

Please let us know if you have any questions..

NCSU IRB Office