

Appendix M

COVID-19 Additional Procedures (Year 4 study)

Participant Population Description and Screening

- 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. This population is not considered at risk because participants are below the age of 65 and not living in a long term care/retirement facility.
- The Covid-19 screener questions will be integrated into the initial project screener because this project will most likely take place entirely during the Covid-19 pandemic. Eligible participants will receive a phone call to schedule date/time for participation. During this phone call, participant will be reminded of “day of” screening procedures. Upon scheduling a date/time, the participant will receive a confirmation email with date/time, driving directions, cleaning and sanitizing procedures and precautions including mandatory use of face coverings, and another reminder of “day of” screening procedures.
- When the participant arrives at the Dinah E. Gore Teaching and Research Kitchens, the researcher will greet participant at the door and administer the “day of” screening tool. Answers will be recorded on Google forms using a project iPad. If participant is eligible, then researcher will direct participant to the waiting area of the kitchen. If the participant is not eligible, participant will receive the message stating the following: “Please contact your medical provider to discuss your needs. In addition to contacting your medical provider, if you are an NC State University employee, use this form to self-report: [Employee Self Report Form](#). If you are an NC State University student use this form to report: [Student Self Report Form](#). If you are unaffiliated with NC State University, please call your medical provider to report symptoms.”

Research Procedures Employed that May Increase Risk to Participants

- As part of the study, participants will be preparing a simple meal which will involve handling of several food items. However, this food is not consumed, and participants are told very specifically to not eat or take any food home. These instructions are part of the normal study design--not due to the Covid-19 pandemic--but the researcher will emphasize this point at the beginning of the observation.
- The Covid-19 information collected as part of the initial screening and day of surveys are not subject to HIPAA and will not be used as part of the research. The data collected in Google forms will not be linked to the research study and will be kept separately in a secure Google environment to not allow for the reidentification of participants. Only the project coordinator and principal investigator will have access to the file. The information in this file will not be shared with RTI or FSIS.

Informed Consent Plan, Reviewing the COVID-19 Addendum, and Participant Tracking

- The informed consent form with Covid-19 addendum will be made available to the participant prior to arrival via a hyperlink in conformation email. Upon arrival and, if deemed eligible based on 'day of' screener survey, the participant will be provided a paper copy of the consent form to read. The researcher will specifically review the Covid-19 addendum and answer any questions. The participant will also be provided a copy of the consent form to take home.
- The names and dates of participants will be tracked along with the name(s) of the researcher(s) conducting the observation. This information will be kept in a password protected file and stored on NC State Google Drive. Only the project coordinator and principal investigator will have access to the file. The information in this file will not be used for research. This file will be permanently deleted from NC State Google Drive at the two weeks after the end of the data collection for this project. The information in this file will not be shared with RTI or FSIS.
- At the beginning of each day in the kitchen, all researchers conducting observations will be screened for and asked to sign, time, and date to confirm the following: 1) I have not knowingly interacted with someone who has been diagnosed or demonstrated symptoms of Covid-19 and 2) I do not have any symptoms of Covid-19 such as cough, fever, shortness of breath, chills, muscle pain, new loss of taste or smell. These daily forms will be stored in the project coordinator's office and will be maintained throughout data collection, then shredded and disposed of two weeks after the end of data collection.

Facility Use and Physical Distancing Plan

- Dinah E Gore Teaching and Research Kitchens
 - Kitchen Access: There is one door to the test kitchen, and it requires card access.
 - Physical Distancing and Changes to Space: Only one person will be watching the video monitors in the observation room at any given time. Participants are not in the observation at any time during the study. Waiting room chairs will be spaced at least six feet apart; however, only one participant will be in a test kitchen waiting room at a time. One additional researcher may be in the test kitchens, however, this researcher will remain in a separate test kitchen or seated in the larger teaching kitchen.
 - Visible Markers: Two "Stand Here" floor clings will be placed six feet apart in each test kitchen. Floor clings will mark the location of the participant and researcher in the test kitchen during the time the researcher is in the kitchen with the participant highlighting the

function and location of kitchen equipment and supplies that will be used during the study.

- Scheduling: Participants will be scheduled so that observations times do not overlap. This will ensure social distancing between participants and provide enough time in between observations for cleaning, sanitizing, and setting up for the next participant.

Personal Protective Equipment (PPE)

- Researchers will wear either disposable or reusable face masks. If researchers are wearing reusable face masks, he/she will be required to wash the mask overnight before using again. Disposable masks will also be available to the researchers and located in the observation room.
- Participants will be required to wear face coverings. Participants may arrive with their own face coverings to use; however, disposable face masks, which are stored in the observation room, will also be available for participant use.

Cleaning and Sanitization

- Test Kitchens: Before the first observation of the day, all counter and stove surfaces, refrigerator handle and shelves, trash can lids, sinks, and sink faucets will be sanitized using Clorox Clean-Up Cleaner and Bleach Spray (which is on EPA's List N, Disinfectants for use against SARS-CoV-2) for one round: the researcher will spray surfaces listed above, let the spray sit for 30 seconds, then wipe down with a paper towel. Refrigerator and cabinets (including handles) will be clean and sanitized with Clorox Disinfecting Wipes. After each observation, researcher will follow this cleaning and disinfecting procedure, but for **three** rounds of cleaning and sanitizing. The entry (main) door handle and the handles of all test kitchens and the observation room will also be wiped down three times after each observation. Meal preparation items (knives, utensils, plates, etc.) will be cleaned and sanitized in the dishwasher. Any meal prep item that cannot be loaded into the dishwasher will be cleaned and disinfected using either Clorox spray or wipe three times after each observation. All cleaning and sanitizing procedures are part of the study design and the responsibility of the researcher.
- Observation Room: After each observation, all high touch surfaces such as keyboards, monitors, DVRs, and iPads will be sanitized with a Clorox Disinfecting Wipes. Hand sanitizer will also be provided in the observation room. Hand sanitizer will be available at all times, but researchers will use it in the event that the researcher leaves the observation room to answer a question or assist participant in any way.
- Personal Hygiene Expectations for Researchers: All researchers will wash hands in one of the 6 sinks in the kitchen facility following CDC guidelines:
 - Before each observation (prior to arrival of participant)

- Before putting on latex gloves
 - After taking off latex gloves
 - At the end of each observation
 - After using the restroom
 - Before and after eating
 - After blowing nose, coughing, or sneezing
- Personal Hygiene Expectations for Participants: Before beginning the observation, participants will be reminded to wear a face covering for the duration of the observation event. If any participant arrives without a face covering, one will be provided. Researchers will also remind each participant to maintain distancing of at least six feet when interacting with any research team member.
 - Communication Regarding Hygiene and Cleaning and Sanitizing: Researchers will communicate cleaning and sanitizing procedures in the following ways:
 - Once a participant is deemed eligible after the initial screening, researchers will send an email to participants a few days prior to their scheduled observation. This email will contain relevant study information (date, time, and driving directions), but also the following information regarding Covid-19: “This research study is taking place during the Covid-19 pandemic. The researchers involved in this study have no symptoms of Covid-19 and have not knowingly interacted with anyone demonstrating symptoms or diagnosed as Covid-19 positive. In addition, researchers will be cleaning and sanitizing kitchen surfaces including counters, sinks, stove tops, refrigerators and trash cans, cooking equipment, and meal prep items prior to your arrival. Researchers will be wearing face masks at all times during your scheduled observation. As a participant, you are welcome to wear your own face covering, or one will be provided for you. You must wear a face covering while participating in this research. Please do not attend your scheduled observation if:
 - You knowingly interacted with someone who has been diagnosed or demonstrated symptoms of Covid-19.
 - You have any symptoms of Covid-19 such as cough, fever, shortness of breath, chills, muscle pain, or new loss of taste or smell.
 - You do not agree to follow all of the safety and sanitation procedures while participating in this study including wearing the appropriate personal protective equipment (face mask).
 - On the day of the observation, researchers will also remind participants of the cleaning and sanitizing procedures that have taken place prior to their arrival as well as remind participants to social distance whenever possible and wear a face covering throughout the observation.

Reporting COVID-19 Cases

- This research project does not generate any information that diagnoses Covid-19.
- If participants self-report symptoms and/or contact with Covid-19 positive individuals during the “day of” screener we will suggest they seek medical advice and inform IRB staff.
- If any research staff tests positive for Covid-19, or if a health care provider diagnoses any staff member as presumed positive for Covid-19, the researcher should notify NCSU by filling out the form at: go.ncsu.edu/covid-self-report. This procedure is voluntary, but the information on the form helps with contact tracing. Additionally, any research staff member who tests positive for Covid-19 should also notify the project coordinator and principal investigator. The project coordinator or principal investigator will then contact the IRB Office for guidance regarding the next steps for continued research.

Weighing of Risks and Benefits of This Research

Due to the cleaning and sanitizing procedures involved in this study because of the bacterial surrogate, the risk of contracting Covid-19 from kitchen materials or team members is minimal. Additionally, because of screening of both participants and members of the research team plus social distancing and the use of protective personal equipment, the risk of person to person infection is low. The benefit of this research is greater than the risks because this research: 1) helps to better understand consumer food handling behaviors in home kitchen; 2) promotes more effective messaging regarding safe food handling in the home environment; and 3) seeks to reduce the incidence of food borne illness and spread of pathogenic organisms on or inside food items through such messaging.