

Appendix M

COVID-19 Additional Procedures Packet

Section 1: Participant Communications and Day of Screening

Communication to Participants about Day of Screening

From the confirmation email sent to participants:

The study will be held at the Dinah E. Gore Teaching and Research Kitchens at 512 Brickhaven Drive, Raleigh, NC 27606. Please click [here](#) for directions. When you arrive, a researcher will meet you at the entry door to the Dinah E. Gore Teaching and Research Kitchen. The kitchen is located on the first floor of the building and to the left of the welcome desk. Before normal research procedures for this study occur, there will be a “day of” screening for COVID-19 related issues which may determine your ineligibility. This screening will include questions related to Covid-19 symptoms and exposure.

Please note that these research activities are 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. The sanitation and cleaning measures in place during all study activities include cleaning and sanitizing with Clorox Clean-up Cleaner and Bleach Spray and Clorox Disinfecting Wipes. All kitchen equipment and surfaces will be sanitized prior to your arrival. The personal protective equipment that the researchers will use includes face coverings and gloves. As a participant, you will be provided a disposable face mask as personal protective equipment and you must wear it while participating in this research.

Please do not attend this data collection session 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, new loss of taste or smell, or sore throat.
- You have tested positive for COVID within the last 10 days.
- You do not agree to follow all safety and sanitation procedures while participating in this study including wearing appropriate personal protective equipment.

Required Day of Screening Questions for Participants

- Do you have a fever and/or shortness of breath, unexplained cough, extreme fatigue?
 - Yes/No to any. If yes, disqualify and recommend seeking health care.
- In the last 7 days, have you been in close contact with someone who has been diagnosed as having COVID-19 by a healthcare professional?
 - Yes/No. If yes, disqualify
- Have you had a positive COVID test in the last 10 days?
 - Yes/No. If yes, disqualify

If yes to any of the above questions for “Day Of Screening,” deem ineligible and tell them to “Please contact your medical provider to discuss your needs. If you are a student at NC State University, you may contact Student Health Services at 919.515.2563. 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.”

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.

Section 2: 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.

Section 3: Collection of Biological Samples that May Increase Risk of COVID-19 transmission

- N/A. This project does not collect biological samples.

Section 4: COVID-19 Informed Consent Addendum

- 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.

Section 5: Participant Tracking and Reporting COVID-19 Cases

- 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.
- 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.

- If there is a COVID -19 exposure (such as a research team member coming into contact with someone who has symptoms of COVID-19/is COVID-19 positive/they are themselves COVID 19 positive, or a participant has disclosed that they are COVID-19 positive/have been in contact with someone who is) *even if the research team member is fully vaccinated*, immediately do all of the following:
 - Take any immediate action to eliminate immediate hazards
 - Halt in person research procedures
 - Within 24 hours of learning of exposure, notify the IRB and self-report.
 - Self Report:
 - If you are the person who is possibly exposed, contact your medical provider to discuss your medical needs.
 - If you are an NC State University employee, use this form to self report: [Employee Self Report Form](#) (opens in a new window).
 - If you are an NC State University student use this form to report: [Student Self Report Form](#) (opens in a new window). If you are a student at NC State University, you may contact Student Health Services at 919.515.2563.
- Once you self report, the contact tracing process may begin as appropriate to the details of the incident. The IRB expects that you follow any requests or recommendations from this process including confidentially sharing names of participants possibly exposed for contact tracing purposes.
- Affirm here that the research team understands and will implement all procedures related to managing a COVID-19 exposure within the research study's procedures as described in the IRB's COVID-19 guidance (Appendix H). This includes self reporting to NC State within 24 hours of exposure, confidentially providing requested information about participants from the self reporting process to NC State officials as requested, contacting the IRB Director within 24 hours and implementing all requirements and answering all required questions.
- **Type your name here to affirm the above statement: Lisa Shelley_____**

Section 6: Facility Use and Physical Distancing Plan, and PPE

- 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 researcher is in the kitchen with 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 face masks including KN95 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.

Section 7: 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 one minute, then wiped down with a paper towel. Refrigerator and cabinets (including handles) will be clean and sanitized with Clorox Disinfecting Wipes, with enough to be wet for four minutes. After each observation, researcher will follow this cleaning and disinfecting procedure, but for one round 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 once with enough to be wet for four minutes. 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 (for one minute) or wiped once, enough to be wet for four minutes. 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 researcher 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.

Section 8: Proof of Training for all Researchers

- Required: Shelley, CITI training Completion Info
- Required: Chapman, CITI training Completion Info
- Required: Sander, CITI training Completion Info
- Required: Goodson, CITI training Completion Info
- Required: Campbell, CITI training Completion Info
- Required: Chesanek, CITI training Completion Info
- Required: Merrill, CITI training Completion Info