Requirements and Guidelines for Human Subjects Research Activities

General Overview

As the University initiates a phased return to operations, including human subjects research activities involving direct person-to-person interactions and interventions, it necessarily includes considerations of local, state, and national directives related to public health and safety, as needed for protecting the health and well-being of the research team and study participants.

The following guiding principles direct the Office of Research Protections and Integrity (ORPI) and IRB expectations and requirements for conducting Human Subjects Research (HSR) activities.

1. Any/all HSR activities that can be conducted virtually/remotely should be conducted virtually/remotely. This allows for HSR activities to continue while maintaining the highest safety level for researchers and study participants.
2. The operational status of the research/study location where HSR activities will occur will guide whether the activities should occur.
3. Regardless of the operational status of the research location (e.g., University, organization, school, business, etc.), principle #1 applies.
4. Further, researchers should take steps to minimize risk to the research team and study participants when conducting direct person-to-person human subjects research activities.
5. A foundational ethical principle for conducting HSR is ‘respect for persons.’ Therefore, research study participation must be voluntary. Informed consent should be provided such that individuals may make an informed decision as to whether or not to participate in HSR activities, whether they be direct person-to-person activities or virtual/remote activities.

Be aware that the IRB protocol approval alone does not accord the approval to start or restart research activities. Researchers must comply with University, local, and state requirements as well as requirements of sponsors, collaborating organizations, and institutions.

The following information aligns with the University’s framework and guidelines for campus operations and includes a discussion of Human Subjects Research activities occurring:

- Online/virtual HSR activities (no direct person-to-person interaction)
- On-campus HSR activities involving direct person-to-person interaction
- Off-campus HSR activities involving direct person-to-person interaction.

This guidance will be updated as new information and recommendations are available. After reviewing this information, contact the Office of Research Protections and Integrity (uncc-irb@uncc.edu) should you have any questions.
**Online/Virtual Human Subjects Research Activities:**

Studies that have always been conducted online/virtually without direct person-to-person interaction may continue. These studies do not require additional permission to restart or begin.

- Online/web surveys
- Interviews and/or focus groups conducted by telephone or using online platforms.
- Research sessions/activities that may be conducted remotely.

**On-campus Human Subjects Research Activities Involving Direct Person-to-Person Interaction:**

Conducting Human Subjects Research activities on-campus (Main campus, Center City campus, and other locations that may be extensions of the University) is subject to the operational status of the University.

When the University is in restricted operations (e.g. closure as mandated by the UNC System, state, or local requirements) and access to campus is prohibited or highly restricted, all HSR activities involving direct person-to-person interactions and interventions with participants requires University-level approval to continue.

When the University is open and access to campus is not prohibited or restricted, HSR activities may occur with the following expectations and requirements:

- Any/all HSR activities that can be conducted virtually/remote should be conducted virtually/remotely.
- IRB-approved protocols must be followed.
- Researchers must adhere to all University, local, and state public health and safety requirements including wearing face coverings whenever indoors (even if not within six feet of another person) and maintaining physical distancing.
- Researchers must adhere to the Niner Nation Cares requirements including the 6 Ws (Wash, Wear, Wait, Wipe, Watch, and Wave) and limitations on gatherings (10-person limit indoors and 25-person limit outdoors).
- Face coverings must be worn by research team members and study participants.
- Have face coverings available for participants who do not have them and/or be prepared to reschedule participants who do not have face coverings.
- Schedule appointments with participants to allow for appropriate social distancing requirements (6 feet or greater). This may include the need to schedule appointments with participants to avoid overlapping with appointments of other participants.
- Have procedures and processes to notify participants prior to the research session that the
participant should self-screen for any symptoms of the Covid-19 and should not attend the research session if they have any symptoms.

- Have procedures in place that allow for contacting participants who may have been exposed to Covid-19 by a member of the research team. Likewise, procedures to allow the participant to notify the research team should the participant confirm having been exposed to Covid-19 and having exposed the research team.
- Sanitize research areas and equipment between participants.
- Limit the number of research team members present at research visits.
- Adhere to standard lab health and safety best practices.

**Status Change:** Should the University’s operational status change by University decision or as required due to local, and/or state requirements and restrictions (e.g., stay-at-home orders, highly restricted campus operations, etc.), researchers must comply with these requirements. This may include halting the human subjects research activities.

**Off-campus Human Subjects Research Activities Involving Direct Person-to-Person Interaction:**

**Research in clinical settings**

- The policies and requirements of the clinic, health care provider, hospital system, institution, etc. apply, regardless of the clinical setting.
  - This includes routine policies and requirements in addition to Covid-19 specific policies and requirements. (e.g., wearing face coverings and other personal protective equipment)
  - If the UNC Charlotte IRB is not the IRB of record for the research, researchers should consult with the IRB overseeing the research.
  - If the UNC Charlotte IRB is the IRB of record for the research as would be the case in an independent clinic, the clinic’s policies and requirements apply.
- Research that is NOT directly part of the standard of care delivery (e.g., research sessions that are independent of routine clinical visits or visits that are in addition to routine visits) may only proceed with authorization from or in accordance with the organization’s policies and requirements.
- Modify protocols to conduct online when/if feasible.
- **Researchers should confirm and document authorization to resume and/or continue research in these settings with the organization.**
- It is the responsibility of the researcher to be aware of and monitor the status of and requirements of the organization.
- Funded research must adhere to sponsor related requirements including any travel restrictions.
- If the status of the organization changes such that organizational, sponsor (for local, state, and/or federal requirements and restrictions are reinstated (e.g., stay-at-home orders, restriction on access, etc.), the research must halt.
Research in established, non-clinical institutions (schools, businesses, prisons, etc.)

- The policies of the external institution or organization apply.
  - This includes routine policies and requirements in addition to Covid-19 specific policies and requirements. (e.g., wearing face coverings and other personal protective equipment)
- **Researchers should confirm and document authorization to resume and/or continue research in these settings with the organization.**
  - The lifting of University, local, and state restrictions related to Covid-19 does not necessarily mean that the organization will allow the research to continue.
  - Schools may reopen but may prohibit non-school personnel from entering the school building. Researchers will be asked to confirm the authorization to resume and/or continue research in these settings.
  - Businesses may reopen but may prohibit the research activities.
- Research that is NOT directly part of standard operations (e.g., research sessions that are independent of routine educational instruction or would be additional visits beyond routine operations) may only proceed with authorization from or in accordance with the organization’s policies and requirements.
- Modify protocols to conduct online when/if feasible.
- **It is the responsibility of the researcher to be aware of and monitor the status and requirements of the organization.**
- Funded research must adhere to sponsor related requirements including any travel restrictions.
- If the status of the organization changes such that organizational, local, state, and/or federal requirements and restrictions are reinstated (e.g., stay-at-home orders, restriction on access, etc.), the research must pause.

Research in non-institutional community settings (farmer’s market, on the street, parks, etc.)

- Researchers must comply with local, state, and/or federal requirements.
  - Face coverings must be worn and social distancing maintained.
  - If a farmer’s market is limiting the number of people in the market space, researchers should adhere to these requirements.
  - If a park is closed to visitors, the researcher should abide by this.
- Modify protocols to conduct procedures online when/if feasible.

**Additional considerations:**

Researchers should consider and be mindful of the following additional items:

- **Modifications to the IRB protocol are required to change approved procedures, including changing procedures from direct person-to-person data collection to online or remote data collection.**
● The use of Covid-19 screening protocols, personal protective equipment (PPE), and other safety precautions do not have to be added to the IRB protocol, UNLESS
  ○ The screening information will be collected for use in data analysis as part of the research. A modification must be made to the IRB protocol to allow this.
● Consider if it is appropriate to exclude individuals from higher-risk groups such as older adults (age 65+), children, pregnant women, and individuals who are immunocompromised, individuals with underlying health conditions (heart disease, lung disease, or diabetes).
  ○ This would require modification to the IRB protocol and study materials (recruitment materials and consents). Prospective participants may then self-identify as not being eligible for participation.
● Adhere to standard lab health and safety best practices.
  ○ Sanitize in between uses, all equipment that will be used by participants.
● Research participation is voluntary. Participants who enrolled or consented to participate previously and prospective participants may decide to withdraw from study participation or decline participation.
● As always, researchers are expected to follow the ITS Guidelines for Data Handling of Level 2 data.
● Refer to ITS guidance on ways to secure web conferences/meetings.

Things to Keep in Mind

These are suggestions for research teams to keep in mind when preparing for and conducting research sessions with Human Subjects.

Research Team

● Ensure that all research team members are trained on the research restart plan details. Team members should be fully informed of the plan requirements, including details for appropriate cleaning and infection control procedures.
● Keep study procedures streamlined and efficient during research sessions to reduce time and minimize exposure.
● Wear masks/facial coverings when conducting research sessions. Consider if other safety protections are appropriate such as safety glasses and/or face shields.
● Wash and sanitize hands frequently. Establish this standard and model this standard during all interactions with research participants.

Research Setting/Room

● Confirm that the location/room is of sufficient size to allow for appropriate physical distancing (6 feet) between the research team and participants.
● Have the research setting set up before the session to allow for physical distancing
  ○ Post signs to remind participants about physical distancing.
Arrange seating as needed. Including marking/taping, which seating should not be used in order to allow for physical distancing (6 feet separation).

- Have computer spaces marked/labeled for use and non-use in order to allow for physical distancing (6 feet separation).
- Have areas marked or labeled to help guide participants. For example, have a designated area for consent forms to be returned and have it labeled as such.
- If there are different steps or activities a participant must complete, have areas in the space designated and labeled for each step/activity.

- Be prepared to orient the participants to the research setting; Provide instructions and point out where they should sit (or not sit), how you will be interacting with them to maintain physical distancing, how they should be aware of physical distancing, if participants are wearing face coverings, consider wearing a face covering yourself, etc.
- Allow time for study participants to wash their hands upon arriving to the research sessions and prior to leaving the research session.
- Only research team members needed for study implementation and participants should be present.
- Be aware of and monitor the number of people in the room.

Consent Procedures

Be prepared to have a consent process that allows for physical distancing and other precautions as appropriate.

- Have consent forms printed and ready.
- Ask individuals to retrieve/pick up the consent from a stack rather than handing consent forms to individuals.
- Encourage individuals to use their own pen when signing consent forms. Or provide individuals with a pen that they can use during the research session and take with them when they leave.
- Ask individuals to sanitize their hands before and after using any researcher-provided materials.
- Have participants leave the completed consent forms in a designated location.
- *If and when* appropriate, the consent process may be documented electronically using UNC Charlotte DocuSign. DocuSign allows for eSignatures. Note: If this method is not currently part of the approved consent process, a protocol modification is needed to change the consent process from paper-pencil to electronic.

Sanitizing & Hygiene

- Consider having a designated research team member responsible for sanitizing research areas (desk top, computer areas, touch screens, keyboard, mouse, doorknobs, etc.) between participants.
- Have hand sanitizer readily available for use and have individuals use it frequently.
- Allow time for study participants to wash their hands upon arriving to the research sessions and prior to leaving the research session.
Allow sufficient time for cleaning and disinfecting between research sessions.
Disinfect medical and other study equipment that will be used by multiple participants after each participant.
If feasible, allow research team members to have their own designated equipment (e.g., pens, clipboards, computers, tablets, etc.). If not, team members should appropriately sanitize the equipment before it is used by other team members.

Study Examples*

1) **Summary:** A Researcher submits a protocol that requires participants to complete computer-based activities followed by an interview with a researcher. Participants complete standardized measures online and then complete one of several (depending on the experimental group they are randomly assigned to) computer-based tasks. Following the computer tasks, the participant is interviewed by the researcher to discuss the tasks.

**Operational Status:** The University is operational without restriction. Campus is open.

**Response:** The Researcher’s IRB protocol includes procedures for online implementation of the study questionnaires as well as an in-person lab session to complete computer-based tasks. As a result of the University’s operational status, the study may proceed with the following additional requirements for physical distancing and safety measures that adhere to University requirements.

- Facial coverings/masks will be worn at all times during the research sessions for all research team members and participants.
- The Researcher will implement a scheduling protocol such that research sessions do not overlap participants. The research team members present will be limited to two such that the total number of persons present will be three; two research team members and one study participant.
- The Researcher will have a pre-research session protocol to notify participants prior to the research session that the participant should self-screen for any symptoms of the Covid-19 and should not attend the research session if they have any symptoms.
- Upon arrival, the participant will be asked to provide contact information for use only to notify the participant of any changes to Covid-19 status following the research session. The contact information will be maintained separately and not linked to the participant’s study data.
- The research area will be appropriately sanitized between participants by wiping down all equipment (computer, keyboard, mouse, pens, etc.) and surfaces (desk, chair, door knobs, etc.).
- Physical distancing of 6 feet or more will be maintained by conducting the consent process
at an appropriate distance.

- There will be hand sanitizer readily available and used liberally.
- The interview will occur at an appropriate distance as well.
- The entire research session as per the approved IRB protocol will last one hour.

**IRB Protocol Modification:** Not Required.

**Additional Approvals Needed:** None. The IRB protocol reflects the study procedures and the University is operational.

2) **Summary:** A Researcher planned to conduct a study that required participants to complete computer-based activities followed by an interview with a researcher. Participants complete standardized measures online and then complete one of several (depending on the experimental group they are randomly assigned to) computer-based tasks. Following the computer tasks, the participant is interviewed by the researcher to discuss the tasks.

**Operational Status:** The University is closed as a result of University, local, and state requirements and restrictions related to the Covid-19 pandemic. This research was paused.

**Response:** Resuming this research requires University-level approval. The Researcher submits a request for Research Restart. The request includes the researcher’s plan to implement appropriate social distancing and safety measures that adhere to University requirements.

The plan includes but is not limited to:

- Facial coverings/masks will be worn at all times during the research sessions for all research team members and participants.
- The Researcher will implement a scheduling protocol such that research sessions do not overlap participants. The research team members present will be limited to two such that the total number of persons present will be three; two research team members and one study participant.
- The Researcher will have a pre-research session protocol to notify participants prior to the research session that the participant should self-screen for any symptoms of the Covid-19 and should not attend the research session if they have any symptoms.
- Upon arrival, the participant will be asked to provide contact information for use only to notify the participant of any changes to Covid-19 status following the research session. The contact information will be maintained separately and not linked to the participant’s study data.
- The research area will be appropriately sanitized between participants by wiping down all equipment (computer, keyboard, mouse, pens, etc.) and surfaces (desk, chair, door knobs, etc.).
- Physical distancing of 6 feet or more will be maintained by conducting the consent process
at an appropriate distance.

- There will be hand sanitizer readily available and used liberally.
- The interview will occur at an appropriate distance as well.
- The entire research session as per the approved IRB protocol will last one hour.

**IRB Protocol Modification:** Not Required.

**Additional Approvals Needed:** Yes. University-level approval is needed to resume research activities.

3) **Summary:** A Researcher planned to conduct a study that required participants to complete computer-based activities followed by an interview with a researcher. Participants complete standardized measures online and then complete one of several (depending on the experimental group they are randomly assigned to) computer-based tasks. Following the computer tasks, the participant is interviewed by the researcher to discuss the tasks.

**Operational Status:** The University is closed as a result of University, local, and state requirements and restrictions related to the Covid-19 pandemic. This research was paused.

**Response:** The Researcher revises the study plan such that all research activities can occur remotely/virtually. The initial questionnaires were already to be administered online and will continue as such. The computer-based task has been redesigned such that it can occur online as well during a research session that will occur via Zoom. The Researcher and participant will interact via Zoom. When the participant completes the computer-based tasks, the closing interview will occur.

**IRB Protocol Modification:** Yes. The IRB protocol must be modified to include the virtual research session. The modification explains the procedures for completing the computer-based task and interview virtually via Zoom. In addition, the consent process is modified to allow for consent to be obtained using UNCC DocuSign. All study materials are updated as well to reflect the modification changes.

**Additional Approvals Needed:** None. Upon IRB approval of the study modifications, the research may begin.

4) **Summary:** A Researcher discontinued the direct person-to-person research that was ongoing at a local school as required by the University, local, and state requirements (e.g., stay-at-home order and closure of the school site). The study included an educational intervention, surveying students, and interviewing teachers.
Operational Status: The University is closed as a result of University, local, and state requirements and restrictions related to the Covid-19 pandemic. The school district is conducting all instruction virtually/remotely. This research was paused.

Response: The Researcher discussed with the local school leadership and enrolled teachers, whether it was feasible to continue study implementation online. School leadership and teachers were supportive of this plan.

IRB Protocol Modification: Required.

The Researcher submits a modification to the protocol to implement the educational intervention in the online classroom learning environment that the school is now using. The modification includes procedures for collecting survey data online and conducting teacher interviews virtually. The researcher confirms with the school that the school continues to support the researcher in conducting this research in the online/virtual environment and provides an updated Letter of Support from the school as part of the protocol modification. The modification is approved by the IRB. The researcher will continue to implement this study in this manner.

Additional Approvals Needed: None. Upon IRB approval of the study modifications, the research may begin.

5) Summary: A Researcher discontinued the direct person-to-person research that was ongoing at a local school. The study included an educational intervention, surveying students, and interviewing teachers, all of which required the Researcher be in the classroom with the teacher and students. The school site is conducting all instruction remotely.

Operational Status: The school district is conducting all instruction virtually/remotely. The University is operational/open. This research was paused.

Response: The Researcher discussed restarting the research with the school (principal and school district). However, going forward, the school and school district are restricting activities to instruction only. The school/school district is not allowing Researchers to conduct research, even remotely/virtually. The research cannot continue.

IRB Protocol Modification: Not Required. The research cannot continue.

Additional Approvals Needed: None. The research cannot continue.

6) Summary: A Researcher is planning a study that originally includes questionnaires, a group
activity, and a group discussion. The questionnaires will be administered after participants provide online consent and before the group activity and discussion. The Researcher will use the questionnaire data to assign participants to two groups of 10 participants each for a total of 20 participants at each research session. A total of 5 research sessions are planned, each lasting two hours. The group activity and group discussion must be completed in-person.

Operational Status: The University is operational without restriction. Campus is open.

Response: The Researcher reviews the University’s Niner Cares requirements including the requirement for facial coverings, physical distancing, limitations on group gatherings, and the 6Ws (Wash, Wait, Wipe, Watch, and Wave).

The Researcher changes the original study plan as a result of considering the above mentioned requirements. The Researcher submits an IRB protocol application that includes having smaller group sizes. The Researcher will use the questionnaire data to assign participants to two groups of four participants for a total of 8 participants at a research session. A total of 12 research sessions will be scheduled to reach the needed number of participants. The group discussion will be video recorded. Given the smaller group sizes and use of video recording, the research sessions are expected to last no more than one hour.

In addition, the Researcher develops protocols for use by the research team to ensure adherence to University requirements. The protocols include:

- Limiting the number of research team members present to two. The total number of people present at the group sessions will be 6 (4 participants and 2 research team members). This is within the University’s indoor limitation on gatherings/meetings.
- Two research sessions will occur simultaneously but each session will occur in a separate space/room.
- Two larger lab/conference rooms will be used for the group activity to allow for the 4 participants in each group to have appropriate social distancing (6 feet minimum). I.e. two rooms with 6 people total in each room.
- The 1-hour research sessions will be scheduled further apart (e.g., 10 a.m. session and 2 p.m. session) in order to allow more time between sessions for sanitizing the study spaces, desks, etc.
- Facial coverings/masks will be worn at all times during the research sessions for all research team members and participants.
- A protocol to notify participants prior to the research session that the participant should self-screen for any symptoms of the Covid-19 and should not attend the research session if they have any symptoms.
- When participants are notified of their scheduled study session they will be reminded that if they are feeling ill on the day of the study sessions, they should not attend the session. In
addition, they will be notified of the steps the research team will be implementing to allow for social distancing and sanitizing the lab/study spaces and any materials the participants may use during the group activity.

- Upon arrival the participant will be asked to provide contact information for use only to notify the participant of any changes to Covid-19 status following the research session. The contact information will be maintained separately and not linked to the participant’s study data.
- Participants will be asked to wash their hands before starting the research sessions and at the conclusion of the research session.
- There will be hand sanitizer readily available and used liberally.

**IRB Protocol Modification:** None. This is an initial IRB protocol submission. Once the protocol is approved, the research may begin.

**Additional Approvals Needed:** None. The research may begin upon IRB protocol approval.

7) **Summary:** A Researcher has IRB approval to conduct a study that includes questionnaires, a group activity, and a group discussion. The questionnaires will be administered after participants provide consent, also online. The researcher will use the questionnaire data to assign participants to two groups of 10 participants each for a total of 20 participants at each research session. A total of 5 research sessions are planned. The research was paused in Spring 2020 as a result of the University’s halt to Human Subjects Research activities. The group activity and group discussion must be completed in-person. Therefore, the research remained paused.

**Operational Status:** It is Fall 2020 and the University is operational without restriction. Campus is open.

**Response:** The Researcher wants to resume the study and reviews the IRB protocol as well as the University’s Niner Cares requirements including the requirement for facial coverings, physical distancing, limitations on group gatherings, and the 6Ws (Wash, Wait, Wipe, Watch, and Wave).

The Researcher determines that the study procedures need to be revised in addition to developing plans and protocols for use by the research team to ensure adherence to University requirements.

The Researcher’s plan includes but is not limited to:

- Limiting the number of research team members present to two. The total number of people present at the group sessions will be 6 (4 participants and 2 research team members). This is within the University’s indoor limitation on gatherings/meetings.
- Two research sessions will occur simultaneously but each session will occur in a separate,
space/room.
- Two larger lab/conference rooms will be used for the group activity to allow for the 4 participants in each group to have appropriate social distancing (6 feet minimum). I.e. two rooms with 6 people total in each room.
- The 1-hour research sessions will be scheduled further apart (e.g., 10 a.m. session and 2 p.m. session) in order to allow more time between sessions for sanitizing the study spaces, desks, etc.
- Facial coverings/masks will be worn at all times during the research sessions for all research team members and participants.
- A protocol to notify participants prior to the research session that the participant should self-screen for any symptoms of the Covid-19 and should not attend the research session if they have any symptoms.
- The group discussion will be video recorded now as a result of having less research team members present for note taking and observation and will take place in a larger classroom that will allow for appropriate social distancing.
- In addition, the researcher will schedule the 1-hour research sessions further apart (e.g., 10 a.m. session and 2 p.m. session) in order to allow more time between sessions for sanitizing the study spaces, desks, etc.
- When participants are notified of their scheduled study session they will be reminded that if they are feeling ill on the day of the study sessions, they should not attend the session. In addition, they will be notified of the steps the research team will be implementing to allow for social distancing and sanitizing the lab/study spaces and any materials the participants may use during the group activity.
- Upon arrival the participant will be asked to provide contact information for use only to notify the participant of any changes to Covid-19 status following the research session. The contact information will be maintained separately and not linked to the participant’s study data.
- Participants will be asked to wash their hands before starting the research sessions and at the conclusion of the research session.
- There will be hand sanitizer readily available and used liberally.

**IRB Protocol Modification:** Required

The Researcher submits a modification to allow for the use of video recording of the group discussion and to increase the total number of group sessions from 5 to 12 sessions total, given that the groups will be smaller. The Covid-19 screening protocols do not require modification to the protocol itself, however, the scheduling contact messages will be modified to include an explanation of these protocols. As such, the contact scripts are modified. Lastly, the consent materials are updated to reflect needed changes.

**Additional Approvals Needed:** None. The research may begin upon IRB approval of the protocol modification.
Summary: A Researcher planned to conduct a study that required participants to complete activities including having blood pressure measurements taken, wearing a heart rate monitor during physical activity in the lab (treadmill walking, exercise training), having blood samples taken (venipuncture), completing questionnaires, and having physical manipulations (such as soft tissue manipulation and muscle massage). The participant population includes generally healthy adults ages 18-45 and excludes individuals with heart conditions, diabetes, and other diseases. This research was paused as a result of University, local, and state requirements and restrictions related to the Covid-19 pandemic.

Operational Status: It is Fall 2020 and the University is operational without restriction. Campus is open.

Response: The Researcher wants to resume the study and reviews the IRB protocol as well as the University’s Niner Cares requirements including the requirement for facial coverings, physical distancing, limitations on group gatherings, and the 6Ws (Wash, Wait, Wipe, Watch, and Wave).

The Researcher determines that the study procedures need to be revised in addition to developing plans and protocols for use by the research team to ensure adherence to University requirements.

The Researcher's plan includes but is not limited to:

- A screening protocol for participants to self-report any Covid-19 diagnosis (yes/no), experiencing Covid-19 symptoms (yes/no have they had symptoms), known contact with someone who has a Covid-19 diagnosis (yes/no) in advance of the scheduled research session as well as upon arriving to the research session.
- A scheduling protocol such that research sessions do not overlap participants. The research team members present will be limited to two.
- Participant research sessions will be scheduled to allow for only two participants per day. This will allow for the appropriate time to sanitize the lab and equipment as required.
- Facial coverings/masks will be worn at all times during the research sessions for all research team members and participants.
- Upon arrival the participant will be asked to provide contact information for use only to notify the participant of any changes to Covid-19 status following the research session.
- The research area will be appropriately sanitized between participants by wiping down all equipment (computer, keyboard, mouse, pens, etc.) and surfaces (desk, chair, door knobs, etc.).
- All equipment that will be used (wrist blood pressure device, heart rate monitor, treadmill, exercise equipment, etc.) will be sanitized before and after each participant.
- Participants will be asked to wash their hands before starting the research sessions and at
the conclusion of the research session.

- Physical distancing will be maintained by conducting the consent process at an appropriate distance.
- Participants will complete questionnaires online after the research session. I.e. using their own devices at home or other location of their choosing.
- Rather than venipuncture, finger stick blood testing will be used. Participants will be instructed on how to conduct the finger stick themselves using disposable materials.
- Participants will also be instructed on the use of the wrist blood pressure device and how to wear the heart rate monitor and use the treadmill.
- The research team will not have to be in close physical contact to the participant beyond giving and receiving the used devices.
- And in all cases, standard and routine lab health and safety procedures, including biosafety procedures, will be in use such as safety glasses, wearing gloves and sanitizing devices.
- The treadmill activity is limited to walking at a comfortable pace. The participant wears a facial covering during the activity.
- The muscle massage part of the study will be completed by the participant following instructions provided by the research team and using devices commonly used in exercise training such as foam rollers, muscles roller stickers, and massage balls. These items will be appropriately sanitized between participants.
- There will be hand sanitizer readily available and used liberally before and after all activities.

**IRB Protocol Modification:** Required

The Researcher submits a modification to capture the following changes to the study:

- Collection of Covid-19 screening information. The research team will collect this information for use in the research. This information will be collected with consent, online prior to the research session. In addition, this information will be confirmed verbally upon arrival by the participant to the research session.
- Other questionnaires will be administered online after the research session.
- Use of finger stick instead of venipuncture.
- Change in procedures related to the muscle massage.
- Participants will walk at a comfortable pace on the treadmill for a longer period of time.
- The scheduling contact messages will be modified to include an explanation of these Covid-19 screening protocols.
- Recruitment materials are updated as needed.
- Consent materials are updated as needed.

**Additional Approvals Needed:** None. The research may begin upon IRB approval of the
9) **Summary:** A Researcher submits a protocol for IRB review for a study that requires participants to complete activities including having blood pressure measurements taken, wearing a heart rate monitor during physical activity in the lab (treadmill walking and exercise training), having blood samples taken (venipuncture), completing questionnaires, and having physical manipulations (such as soft tissue manipulation and muscle massage). The participant population generally includes healthy adults ages 18-45 and excludes individuals with heart conditions, diabetes, and other diseases.

**Response:** The Researcher reviews the University’s Niner Cares requirements including the requirement for facial coverings, physical distancing, limitations on group gatherings, and the 6Ws (Wash, Wait, Wipe, Watch, and Wave). However, the planned research activities are required and cannot all be adjusted. Therefore, the study procedures do not adhere to University requirements. As such, the research cannot proceed until University restrictions are lifted.

*These examples are provided to illustrate different types of studies and potential actions needed. Each study is unique in some way and may require different actions. Contact the Office of Research Protections and Integrity if you have questions about your specific study.*