Requirements and Guidelines for Restarting Human Subjects Research: Stage 3

The University’s Research Restart and Restoration Task Force has developed a framework and guidelines for the phased return to research that includes consideration of local, state, and national directives related to public health and safety.

General Overview

As the University initiates a phased return to research activities, the re-engaging or restarting of human subjects activities involving direct person-to-person interactions and interventions necessarily includes considerations for protecting the health and well-being of the research team and study participants.

The following information and requirements will remain in effect until further notice. Please check this page regularly for updated information.

Only with appropriate University-level permission may a limited set of human subject research activities involving direct person-to-person interactions and interventions with participants proceed at Stage 3 of the University’s research restart and restoration plan. This applies to all studies, including studies conducted on-campus and off-campus. 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.

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 collaborating organizations and institutions.

Researchers without appropriate University-level permission to conduct direct person-to-person human subjects research activities should continue to conduct research activities remotely using telephone or online/virtual platforms such as online survey platforms or virtual face-to-face platforms (e.g., Google Hangouts, WebEx, Zoom, etc.) as much as possible.

Researchers should review the Research Restart and Restoration Task Force Report and be familiar with the guidelines established in the Report. The following information aligns with the University’s framework and guidelines. After reviewing this information, contact the Office of Research Compliance (uncc-irb@uncc.edu) should you have any questions.

Research Activities That May Continue:

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

- Online/web surveys
- Interviews and/or focus groups conducted by telephone or using online platforms.
- Research sessions/activities that may be conducted remotely.
**Research Activities That May Resume in Stage 3 of Restart and Restoration:**

Direct person-to-person activities with required social distancing (minimum of 6 feet).

- On-campus
- Off-campus

**Requirements for ON-campus Research activities (Direct Person-to-Person):**

- Only with appropriate University-level permission.
- **Should the University’s status change by University decision or as required due to local, state, and/or federal requirements and restrictions are reinstated (e.g., stay-at-home orders, restriction on-campus access, etc.), the research must pause.**
- 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.
- Use face covers and have them available to participants that might need them.
- Limit the number of research team members present at research visits.
- Adhere to standard lab health and safety best practices.

**Requirements for OFF-campus Research activities (Direct Person-to-Person):**

1. **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.
     - 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.
   - **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. 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.

2. 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.
   ● 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 such (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.
   ● It is the responsibility of the researcher to be aware of and monitor the status and requirements of the organization. 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.

3. Research in non-institutional community settings (farmer’s market, on the street, parks, etc.)
   ● Researchers must comply with local, state, and/or federal requirements.
     ○ 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 online if feasible.
   ● 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.
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, 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. These are not requirements.

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.
- Try to keep study procedures streamlined and efficient during research sessions to reduce time and minimize exposure.
- Consider wearing masks or other facial covering when conducting research sessions.
- 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.
- 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.

**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 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 planned to conduct a study that required participants to complete computer-based activities followed by an interview with a researcher. This research was paused as a result of University, local, and state requirements and restrictions related to the Covid-19 pandemic.

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.

**Response:** 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:
- A scheduling protocol such that research sessions do not overlap participants. The research team members present will be limited to two.
- 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.
- 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.).
- Social 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.

**IRB Protocol Modification:** Not Required.

2) **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.

**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 submitted a modification to the protocol to implement the educational intervention in the online classroom learning environment that the school was now using. The modification included procedures for collecting survey data online and conducting teacher interviews virtually. The researcher confirmed with the school that the school continued to support the researcher in conducting this research in the online/virtual environment. The modification was approved by the IRB. The researcher will continue to implement this study in this manner.

3) 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.

Response: The Researcher considered continuing study implementation online but determined that it was not feasible.

Note: The school site will reopen for the Fall academic year. The researcher discussed restarting the research with the school (principal and school district). However, going forward, the school and school district are restricting access to the school to enrolled students, their parents, and school employees. The research cannot continue.

IRB Protocol Modification: Not Required. The research was paused.

4) Summary: A Researcher planned 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 group activity and group discussion must be completed in-person.

Response: 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:
- 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.
- Reducing the group sizes to 4 for a total of 8 participants at a research session.
- The research team members present will be limited to two.
- The researcher will use two larger lab/conference rooms for the group activity to allow for the 4 participants in each group to have appropriate social distancing (6 feet minimum).
• The group discussion involving all 8 participants 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 2-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.

• 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, given that the groups will be smaller. The Covid-19 screening protocols do not require modification 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.

5) 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.

Response: 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:

• 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.
- 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.
- Social distancing will be maintained by conducting the consent process at an appropriate distance.
- Participants will complete questionnaires online after the research session.
- 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 wearing gloves and sanitizing devices. In addition, the research team will wear masks.
- The treadmill activity is limited to walking at a comfortable pace.
- 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.

6) **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:** During the review process, the Compliance Office and researcher discuss ways to adjust the study procedures to allow for appropriate social distancing (minimum of 6 feet) and safety measures that adhere to current University guidelines. The planned research activities are required and cannot all be adjusted to adhere to requirements. Therefore, while the IRB review of this study will proceed and IRB approval granted, the researcher will not be able to conduct the study during Stage 3 of the research restart and restoration.

*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 Compliance if you have questions about your specific study.*