

NDSU Institutional Review Board (IRB) - COVID-19 Face-to-face Research Restart Guidelines

North Dakota State University is committed to protecting the rights, safety and welfare of all individuals participating in NDSU research projects. These protections ensure that: risks to participants are minimized, risks are reasonable in relation to benefits, recruitment procedures are fair, subjects are sufficiently informed and able to make a voluntary choice, their privacy and confidentiality are respected, and extra protections are in place for vulnerable groups.

During the ongoing COVID-19 pandemic, additional precautions need to be taken to ensure that human subjects in research are protected. These guidelines are intended to help researchers identify best practices for conducting face-to-face (F2F) research at NDSU while minimizing the risks of infection by COVID-19. Our recommendations are organized according to the type of interactions you expect researchers and participants will have during F2F research. Specifically, we consider both the amount of **time** individuals spend in the same space and the **physical distance** individuals can maintain during an interaction. **Both increased time and reduced distance between people make F2F interactions higher risk.** Beyond these specific recommendations, all research laboratories and research groups should consider how to minimize the time individuals spend in the same space and maximize the physical distance between individuals. In addition, the design of the physical research space (e.g., ventilation, room size, time spent in room, etc.) can also be factors that drive infection risk.

Do you need to conduct F2F research at all?

Depending on your research needs, you may be able to replace F2F data collection with other means such as online, phone, mail, etc. Below we have listed several links to different platforms that facilitate online data collection. If you have questions about these platforms, please contact benjamin.balas@ndsu.edu for more information about any of these possible ways to deploy your research online.

- Qualtrics - Online survey development and deployment
<https://www.ndsu.edu/gdc/qualtrics/>
- Microsoft Teams
- Zoom

Use of other software and online resources may need approval by NDSU ITS. Information on license review of software and online resources can be found [here](#).

Minimum Recommendations for ALL researchers conducting F2F research

These recommendations apply to all researchers who plan to invite participants to visit NDSU facilities for data collection, or who plan to visit participants off-campus to conduct research.

- **Screen for COVID-19.** Do NOT continue a scheduled testing session if the participant(s) or any member of the research team participating in the session are ill. The CDC has identified 9 symptoms that indicate a potential COVID-19 infection including: **Fever, Cough, Shortness of Breath, Fatigue, Muscle or Body Aches, Headache, New Loss**

of Smell/Taste, Sore Throat, Runny Nose/Congestion, Nausea or Vomiting and Diarrhea. All laboratories/research teams should screen participants and any individuals accompanying participants for these symptoms **before** they arrive to participate in the study and ask research assistants to indicate the presence/absence of these symptoms before each day of work. The presence of any of these symptoms in either participant(s) (and any guardians/companions) or research staff should lead to the cancellation of scheduled F2F testing. Participants who exhibit symptoms should not be rescheduled until they are considered “recovered” from their COVID infection by a medical provider. Members of the research team who exhibit symptoms should also not return to work until they are considered “recovered” from COVID.

- **Personal Protective Equipment (PPE).** Both participant(s) and research staff should wear cloth or paper masks throughout the data collection session. Laboratories should maintain a stock of such masks so that participants and research staff have these available for all sessions. **Do not carry out F2F interactions without such masks worn properly (covering the nose and mouth and secured appropriately).**
Note that both surgical masks and N95 masks continue to be in short supply and are of critical importance to health care providers. Further, N95 masks are only highly effective if they have been properly fit and fit-tested per individual. As such, we anticipate that most researchers at NDSU will use either disposable surgical masks or reusable cloth masks. Neither of these offers complete protection from COVID-19 infection, but both reduce the number of respiratory droplets resulting from normal breathing and talking and reduce the distance those droplets travel.
- **Disinfecting.** All non-porous surfaces, including desks and tabletops, chairs, door handles, and testing equipment (keyboards, response boxes, and other hardware) should be disinfected before and after each data collection session. We recommend that laboratories maintain a cleaning log for each space documenting when surfaces in that room were last cleaned and by whom.
- **Hand sanitizing.** CDC-approved hand sanitizer should be made available and both participants and research assistants should apply hand sanitizer appropriately before beginning data collection.
- **Physical distancing.** To the extent possible, maintain a minimum distance of 6 feet between individuals at all times. This includes interactions between research assistants and participants during the recruitment and informed consent process as well as any interactions between multiple research participants. **Participants should not congregate in any waiting area prior to participating in research.** PIs who plan to recruit multiple participants should establish a plan for staggering arrivals and/or establishing procedures for ensuring participants do not gather while waiting to begin a session. Please also consider the flow of traffic in and around the space that staff and research participants will occupy. If one-way traffic can be imposed via signs or decals (see <https://www.ndsu.edu/vpur/resources/covidsignage/> for examples) please do so to minimize the chance that participants and staff may run into each other while moving through the space.
- **Contact tracing.** To facilitate contact tracing by public health authorities, records describing which participants and research staff were present during research sessions

should be maintained in the event of COVID-19 infection. Ideally, these records should include the date and time of the session, the individuals who interacted during the session, and contact information for all individuals. Such records should be kept independent of the title of the study and the data collected from these individuals during a research session.

- **Physical space.** The size of the room where research activities take place, ventilation levels, how long researchers and participants spend in the room, how long the room is empty between research sessions, and activities participants are asked to perform all can contribute to infection risk. Consider all of these factors in your F2F research design, and follow guidance by health authorities and disciplinary organizations in determining how to best manage the physical research space.

Special Considerations based on Length and Proximity of Interactions:

Research involving single participants and minimal interaction with research staff

Many studies may involve only one participant at time visiting a lab or research group and interacting minimally with research staff. An example of such a study is a scenario in which participants are scheduled to complete a form or carry out a computer-based task in a room by themselves following the informed consent process and a short set of instructions provided by research staff.

For research that matches this description, laboratories should follow all guidelines listed above that apply to all F2F research at NDSU. In addition, research staff should develop a procedure for participants to signal that they are completed with a task that does not require the participant to locate the researcher within a larger laboratory lab space. This latter precaution helps ensure that participants remain physically distant from laboratory staff during a testing session.

Research involving multiple participants and minimal interaction with researchers

Some studies may be designed for groups of participants to complete a task simultaneously, or laboratories may have space that could accommodate multiple participants under normal circumstances. **We recommend that research groups refrain from inviting multiple participants to be tested at once unless this is absolutely necessary for the study under consideration.** While it is certainly more efficient to implement parallel recruitment of multiple participants, we strongly advise PIs to adopt slower, staggered recruitment strategies in the interests of minimizing the risk of COVID-19 infection.

For studies that do require multiple participants to be tested simultaneously, the guidelines below assume that research staff interact with participants only to obtain informed consent and to deliver task instructions.

- Maximize the physical distance between participants at all times. This applies to the informed consent process, the delivery of task instructions to the group by research staff, and to the space participants may wait in prior to beginning a testing session.

Participants should always be at least 6 ft. apart from each other and from research staff. Staff need to monitor the maintenance of appropriate physical distance.

- Given the increased risk of COVID-19 transmission within groups of individuals who share a common space for an extended period of time, we recommend that all research staff and participants wear surgical or procedural masks during testing sessions. These masks reduce the risk of COVID-19 infection via respiratory droplets more effectively than homemade masks or bandannas.
- Participants being tested simultaneously should not share writing implements, keyboards or other testing hardware, or pass objects to one another (including sign-in sheets or data forms).
- If the design of the study involves participants sharing a common space for more than approximately 10-15 minutes (e.g., sitting around a large table to complete a task), we strongly encourage PIs to identify other ways to implement the study in question. We recognize that this may pose substantial challenges, but such scenarios have been found to increase risk of COVID-19 transmission substantially.

Research involving extended interaction (i.e., longer than 15 minutes) between participants and researchers

Some studies may require research staff to interact with single or multiple participants throughout a testing session. For example, a member of the research staff may need to monitor participant behavior during testing, provide ongoing instructions to participants during the completion of a task, or conduct a face-to-face interview with the participant. First, to the extent possible, researchers should identify ways to maximize the distance between individuals during such data collection sessions. For example, can RAs observe participants via webcam from another room, or provide ongoing instructions via Zoom or chat? In circumstances where research staff must occupy the same space as individual participants for an extended period of time, we recommend the following guidelines:

- Given the increased risk of COVID-19 transmission within groups of individuals who share a common space for an extended period of time, we recommend that all research staff and participants wear surgical or procedural masks during data collection sessions lasting longer than 15 minutes. These masks substantially reduce the risk of COVID-19 infection via respiratory droplets.
- Research staff and participants should not share writing implements, keyboards or other testing hardware, or pass objects to one another (including sign-in sheets or data forms).

Research involving close physical interaction between research staff and participants

Finally, some research necessitates close physical contact between research staff and participants so that testing equipment can be applied and calibrated, or so physical measurements can be taken. High intensity exercise and associated increased ventilation increases the distribution of any virus (possibly by aerosolized as well as droplet particles) and thereby increases the risk of infection, especially if the high rates of ventilation persist for more than 5 minutes. This risk is highest in front of the participant (or near the expiratory valve, especially if filters are not used). Spirometry and maximum exercise testing are possibly aerosol

generating procedures and increase the risk of spread beyond the typical 2 meters of social distancing during quiet rest. This type of activity generates droplets, and it is therefore important to decontaminate and disinfect the kit used (mouthpieces etc.) and the surrounding area. **These activities are particularly high-risk for COVID-19 infection and research staff and participants should be made aware of this fact.** In addition to the precautions described above for all F2F activities, we recommend the following procedures:

- Research staff and participants (if possible) should wear surgical or procedural masks during the testing session.
- Research staff should wear disposable gowns during the testing session, when possible, disposing of these immediately after testing.
- Research staff should wear face shields in addition to surgical or procedural masks during the testing session. Face shields should be cleaned appropriately before and after testing.
- All equipment, including sensors, swabs, probes, etc. used during the testing session should be disinfected or disposed of immediately following the testing session.
- Air flow and ventilation are especially important to consider when conducting research that may involve physical activity, loud speech or singing, or extended occupancy of a specific space by either research staff or participants. PIs should carefully evaluate these factors to the best of their ability to determine the risk associated with testing in these scenarios.

We recognize that these are challenging times for F2F human subjects research. We share your commitment to continuing to do exciting work at NDSU and hope that these guidelines help establish procedures for ensuring the safety of the entire NDSU community. If you have questions, comments, or concerns regarding safe F2F research at NDSU, please contact any of the individuals listed below.

Dr. Ben Balas, Psychology Department - benjamin.balas@ndsu.edu, 701-231-6105
Kristy Shirley, IRB Administrator – kristy.shirley@ndsu.edu, 701-231-8995