

## **NDSU Institutional Review Board (IRB) - COVID-19 Face-to-face Research 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. In addition, these same precautions seek to protect research team members conducting face-to-face research.

**While NDSU is returning to normal operations, some groups of research participants remain vulnerable to COVID-19. The IRB recommends that precautions should continue 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 and ensuring that research participants are comfortable while participating in IRB-approved studies. 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 as well as vaccination status of research team members and participants.

**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. We now also recommend that researchers consider vaccination status both of participants and of lab personnel.

### **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. Anyone exhibiting symptoms consistent with COVID should refrain from participating in or conducting F2F research until 10 days after the onset of

symptoms if they test positive or are untested, or if they test negative, once they are feeling better and have been fever free for 24 hours.

- **Verification of Vaccination Status.** If researchers want to verify participants' vaccination status, we recommend that they consider photos of official vaccination cards as sufficient for verification. All research personnel, whether directly interacting with participants or otherwise present in the lab/research setting, should be vaccinated. If individuals on a research team are not vaccinated or if PIs cannot verify vaccination status of specific team members, those individuals may limit their direct contact with participants and/or utilize masking and social distancing protocols. In those cases, as early as possible, research participants should be informed that unvaccinated personnel may be on the research site, or that vaccination status of lab personnel has not been confirmed.
- **Personal Protective Equipment (PPE).** If vaccination status of participants and research team members has not been verified, it is suggested that team members don masks and ask if a participant is comfortable proceeding without masks. **If a participant asks for masks to be worn, please ensure that everyone wears masks properly (covering the nose and mouth and secured appropriately).**
- **Disinfecting.** Research personnel should use discipline-appropriate best practices for disinfecting equipment that participants interact with.
- **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.** In the case that either a research team member or research participant is not vaccinated, 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.

#### 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 for research involving multiple participants, researchers either verify vaccination status or disclose to all participants that the vaccination status of participants has not been verified. Participants are then free to leave the research site if they feel uncomfortable.** If participants' vaccination status cannot be verified, social distancing should be maintained throughout the study and participants should be offered masks to wear.

### **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:

- If vaccination status of both research team members and participants can be verified, distancing and PPE is not required.
- The IRB recommends excluding unvaccinated individuals from F2F research requiring close physical interactions and/or aerosol generating procedures.
- 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](mailto:benjamin.balas@ndsu.edu), 701-231-6105  
Kristy Shirley, IRB Administrator – [kristy.shirley@ndsu.edu](mailto:kristy.shirley@ndsu.edu), 701-231-8995