Mary Clark Provost Leslie Brunelli Sr. Vice Chancellor



COVID-19Protocol for Research, Scholarship, & Creative Work (Issued 05.10.21)

The University has adopted this protocol to comply with applicable state and local public health orders and to be consistent with applicable federal and state guidance. The Provost's Office may issue updated protocols, which become effective upon adoption, to respond to changes in state and local public health orders, to be consistent with new federal and state guidance, and/or to adapt to changing conditions on campus. Please watch for updates to these protocols and regularly check the <u>DU COVID-19 website</u> for news and other important information.

University of Denver COVID-19 Protocols for Research, Scholarship & Creative Work

Researchers must follow the COVID-19 guidelines outlined below for research, scholarship, and creative work spaces associated with their employment and/or academic program at the University of Denver (DU).

Symptom Monitoring Self-Assessment Survey

Before an unvaccinated or not fully vaccinated employee or student may report to campus for work or learning each day, the individual must complete a symptom monitoring self-assessment <u>survey</u> pursuant to the DU COVID-19 <u>Symptom</u> <u>Monitoring Protocol</u>). Symptom monitoring is not currently required for verified fully vaccinated students, faculty, or staff, except following an exposure.

Arriving at Your DU Research Lab or Site

Any individual (faculty, staff or student) who has been approved for campus access must also follow all of the applicable DU COVID-19 Protocols and other applicable policies, procedures, and protocols.

• <u>All individuals must follow applicable University protocols, including but not limited to COVID-19 Protocols for</u> <u>symptom monitoring, face coverings and social distancing.</u> Face coverings must not interfere with PPE, e.g. eye shields, required for safety and must be compatible with all safety requirements.

Promoting Safety in Work Spaces

 All employees, students, and visitors must follow all applicable COVID-19 protocols to maintain a safe laboratory environment. Because these requirements may vary based on vaccination status, laboratory space may need to be adjusted to comply with the requirements.

Create a plan for safe practices in the lab and workplace.

• Please refer to the section "Guidelines for Enhanced Cleaning and Prevention" below.

Create a plan for interactions with others outside the lab.

• Arrange the use of shared facilities and other labs' equipment in advance to promote safe laboratory practices. Communicate lab sign-in & reservation procedures.

Enhancing Cleaning and Prevention

In high occupancy labs, increase the frequency of cleaning and disinfecting, **focusing on high-touch surfaces**, such as buttons, handrails, tables, faucets, doorknobs, testing materials, shared keyboards, microscopes, touch pads, and reagent bottles. Increased frequency of cleaning and disinfecting with attention to these areas helps remove bacteria and viruses, including the novel coronavirus.

DU COVID-19 Research Protocol Issued 7.02.2020

Disinfectant materials are available from Facilities. Please email <u>covidresearch@du.edu</u> for information regarding how to obtain these materials. If you decide to purchase your own supplies, the disinfectant materials must be on the <u>EPA-registered household disinfectant</u> list.

Conducting Human Subjects Research

During Alert Level Purple, in person Human Subjects' Research is prohibited.

During Alert Level Red or Orange, human subjects research on DU's campus, at other institutions of higher education, or at other community-based organizations (that have developed their own safety protocols) may be permitted to support funding and/or educational obligation. Please submit an exemption request via email to <u>IRBAdminstrator@du.edu</u>. Exemption requests should describe how researchers and participants will follow all applicable policies, procedures and protocols. Human subjects' data collection that involves bodily fluids (i.e., blood draws, sputum samples) may be permitted while following protocols already approved and in place with the IRB. During Alert Level Red and Orange, researchers shall not conduct in-home visits.

During Alert Level Yellow and Blue, investigators can request to resume all human subjects research (including home/field visits) by exemption. To request an exemption, email <u>IRBAdministrator@du.edu</u> to describe the funding or educational needs requiring resumption of in person human subjects' research. During Alert Levels Yellow and Blue, we require that students, faculty and staff engaged in in-person human subjects' research have High Contact clearance (see campus access status, top left after logging into PioneerWeb to determine your clearance, or contact the COVIDcoordinator team to determine if a set of individuals meets this criteria). High Contact clearance requires verified full vaccination as well as up-to-date testing compliance.

During Alert Level Green and Clear, all in person research can resume without exemption required. We recommend that students, faculty and staff engaged in in-person human subjects' research have High Contact clearance (see campus access status, top left after logging into PioneerWeb to determine your clearance, or contact the COVIDcoordinator team to determine if a set of individuals meets this criteria. High Contact clearance requires verified full vaccination as well as up-to-date testing compliance.

Scheduling Human Subjects' Access to Campus

The DU employee seeking to bring a human subject participant to campus should continue to consult with their COVID Access Manager to determine if there are restrictions in place regarding scheduling visitors. During Alert levels orange and red, individual researchers and research groups may need to coordinate scheduling of visits with their COVID Access Manager to comply with building occupancy issues.

To schedule in-person visits to campus, research staff should contact participants to determine if they are interested in participating in in-person research and, if so, to share the applicable COVID-19 protocols, including the <u>Protocol for Face</u> <u>Coverings and Social Distancing</u>, Symptom Monitoring Protocol and <u>Visitor Protocol</u>.

Pre-Screening Research Participants

PI or research staff inviting research participants to campus for in-person data collection must follow the DU Visitor Protocol. Ahead of the scheduled visit, PIs or research staff must send all research participants coming to campus the <u>Visitor Screening Survey</u> to complete within 12 hours prior to arriving to campus to conduct symptom monitoring and to inform the visitor of the requirements of DU's protocols including, but not limited to, the <u>Face Covering and Social</u> <u>Distancing Protocol</u> and the <u>Visitor Protocol</u>.

If the visitor does not complete the survey online or cannot check their temperature before coming to campus, the PI should contact their supervisor or COVIDCoordinator@du.edu with questions or to request support in advance of the visitor's arrival to campus. PIs will need to provide thermometers for screening participants outside the DU campus building they are visiting.

If the participant cannot or does not want to be screened or will not agree to follow applicable COVID-19protocols, the PI must postpone their visit to campus until the visitor is willing to be screened are willing to do so or attempt remote data collection or delay interactions.

- Have participants call their DU host when they arrive and wait to be escorted into DU buildings.
- Arrange waiting rooms such that individuals from one household are separated from those from another household. Finding ways to limit waiting room use is preferred.
- Use disinfection procedures on all relevant surface areas before and after each participant visit, require staff and encourage visitors to wash their hands thoroughly before and after each visit.

Requirements for All Research Participants Coming on DU Campus

- Successfully complete the Visitor Survey.
- Unvaccinated or not fully vaccinated research staff and research participants (including any accompanying family members) must wear a face covering at all times while in a DU building as required by the protocol for <u>Face</u> <u>Coverings and Social Distancing</u>. Be sure to have disposable face coverings available. Consider whether characteristics of the research population or location would recommend face coverings for staff and participants.
- If a research participant arrives for their appointment and starts showing any possible symptoms of illness while on campus, follow the applicable provisions of the <u>Visitor Protocol</u>.

Submitting an ADDENDUM to a Human Subjects Protocol related to COVID-19 Precautions

Investigators who incorporate in-person interactions or interventions with human subject participants during the COVID-19 pandemic during Alert Levels Red or Orange for all in-person interaction on campus and off campus and those incorporating in-person home/field research during Alert Level Yellow or Blue must submit an addendum to their current IRB-approved protocol or any new IRB protocol submission to document the requirements of DU's COVID-19 <u>Visitor</u> <u>Protocol</u>. No addendum is necessary addressing COVID-19 protocols during Alert Levels Green or Clear regardless of project location. Investigators have the option to use the <u>Addendum template</u> or customize the Addendum template for use in a research protocol and consent documents. This Addendum may be (1) posted as a separate document when submitting a new research project application in IRBNet, or (2) posted as a separate document within an amendment request for a currently approved project (i.e., submitted alone within an Amendment/Modification package in IRBNet).

Conducting Research at Other Institutions and Organizations

Before beginning research at other institutions or organizations during Alert Levels Red, Orange, Yellow or Blue, a researcher must submit an IRB amendment through IRBNet along with the other institutions' safety protocol. During all Alert Levels – Red through Clear, researchers must review additional requirements mandated by the affiliated research facility (i.e., CU Imaging Facility) or community-based organization. For example, researchers may be required to be escorted into and out of the facility by a research staff member, change into scrubs upon arrival to the facility, bring a face covering to wear at all times, and/or stay in a designated room during the research visit. If research will be conducted at a partnering institution (i.e., higher educational institution), DU investigators must comply with that institution's safety protocols in addition to applicable DU protocols. If institutions have protocols that are less strict than DU's safety protocols, DU investigators must comply with DU's safety protocols.

If you begin to work at partnering institutions or organizations and you start showing any possible symptoms of illness, you must leave the partnering institution or organization immediately, not return to campus, and follow the DU Symptom Monitoring Protocol.

Purchasing PPE

PIs are expected to purchase appropriate face coverings for their labs if they have sufficient lab funds to do so. If a PI does not have sufficient lab funds to provide appropriate face coverings to research personnel, the PI should request appropriate personal protective equipment at <u>orspadmin@du.edu</u>. OSRP will determine whether adequate supplies are available to fulfill the request.

For questions about implementing this protocol, please contact the SPARC representative or jerry.mauck@du.edu.