

UNM IRB Plan for Resuming or Starting Human Research Projects that Involve Face-to Face Interactions with Participants

Consistent with [President Stokes' plan](#) dated 5/22/2020, there are steps to take before research participants and research personnel may interact face-to-face. General requirements and guidance regarding the opening of research spaces will be forthcoming; the present document describes additional guidance and requirements for resuming face-to-face studies with human participants. As the UNM administration allows the faculty, staff and student employees to resume limited on-campus operations, researchers whose studies involve face-to-face data collection activities need to follow several important guidelines to minimize risk of possible COVID-19 exposure for both participants and research personnel. **The university's plan to resume research will strictly follow the state's COVID Safe Practices (CSP) for all sites, be phased with the state's reopening plans, and will evolve continuously in response to the public health conditions and the needs of UNM and the State of New Mexico to ensure the health and safety of all. The fundamental guidance is built around physical and policy approaches to hygiene, screening, distancing, and mask-wearing.** The possibility of COVID-19 infection will still be present after resuming research operations. Although the risk of exposure may now be considered a risk that participants are exposed to in everyday life, researchers should re-evaluate research protocols and develop plans to manage this risk. Studies with in-person procedures that were originally considered minimal risk (e.g., large focus groups, blood draws, etc.) may need re-consideration as greater than minimal risk, due to the risk of COVID-19 infection. The risk-benefit analysis for a protocol may have shifted. The adequacy of provisions to minimize risk, to monitor safety, and to protect privacy and confidentiality may need to be re-evaluated. It may no longer be feasible to resume certain research as originally proposed and approved due to varying circumstances.

Though this risk cannot be entirely mitigated, following the requirements below provides additional steps to protect human research participants from exposure due to their involvement with in-person research. **For studies requiring approval as noted below, PIs must first obtain approval to resume in person activities from their department Chair/Center Director and their Associate Dean for Research (ADR). The PI must then email this approval and detailed justification to the OIRB Director at petreel@unm.edu. Decisions will be made in collaboration with the IRB Chair (and/or full board if needed) on a case by case basis.**

For a research study involving face-to-face data collection from human participants to resume, approval is required from the UNM IRB for any of the following types of studies:

- Direct physical contact with participants, including handling of bodily fluids (e.g., saliva, sweat, urine, blood);
- Intense physical exertion by participants (e.g., VO₂ max test, lifting weights);
- Populations at [higher risk of severe illness from COVID-19](#) (e.g., people 65 years and older, with underlying medical conditions, severely obese individuals BMI>40, those with compromised immune systems, those with severe asthma);
- Participants coming on-campus;
- Gatherings of more than 5 people in a limited space setting (e.g., classrooms, labs);
- Face-to-face data collection (e.g., surveys, interviews, focus groups, administration of instruments/measures) in limited space settings (e.g., conference rooms, participants' homes, coffee shops) where the use of virtual/remote options (e.g., Qualtrics, phone, Zoom) is not feasible;
- Observation or video recording in limited space settings (e.g., homes, classrooms, labs).

When requesting approval to resume in person activities or when developing a new study that involves face-to-face data collection, Principal Investigators (and Student Investigators, if applicable) need to submit a plan to address #1-6 below:

1. Discussion with research personnel before resuming a study the possible risk of COVID-19 exposure as it pertains to working with participants on the research study, and only involve those who agree (without undue influence or coercion).
2. Changing (where possible) study procedures (recruitment, consent, or data collection) to occur remotely to minimize exposure.
3. Limiting the number of research personnel working with participants to the minimum necessary to safely collect the data.
4. Confirming that all research personnel have been trained before commencing data collection on any new procedures adopted to prevent exposure to COVID-19 (see [OVPR memo dated 5/11/2020](#)).
5. Outlining contingency plans if studies have to stop again on short notice in the event that the university stops all on-campus operations and research again due to public health concerns related to COVID-19.
6. Though it may be impossible to know where exposure to the virus occurred, the PI needs to provide a plan in the event that a member of the research team or a participant reports exposure to, develops symptoms possibly associated with, or tests positive for COVID-19 within 14 days of a data collection event (e.g., visit to a lab, in-person interview). The plan should explain reporting procedures and the assessment of whether to continue the study and any changes or measures implemented to minimize further exposure to COVID-19 for research personnel and other participants. An example of this is a “contact log” where researchers document all interactions (both < and > 6 ft.) with non-research personnel.

Different types of studies may need different measures to prevent exposure to COVID-19. Measures to minimize the risk of COVID-19 exposure that researchers need to implement, as appropriate for the research setting and the study, may include, but are not limited to:

1. Confirm the following are in place where applicable and as appropriate, following University guidance:
 - a. Procedures for screening of research personnel and research participants for potential risk before they travel to the data collection site or before data collection and documenting such screening (not part of the research record). See screening questions below.
 - b. Research personnel and participants have the appropriate Personal Protective Equipment (PPE) (e.g., gloves, masks) and have been trained in their use (and documentation of such).
 - c. Procedures for cleaning and disinfecting surfaces, equipment, furniture, door handles, etc. regularly and between participants.
 - d. Procedures for personal hand hygiene following direct contact with participants or high touch surfaces.
 - e. Social distancing requirements among research personnel and participants (6') except for when necessary to collect data (e.g., to draw blood, place equipment such as blood pressure cuff or electrodes on a participant).
2. Provide participants with written information about the possible risk of COVID-19 exposure as it pertains to their participation in the research study.
3. Provide research personnel and participants instructions on contacting the PI immediately if they contract COVID-19 (including showing symptoms or testing positive).
4. Require self-reporting if individuals on campus are diagnosed or display signs or symptoms of COVID-19 illness (i.e., flu-like symptoms with fever > 100; cough; shortness of breath; loss of smell; or loss of taste), according to [UNM policy](#).

5. Minimize and stagger participant study visits to reduce exposure of participants and research personnel and to give time to sanitize the areas where the research took place.
6. While implementation of some measures for existing studies will not require an amendment to an IRB-approved protocol (e.g., verbal COVID screening, social distancing, use of PPE), others will. If contracting COVID-19 is now a potential risk as a result of participation in a research study (i.e. mandatory physical contact, small spaces, etc.), researchers need to submit an amendment request to the IRB before resuming data collection addressing this new risk, including plans to minimize the risk as noted above, an updated assessment of the study's risk-benefit ratio, and updated consent information. For new studies (not yet reviewed by the IRB), researchers should address possible COVID-19 exposure as a risk in their application if studies are the type listed above.

Community Based Research Work

For personnel engaged in community-based research (research outside of the UNM Campus), personnel should continue to conduct research through the use of electronic methods- Zoom, phone calls, emails- to mitigate the chance of cross contamination between communities. Travel to areas or communities in New Mexico who have emergency stay at home orders in place will not be permitted. Essential, off-campus activities will be minimized to the extent possible while still advancing research efforts.

When in-person visits are necessary, a location is available that meets the public health guidelines for that area, and all required approvals have been obtained, continue to reduce exposure risk by including the following steps:

- a. Stay home when experiencing COVID-19 symptoms
- b. Wear a cloth mask at all times
- c. Maintain physical distancing (6') in all work/common areas
- d. Reduce the number of people in a room to no greater than 5 at a time
- e. Minimize the number of staff who have "hands on" contact with study participants
- f. Clean workspaces regularly and wash your hands before and after contact with participants

Screening requirements for all face-to-face human research until an effective vaccine for COVID-19 is widely available

Participants and study personnel should be screened for COVID symptoms prior to entering any areas on campus. Family members/friends may not be allowed to accompany the participant to the visit. However, if family members are required *participants* in in-person study activities (e.g., family behavioral health intervention), they must also be screened as above. Passing requires an answer of "No" to all of the following:

- Have you **recently started** experiencing any of these symptoms?
- Fever or chills?
- Mild or moderate difficulty breathing?
- New or worsening cough?
- Sustained loss of smell, taste, or appetite?
- Sore throat?
- Vomiting or diarrhea?
- Aching throughout the body?

Sources:

<https://hr.unm.edu/docs/hr/eeoc-ada-covid-policy-statement.pdf>

<https://www.cdc.gov/coronavirus/2019-ncov/index.html>

<https://www.cdc.gov/infectioncontrol/guidelines/disinfection/disinfection-methods/chemical.html>

<https://www.epa.gov/pesticide-registration/list-n-disinfectants-use-against-sars-cov-2>

Please note that [the University of New Mexico also has a webpage](#) that is updated frequently if you have specific questions regarding the University's response to the ongoing situation.

Acknowledgement: Adapted from *Considerations for Resuming Human Research*, University of New Hampshire, Research Integrity Service and *Phased Approach to Return to Full Operations in Research*, UNM HSC Office of Research.