

Research Continuity Guidance for Clinical Trial Research Faculty and Staff

HSC PIs and their research staff should abide by the most recent published recommendations and orders from UNMH Infection Control Office, UNM HSC Office of Research, UNM School of Medicine, and UNMH Clinical Affairs.

Additional guidance can be found at these sites:

UNM HSC Office of Research webpage: <https://hsc.unm.edu/research/>

NM Department of Health COVID-19 Updates webpage: <https://cv.nmhealth.org>

CDC COVID-19 website: <https://www.cdc.gov/coronavirus/2019-ncov/prepare/prevention.html>

Guidance for Staff:

In general, employees should be allowed to do as much work from home as possible. Employees whose positions are Tier 1 will need to continue to report to work unless otherwise directed by the department's administration and principal investigators.

To reduce risk of infection and protect staff and subjects, please follow these recommendations:

- Frequently wash your hand with soap and water for 20 seconds, and use hand sanitizer.
- Avoid touching your eyes, nose, and mouth.
- If you cough or sneeze, cover your nose and mouth with a tissue, and throw the tissue in the trash.
- If pushing elevator knobs, using knuckles not fingers.
- Use automatic door openers when available.
- Report any recent travel to the Infection Control Office and follow their recommendations for self-isolation, medical treatment, or release to work.
- Move all meetings and work activity to online or home access whenever possible
- Maintain social distancing (>6 feet from other persons).
- If feeling unwell, do not come into work, except to get medical care. Call the NM DOH hotline (1-855-600-3453) for instructions regarding next steps.
- Disinfect "high-touch" surfaces such as doorknobs, sink handles, telephones, etc. daily using an EPA-registered household disinfectant. see CDC webpage for details:
<https://www.cdc.gov/coronavirus/2019ncov/prepare/prevention.html>
- Continue to monitor UNM HSC email alerts.

Guidance for Clinical Trial Research Continuity:

Given the highly variable nature of study activities in different labs, it is expected that PIs will make different determinations regarding the risks and benefits of continuing or delaying research activities.

- 1) PIs should assess whether a study activity or clinical trial can be delayed, and if able, should do so.
- 2) Participants in research studies may continue to receive standard of care and/or experimental treatment of their disease as usual.
- 3) Principal Investigators need to take into account whether any reduction in the staff makes it unsafe to complete the planned research visit, and plan accordingly.
- 4) Any study activity that can be conducted by phone or video conferencing should be performed as such.
- 5) Changes such as the above will generally be allowed, and considered as minor protocol deviations.
- 6) Any non-emergent change to a study design and protocol deviation must still be reported to the IRB office.

Further considerations for research continuation may include:

- Plan for when staff are quarantined or unable to come to work, or the entire campus is closed
 - Plan to protect against disruptions in the availability of critical supplies or materials
 - Plan for when core facilities and other fee-for-service resources, such as clean rooms or machine shops, are not available
 - Plan for means of communication between staff members
 - Plan for areas of cross-training that could be organized in the lab
 - Plan for outages of services of electricity and other utilities, in case brief outages occur
 - Consider staggering work times in the lab; find alternatives to write-up spaces in close quarters
 - Consider whether cell lines or tissues that could be preserved by freezing
 - Consider whether other labs could assist in maintaining crucial functions
 - Consider how long it would take to shut down equipment and experiments, and the safest and most expeditious procedures for doing so
 - Consider remote control monitoring devices or back-up power supplies that could help maintain critical equipment.
- Review contingency planning and emergency procedures with all researchers and staff in a lab group

Guidance for Screening Clinical Trial Subjects for COVID-19

- 1) Encourage social distancing and good hand hygiene in all screening and in-person visits.
- 2) If in-person visits are required, screen all participants by phone before planned study visits.
 - Ask about feeling unwell, fever, cough, shortness of breath, sore throat.
 - Ask about recent travel to high risk areas for infection, both international and domestic, in the past two weeks.
 - If there are any affirmative responses, do not have the participant present for the visit.
 - Advise them to reschedule for when they are feeling well.
 - Advise them to call the NM DOH hotline (1-855-600-3453) for further instructions.
- 3) If participants express concerns about their health, offer alternate visit options, such as delaying the visit, conducting it by phone, or conducting it by video conference, if possible.
- 4) If a subject manifests the above symptoms during a study visit, perform the following:
 - Terminate the visit.
 - Give them a mask to prevent spread of droplets.
 - Advise them to return home and call the NM DOH hotline (1-855-600-3453) for further instructions.
- 5) If a subject manifests the above symptoms on arrival for a study visit, perform the following:
 - The front desk staff will offer a mask and hand sanitizer and will instruct the participant to sit in a separate designated area.
 - The front desk staff will inform the research team immediately, and the research team will determine if study visit is to be terminated.
 - If so, the subject is sent home and advised to call the NM DOH hotline (1-855-600-3453) for further instructions.

Attention:

If you feel sick or think you might be sick, please let the front desk staff know. The receptionist will let you know where to sit

and will provide you with a mask and hand sanitizer. Your research contact will come to greet you and help determine the next steps.

Thank you.

Atención:

Si se siente enfermo o cree que podría estar enfermo, informe al personal de recepción. La recepcionista le informará dónde sentarse y le proporcionará una máscara y desinfectante para manos. Su contacto de investigación lo saludarán y ayudarán a determinar los próximos pasos. Muchas Gracias.