colorado school of public health

Human Subjects Research Best Practices during COVID-19 Pandemic
Colorado School of Public Health
Updated as of May 29, 2020

Purpose

This document provides best practices for implementing safety precautions for human subjects research in a COVID-19 environment. The University of Colorado Anschutz encourages minimizing face-to-face interactions and performing as many research tasks as possible virtually. Guidelines in this document apply to research that, for scientifically justified reasons, involves face-to-face contact. The document also describes situations in which working remotely can impose risks to research staff and subjects. The document will continue to be updated as the COVID-19 environment evolves.

All employees must comply with University policies while on campus. All employees must also complete an online training module entitled "CU: COVID-19 Return to Campus" prior to returning to campus. This training can be found in the SkillSoft section of the My CU portal. Enter the CU Denver | Anschutz training menu and click on the COVID-19 category on the left side of the page.

Research Committee

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Scope

These "best practices" are intended for human subjects research other than clinical drug trials and includes participants in clinical settings (e.g., behavioral interventions that occur in a clinical setting) and community settings. Studies that involve basic laboratory research and interventional drug trials will need to refer to separate guidelines. Not all human subjects research projects will return to campus immediately. Activities will resume in a gradual manner, and for some projects there could potentially be a significant time period before they are able to return.
Guidance on clinical research
Guidance on basic science research

Research conducted off campus will follow local guidelines (e.g., social distancing, use of personal protective equipment). Site Principal Investigators (PIs) may be bound by protocols set by the primary institution. PIs must carefully weigh risks to employees and human subjects when local or primary site guidelines are less stringent than the guidelines recommended by the University and those set forth in this document.

Objectives

- Ensure best practices are applied to ongoing research conducted remotely to protect the health and safety of research staff and participants.
- Allow for the resumption of human participants research on campus and off-site.
- Communicate best practices to all unit leaders, PIs, and research staff.

Notes

Researchers should frequently check State, Colorado Department of Public Health and Environment, University, and sponsor guidelines as they could change as circumstances

and requirements evolve. Please contact Cathy Bradley, Associate Dean for Research, at Cathy.Bradley@cuanschutz.edu with questions.

Process

All units/PIs must create a plan for research that involves human subject contact including those that involve in-person contact either on the Anschutz Medical Campus or elsewhere, or remote contact online or by phone. If there are multiple related studies within a unit, a consolidated plan can be developed. These plans will assist university administrators by notifying when on campus projects will restart, how workspace will be allocated, and confirming that appropriate safety measures have been considered, even in studies where all activities are conducted remotely. These plans can include:

- Priority level of the study as determined by the PI and unit level supervisor. Refer to "CU Anschutz Medical Campus Principles and Framework Guiding a Phased Approach to Ramping up Clinical Research Activities." (A link will be added to this document when it becomes available.)
- Requested workspace (specify building, floor, and work areas) or if the research will occur off-site (specify location).
- Anticipated routes of travel within the building.
- Number of staff participating in research and their roles.
- Safety measures that will be adopted for participants and research staff.

PIs will submit a plan through an online form:
Return to Campus: Remote Only, No In-Person Human Subject Contact Research Form
Return to Campus: Community and Off-Campus Research Form (link will be added when this form is available)
Return to Campus: On Campus Research Form (link will be added when this form is available)

This plan will be submitted to the unit level supervisor prior to research resumption. After receiving unit level approval, plans will be submitted to the Associate Dean for Research and the Dean of the Colorado School of Public Health to ensure best practices are followed and that the plan is consistent with evolving campus guidelines. The Associate Dean for Research will communicate with the Vice Chancellor for Research, if required. Unit level supervisors cannot review their own plan and must submit their plan to the Associate Dean for Research and the Dean, Colorado School of Public Health.

Unit supervisors will serve as COVID-19 officers and are responsible for enforcing best practices regarding use of space (e.g., overcrowding, face mask use) and reporting conditions (e.g., absence of sanitizer, cleaning of high touch points) that violate best practices to the Associate Dean for Administration and Finance, Christine Gillen, Christine.Gillen@cuschutz.edu.

The responsibility and accountability for the safety of study subjects and research staff ultimately lies with the Principal Investigator (PI). OSHA Safety and Health Program Management Guidelines outline a comprehensive process through which PI's can implement appropriate precautions.

For studies in need of immediate access to campus facilities prior to the official opening of campus, complete the CU Anschutz Non-Clinical Research Closure Exemption Request.

Best Practices

Screening research participants for COVID-19

PIs are encouraged to screen research participants and accompanying caregivers for COVID-19 symptoms prior to in-person interaction with study staff. Below is a suggested approach:

- Call participant prior to their scheduled visit and screen on the phone for new onset (in last 7 days) of symptoms of possible COVID-19 (fever >=100.4, cough, shortness of breath, chills, repeated shaking with chills, muscle pain, sore throat, new loss of taste or smell, and/or GI symptoms such as nausea, vomiting, or diarrhea). If any symptoms are present, advise the participant to contact his/her provider/health facility; the visit should be rescheduled after a 3-day period of being fever-free, other symptoms have improved, and 10 days have passed since the onset of symptoms. If the screen is negative, and participant wishes to proceed with a visit, he/she is invited to come to the research site.
- If studying children, be aware that they may present with less severe symptoms.
- Ask the potential subject if they fit into one of the categories considered "vulnerable" for COVID-19 and a poor outcome. See section on **Vulnerable Populations** for guidance (below).
- When a participant arrives at the research site (or research staff arrives at the research site, including participants' homes), research staff should re-ask the screening questions in a private location. If the screen is positive, the participant should be advised to contact his/her provider/health facility and reminded about contact and droplet precautions and not allowed to proceed with the study visit. (Consult the CDC guidelines for guidance for positive cases). If negative, he/she can continue with the study visit. Staff screening a research participant in person should maintain at least six feet of distance from the participant. Participants and research staff will be required to wear a mask.
- See the Participant Screening Questionnaire that is available for use by research projects.

Scheduling research participants

The Principal Investigator should consider spacing research participants:

- Study visits should be staggered so there is no congregation of participants at the research site and to maintain 6 feet of separation between participants. It is the PI's responsibility that all participants are compliant with evolving social distancing guidelines.
- Certain activities such as focus groups, group training, or counseling (e.g., behavioral interventions) may need larger rooms to accommodate distancing and when possible, done in a virtual format through a Zoom or other web-based venue.
- Time to conduct cleaning between participants should be allocated in the schedule.
- Participants will wear face masks on campus and will provide their own face masks.
- Participants will comply with all building access control procedures which are in place at the time of their visit.

Vulnerable populations

Principal Investigators are encouraged to consider implications for the recruitment and involvement of persons who are more vulnerable to COVID-19 before inviting them to participant in research. Although our understanding of COVID-19 is evolving, the known risk factors are age, comorbid conditions (e.g., diabetes, cardiac conditions, chronic obstructive pulmonary disease, other pulmonary conditions, etc.), obesity, undergoing treatment for cancer, immune compromising conditions, and pregnancy. Some racial and ethnic minority groups may be at risk of poor outcomes from COVID-19. In addition, persons living in low-income housing, or in areas with a high prevalence of COVID-19 may be especially vulnerable. Research staff who engage face-to-face with these populations may also be at increased risk. Rural areas or low-income areas may not have adequate health care infrastructure to deal with additional COVID-19 outbreaks. Remember that researchers from outside a community can unintentionally spread disease.

Exclusions based on perceived vulnerability may disproportionately exclude underrepresented populations. Therefore, exclusions should be carefully considered and alternatives for making subjects and research staff safe investigated.

Suggested approaches for vulnerable human subjects and staff:

- During the initial phases of resuming human subjects interactions, consider enrolling lower risk subjects as procedures for managing human subjects interaction are refined and recalibrated. New information to inform best practices will emerge.
- If vulnerable populations are included, consider designating special hours when workspace is less crowded or designated areas with the fewest possible encounters.
- Research staff or their families may also be considered vulnerable in a COVID-19 environment. Safety measures and accommodations such as reassignment of duties or changes to the work environment may be considered.
- Because public transportation may pose a risk for contracting COVID-19, researchers could consider enquiring about modes of transportation and consider options for helping participants arrange for safe transportation to and from the study site.

What if research participants or staff become sick?

For the latest information on COVID-19 and the illness reporting process, refer to the University COVID-19 webpage. Measures need to be in place for illness notification and contact tracing:

- Participants should be advised that, if they experience a new onset of symptoms, they need to contact their health care provider and call the research team to inform them as soon as possible. Primary and secondary contact information for all participants will be required.
- Researcher staff can provide a one-page follow-up document to participants that details what to do if they experience an onset of symptoms.
- If a research participant becomes ill, the person receiving the call will take the following steps:
    1. Encourage the research participant to seek medical care as soon as possible
    2. Report the illness to a supervisor/PI of the research study
    3. The supervisor/PI will contact Occupational Health to notify them of the illness, along with any locations in the building visited by the participant and any employees who came in contact with the participant.

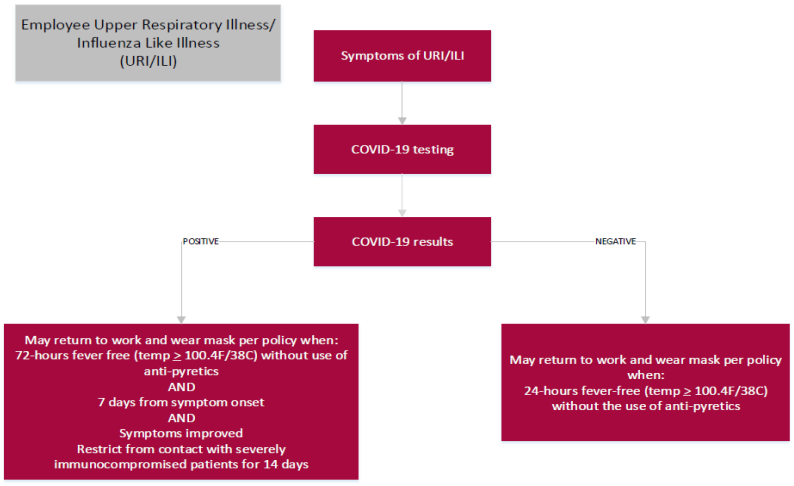
4. Occupational Health will follow-up with the affected employees and unit per University and local public health guidelines.

- Contracting COVID-19 may be considered a reportable event to COMIRB and the Data Safety Monitoring Board, if applicable. Please refer to COMIRB for guidance.
- According to University of Colorado Anschutz policy, if an employee becomes ill, they will take the following steps:
  1. If they are on campus, they will leave campus immediately.
  2. Report his/her illness to a supervisor.
  3. Seek medical care as needed.
  4. Submit a self-report to Human Resources using the online questionnaire.
  5. If the employee tests positive for COVID-19, he/she should report this to a supervisor and complete a second online questionnaire form to update their status immediately.
  6. Do **NOT** return to work until cleared to do so by a health care provider.

The employee's supervisor will take the following steps upon being notified of the employee's illness:

1. If the employee is on campus, direct them to immediately leave the facility.
2. Encourage the employee to seek medical care as needed.
3. Confirm with the employee areas in the building beyond his/her work area that were visited within the last 72 hours.
4. All research participants with whom the staff member had personal contact will be notified and encourage to seek medical attention. Participants can be referred to UCHealth's guidance on COVID-19. Primary and secondary contact for all participants will be required.
5. Emphasize to the employee that they are not to come to campus until he/she is cleared to do so by a health care provider.
6. Contact Occupational Health to notify them of the illness, and the locations in the building visited by the employee
7. If the employee reports a positive COVID-19 test result, immediately report this information to Occupational Health.

Occupational Health will follow-up with employees who test positive, provide appropriate guidance, and investigate to determine others who may be at risk. Once an employee meets the following criteria they may return to campus:



Considerations for research staff working remotely

Research staff working from home may be vulnerable to having their personal contact information inadvertently made available to research subjects. To protect staff working from home, the following guidelines are suggested:

- If research staff call participants from their personal cell phone, have the call routed through a University phone number so staff phone numbers are not revealed. To route calls through a University phone number, contact OIT. They will help set up Cisco Jabber, a free service, on a phone or computer to make calls using a campus office phone number. Alternatively, consider purchasing separate cell phones for research staff use.
- You have the option of creating a blocked number but be aware that people are often reluctant to answer these calls.
- Arrange call back numbers to a university phone number that can either be forwarded to research staff or checked by research staff working remotely.
- If using Zoom or other web-based platforms to conduct research, use a university link (password protected) that is sent to only to those participating in the study.

Recording HIPAA protected and other research data while working remotely.

It is the PI's responsibility to ensure the protection of human subjects' information collected and recorded as part of a research study.

- Research staff should only use secure password protected WIFI connections when collecting or transmitting human subjects information electronically. The use of unsecure WIFI connections is prohibited.
- Research subject information must be stored on a HIPAA compliant server to which research staff connect through the university VPN.
- When conducting web-based data collection, research staff must be instructed that if the VPN is unavailable to them due to technological difficulties, interactions with the research subject must be rescheduled until a time when the VPN becomes available.

Protocol Modifications

It is strongly advised that all protocol modifications are discussed with the sponsor (i.e., project officer) and COMIRB personnel to seek guidance for documentation of

amendments. Consent forms may require modification to identify potential risks for COVID-19 exposure and subject agreement to contact research staff if new onset of symptoms is experienced. Please refer to the COMIRB webpage.

Additional references

Below are references to general guidance you may find helpful should you move components of your research online. If you have other resources, please send them to Cathy.Bradley@cuanschutz.edu to be posted on the research website.

- Online surveys

https://www.umass.edu/research/guidance/survey-guidelines
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5506389/

- Qualitative research conducted online

https://www.betterevaluation.org/sites/default/files/43888_1.pdf