University Research

UNIVERSITY OF COLORADO **DENVER | ANSCHUTZ MEDICAL CAMPUS**

Campus COVID-19

Clinical Research Reconstitution Plan

Purpose

This document guides the actions of the CU Anschutz Medical Campus as it restarts clinical research operations during the COVID-19 pandemic.

Scope

This document applies to clinical research that takes place on the CU Anschutz Medical Campus. The Affiliate Hospitals have their own guidelines that need to be followed in their facilities. Guidelines in this document apply to research that for scientifically justified reasons involves face-to-face contact with participants.

These guidelines are intended for studies that involve research participants who may or may not be participating in interventional clinical trials (i.e., drug trials) and includes participants in clinical and community settings.

Objectives

The University's objectives during research reconstitution are to:

- Allow for the progressive resumption of clinical research on the CU Anschutz Medical Campus
- Ensure in-person research activities are conducted in as safe a manner as possible to ensure the health and wellbeing of research personnel and research participants.

Assumptions

The following assumptions informed this document:

- The prioritization of which research projects to ramp up will be detailed in the accompanying document: "Principles and Framework Guiding a Phased Approach to Ramping up Clinical Research Activity"
- Only work requiring a physical presence on campus will be conducted on campus. Research-related administrative functions will primarily continue from remote locations. All work, including data entry and visit preparation, that can be done remotely, will continue to be done remotely.
- Principal Investigators (PI)s utilizing non-university space will follow the requirements of the affiliate hospital or research site institution
- PI's are responsible for supplying or arranging for the supply of appropriate Personal Protective Equipment (PPE) for their research personnel prior to restarting or beginning research
- Core resources – including those facilities outside of their research unit – such as PET CT or MRI will coordinate with PI when appointment is scheduled as to the availability of PPE.

Note: Researchers should frequently check State, CDPHE, University, and sponsor guidelines as they could change as circumstances and requirements evolve.

Research Reconstitution Group

The Clinical Research Reconstitution Group is chaired by the Associate Vice Chancellor for Regulatory Compliance and is composed of representative leadership from across the CU Anschutz Medical Campus and Affiliates. This group will advise and coordinate with Research Administration, Facilities, the Office of Information Technology, Environmental Health and Safety, and the Police Department to ensure support services are in place for restart activities and provide input on the process overtime.

Space Plans

A COVID-19 official will be designated on each clinical research area to ensure the combined activities on the floor do not violate the physical distancing and safety requirements listed below based on a participant scheduling plan. The COVID-19 official may appoint one or more COVID-19 coordinators to assist them with implementation of their responsibilities. Additionally, the COVID-19 official will determine if break rooms, conference rooms etc. will be available for use and if so the number of people permitted in each large space. The COVID-19 official will submit these space designations to research administration for review and approval, prior to any increased research activity in their area. Upon approval, the COVID-19 official will create and post appropriate signage for each space noting its status and the maximum number of people allowed to use the space and maintain adherence. If facilities beyond the research area will be utilized (i.e., sample transport to Leprino building, BIC), the COVID-19 officials between those areas will need to coordinate to ensure proper physical distancing and space planning.

The clinical area must create a plan for research that involves participant contact. Research studies that solely use secondary data are not required to submit a plan. If there are multiple related studies within a clinical area, a consolidated plan can be developed based on the accompanying framework document. These plans will assist university administrators by notifying proposed restart dates, how workspace will be allocated, and confirming that appropriate safety measures have been considered, even in studies where all activities can be conducted remotely. These plans should include:

- Priority level of the studies to be conducted based on the accompanying framework document.
- Requested clinical area (specify any additional building, floor, and work areas also needed) or if the research will occur offsite (specify location).
- Anticipated routes of travel or traffic flow in the building
- Number of staff and their roles that will be returning to campus.
- Safety measures that will be adopted.
- PPE required for the study procedures and verification adequate supplies are on site
- How patients will be scheduled to minimize contact with staff and other patients
- How clinical samples will be transported on campus for laboratory analysis

Individual clinical research units will determine shift lengths and schedules of their personnel with goal of minimizing the number of people in any one room/area at a time.

All such plans, schedules, and maps shall be submitted for review and approval by the clinic director, COVID-19 official, and research administration prior to research resumption.

Protocol Activation Process

All clinical research requesting to be conducted on campus must be reviewed by Taskforce Clinical Research Review Committee in accordance with the group prioritization established in the Framework document:

This review is conducted to manage:

- Gradual increase of clinical research on campus
- Ensure any visits that can be done remotely have been modified accordingly
- That it is feasible to accommodate all required visits
- The necessary ancillary services needed are available
- The appropriate schedule can be accommodated in the space requested
- Anticipated routes of travel within the building for participants and/or specimens if different from approved space plan
- Number of research team that will be returning and their roles

The responsibility and accountability for the safety of study participants and research staff ultimately lies with the Principal Investigator in accordance with the clinical space utilization plan.

Participant Screening for COVID-19

PIs will ensure research participants are screened for COVID-19 symptoms in advance of their scheduled visit and on arrival on campus.

Below is the preferred approach:

Participants and any accompanying caregivers will be asked whether they have experienced COVID-19 symptoms within the last seven days or have been in close contact with sick people (REFERENCE SCREENING QUESTIONNAIRE HERE) Currently known symptoms of COVID-19 infection include:

- A fever greater than 100.4 °F
- Cough
- Shortness of breath
- Sore throat
- Headache
- Gastrointestinal upset
- Muscle pain
- Chills
- Repeated shaking with chills
- New loss of taste or smell

If the result is negative, a visit will be scheduled. If positive, advise the research participant to seek medical care and reschedule the visit for a later time.

Note: If studying children, be aware that they may present with less severe symptoms

This screening will occur as designated for each clinical space building at check-in or sooner.

Note: Any modifications from the above screening process must be approved by unit level supervisor, COVID-19 Official, and research administration prior to implementation

Participant scheduling

Participant visits will be scheduled to stagger their arrival and avoid subjects congregating in waiting areas. Schedule time allocations need to be adjusted accordingly.

Ensure that participant scheduling includes sufficient time to conduct appropriate cleaning protocol between participants.

Certain activities such as focus groups, group training or counseling (i.e. behavioral interventions) will be done remotely whenever possible If in person attendance is required larger rooms may be needed to accommodate physical distancing and will be limited to fewer than 10 research participants.

Note: In person gatherings of research participants must be thoroughly described in the research restart plan required above.

Recruitment considerations

Researchers should consider possible implications for the recruitment and involvement of persons who are more vulnerable to COVID-19. Currently 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. These individuals may be at greater risk from participating in or staffing a research study and may need to be either excluded or given additional protection. These exclusions may disproportionately exclude underrepresented populations. Therefore, exclusions should be carefully considered and alternatives for increasing research participant safety investigated.

Some suggested approaches for vulnerable research participants and staff include:

- During the initial phases of resuming research participant interactions, consider enrolling lower risk subjects as procedures for managing research participant interaction are refined, based on emergent best practices.
- 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 vulnerable in a COVID-19 environment. Safety measures and accommodations such as reassignment of duties or changes to the work environment may be considered.

Research participants that rely on public transportation may be at more risk for contracting COVID-19. Researchers should inquire about research participants' mode

of transportation and consider options for helping participants arrange for safe transportation to and from the study location.

Physical Distancing / Safety Requirements

All employees and participants working on campus should, at a minimum, engage in the physical distancing and safety measures listed below. Individual research units will determine the best ways to educate their employees about these requirements in addition to the return to campus training.

Employees who do not follow these requirements will be referred to their supervisor/PI for remedial training and reinforcement of these requirements. If a specific unit/floor is found to be out of compliance, that area may again be closed to activity.

Definition of physical distancing:

- Work space population calculations will be based on 120 square feet per person for researchers actively working in a lab or work area.
- Maintain at least 6 feet between themselves and other individuals at all times
- Do not loiter or congregate in public areas, hallways, work areas, etc.
- Employees should carefully inspect all equipment and work areas for potential safety concerns prior to beginning work
- Clean their work areas, including high touch areas, prior to beginning their work shift and after each participant visit for clinical space or at the end of their work shift
- Clean any area, high touch surfaces, and equipment before and after use

Note: Guidance for cleaning of clinical research spaces and equipment can be found at: https://www.cuanschutz.edu/coronavirus/research-guidance

Research participants will comply with all access control procedures which are in place at the time of their visit

Environment requirements

Research participants will follow all posted building specific guidance on personal movement within campus buildings

Research staff will be contacted by their supervisor/PI and told they can return to campus in coordination with the facility COVID-19 official

Clinical Research staff

Note: Those staffing entry points will be provided with PPE appropriate to this task

Note: Whichever access option is in effect will be the minimum requirement. Schools and departments may choose to enact more restrictive entry requirements for their areas.

Employees working on campus will wear a face mask at all times

Employees may utilize improvised face masks constructed in accordance with CDC guidance for non-clinical activities. The PI (or their school/department) may provide disposable or reusable facemasks to all personnel if supplies are available.

Any decorations on the materials used to make the face masks will comply with the dress code standards regarding logos and appropriate work content established for other forms of dress and/or uniform standards

Employees will regularly maintain their face masks as instructed

Cloth face masks will only be removed when manufactured PPE is required to be worn in its place for specific operational requirements

If an employee discovers a conflict between this requirement and operational requirements, they will not begin, or will cease that operation and contact their supervisor/PI. The supervisor/PI will consult with Environmental Health and Safety for alternative measures before resuming that operation. (Industrial.Hygiene@ucdenver.edu)

Personnel Movement Discipline

In an effort to limit areas needing sanitization should an employee become ill with COVID-19, all employees shall limit their movement in their work buildings the following ways:

- Follow building specific signs, posters etc. which direct movement to entry and exit points to minimize interpersonal contact
- Take the most direct route from the point of entry to their work location
- Stay within their assigned work location except to perform essential functions identified by the COVID-19 official
- Utilize the restroom facility closest to their work location whenever feasible
- When retrieving supplies or equipment employees will make every possible effort to minimize trips while safely transporting needed supplies using dollies, carts, etc. The employee will clean transportation aids immediately once they are finished using them.

Note: Guidance for cleaning of laboratory spaces and equipment can be found at: https://www.cuanschutz.edu/coronavirus/research-guidance

Monitors

Industry clinical trial monitors must coordinate with the research team and obtain permission to be on campus from the PI of the study and the COVD-19 official. The expectation is that the monitoring visit will be conducted remotely as much as possible. The monitors should be on campus for the minimum time necessary.

All requirements for physical distancing should be followed as outlined above.

The monitor must wear a face mask while on campus

Illness Reporting

The information below provides the basic steps for the reporting of COVID-19 illness and exposure to the university. For the latest information on COVID-19 and more details about the reporting process please visit the University COVID-19 page at: https://www.cuanschutz.edu/coronavirus

Note: These actions only apply to the CU Anschutz Medical Campus. If the research is performed at an affiliate hospital employees shall follow the established protocols for that organization/location.

If a member of the research team reports they have fallen ill with COVID-19 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 employee illness to their supervisor/PI
3. The supervisor/PI will coordinate with occupational health (cody.coburn@cuanschutz.edu) to notify them of the illness along with the locations in the building frequented by the research participant and any employees who worked with the research participant.
4. Occupational health will follow-up with the affected employees and unit per University and local public health guidelines.

Note: 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.

If an employee becomes symptomatic they will take the following steps:

1. Report their symptoms/illness to their supervisor/PI
2. After notifying their supervisor/PI seek medical care
3. Do **NOT** come to campus under any circumstances
4. Submit a self-report to Human Resources using the online questionnaire: (https://ucdenverdata.formstack.com/forms/covid_form_copy)
5. If the employee tests positive for COVID-19 they shall report this to their supervisor and complete a second on-line questionnaire form to update their status: (https://ucdenverdata.formstack.com/forms/covid_form_copy)
6. Do **NOT** return to campus until cleared to do so

If an employee develops any of the following symptoms while on campus they will leave campus immediately and notify their supervisor/PI:

- Fever
- Cough
- Shortness of breath
- Sore throat
- Headache
- Muscle pain
- Chills
- Repeated shaking with chills
- New loss of taste or smell

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. Instruct the employee to seek medical care
3. Confirm with the employee areas in the building beyond their work area they may have frequented within the last 48 hours

4. All research participants with whom the staff member had personal contact will be notified and encouraged to seek medical attention. You can refer research participants to https://www.uchealth.org/today/covid-19-coronavirus-recent-updates/. Primary and secondary contact information for all participants will be required.
5. Emphasize the employee is not to come to campus until they are cleared to do so
6. Contact occupational health to notify them of the illness and the locations in the building frequented by the employee
7. If the employee reports a positive COVID-19 test result, immediately report this information to Occupational Health.

If an employee believes they were exposed to a COVID-19 positive person at work or at home they should take the following steps:

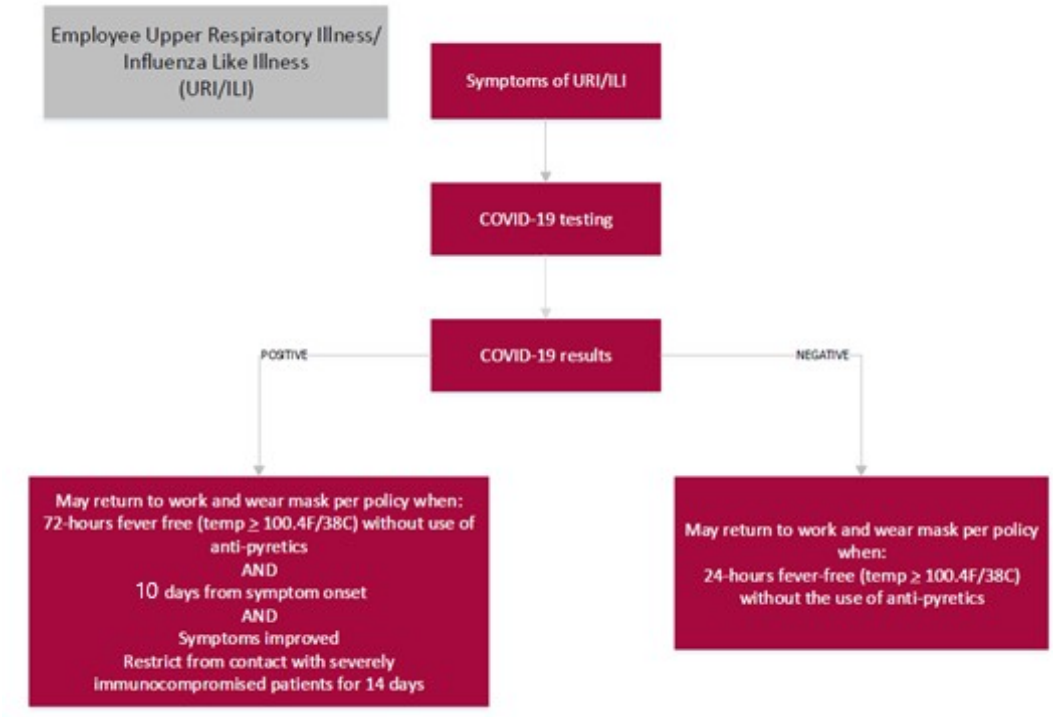
- Report their exposure to their supervisor/PI
- Do **NOT** come to campus under any circumstances
- Submit a self-report to Human Resources using the online questionnaire: (https://ucdenverdata.formstack.com/forms/covid_form_copy)

The employee's supervisor/PI will take the following steps upon being notified of the person's exposure:

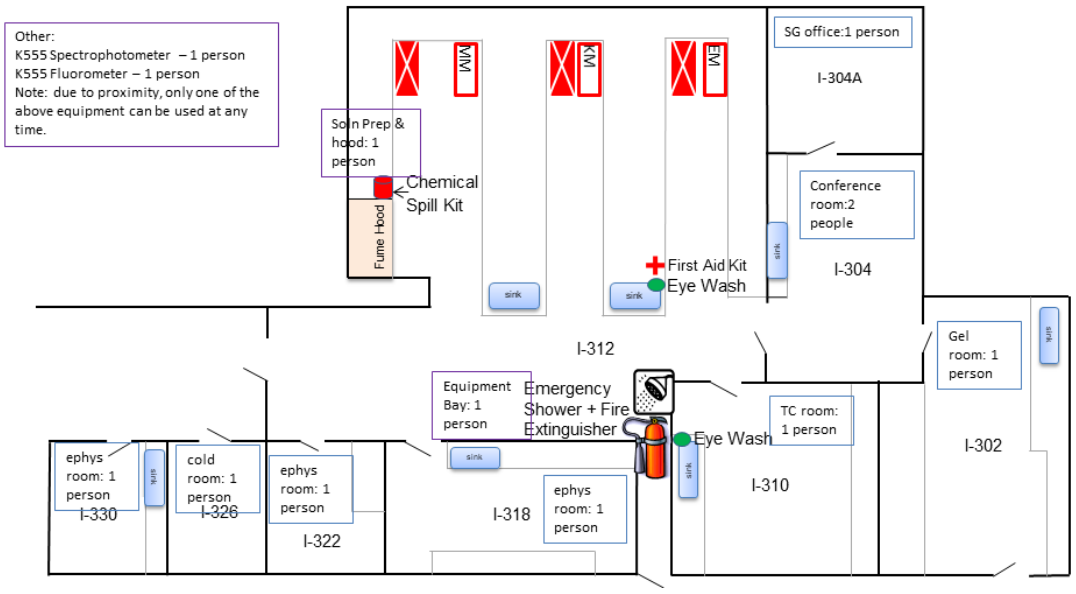
- Instruct the employee member **NOT** to report to campus until cleared to do so by their medical provider or occupational health.
- Confirm with the employee areas in the building beyond their work area they may have frequented within the last 48 hours
- Contact occupational health (cody.coburn@cuanschutz.edu) to notify them of the illness and the locations in the building frequented by employee

Occupational Health will follow-up with employees who test positive (or believe they have been exposed to a COVID-19 positive person), provide appropriate guidance, and investigate to determine others who may be at risk. Multiple cases in a single location will be investigated to determine systemic issues.

Once an employee meets the following criteria they may return to campus (masks will be provided by the University):



Occupancy Map Example



References

Colorado Department of Public Health and Environment, Public Health Order 20-28 Safer At Home

Colorado Executive Order D 2020 39 "Ordering Workers in Critical Businesses and Critical Government Functions to Wear Non-Medical Face Coverings"