

Agency for Toxic Substances and Disease Registry

CO SCOPE COVID Safety Plan

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Introduction

CO SCOPE (Colorado Study on Community Outcomes from PFAS Exposure) is one of seven sites of the national, multi-site study, which will look at the human health effects [of per- and polyfluoroalkyl substances](#) (PFAS) exposure through drinking contaminated water. The main goals of this study are to examine associations between measured and historically reconstructed serum levels of PFAS, including PFOA, PFOS, and PFHxS, and selected health outcomes as described below and detailed in the study hypotheses.

CO SCOPE addresses a critical public health need to further understand the relationship between PFAS exposure and health effects. Fieldwork for CO SCOPE, including face to face interactions for blood draws and neurobehavioral testing, is expected to begin in June 2021. These face to face interactions will require that precautions be put in place to ensure that staff and members of the public are protected from COVID-19. This plan is based on [interim CDC guidance for non-COVID-19 public health activities that require face-to-face interaction](#) and the University of Colorado's [ramping up community based research activity principles and framework guide](#) during the COVID-19 pandemic and will be used to outline practices for conducting CO SCOPE activities. The CO SCOPE team will follow state and local guidelines to determine if community spread in the study area warrants a temporary halt to face-to-face research activities.

Changes in the initial CO SCOPE procedures are proposed to reduce or eliminate close contact (within 6 feet) between study staff and the public when possible to prevent the spread of COVID-19 during study activities. The precautions and personal protective equipment (PPE) recommended in this plan will be reevaluated at least monthly and more often as needed to ensure they are still in line with CDC, State, local, and University of Colorado COVID-19 guidance that may be revised to add or remove precautions, as needed. Precautions may vary based on conditions on the ground and the timing of when study activities are conducted.

Plan Objectives

- Minimize risk of exposure, illness, and spread of disease among staff conducting CO SCOPE;
- Minimize risk of exposure, illness, and spread of disease among members of the public and CO SCOPE participants at CO SCOPE activities; and preserve essential functions of CO SCOPE.

Schedule Considerations:

In April 2021 Colorado removed its state-wide COVID-19 dial allowing counties to make their own determinations about COVID restrictions. As of April 15th, the county in which CO SCOPE will be conducted, El Paso County, [has greatly reduced COVID-19 restrictions](#) for events and businesses. Local COVID-19 orders will be evaluated prior to any planned face-to face recruiting events and the start of fieldwork which are not expected to begin until late spring to summer 2021.

Scheduling study activities will take into account:

- the level of local COVID-19 transmission (number of new cases, emergency department visits, and percent positive for testing in each community).
- [state and local guidance/mandates](#)
- other site-specific factors as described later in this document.

COVID-19 Safety Precautions in CO SCOPE

Staffing:

CO SCOPE field staff will be provided with clear information about new procedures and PPE requirements (as described in table below). All PPE will be provided to staff prior to initiation of activities. Staff will have an opportunity to ask questions about the precautions and PPE requirements. Staff at [higher risk](#) for severe illness from COVID-19, including older adults and those with underlying medical conditions, will be encouraged to discuss any concerns with their supervisors.

There is now good scientific evidence that properly used face coverings can [slow the spread](#) of COVID-19. The cloth face cover is meant to protect other people in case the wearer is infected, while surgical masks and N-95 respirators will protect the wearer. All face coverings [should cover the nose and mouth and be secured under the chin](#). Cloth face coverings are not surgical masks or N95 respirators; cloth coverings are useful for the protection of others and are not PPE for the wearer. Face coverings should not be placed on anyone who has trouble breathing, or is unconscious, incapacitated or otherwise unable to remove the mask without assistance. All staff will be provided with either surgical masks or N95 respirators. To ensure protection of both participants and staff, all participants will be provided a disposable surgical mask when they arrive at the clinic, regardless of if they arrive with their own mask or not. Participants will be told ahead of time that CO SCOPE staff will be providing masks upon clinic entry. If participants are unable to wear a surgical mask due to medical conditions, staff will always maintain at least six feet of distance and will wear a surgical mask at all times.

Community Meetings:

CO SCOPE Community Advisory Panel (CAP)

In the past, members of the CO SCOPE study team have held in person meetings with the CO SCOPE CAP on a quarterly basis. The CO SCOPE team and the CAP will decide whether future meetings will be held in person or online depending on State, local and University guidelines and venue availability, among other considerations. When weather allows, in person CAP meetings will be held outdoors and socially distanced.

CO SCOPE Study Recruitment Outreach Activities

CO SCOPE and members of the CO SCOPE CAP plan to conduct media and community outreach to increase awareness and enrollment in CO SCOPE. Example activities include, conducting media interviews, holding public meetings and staffing tables at local events and festivals. Many of the proposed outreach activities are dependent on reopening of local businesses and resumption of previously scheduled community events. The study team will work closely with the CO SCOPE CAP to identify and schedule outreach activities. Media interviews will be conducted over the phone or via videoconference. In person activities, such as public meetings, will be held online or structured to allow less than ten participants at a time to ensure social distancing of study staff and the public. If participants are unable to wear a cloth face covering or surgical mask due to medical conditions, staff will maintain at least six feet of distance at all times and will wear a surgical mask if closer interaction is required. When weather allows, community meetings will be held outdoors. The guidelines delineated above will be revisited on a monthly basis to evaluate the safety of in person public meetings.

Ahead of any in-person meetings, CO SCOPE staff will communicate guidance for social distancing, wearing a face covering, and [symptom](#) screening with meeting participants. All attendees will be screened for COVID-19 symptoms with a [symptom](#) questionnaire, visual assessment, and temperature check prior to entry and sessions will be set up to promote social distancing of staff from community members and among community members. CO SCOPE staff will deny entry to participants if they report [symptoms of COVID-19](#), have a temperature over 100.4° F, or if CO SCOPE staff observe signs associated with COVID-19 (e.g., coughing). If a participant is denied

physical entry, CO SCOPE staff will offer to have a phone conversation to share information and answer any questions they might have.

Face coverings for all study staff and community members will be used in accordance with CDC guidance and hand washing facilities with soap and water will be provided. Hand sanitizer will also be available near the door, and surgical masks will be provided to all participants and staff. If a participant exhibits symptoms after entering the facility they will be asked to leave and the facility will be cleaned and [disinfected](#) with a disinfectant listed on [EPA List N](#), following CDC guidance, before reopening.

Screening of CO SCOPE Staff and Study Participants

Before entering the study office, all study staff will be screened for symptoms and will have temperature checks prior to arrival of the first participant. Screening will include a temperature check as well as questions about the presence of any symptoms associated with COVID-19. Questions on symptoms will include presence of any of the following:

- Fever or chills
- Cough
- Shortness of breath or difficulty breathing
- Fatigue
- Muscle or body aches
- Headache
- New loss of taste or smell
- Sore throat
- Congestion or runny nose
- Nausea, vomiting or diarrhea

If any staff develop symptoms they will be instructed not to come to work and to inform the CO SCOPE office coordinator and study manager. If a staff member develops symptoms consistent with COVID-19, CO SCOPE will pause all enrollment activities. If the staff member subsequently tests negative, we will consult with CDC, University of Colorado and local/state public health professionals before resuming activities. If the staff member tests positive, CO SCOPE will notify all staff and participants who have been in contact with the positive individual and consult local/state guidelines and University policy to determine additional public health actions. The staff member will file a self-report per University policy and follow guidelines provided by the University's contact tracing team. Staff will keep a detailed log of all face to face interaction that occur at the clinic, between both other staff and participants. Participants will be explicitly informed during the consent process that their contact information will be provided to University or public health officials in the event they are in contact with a COVID-19 positive individual while participating in a CO SCOPE study activity.

CO SCOPE participants will be informed of screening procedures and be required to wear clinic-provided surgical mask throughout their appointment. They will also be instructed not to come for their appointment if they are experiencing COVID-19 symptoms (as defined in the list above). Participants will be asked about symptoms in a reminder call the day before their scheduled appointment. If participants are found to have symptoms during screening, they will be denied entry to the study office and will be encouraged to consult with their primary care provider. If a participant exhibits symptoms after entering the facility they will be asked to leave, encouraged to consult with their primary care provider, and high touch surfaces will be disinfected with a disinfectant listed on EPA List N. Participants will be asked to inform study staff voluntarily if they test positive to COVID-19 following identification of symptoms during screening procedures. Participants will also be asked to inform staff voluntarily if they develop symptoms or test positive for COVID-19 in the 7 days following their study visit. At this time staff will advise the participants on local and CDC guidelines for isolating, quarantining and/or obtaining a COVID test.

Biological Sample Collection:

All staff will be screened daily for COVID-19 symptoms prior to entry to the sample collection location using a symptom questionnaire and temperature check. Staff will follow current guidance for PPE as outlined in the table at the end of this document. Staff will also be instructed to stay home if they are experiencing any COVID-19 symptoms and will be screened twice daily. If symptoms develop, staff will be instructed to contact the CO SCOPE office coordinator and/or study manager for guidance.

Study participants will be instructed not to come for their appointment if they are experiencing COVID-19 symptoms (as defined in the list above). All participants will be informed of screening procedures and asked to wear a clinic-provided surgical mask throughout appointments. Participants will be asked about symptoms in a reminder call the day before their scheduled appointment. If a potential participant is found to have symptoms during screening, they will be denied entry to the sample collection venue and will be encouraged to consult with their primary care provider. Once the interested participant receives a negative COVID-19 test result or is symptom free and self-quarantined for a time period consistent with CDC, State, or local guidance, they can be rescheduled for a clinic visit. If a participant or staff member exhibits symptoms after entering the facility they will be asked to leave and the facility will be cleaned and [disinfected](#), with a disinfectant listed on [EPA List N](#), following CDC guidance, before reopening. If there is a potential exposure, staff will notify the CO SCOPE coordinator and manager for guidance on appropriate actions. Staff will share information about the interaction that led to a suspected exposure and will follow guidance from the University of Colorado and the CDC on appropriate actions.

Additional actions that will be used to reduce the potential for COVID-19 transmission include:

- Scheduling appointments such that no more than 9 individuals (staff and participants, based on the size and configuration of the space) are in the facility at the same time.
- Increasing physical space between employees and participants (e.g., physical barriers such as partitions).
- Using signs, tape marks, or other visual cues such as decals or colored tape on the floor, placed 6 feet apart, to indicate where to stand when physical barriers are not possible.
- Requiring use of surgical masks for staff and participants.
- Limiting sampling area access to a maximum of 9 people (based on area size and configuration) at a time, with a door monitor allowing one person inside for each person that exits.
- Providing proper hand washing facilities.
- Providing hand sanitizer and surgical masks for all participants upon entry into the facility for an in person appointment.
- Providing [signage](#) showing reasons for precautions and proper use surgical masks.

Questionnaire

Questionnaires will be transitioned from in-person to telephone administration. Copies of questionnaires will be emailed and consent for the phone questionnaire will be obtained both verbally and in the main consent form that participants will sign when they come into the clinic. The participant will sign the informed consent form when visiting the office for the blood draw and body measurements after being screened. This change will reduce contact time between participants and study staff.

Additional Considerations:

There will be a separate area for eating/drinking for staff and a separate area for eating and drinking for participants. Because masks cannot be worn while eating, a maximum of one participant will be permitted in the eating area at a time, with the exception of participants who reside in the same household. Staff eating areas will be set up with limited seating to promote social distancing. Break areas will be cleaned and disinfected a minimum of two times per day. Participants will not enter the staff food area.

To the best of our ability we will implement measures to improve ventilation in our office space [as recommended by the CDC](#). This includes:

- Opening operable windows and both the front and back doors to improve airflow when weather allows
- Ensuring an appropriately functioning HVAC system which is properly maintained (i.e., regularly change filters)
- Purchasing portable high-efficiency air (HEPA) filters for extra filtration. We will utilize [EPA's Guide to Air Cleaners in the Home](#) to be certain the purchased filters are appropriate for the size of the space they are being used in.
- Use fans in conjunction with open windows and doors to improve airflow; Use fans to move air out of enclosed spaces.

The following administrative controls will be instituted:

- Staff education on COVID-19, instruction on appropriate PPE for given tasks and how to don and doff PPE,
- Hand hygiene instruction,
- Staff will be instructed on how to encourage participants to use proper PPE and inform them on the COVID-19 infection control measures taken to protect participants,
- and Instructions for staff to remain home if experiencing any symptoms.

Travel Guidelines

During travel CO SCOPE staff will be directed to the considerations at <https://www.cdc.gov/coronavirus/2019-ncov/travelers/travel-in-the-us.html>. Staff will also be provided with the guidance below.

Protect yourself and others during your trip:

- Clean your hands often.
 - [Wash your hands](#) often with soap and water for at least 20 seconds especially after you have been in a public place, or after blowing your nose, coughing, or sneezing.
 - If soap and water are not readily available, use a hand sanitizer that contains at least 60% alcohol. Cover all surfaces of your hands and rub your hands together until they feel dry.
- Avoid touching your eyes, nose, and mouth.
- Avoid close contact with others.
 - Keep 6 feet of physical distance from others.
 - Avoiding close contact is especially important if you [are at higher risk of getting sick](#) from COVID-19.
- [Wear a face covering in public.](#)
- Cover coughs and sneezes.
- Pick up food at drive-throughs, curbside restaurant service, or stores. Do not dine in restaurants if that is prohibited by state or local guidance.

When staying in a hotel:

- Take the same [steps](#) you would in other public places—for example, avoid close contact with others, wash your hands often, and wear a cloth face covering.
- When you get to your room, [clean and disinfect](#) all high-touch surfaces. This includes tables, doorknobs, light switches, countertops, handles, desks, phones, remote controls, toilets, and sink faucets.
 - Bring an EPA-registered disinfectant and other personal [cleaning supplies](#), including cloths and disposable gloves.
- Wash any plates, cups, or silverware (other than pre-wrapped plastic) before using.

Protective Measures

Specific study activities are shown in the table below with recommended PPE, and additional precautions. All PPE for study staff and participants will be provided by the Colorado School of Public Health. CDC/ATSDR will provide additional PPE as needed from the table below.

Activity	Description	PPE	Additional Precautions
Travel	Time spent in ride share/public transportation, in airport, on airplane, time spent in public venues while traveling	None	<ul style="list-style-type: none"> • Frequent handwashing • Cloth face coverings • General travel precautions • Ride sharing and public transportation
Biological sample collection screener	Greet participants outside the study office, take temperature, ask symptom screening questions	Disposable surgical mask, disposable gloves	<ul style="list-style-type: none"> • Confirm participants are symptom and fever free before allowing entry to study office, • Ensure occupancy limit allows entry
Urine sample processing	Take urine samples from participants, process samples and place in storage	Disposable surgical mask, disposable gloves (already included in protocol)	<ul style="list-style-type: none"> • Frequent handwashing • Cleaning and disinfection of surfaces between participants/groups
Blood sample collection/processing	Collect blood samples	Phlebotomists: disposable surgical mask, disposable gloves (already included in protocol), disposable gown (already included in protocol), face shield or goggles (already included)	<ul style="list-style-type: none"> • Frequent handwashing • Cleaning and disinfection of surfaces between participants • Blood and plasma collection precautions
Neurobehavioral testing	Conduct neurobehavioral testing	disposable surgical mask, disposable gloves, wipe down any materials used for testing between appointments.	<ul style="list-style-type: none"> • Frequent handwashing • Cleaning and disinfection of surfaces between participants/groups
Body measurements	Collect body measurements	disposable surgical mask, disposable gloves, wipe down any materials used for testing between appointments.	<ul style="list-style-type: none"> • Frequent handwashing • Cleaning and disinfection of surfaces between participants/groups