**OHIO University Guidance for Restart of In-person Human Subject Research**

**(In-field and on-campus)**

Updated October 12, 2020

**Background.** With announcements underway by the State of Ohio for public health restrictions linked to COVID-19, Ohio University is taking steps for a phased opening of research and creative activities that have been on hiatus during the pandemic. Planning is being led by a committee chaired by Vice President for Research & Creative Activity Joseph Shields and College of Fine Arts Dean Matthew Shaftel, in coordination with larger university efforts to selectively resume activity while remaining sensitive to safety considerations.

At the current time planning is being initiated for the resumption of Human Subject Research requiring face-face interaction with human subjects for recruitment, testing and/or intervention. Regardless, all research studies or research activities (e.g., consent processes, screening, focus groups, questionnaire responses, etc.) that can continue remotely, must continue to do so, using email, phone, or teleconferencing technology. It is also important that all subjects and study personnel involved in face-to-face or in-person research follow all guidelines below to reduce the likelihood of COVID-19 spread. As we cannot anticipate all scenarios and situations, each research protocol’s restart proposal will be reviewed separately to determine if best practices are being adhered to for the safety of all involved.

**Guiding Principles.** In preparation for re-opening human subject research during the COVID-19 pandemic, the Ohio University Institutional Review Boards (IRBs) have developed guidelines to help ensure subject and research team health and safety. Any researcher wishing to resume research within their lab must complete the attached restart form to detail how they will modify their research activities within their facilities to meet or exceed these guidelines. This restart form can also be used to apply for exemptions for any of these guidelines, as necessary.

Ensuring the safety of study participants is paramount. Researchers should consider each circumstance (each study and each study activity), focusing on the potential impact on the safety of study participants, and modify study conduct accordingly. In all cases, it is critical that participants are kept informed of any changes to the research activities and monitoring plans that could impact them. These guidelines apply to all in-person human subject research that has been approved by one of Ohio University’s IRB. This does not apply to student internships or practicums that require face-to-face contact with clients. If your research is taking place within a Clinic, please provide the measures that are in place at this facility for review.

These guidelines are based on the current pandemic status of Athens County according to the Public Health Advisory System for COVID-19. If Athens County, or the location of the off-campus research remains at Level 1 or 2, these are the guidelines to follow for conducting face-to-face research activities. If the COVID-19 risk status rises to Level 3 or 4 for the location of the PI’s research activities (or the equivalent for the local research site), researchers need to be aware that face-to-face research in that location may need to halt or pause until new guidance is provided or until the risk returns to Level 1 or 2. Notification of an increase to Level 3 or 4 in Athens Country will come from the Office of Research. For research facilities outside of Athens County, please refer to the published risk levels from the Public Health Advisory System.

Ohio: <https://coronavirus.ohio.gov/wps/portal/gov/covid-19/public-health-advisory-system/>

Outside of Ohio:  [https://covidactnow.org/?s=824153](https://nam03.safelinks.protection.outlook.com/?url=https%3A%2F%2Fcovidactnow.org%2F%3Fs%3D824153&data=02%7C01%7Chowec%40ohio.edu%7C275ecf56eff04986760a08d83a31d36c%7Cf3308007477c4a70888934611817c55a%7C0%7C0%7C637323332961781212&sdata=lg2L4BQzvjKYc6poDNvhrW%2FtLJDcCnTka12F6rvIcoY%3D&reserved=0)

International:  <https://www.cdc.gov/coronavirus/2019-ncov/travelers/map-and-travel-notices.html>

In such cases when the risk levels increase, researchers should look to the VP for Research for further guidance as to whether or not their research protocol may continue or not. It is also recognized that as the CDC and HHS learn more about the virus, these guidelines may be modified accordingly.

Submitted restart forms for in-person human subject research are currently being evaluated at the regular monthly IRB meetings. Please plan accordingly.

**Face-to-Face Human Subject Research Guidelines:**

1. **Research staff requirements and recommendations**
	1. Determine the minimum personnel required for testing
		1. Personnel listed for each approved study protocol must be approved by the principal investigator’s department chair/school director and the Associate Dean for Research in their college. This list must contain the bare minimum required to safely complete study activities.
		2. Participation of undergraduates as research assistants in human subject research must be limited to instances in which their role is essential to the success of the project or to the completion of academic program requirements (i.e., HTC tutorials, honors or masters theses).
		3. **Vulnerability check:** any personnel with increased vulnerability may choose to not assist with face-to-face research activities at this time or to seek reasonable accommodations where possible. Personnel are not required to divulge the reason for designating themselves “vulnerable” to maintain their privacy and they must not be penalized or questioned for their self-designation. This includes those personnel with:
			* Breathing issues: chronic lung disease, asthma, cystic fibrosis, etc.
			* Chronic diseases: e.g., heart condition, diabetes, hypertension, autoimmune disease, weakened immune system, kidney dysfunction, liver disease, severe obesity, HIV, and anyone taking medications that suppress immune system functioning
			* Pregnancy
	2. Prior to restarting research
		1. Prior to conducting research, all personnel are required to complete the **Blackboard COVID-19** training about how this virus is transmitted and how to prevent its spread. An email document is provided at the end of the training that can be used to document completion of this training.
		2. It will be the responsibility of the Principal Investigator of each study protocol to confirm that this training has been completed by each member of their research team.
	3. Personal Protection Equipment (PPE)
		1. All personnel must wear a **face mask** that covers mouth, nose, and chin (minimum requirement).
		2. If conducting invasive procedures, a **face shield** or goggles must also be worn.
		3. If electing to use an **N95 face** mask, please be aware that they need to be properly fitted to be effective.
		4. If researchers with comorbid conditions (higher risk research personnel as identified in 1.a.iii) elect to conduct research, special consideration must be given to higher PPE levels necessary to protect them from exposure. For example, a researcher with diabetes or high blood pressure or over the age of 50 should use N-95, face shield or goggles, gown and gloves, when working with research subjects in close contact as defined by the CDC; <6 feet for ≥15 minutes. Researchers with higher risks should consider using a powered air purifying respirator (PAPR) to protect themselves from exposure. The PAPR provides positive airflow to prevent exposure to potential aerosolized transmission of the virus.
		5. For any procedure that involves the potential aerosolization of tissues or bodily fluids, the minimum protective equipment for researchers without underlying health risks is an N-95 mask, face shield or goggles, gown and gloves, unless this aerosolization is being properly filtered (e.g., during VO2max test with proper filters on expired air).
		6. Any researcher employing the use of PPE for research purposes will have a protocol delineating proper donning, doffing and laundering/cleaning procedures for that PPE. A plan for disposal of PPE must also be present and researchers are encouraged to avoid the use of street clothing for lab work. If social distancing and PPE are not possible during research activities, any clothing worn during in-person human subject research must be doffed prior to leaving the lab or research facility, contained in a suitable non-permeable plastic bag for transport to home and immediately laundered with detergent. For biomedical research protocols, researchers must adhere to this process regardless of other precautions, such as using PPE and social distancing. Research personnel need to be clearly educated on proper infection control methods for managing research and laboratory attire.
		7. When working with vulnerable research participants or working with a study participant who cannot wear PPE (e.g., young children), researchers should wear an N-95 mask and face shield or goggles. If possible and tolerated, vulnerable research participants should wear both a simple face mask and shield or goggles.
	4. Cleaning and disinfecting:
		1. On-campus
			* Daily and between-subject cleaning of all surfaces within the research space is required; cleaning schedules/logs must be posted in each room, including bathrooms and common spaces.
			* Suitable, safe and effective EPA-registered disinfectants must be used. Ohio University will be providing suitable cleaning and disinfecting supplies. If using any other supplies than what is being supplied by the university, the Principal Investigator is responsible to ensuring its effectiveness on COVID-19 and providing that information in the restart form.
			* The material safety data sheets of these products must be readily available to all lab personnel and their location marked so that in the event of high risk contact with these agents proper decontamination and care can be rendered to researchers and or exposed subjects. Researchers must be briefed on the mitigation measures for health risk exposures of these agents.
			* <https://www.epa.gov/pesticide-registration/list-n-disinfectants-use-against-sars-cov-2-covid-19>
		2. Off-campus
			* Specify differences in products being used by the off-campus research sites and provide material safety data sheets on these products
			* Provide the off-campus research facility’s cleaning schedule and how the researcher will adjust their testing schedule or research protocol to ensure between subject disinfecting
	5. All personnel must do a daily COVID-19 screening prior to seeing human subjects, including:
		1. **Symptom check:** (see Appendices)
			* Temperature check: must be below 100.4 F
			* Related Symptoms: Cough, shortness of breath, fatigue, fever, sweating, sore throat, body aches, vomiting, diarrhea, anosmia (loss of smell)
			* If any research personnel are “not feeling well” or are concerned about any symptoms (especially students), they are required to contact the principal investigator on the project to let them know they will not be available for research and they are to stay at home. This action must not result in any penalty or discrimination for this person. In this instance, the person must not return to the research facility until they have completed the 14-day quarantine and are asymptomatic (no fever for at least 3 days unmedicated) according to the CDC guidelines.
		2. **Travel recommendations:**
			* While participating in regular research activities involving human subjects, all research personnel must restrict all travel beyond counties surrounding the research facility.
			* Members of the research team who travel outside the surrounding counties of the research site into a region with a higher risk level (Level 3 or 4) must not return to the research facility until after a 14-day quarantine from the date they return and are asymptomatic for at least 3 days (unmedicated).
			* Members of the research team who travel to any region deemed as Risk Level 3 or higher according to the Public Health Advisory, must quarantine for 14 days and be asymptomatic for at least 3 days (unmedicated) prior to conducting any human-subject research. Public Health Advisory System website: <https://coronavirus.ohio.gov/wps/portal/gov/covid-19/public-health-advisory-system/>
			* In the situation where a researcher resides in a different county from the research facility and the risk level is higher than that of Athens County (i.e., resides in Columbus but visits Athens to assist on a research protocol), the PI must ensure due diligence of appropriate and regular PPE use by this researcher to reduce the risk of virus spread while conducting research. This researchers must also exercise a higher degree of reverse isolation to avoid exposure and undergo periodic monitoring with PCR to minimize potential spread if they are shedding asymptomatically.
			* Members of the research team who travel out of state or internationally, must confirm that the region they visited was less than Level 3 equivalent on the Public Health Advisory system or they must quarantine for 14 days and be asymptomatic for at least 3 days (unmedicated) prior to conducting face-to-face human subject research
		3. **COVID-19 Exposure:**
			* While participating in regular research activities involving human subjects, all personnel must
				1. Refrain from visiting places where social distancing is difficult (e.g., crowded restaurants, bars, concerts, sporting events, etc.)
				2. Limit exposure to or visits from people outside of the members of their immediate household (e.g., family, friends, etc.)
				3. Keep a daily log, including (**see Appendices**)

All locations visited (e.g., grocery stores, etc.)

Visitors who do not reside within the household

Was social distancing maintained

Was PPE worn (e.g., masks)

* + - * If exposed to someone who tested positive for COVID-19 (or is exhibiting symptoms), quarantine at home for a minimum of 14 days from the time of exposure and be asymptomatic for at least 3 days (unmedicated).
			* If tested positive for COVID-19, they must follow these recommendations prior to returning to face-to-face human subject research activities:
				1. Three days without fever (unmedicated)
				2. Respiratory symptoms have improved
				3. 10 days since symptoms first appeared
1. **Human Subject Health and Safety.** All potential research subjects must adhere to all recommendations for reducing the likelihood of spreading COVID-19 as indicated by the CDC and the local health authority for the area in which research is conducted (e.g., the Ohio Department of Health for research conducted in Athens), whichever is more stringent, if they agree to participate in research at Ohio University.
	1. **Research Team must provide COVID-19 related information to the subject**
		1. Separate from the consent process, provide all subjects with a document (**see appendices**) that informs them that, whereas all precautions are being met to prevent the spread of COVID-19, there is still a risk of being infected with the virus. This document must also inform subjects of the steps the research team is taking to protect against COVID-19 exposure. If appropriate, this document should be signed or initialed and placed in their study folder as documentation. If not appropriate, notation should be made in the participants’ folder that this document was provided.
		2. Provide adequate signage throughout the space to remind of COVID-19 recommendations and clearly mark facilities (e.g., hand washing stations)
		3. Additional symptom checks that are conducted prior to a subject participating in research are not considered part of the research protocol nor the consent process.
	2. **COVID-19 screening**
		1. Prior to attending a study visit, the participant must go through a pre-screening for COVID-19. Options/Suggestions on how to accomplish this pre-screening:
			* Upon entering the research facility for a study visit, each participant must provide a COVID-19 self-screening document that was completed at home just prior to the visit;
			* Signage could be displayed with research study contact information at the entrance of the research facility for the participants to call before entering the building in order to conduct the pre-screening by phone. This method would require the participant to be able to take their own temperature.
			* The research lab could provide an external tent or facility for the research team to conduct the pre-screening prior to entering the building or facility.
			* If any of these options are not suitable, the research team can devise their own process for approval.
		2. The pre-screening must include:
			* **Vulnerability check:** any subject with increased vulnerability who wishes to participate in face-to-face research activities is not required to divulge the reason for designating themselves as “vulnerable”, unless this is part of the study eligibility screening process. If they indicate they are vulnerable to COVID, their ability to participate must not be compromised, unless the underlying reason is listed as an exclusionary criteria for the study. A study participant is considered vulnerable is they have:
				1. Breathing issues: chronic lung disease, asthma, cystic fibrosis, etc.
				2. Chronic diseases: e.g., heart condition, diabetes, hypertension, autoimmune disease, weakened immune system, kidney dysfunction, liver disease, severe obesity, HIV, and anyone taking medications that suppress immune system functioning
				3. Pregnancy
			* **Symptom check:** same as above. If research is being conducted within a facility where symptoms are already routinely checked (e.g., clinics or schools) additional symptom checks are not required.
			* **Travel check:** subject must not have traveled outside of the location of the research site and surrounding counties, especially to an area classified as Level 3 or 4 on the Public Health Advisory System. If they have traveled to such areas, they must quarantine at home for 14 days and be asymptomatic for at least 3 days (unmedicated) prior to participating in research as a human subject.
			* **Exposure check:** determining if a subject has been exposed to someone with the virus in the past 14 days can be somewhat subjective. The research team must ask if the participant has had visitors (including family) in the home or have visited in another person’s home. List all locations they have visited (e.g., grocery stores, etc.) in the past two weeks. Inquire if they have worn a mask and adhered to appropriate social distancing while outside of the home or during these in-home visits. If they are deemed low risk (see below), participating as a subject in research might be appropriate. If greater than low risk, the subject must presume exposure to the virus and quarantine for 14 days and be 3 days asymptomatic (unmedicated) prior to participation.
				1. **Low risk:** limited locations (no locations listed within Level 3 or 4 on the Public Health Advisory System) and visits were conducted with appropriate social distancing and PPE worn – these participants are considered relatively safe for participating in human subject research
				2. **High risk:** visiting highly condensed locations (e.g., concert, beaches, church, bars, etc.) and/or not wearing masks or abiding by social distancing – these participants should not be involved in human subject research at this time.
	3. **Social Distancing**
		1. In shared, larger research facilities, create a daily schedule for testing to control for physical distancing (≥6 feet). If air quality or circulation is poor, the schedule must also accommodate for temporal distancing between research participants (recommended duration is based on ventilation quality: poor air circulation = 2-3 hours between subjects; good air circulation = time between subjects could be as low as 20-30 minutes).
		2. It will be the responsibility of the principal investigator to determine ventilation quality within their research facilities. Assistance for this purpose can be obtained by contacting Facilities Manager Jeff Hamilton (hamiltj2@ohio.edu). It is presumed that if air is exchanged (circulated) 2-3 times between subjects, this should be sufficient.
		3. If air circulation is poor, plexiglass might be another option to provide protection against droplet exchange between participants and reduce the need for temporal distancing.
		4. Encourage use of stairs instead of elevators. If possible, designate some stairs for ascent and others for descent to avoid participants crossing in the stairwell. When necessary, encourage single occupancy in elevators unless the elevator is large enough to accommodate the 6 feet distancing recommendation.
		5. If research space is small, the research team must create a designated traffic flow within the research space to accommodate social distancing between participants during visits.
	4. **Wearing PPE**
		1. Face masks are to be worn by all research subjects. If a subject cannot wear a face mask then a face shield is to be worn.
			* The research team must make masks and/or shields available to all subjects upon entering the building or research facility.
		2. If face masks/shields are not possible due to the nature of the research activities, barriers, such as plastic face-guards, plexiglass barriers, or air filters (as used in oxygen consumption measures) must be used to prevent droplet exchange between the researcher and participant.
	5. **Personal Hygiene**
		1. Hand sanitizer or hand-washing stations are to be available for subjects upon entering the research space and in each room
		2. All personnel must routinely wash hands between research activities (e.g., study sessions)

**Implementation.** Any researcher wishing to resume in-person human subject research, must complete the attached form. The form must address all of the guidelines listed above. All PIs must understand and consider the risk of restarting their research, recognizing that work could be shut down with little notice under one or more of the above principles.

**Mitigation.** Understanding the Novel Corona Virus SARS CoV2 is an emerging phenomenon. This document represents the best efforts of the IRBs and Ohio University Institutional Official to protect the interests of Ohio University, Ohio University researchers and the human subjects that agree to participate in the quest for generalizable knowledge. These recommendations are current as of July 2020 but as knowledge of SARS CoV2 develops the guidelines will change to reflect the best methods for supporting the various interests involved in Ohio University research. What bears repeating is that because of the great potential for serious harm that a SARS CoV2 outbreak could have at Ohio University it is critical that all human subjects researchers maintain the highest standards for their research facilities and that they have the documentation to assist contact tracers in the event that outbreaks occur. Failure in this regard could cause additional interruptions in Human Subjects Research at Ohio University in order to protect the public.

**Approval Process.** The Research Restart form must be approved by the researcher’s department head (director/chair) and Associate Dean for Research from their college prior to being forwarded to the IRB for review via an amendment or new submission. The Research Restart form and any appendices can be uploaded as a single PDF document within the Instrument section of the LEO form for review. You may not conduct face-to-face research until the Research Restart Form has been approved as noted above, and the IRB has approved the proposal or amendment submission.

**Appendices**

**Ohio University – Research Restart Form**

**Human Subject Research**

Complete and submit electronically to your Chair/Director, who upon approval will submit to the Associate Dean for Research for review. Be as thorough as possible.

**Research Operation Plan**

1. Principal Investigator Name:
	1. Email address:
2. Submission Date:
3. Project Title:
	1. Brief summary/description of research activities to be performed (brief paragraph – should match LEO form).
	2. Describe impact if activity is delayed.
	3. Does this research include persons vulnerable to COVID-19 (e.g., advanced age, obesity, diabetes, HIV, etc.)?
4. List of involved personnel. For each individual provide:
5. Full name
6. Status (faculty, staff, postdoc, grad student, undergrad)
7. PID
8. OU email
9. If undergraduate students are included on the personnel list, explain the necessity of their inclusion for the success of the project or completion of academic program requirements.
10. Describe the role of each of the personnel listed and their typical daily research activities.
11. Provide a list of research activity locations (buildings, rooms).

**Research / Creative Activity Health and Safety Plan:**

1. Describe which of the research activities are going to be conducted in-person and which will remain remote only.
2. Provide the information sheet used that will inform subjects of the added risk of exposure to COVID-19 and all the steps the research team is taking to minimize this risk.
	1. See attached template – this can be modified for each research facility/protocol but must include the current recommendations as set forth by the CDC and ODH
3. Describe your daily COVID-19 pre-screening process for research personnel *and* participants.
	1. Include details as to where, how and by whom this COVID-19 pre-screening of participants will occur.
	2. See attached template – this form may be modified for each research facility/protocol but must include the current CDC/ODH recommendations for preventing the spread of COVID-19.
4. Plans for social distancing (if applicable)
	1. Physical distancing (strongly recommended) – e.g., space layout, separation of work-stations, coordination of movements (traffic flow) between and within shared spaces and work shifts to enable isolation
	2. Temporal distancing (recommended – if possible) – e.g., staggering research activities or research study visits (recommendation ranges from 20 minute to 3 hours between study participants, based on quality of air circulation and existence of appropriate barriers)
	3. Identify the maximum number of people to be working simultaneously in any research facility space (room).
	4. What measures are being used to ensure adequate space (e.g., removal of unused equipment) in the designated rooms to allow for social distancing?
5. Describe any planned use of personal protective equipment (PPE), as applicable
	1. Describe this separately for study personnel and human subjects
	2. Do you have sufficient PPE to start/maintain your proposed research activity?
	3. How will PPE be cleaned and maintained from day to day?
	4. How will you manage clothing used in the research facility to mitigate pathogen transfer to home or other university areas outside of the laboratory/facility?
	5. How will lab clothing or PPE (masks) be cleaned and at what frequency (a minimum cleaning cycle is daily for any scrubs or lab clothing used for research, that is, a researcher may wear a set of scrubs for a day of lab work but that clothing must be laundered before another day of use is allowed.)
6. Describe hand washing / disinfecting stations available throughout the research space
7. Describe equipment and high-touch surfaces (e.g., table surfaces and door knobs) used for research activities, and plans for cleaning / disinfection (equipment list must match your LEO protocol):
	1. Frequency
	2. Cleaning or disinfecting materials used
	3. How this will be implemented and tracked. Provide checklists for tracking.
8. Identify any additional shared equipment facilities/core facilities to be used. Provide sample schedule for shared use and disinfecting
9. Describe other measures to be deployed that are unique to the specific research activity.
10. Describe what will be required to stop or pause the research protocol if pandemic conditions necessitate another lockdown (if applicable).

Signature Endorsements (digital or scanned signatures are acceptable):

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| --- | --- | --- |
|  | Signature |  |
| Principal Investigator | Name |  |
|  | Dept/School |  |
|  | Date |  |
|  | Signature |  |
| Dept Chair/School Director | Name |  |
|  | Dept/School |  |
|  | Date |  |
|  | Signature |  |
| Assoc Dean for Research | College |  |
|  | Date |  |

Template

**Vulnerability Check**

To be completed one time, before study begins, for each member of the research team and each study participant before their participation in human subject research.

Researcher’s Name or Participant ID Number:

Date:

Do you have any of the following conditions or consider yourself vulnerable to COVID-19 for some other reason?□ **Yes**  □ **No**

* Chronic kidney or liver disease
* COPD (chronic obstructive pulmonary disease)
* Other respiratory illnesses (cystic fibrosis, moderate/severe asthma, emphysema, etc.)
* Current smoker
* Immunocompromised state (weakened immune system) from solid organ transplant or immune deficiencies (i.e., HIV)
* Obesity (body mass index [BMI] of 30 kg/m2 or greater)
* Heart conditions, such as heart failure, coronary artery disease, or cardiomyopathies
* Sickle cell disease
* Type 1 or 2 diabetes mellitus
* Hypertension
* Thalassemia (or related blood disorders)
* Pregnancy

**If you answered YES, you may choose to not participate in face-to-face research activities at this time or to seek reasonable accommodations where possible.**

Template

**COVID Symptom Check**

This form can be used to monitor/record daily symptoms for all active members of the research team. This may be used as a shared document for the principal investigator, or designee, to track the health of their team or may be provided for each person to self-monitor their symptoms. A similar document can be created in Excel, Forms or other electronic formats for daily monitoring. It is important that these checks are completed and recorded daily while participating in ongoing research activities.

**Researcher Name / Participant ID Number:**

**Date:**

**Are you experiencing any of the following?** □ **Yes** □ **No**

* Trouble breathing
* Persistent pain or pressure in the chest
* Inability to wake or stay awake
* New onset of confusion
* Bluish lips or face

If yes, this is an emergency sign of COVID-19. Seek emergency medical care immediately. After you receive care, call your PI and inform them that you are unable to come to the lab/research site for the next 14 days.

**Are you feeling well today?**

□ Yes □ No

If no, please review the following symptoms:

**Are you experiencing any of the following?** □ **Yes** □ **No**

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

If you are experiencing any of these symptoms, this may be a sign of COVID-19. Call the principal investigator for all research protocols in which you are involved and inform them that you are unable to come to the lab/research facility for the next 14 days. You may wish to seek medical care. You must not return to the research facility until after 10 days following the onset of these symptoms and 3 days asymptomatic (unmedicated). You may wish to arrange for a COVID- 19 test to be conducted 14 days from today. If you do, this test must be negative.

**What is your temperature today? \_\_\_\_\_\_\_\_\_\_**

If your temperature is 100.4 Fahrenheit / 38 Centigrade or higher this may be a sign of COVID-19. Call principal investigator for all research protocols in which you are involved and inform them that you are unable to come to the lab/research facility for the next 14 days. You may wish to seek medical care. You must not return to the research facility until after 10 days following the onset of these symptoms and 3 days asymptomatic (unmedicated). You may wish to arrange for a COVID- 19 test to be conducted 14 days from today. If you do, this test must be negative.

**If you are experiencing any of these symptoms or if you feel unwell, you should call your PI and inform them that you are unable to work. There is no penalty for calling off from work when you feel unwell. There is no reward for working when you feel unwell.**

Template

**COVID-19 Exposure Log**

This form, or something similar, should be used to track potential COVID-19 exposure for each member of the research team. The purpose of this exposure log is to verify that potential exposure is being minimized by members of the research team (reverse isolation). This document, regardless of the format (Word, Excel, Smartsheet), should be shared electronically with the Principal Investigator, or research team designee, to monitor the level of exposure risk of the research team. This form must be up to date prior to participating in any research activities each day but it can be used for self-monitoring purposes.

To protect a researcher’s privacy, specifics such as location name, name(s) of visitor(s) can be replaced with generic terms (i.e., indoor restaurant dining rather than a specific name of the restaurant). However, provide as much detail as possible for the PI to make a determination if it is safe for you to assist with research and for potential contact tracing.

Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

|  |  |  |  |
| --- | --- | --- | --- |
| **Date** | **Location Visited\*** | **PPE Worn? (Describe)** | **Social Distancing? (Yes or No)** |
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\* For each location visited, list the details of the event (e.g., location details, personal visitation, etc.). Detailed tracking of each member of the research team will facilitate calculation of the overall risk of continuing human subject research. If there was no exposure on any given date, this also needs to be noted in this log.

Infographics such as this can be modified to provide each potential research participant information about how your research team/facility is meeting or exceeding the recommended guidelines to prevent the spread of COVID-19 during human subject research participation.

All members of research team will be maintaining social distancing and …

All members of research team wear masks and any other necessary barriers to prevent the spread….

All surfaces and research equipment will be disinfected prior to each study visit…

All members of research team will stay home if they have symptoms…

Additional wash / hand sanitizer stations are provided to enhanced personal hygiene….

Be sure to add a statement similar to this in the final document: *While all these measures (please include all that are being instituted as outlined in your restart form) are being implemented to help prevent the spread of COVID-19 in this research facility, there is always a chance to be exposed to the virus when participating in face-to-face human subject research.*

Other samples that can be used as a template: <https://www.cdc.gov/coronavirus/2019-ncov/downloads/stop-the-spread-of-germs-11x17-en.pdf>

