

CGU COVID-19 Policy for Research Involving Human Subjects

This policy addresses human subjects research (HSR) at CGU during the COVID-19 epidemic. The policy was developed in accordance with [California's Blueprint for a Safer Economy](#), which provides updated county-specific status tiers based on test positivity and adjusted case rates. The policy provides guidance for HSR activities to minimize risk and to ensure health and safety of research subjects, investigators, and staff. In addition to the details included here, all general CGU guiding principles, policies, and protocols laid out in the [CGU Campus Visit Procedures](#) must be adhered to.

For the purposes of this policy:

- "HSR" is expanded to include those scholarly activities that involve humans but are excluded from the federal regulatory definition of 'human subjects research' (e.g., evaluation, oral history, journalistic or historical interviews, product development, program improvement activities) because of the potential to involve in-person engagement with human persons for the purpose of research.
- "Subjects" refers to *all* human persons who are participating as subjects in research.
- "Remote" refers to research settings in which there is an absence of in-person contact/engagement with research subjects.

To mitigate the impact of COVID-19, it is expected that CGU investigators will explore alternative means to in-person research and employ these means whenever possible. Risk and potential benefit to subjects should be balanced while implementing appropriate risk reduction strategies to maximize the health and safety of all involved. During the COVID-19 pandemic, all research that can be conducted remotely should be done so.

Given the risks due to COVID-19 exposure, all research team members have the right to avoid involvement with on-site or in-person research activities without fear of reprisal. Employees with concerns about infringement of these rights should contact CGU Human Resources. Students with such concerns should contact the Dean of Students Office.

It is important to note that an undesirable trajectory of the COVID-19 pandemic, the appearance of SARS-CoV-2 infection in HSR team members or subjects, and/or evidence of significant non-compliance with the directives outlined below (thereby putting the larger public at risk), may lead to more restrictive directives and sanctions for research activities.

Practical Considerations and Implications

Several factors influence decisions concerning the permissibility of research during the COVID-19 pandemic and the modifications that would be needed to conduct such research safely. In addition, regardless of the form of the research being conducted, certain procedures will need to be followed to maximize the safety and well-being for research personnel and subjects. These considerations are discussed below. The accompanying decision tree (**Appendix 4**) shows the steps involved in implementing this policy.

CGU investigators should first evaluate whether research procedures can be modified to eliminate in-person contact/engagement with research subjects. If alternative approaches can be employed, the investigator and their research teams should modify their research procedures and, if applicable, IRB protocols. Investigators needing assistance with either of these processes should consult with the Office of Research, Sponsored Project and Grants (ORSPG).

Some *essential* research may need to continue, even if modifications cannot be made to eliminate in-person contact. The foremost example would be existing research for which interruption or modifications to procedures could create greater risks to human subjects. The determination of “essential” research activities will be made jointly by the Primary Investigator (or Faculty Supervisor in the case of student PIs) and the department chair or school dean. Examples of essential research may include, but are not limited to, research that would (a) harm subjects if paused or stopped, (b) severely limit student or faculty progress on achieving time-sensitive research milestones such as those tied to grants, (c) prevent students from completing degree requirements in a timely manner.

Under the Blueprint, the County’s tier status determines what activities are allowable at a given time. CGU investigators should determine the current tier status of Los Angeles County (for research taking place on Campus) or of the California county where research is taking place by checking the [California’s Blueprint for a Safer Economy](#).

The Blueprint does not provide industry-specific guidance for ‘research’ activities, and guidance for “schools and universities” focus on instructional activities involving students, faculty and staff (see: <https://covid19.ca.gov/industry-guidance/>). Minimal guidance for research activities is provided by the Los Angeles County Department of Public Health [protocols for institutes of higher education](#), which permit “essential” research on college and university campuses (see: http://publichealth.lacounty.gov/media/coronavirus/docs/protocols/Reopening_HigherEducation.pdf, last updated 9/14/20).

After ascertaining the current tier status, the next factor for determining what/whether research is permissible is the setting of the research. This CGU policy assumes that (1) research conducted by CGU investigators occurs outdoors either in field locations in the community **or** in office-based labs on the CGU campus or elsewhere, **and** (2) CGU labs are roughly equivalent to office-based locations covered under the Blueprint’s industry-specific guidance. Therefore, the policy utilizes both State and County recommendations appropriate to these scenarios.

CGU investigators should determine the location (indoor/lab-based or outdoor/field, community-based) where the HSR will engage with research subjects.

For *community-based or field HSR*, CGU investigators should confirm that they have permission to be on site (investigators may be required to submit proof of such permission) and follow pre-screening (**Appendix 1**) and safety procedures (**Appendix 2**). It is also expected that investigators follow guidelines prescribed by the non-CGU site.

For *indoor/lab-based HSR*, according to the Blueprint, county tier status determines what is allowable for office-based activities as follows¹:

SECTOR	Widespread Tier 1	Substantial Tier 2	Moderate Tier 3	Minimal Tier 4
Offices	Remote	Remote	Open indoors with modifications <ul style="list-style-type: none"> Encourage telework 	Open indoors with modifications <ul style="list-style-type: none"> Encourage telework

Therefore, with the exception of essential research, *only* HSR that can be conducted remotely is permitted under Tier 1 or Tier 2. Under Tier 3 and Tier 4, indoor/lab-based HSR is allowed with modifications, though researchers should aim to conduct as many activities remotely as possible.

Under all tiers, CGU investigators whose research cannot be modified to eliminate in-person contact/engagement with human subjects must submit a “Risk Mitigation Plan” described below and follow pre-screening (**Appendix 1**) and safety procedures (**Appendix 2**).

Risk Mitigation Plan

All HSR must be performed in a manner that minimizes risk to subjects and research team members. To this end, all research activities must comply with the [CGU Campus Visit Procedures](#) and investigators must submit a **Risk Mitigation Plan** for approval by the Research Protocols Risk Assessment Committee (RPRAC) (**Appendix 3**).

A **Risk Mitigation Plan** for all HSR must be completed by the principal investigator and submitted through Axiom Mentor (<https://www.axiommentor.com/login/shibLogin.cfm?i=cgu>). The Plan should describe how the investigator and his/her study team will implement their study procedures with adjustments made for pre-screening (**Appendix 1**) and safety procedures (**Appendix 2**), as applicable.

The RPRAC Chair will forward committee-approved Risk Mitigation Plans to the Provost. In-person HSR may only proceed *after* a Risk Mitigation Plan has been approved by RPRAC and the Provost. CGU Facilities will conduct spot checks to ensure compliance with approved Risk Mitigation Plans to identify areas where there is inappropriate density of study team members in lab spaces, lack of distancing and protective measures, or failure to comply with other components of a study’s approved mitigation plan. Non-compliance with policies could lead to the suspension of HSR activities in the non-compliant area.

All HSR conducted on-campus at CGU must be conducted in designated and approved spaces. Onsite research team members are limited primarily to those directly conducting subject-facing study activities that cannot be performed remotely. To ensure that appropriate physical

¹ This information and table excerpt are current as of October 6, 2020. For more information, or to confirm that it is still current, go to: <https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/COVID-19/COVID19CountyMonitoringOverview.aspx> and click on “[Understand which activities and businesses are open in the four tiers](#)”

distancing and other risk mitigation factors are achievable—not only in offices or other workspaces but in common spaces such as elevators, hallways, restrooms, and break rooms—plans should be implemented to allow only the minimum number of subjects in a lab at a time, operate labs on alternating days or at alternating times (**Appendix 2**), and follow general CGU visitor guidelines.

Appendix 1. Pre-screening of Investigators, Research Team Members, and Research Subjects

All CGU investigators and research team members are required to self-screen for COVID-19 symptoms prior to engaging in any HSR with in-person contact/engagement or coming to campus following the [CGU Campus Visit Procedures](#). Any team members who do not pass a temperature check and symptom screening should not engage with research subjects or come to campus. If another research team member is not available to cover the planned study visit(s), that/those visit(s) should be rescheduled.

Research team members who have experienced COVID symptoms should not engage with research subjects or return to campus until the following conditions have been met:

- 10 days since first appearance of symptoms **and**
- 24 hours since the subject has had no fever without the use of fever-reducing medications **and**
- Other COVID-19 symptoms are improving (note that loss of taste and smell may persist for weeks or months after recovery and need not delay the end of isolation)

All research subjects attending a scheduled appointment for research-related purposes must be pre-screened for COVID-19 symptoms using the checklist below **prior to** data collection, via telephone, video conference or in-person, **and again upon arrival** to campus, if research is being conducted on campus. Digital infrared thermometers are available at CGU and can be used to screen research subjects.

Only subjects who answer “No” to all questions are eligible for participating in data collection or other study-related procedures.

Research team members are responsible for maintaining a record of completed pre-screening checklists for all research subjects. Audits to ensure compliance may occur.

A sample pre-screening checklist is provided below.

Pre-Screening Checklist for Research Subjects

- Is forehead temperature <100.4° F? Yes No
- In the last 30 days, have you had a positive COVID-19 test? Yes No
- In the last 14 days, have you had sustained close contact (such as a household contact) with a person with a positive COVID-19 test? Yes No
- In the last 14 days, have you had a fever, cough or diarrhea? Yes No
- In the last 14 days, have you had cold or flu-like symptoms? Yes No
- In the last 14 days, do you have concerns regarding other potential symptoms (loss of taste, loss of smell, eye redness or discharge, confusion, dizziness, unexplained muscle aches) related to COVID-19? Yes No

If all responses are NO, the in-person visit may proceed.

PI/Sub PI who is providing approval: _____

Enter the date approval received for in-person visit: _____

Appendix 2. Safety Procedures for Interactions with Research Subjects

All CGU investigators and members of research teams should be aware of and comply with strategies for maximizing the safety of themselves and research subjects.

1. Location and Travel

- For research conducted off the CGU campus at locations within the community, CGU investigators should aim to travel in separate cars to research sites. If investigators must travel together, no more than two people should occupy a vehicle to, from, and at the community site. Cloth face coverings are to be worn in vehicles when two people are traveling together. Whenever possible, travel with windows open or with outdoor air entering and circulating in the cabin of the vehicle. High touch areas (e.g., vehicle keys, door handles, steering wheel) should be disinfected before and after the field work day.
- For day trips, all investigators should bring ample food and fluids for themselves. No sharing of food or drinks is allowed.

2. Scheduling, if applicable

- For subjects **without** COVID symptoms, offer subjects the option of either a virtual visit (if possible per study protocol) or an in-person visit with the PI/research team members. Research team members must specifically inform subjects if the research study protocol requires an in-person visit.
- For subjects **with** COVID symptoms, PI must be notified and the subject should be scheduled for a remote visit **OR** scheduling for the in-person study visit shall be delayed until it has been
 - 10 days since first appearance of symptoms first appeared **and**
 - 24 hours since the subject has had no fever without the use of fever-reducing medications **and**
 - Other COVID-19 symptoms are improving (note that loss of taste and smell may persist for weeks or months after recovery and need not delay the end of isolation)

3. Face covering/masks, PPE and Handwashing

- Use of masks and other appropriate PPE should follow all guidance provided by CGU, the Los Angeles County Department of Public Health, and the CDC.
- Research subjects should be instructed to wear a cloth or similar face covering. Masks will be provided to research subjects prior to the screening process if they did not bring their own.
- Masks or cloth face coverings must be worn at all times by research team members around subjects and other members of the study team. Face coverings are always required when conducting tasks involving personal interactions at less than six feet distance.

- Masks or cloth face coverings should be changed whenever soiled, wet, or damaged. Cloth face coverings should be laundered with warm water and detergent daily or whenever they are visibly soiled.
- The mask or cloth face covering may be removed when eating/drinking.
- All CGU investigators and members of research teams should wash their hands before and after any interaction with research subjects.

4. Arrival/Check-in/Waiting

- Ask research subjects to check in via a phone call or text message to a research team member who will coordinate the subjects' entry into the facility.
- When subjects call to check in, let them know that they should wait in their car or outside the building until the research space is ready.
- A designated member of the research team will meet the subject at the entry to the building.
 - This research team member will conduct symptom and temperature screening at the entry to the building.
 - Subjects with a positive screen will not be allowed to continue their research visit and will be rescheduled following the conditions outlined in #2 above.
 - Every subject will be asked to wear a mask upon arrival, and will be provided one if needed. Visitors will also follow the same policy.
 - This research team member will then escort the subject to the research space.
- Hand sanitizer will be made available for subjects, and research team members will ask subjects to sanitize their hands upon entry to the research space. Study team members will point out bathroom locations where there is soap and water for handwashing.
- Adhere to all other [CGU Campus Visit Procedures](#).

5. Research Spaces/Data Collection Areas

- Seating or other congregating in research areas should be set up to allow for 6 feet of physical distancing between persons.
- Separate entrances and exits and or "traffic" flow designations should be utilized to allow for one direction of travel in research/data collection areas.
- Direct subjects into the designated research office as soon as the space is available.
- Research teams should designate an "air traffic controller" to optimize the flow of subjects safely through the research area from check in to check out, if and when there are multiple research visits scheduled close in time.

- Maximum capacity in-person for the research space that allows for appropriate physical distancing of 6 feet between persons should be assessed. Use the procedures described below to ensure volume does not exceed this capacity at any given time.

- Investigators will stagger the schedule of virtual/remote visits with in-person visits to minimize the number of subjects waiting at any point in time.

- Investigators will implement extended hours (in the early morning or evening) for research visit types to minimize the number of subjects waiting at a given time.

6. Physical Workspaces

- Utilize additional offices in designated building to ensure physical distancing between study team members as needed.
- Consider plexiglass partitions between workstations to facilitate infection prevention.
- Ensure that all computers have necessary software and webcams to conduct remote/virtual research visits.
- Consider using noise cancelling headphones or headsets with directed microphones (for individual use only).

5. Cleaning and Disinfection

- Once the visit is complete and the subject has left the research space, study materials and equipment should be immediately disinfected with products provided by CGU Facilities and following standard precautions. Disinfecting wipes may be used to disinfect surfaces, tablets, pens and any other items involved in the data collection.
- Where applicable, research team members' desk spaces should not be used by other research team members. Any shared items should also be promptly cleaned in between use.

Appendix 3. Research Protocols Risk Assessment Committee (RPRAC)

Under CGU's COVID-19 Policy for Research Involving Human Subjects, investigators conducting research involving in-person contact with human subjects during the COVID-19 pandemic must submit a Risk Mitigation Plan ('plan') to the Research Protocols Risk Assessment Committee (RPRAC). This document provides guidance for the membership, processes, and reporting structure for the RPRAC ad hoc committee ('committee').

Committee composition and review panels

The committee will have a minimum of three members comprised of representatives from the following categories:

1. ORSPG
2. Operations and Auxiliary Services
3. Expertise in epidemiology/public health

Multiple members may be appointed to each category to distribute the administrative burden of review. (It is not necessary to have equal numbers of committee members for each category.)

Each plan will be reviewed by a panel of three committee members. As long as each category is represented in the review of each plan, panel assignment may be dynamic. An ORSPG representative will serve as the chair for each panel.

Plan submission procedures and review process

Investigators wishing to conduct in-person research will submit a Risk Mitigation Plan through Axiom Mentor—the same platform CGU currently uses to manage IRB protocols. An item has been added to the main protocol page requiring investigators to indicate whether their research involves in-person interaction. Indicating that research involves in-person interaction will trigger the application section for a Risk Mitigation Plan. When a Risk Mitigation Plan is submitted in Mentor, a Mentor administrator will assign a panel of reviewers and a panel chair. Each member will be notified by email and will have access to the plan in Mentor.

- A two-week turnaround time unless otherwise specified is allocated for reviewing each plan. (Deadlines and reminders can be set in Mentor.)
- After all panel members have completed their review, the panel chair will synthesize the findings and proceed as follows:
 - If revisions are required or plan is denied, the panel chair or a Mentor admin will send notification to the investigator
 - If the committee approves the plan, the panel chair will forward the plan to the Provost for review.
- One a plan is approved by both the committee and Provost, the investigator will be notified by Mentor.
- A copy of the plan can be sent to the various relevant parties or maintained in Mentor with access granted to those parties.

Criteria for review

The research mentioned in the plan must be permitted under the tier for the county and setting where the research is being conducted (e.g., under the Purple or Red tiers, only outdoor or essential research may be conducted)

The plan must:

- a) Describe how investigators and study team members will adjust research procedures to include the safety procedures applicable for the tier and setting in which the study is being conducted.
- b) Conform to all of the requirements for that tier and setting (e.g. may not exceed the % capacity allowed in indoor spaces for that tier/setting, etc.)
- c) Define research personnel roles specifically in terms of who will be responsible for specific research procedures and safety procedures, i.e., designate who will:
 - verify appointments and pre-visit symptom screening
 - clean, disinfect, and arrange research space before beginning research activities for the day/shift and after completing research activities for the day/shift
 - retrieve thermometer and PPE (from human resources) before beginning research activities for the day/shift
 - verify symptom screening and take temperature at the time of the visit
 - greet and accompany subjects to the lab (or designated outdoor) space
 - interact with subjects for research purposes
- d) Describe
 - where subjects will wait and be met by research personnel
 - the process for informing subjects of appropriate safety procedures and PPE and for providing PPE to subjects who arrive without it
 - what equipment/PPE will research team member wear/use to protect subjects and themselves
 - how space will be configured to comply with space/capacity requirements
 - (for field research) how team members will travel to site (and what precautions will be taken when members travel together)
- e) Describe processes for
 - reporting an encounter with a subject who later notifies personnel of COVID-19 positive status
 - reporting a COVID-19 positive team member who has been interacting with subjects
 - addressing/reporting a lapse in or failure to follow safety protocols
 - addressing/reporting an encounter in which a subject refuses to comply with safety protocols

Appendix 4. Decision Tree

