



Re-Opening Research during
COVID-19:

Human Subjects Research

DOR/Research Integrity & Oversight Office

Coming Back to Campus

- [Online form](#) to be submitted by PI
 - Per building, listing all personnel who will be on campus
 - All must have taken online training (Access UH, TAP)
 - Consent from students and employees
 - Must have college ADR approval
 - Once approved by DOR; info is shared with applicable parties
- Review [EHS guidance document](#)
- Buildings require Cougar Card access
- Detailed info on [DOR Re-Opening Research](#) page

General Guidelines – All Research

- University travel restrictions remain in place
- * [CDC guidelines](#) should be followed – social distancing, sanitization, cough etiquette
- * Masks must be worn by faculty, staff, students, visitors who will be working within 6 feet of others
- * Self-health checks prior to coming to work; stay home if any symptoms checked
- * Reporting requirements
- Contact Tracing
- No gathering in common areas (kitchens, etc.)

* - addl requirements for HSR

Shared Research Spaces

- Spacing – 1 individual per 200 sq ft, desks 10 feet apart
- Staggered work schedules, work schedule posted in accessible area and 15-minute gap between shifts
- Restrictions on face-to-face lab meetings
- *Disinfection of common research areas and frequently touched surfaces per shift (initial on work schedule) and equipment between individual uses
- *PPE – masks/gloves must be available in shared areas and used when in close proximity/using shared equipment. Obtaining PPE is the responsibility of the PI.
- Safety precautions when only one individual is in a lab normally populated by more
- Additional requirements for core facilities

* - addl requirements for HSR

Human Subjects Research

Important Considerations:

- Human subjects are volunteers
- We are not always aware of those in higher-risk groups for COVID-19
- UH, and the IRB, must continue to consider risk/benefit ratio for subjects participating in research
- Only limited, lower-risk human subjects activities are currently allowed (preference is for remote interactions whenever possible, for safety)
- When activities are conducted in person, additional precautions to protect both research team members AND subjects apply
- ***IMPORTANT*** – *permissions for human subjects activities may change on a day-to-day, or week-to-week basis, based on the current county/city/state or federal outlook. Please keep a close eye on VPR/ADR emails and the DOR COVID-19 website.*

Human Subjects Research in the Lab

- Verbal pre-screen required prior to coming on campus. Ensure subject:
 - Has not received a diagnosis of COVID-19 in the past fourteen days
 - Does not exhibit any of the COVID-19 symptoms:
 - Cough
 - Shortness of breath or difficulty breathing
 - Chills
 - Repeated shaking with chills
 - Muscle pain
 - Headache
 - Sore throat
 - Loss of taste or smell
 - Diarrhea
 - Feeling feverish or a measured temperature greater than or equal to 100.0 F
 - Has not had known close contact with a person who is lab confirmed to have COVID-19 within 14 days

This information does not need to be maintained as part of the research record unless the data will be analyzed as part of the research (requires protocol modification)

Human Subjects Research in the Lab

- Do not invite subjects in known high-risk groups to campus at this stage:
 - Adults > 65
 - Minors
 - Research requiring the following as inclusion criteria (from CDC website):

| Conditions and Other Risk Factors | |
|--|--|
| Asthma | Liver disease |
| Chronic kidney disease being treated with dialysis | People aged 65 years and older |
| Chronic lung disease | People in nursing homes or long-term care facilities |
| Diabetes | Serious heart conditions |
| Hemoglobin Disorders | Severe obesity |
| Immunocompromised | |

Human Subjects Research in the Lab

- During this phase, social distancing must be maintained. If procedures require less than 6 ft of distance from subjects, they cannot be conducted at this time, except in clinics providing paid health care services.
- Schedule appointments to not overlap with those of other subjects
- Sanitize research area and equipment between subjects
- Frequently sanitize hands during visit.

Human Subjects Research in the Lab

- All subjects and research personnel must wear masks, provided by the lab. Subjects should be given the option to wear gloves.



- Research personnel interacting with subjects must wear gloves and [remove them properly](#) between subjects
- For individual contact tracing purposes, maintain a list of all subjects who come to the lab and who interacted with them

Other Human Subjects Research

- The following may continue:
 - Online interviews, surveys, and focus groups
 - IRB protocols switching to online methodologies, once a modification has been submitted and approved (IRB office priority for quick turnaround)
 - Note DOR/IT guidance for online platforms is at the bottom of [this page](#)
- Research conducted in external clinics and other established institutional settings (schools, prisons) – external institution policy prevails
- Research in non-institutional/community settings – not permissible at this time

Research and Reporting COVID-19

- No state or county reporting is required if a subject self-discloses that he/she has had a lab-confirmed case of COVID-19
- IF, however, you have a new or updated IRB protocol that requires the testing of human subjects for research purposes with an FDA-approved COVID-19 test, both positive and negative cases must be reported to state and local health authorities. This must be addressed in the consent form.
- Contact tracing – the best way to document which individuals had contact with specific HS is to make a note in the research file; this may be accessed later if needed. Do not maintain subject names outside confidential UH locations(i.e. a list kept at home).

Reminders:

- Funding agencies have processes in place for no-cost extensions and are being lenient due to COVID-19 and institutional restrictions. Contact your program officer.
- Re-opening will proceed in phases – stay tuned!
- Thank you for your patience – this is new to us, too 😊
- DOR remains open and operational, and we are here to answer your questions

Contacts/Questions



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