

JUNE 24, 2020

Human Subject Research COVID-19 Emergency Procedures Guidance

This document was developed by the to accompany the University of Rhode Island (URI) Resumption of Research Activities Guidance, issued by the Vice President for Research & Economic Development on 19 May 2020, to provide information specific to Human Subject Research. Given the uncertainty and fluidity of Rhode Island Department of Health guidelines and University Policy due to the situation, the Institutional Review Board (IRB) and the Division of Research and Economic Development are providing the following guidelines for the conduct of human subject research during this period. Please refer to the [URI Resumption of Research Activities Guidance](#) for specific phases referred to in this document. Changes to specific phases, downward or upward, are anticipated over time related to infection prevalence and developments in assays, therapeutic measures and vaccines. Updates of significant changes will be provided to the research community in a timely manner. The official URI Guideline Phase will be posted on the URI Division of Research and Economic Development website as frequently as appropriate.

General Guidelines

- [CDC Guidelines](#) should to be followed – including social distancing, sanitization procedures and cough etiquette.
- **Face coverings** must be worn by faculty, staff, students, visitors who will be working within 6 feet of others, as specified in [Rhode Island Executive Order 20-24](#).
- Self-health checks must be conducted following university guidance for daily symptom screening, including not coming to work if I exhibit any symptoms or if I was potentially exposed to the virus (e.g., member of household tested positive). University guidance is evolving on health checks, an acceptable method presently is using the [CRUSH COVID RI](#) app. Contact Tracing is required in all labs – a record of all personnel, participants and contact information must be recorded on a daily basis.
- Regular handwashing and personal hygiene measures with sufficient access to appropriate handwashing facilities and materials (e.g., soap and water or hand sanitizer).
- No gatherings of personnel in common areas (e.g., kitchens).
- Principal investigators (PI) must ensure facilities are ready to re-open, personnel are ready to return in a safe manner and supplies needed to reopen are available. PIs must submit a COVID safety plan and confirm completion of COVID safety training to their Dean and the Division of Research and Economic Development (tedmyatt@uri.edu). A plan template and training are available at the [URI Division of Research and Economic Development website](#).

Shared Research Spaces

- Allow at least 113 sq. ft of space per person, desks 6 feet apart.
- Staggered work schedules within labs and common work areas with work schedule posted in an accessible area. Required 15-minute gap between work shifts. URI will determine the maximum density of lab/procedure rooms.
- Disinfect common research areas and commonly touched surfaces (doorknobs, switches) between individual uses. Record cleaning on work schedule with initial and time.
- Face coverings and gloves must be available in shared areas and used when in close proximity when using shared equipment is the responsibility of PI.
- Lab meetings should be restricted to virtual meetings unless there are critical reasons to do so.

Important Considerations

- Each study is unique; PIs need to proactively develop plans to mitigate risks to their participants.
- Human Subjects are volunteers.
- We are not always aware if higher-risk groups for COVID-19 who are participants in our research.
- URI and the IRB must continually assess the risk/benefit ratio for research participants.
- Any opportunity to replace in person research with remote should be implemented.
- Consider the study population and determine if study aims can be met without recruiting those at greatest risk for adverse consequences.
- Protection for both research teams and participants must always be assessed.
- Restrict study visits to essential individuals (e.g., subject and legally authorized guardian/representative) and only essential study personnel.
- Have personal protective equipment (e.g., face coverings) available for study subjects and use it as appropriate.

Human Subject Research in the Lab

- Verbal pre-screening is required prior to bringing any research participant on campus.
- All research personnel must be screened daily before allowed to engage in research.
- All participants and personnel must be screened using [CRUSH COVID RI](#), a similar tool and/or current URI guidance for [COVID symptoms and recent exposure history](#).
- **Finally, do not invite any participants in known [high-risk groups](#) to campus at this stage**

including older adults (>65 years old) and people of any age who have serious underlying medical conditions might be at higher risk for severe illness from COVID-19. If necessary for the study, PIs can justify the inclusion of high-risk participants. The IRB will consider these requests on a case-by-case basis.

Examples of Conditions and Other Risk Factors	
Asthma	Immunocompromised
Chronic kidney disease requiring dialysis	Liver disease
Chronic lung disease	People in nursing homes or long-term-care facilities
Diabetes	Serious heart conditions
Hemoglobin disorders	Severe obesity (BMI > 40)

Phase by Phase Experiment/Research Guidelines

<p>Phase 1 and Phase 2</p>	<p>Allowable Research:</p> <ul style="list-style-type: none"> • Online human subject research is that is conducted remotely, without face-to-face contact • Active or new research intended to improve the ability to detect, diagnosis, treat or protect others from COVID-19 virus or • Research and evaluation with community partners engaged in human health activities, where delay would result in negative impact on partners and/or health-related activities.
<p>Guidance:</p> <ul style="list-style-type: none"> • IRB protocols switching to online methodologies, once an amendment has been submitted and approved • Researchers and participants for other research protocols are not allowed on campus. • Strict adherence to social distancing, face mask use and cleaning measures remain in place. No more than two people are permitted in procedure rooms at any one time unless specific arrangements have been made with Associate Vice President of Research Administration (AVP). • Where required, all personnel should familiarize themselves with proper donning and doffing of PPE 	

Phase 3

Allowable Research:

- Research allowable in Phase 1 and Phase 2 can continue
- Research involving one research participant and one researcher for brief periods

Guidance:

- Research involving one research participant and one researcher for brief periods are acceptable, with approval from IRB. Modifications to the study procedures should be made to ensure the minimal amount of contact time as possible.
- All research participants must be pre-screened prior to any in person visit, using CRUSH COVID RI until URI has developed their own procedure.
- Face coverings must be worn by faculty, staff, students, visitors who will be working within 6 feet of others, as specified in Rhode Island Executive Order 20-24
- All researchers and participants must wear additional PPE as warranted by each research protocol.
- Contact Tracing is required in all labs—a record of all personnel, participants and contact information must be recorded on a daily basis. This record is kept for 14 days, and then may be destroyed.
- Appropriate investigator/staff/student densities must be adhered to (i.e. maintaining 6-foot physical distancing) in all hallways, procedure rooms and laboratories.
- Strict adherence to social distancing, face mask use and cleaning measures remain in place. No more than two people are permitted in procedure rooms at any one time.

REQUIRED: IRB requires approval of an amendment (which includes COVID Safety Plan) prior to resumption of research

Phase 4

Allowable Research:

- Research allowable in Phases 1 through 3 can continue
- Research involving more than one researcher and a small group of research participants for brief visits

Guidance:

- Research involving more than one researcher and a small group of research participants for brief visits are acceptable, with approval from IRB. Modifications to the study procedures should be made to ensure the minimal amount of contact time as possible.
- All research participants must be pre-screened prior to any in person visit, using CRUSH COVID RI until URI has developed their own procedure.
- Face coverings must be worn by faculty, staff, students, visitors who will be working within 6 feet of others, as specified in Rhode Island Executive Order 20-24
- All researchers and participants must wear additional PPE as warranted by each research protocol.
- Contact Tracing is required in all labs—a record of all personnel, participants and contact information must be recorded on a daily basis. This record is kept for 14 days, and then may be destroyed.
- Appropriate investigator/staff/student densities must be adhered to (i.e. maintaining 6-foot physical distancing) in all hallways, procedure rooms and laboratories.
- Strict adherence to social distancing, face mask use and cleaning measures remain in place.

REQUIRED: IRB requires approval of an amendment (which includes COVID Safety Plan) prior to resumption of research

Phase 5

Allowable Research:

- Research allowable in Phases 1 through 4 can continue
- Research with all measures of social distancing, use of face coverings, staff densities and cleaning measures adhered to for most all research with individuals who are not at high-risk of serious adverse consequences of COVID-19.

Guidance:

- Research with all measures of social distancing, use of face coverings, staff densities and cleaning measures adhered to for most all research with individuals who are not at high-risk of serious adverse consequences of COVID-19 are acceptable, with approval from IRB. Modifications to the study procedures should be made to ensure the minimal amount of contact time as possible.
- High risk individuals include those that reside in congregant care centers, elderly, or have serious health complications.
- All research participants must be pre-screened prior to any in person visit, using CRUSH COVID RI until URI has developed their own procedure.
- Face coverings must be worn by faculty, staff, students, visitors who will be working within 6 feet of others, as specified in Rhode Island Executive Order 20-24
- All researchers and participants must wear additional PPE as warranted by each research protocol.
- Contact Tracing is required in all labs—a record of all personnel, participants and contact information must be recorded on a daily basis. This record is kept for 14 days, and then may be destroyed.
- Appropriate investigator/staff/student densities must be adhered to (i.e. maintaining 6-foot physical distancing) in all hallways, procedure rooms and laboratories.
- Strict adherence to social distancing, face mask use and cleaning measures remain in place.

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