### Research & COVID-19:

# A Guide for Human Subjects Research



These guidelines are designed to assist UCR researchers who engage in 'human subjects research' under the purview and approval of the IRBs. However, they may also be useful for other types of scholarly activities that involve people. The guidelines are intended to complement the <u>Principles and Framework Guiding a Phased Approach for Ramp-Up and Ramp-Down of On-Campus Research-Related Activity</u>, which provide details regarding campus operations and restrictions during the four phases of ramp-up and ramp-down of research and scholarly activities.

The following requirements provide guidance to all staff, faculty, and students who perform duties as a part of their work or studies. These protocols also apply if you work, study, or do research at UC-leased or affiliated properties, unless the facility has expressly provided different instructions:

- ☐ Complete the online LMS course: <u>COVID-19 Prevention</u>
- Review the Return-to-Work guide and relevant protocols
- □ <u>Daily health screening</u> healthcare or non-healthcare setting
- □ Develop a <u>worksite-specific prevention plan</u>

#### Pro Tip:

Review <u>additional IRB</u> resources for COVID-19 researchers

# **Reducing Risk of Coronavirus Transmission**

### Harm Reduction Tips for Researchers at UCR

- Wear masks
- Maintain distance
- Wash hands

**Risk of Transmission** 

- Limit number of people present
- Ensure good ventilation
  Proactively disinfect or
  avoid sharing equipment





#### Pro Tip:

When talking to participants, use the language of 'reducing risk' of COVID-19



Conducting Research Remotely

One or a Few People (less than 15 minutes) Interacting with More Than One Person Indoors (more than 15 minutes)

### **Note Well:**

The UCR phases ≠ State of CA stages

# **Ensure Risk Mitigation for Research Participants**

- Screen participants for <u>symptoms and susceptibilities</u> before allowing in-person (face-to-face) interaction (for screening purposes only **not** to be used for research)
- Provide options for remote participation as much as possible:
  - Interact online (Zoom, Skype, etc.) or via telephone
  - Be mindful of confidentiality issues when using technology and implement adequate protections (for example, ensure that participants are in a private room, wear headphones)
  - o Be vigilant of any cyber security threats. If you have any concerns, contact infosecoffice@ucr.edu
- Disinfect facilities/equipment frequently and proactively using 1:10 bleach and 70 % EtOH (ethyl alcohol)
  - o Focus on shared equipment, door handles, seats, desks, computers, and other high-touch surfaces
- Notify participants of risks of COVID-19 and steps you are taking to mitigate them; document their consent

# Ensure Physical Distancing Among Research Staff, Lab Personnel & Volunteers

- Require all those (e.g., staff, students or participants) who are experiencing symptoms of COVID-19 to stay home
- Maintain low population density in lab spaces and research facilities (i.e., physical distancing of ~6' or ~2m)
- Limit face-to-face interactions as much as possible especially prolonged interactions (15 min +)
- Wash hands (soap and lather for 20 seconds at least) and disinfect work surfaces frequently
- Cover coughs and sneezes with a tissue (put in trash immediately) or into your elbow, not in your hands
- Masks or face covering over both mouth/nose should be worn when interacting with others

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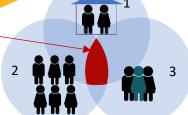
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### As Much as Possible, Avoid the "Three C's"

- 1. Closed spaces, with poor ventilation
- 2. Crowded places, with many people nearby (high density)
- 3. Close-contact settings, such as close-range conversations

The inherent risk is particularly high when the "Three C's" overlap



Research Integrity

### **Ensure Regulatory Compliance for Your Research**

Researchers may deviate from IRB-approved procedures only to remove an immediate hazard, such as:

- Modifying the informed consent process to avoid the need for in-person signatures
- Changing from in-person visits to virtual visits or phone calls instead

#### Pro Tip:

For changes like these two, remove the hazards as soon as possible and then submit a completed <u>Event Report Form</u>.

Incorporating screening questions to identify potential COVID-19 exposure (not used for research purposes) –
 especially for Phase 3 since those at-risk for COVID-19 cannot participate during this phase

For any other change (not intended to remove immediate hazards), first submit a completed <u>Amendment Request Form</u> and then await IRB approval of the proposed change before implementing.

Submit completed forms to irb@ucr.edu

#### Pro Tip:

In general, human subjects research testing (i.e., return of lab results) must be done in CLIA-certified labs

### **UCR Phases and Permitted Research Activities**

Ramp-up or ramp-down of the research and scholarly activities will adhere to criteria of several phases. The campus leadership will determine which phase we are in based on health authorities' orders, University policies, and other recommendations regarding the COVID-19 pandemic; the best scientifically informed recommendations that prioritize health and safety of all personnel; and the ability of our campus to adapt to all such recommendations. See: "Principles and Framework Guiding a Phased Approach..."

Each move to a different phase will be properly announced by the campus leadership and we will remain in such phase until a new announcement is made.

# Phase 1

- Research facilities, offices, studios, and field stations are closed, except where personnel are required to protect life and critical research infrastructure/ capability
- Deans authorized one-time access to faculty offices to pick up books and materials, shut down instrumentation, etc.
- Only clinical human subjects research which is essential to the health and/or well-being of the participants is allowed (i.e., clinical trials with a direct benefit to subjects)
- No on-campus research conducted by undergraduates allowed

## Phase 3

- More flexibility in terms of physical distancing
- Continue to wear face coverings (<u>available through</u> <u>EH&S</u>); require participants to wear them, too
- Human subjects research not allowed in previous phases is now allowed, except if it involves individuals who are deemed high-risk (for example, because of age or pre-existing health conditions)
- Some research-related travel may take place if allowed by the health authorities
- Research and scholarly activities that can be conducted remotely continue to be performed in such a way
- Upon Dean's approval and on a case-by-case basis, oncampus research conducted by undergraduates may be allowed
- Human subjects research involving undergraduates as participants is allowed (unless they are at risk)

### Phase 2

(started at UCR on June 8, 2020)

- Research remains limited by the need for physical distancing
- Human subjects research: Same as Phase 1
- At the Deans' discretion, urgent, time-sensitive research and scholarly activities with immediate deadlines such as external submission for which the sponsor does not allow extensions or delays, exhibitions, or once-in-a-lifetime opportunity may be allowed
- No on-campus research conducted by undergraduates allowed (except by special exemption)

# Phase 4

 Level of on-campus research is largely back to normal, with some modifications

#### **Pro Tip:**

Consult the <u>IRB</u> with questions or concerns you may have about human subjects research