PHASE 3 RESEARCH

Summary of Changes from Phase 2

- Includes all research activities not permitted in Phases 1 or 2, including research performed by undergraduate students, and certain types of human subjects research,
- Eliminates the 30% population density requirement associated with Phase 2 research,
- Establishes a research space population density guideline of at least six (6) feet between occupants, which is based on current applicable CDC guidance and Cal OSHA physical distancing requirements,
- Permits certain invited visitors and guests,
- Establishes safety and mitigation requirements, and
- Provides guidance to Authorized Officials for reviewing and approving Phase 3 research.

Scope

PHASE 3 - Consists of Phase 1 and 2 research activities, and the following:

1. All research activities (including all human subjects research and undergraduate student research) that personnel can perform safely by layering and consistently following required and voluntary safety protocols and protective measures to mitigate virus transmission ("Research Activities").

2. Research Activities may occur in or at:

    a. UCI owned, operated, controlled, or managed facilities, space, locations, sites, and natural reserves ("In-Person Research Activities"), or

    b. A location, facility, or site not owned, operated, controlled, or managed by UCI ("Remote Research Activities").

3. Undergraduate student In-Person Research Activities are limited to enrolled undergraduate students who are either in residence or who regularly commute to UCI.

4. The following types of invited guests and visitors may perform or participate in In-Person Research Activities without Authorized Official approval:

    a. Human subject research participants, as well as one family member or caregiver to physically assist them and/or help them understand the instructions of research

staff.

b. Outside translators for human subject research participants if no UCI-employed translator is or will be available.

c. Representatives of industry sponsors to conduct oversight responsibilities and sponsor business associated with industry-sponsored clinical trials, but only for those activities that they must necessarily perform on-site and in-person.

d. Regulatory agency officials and representatives of accrediting bodies or organizations.

e. Non-UCI researchers at natural reserves managed/operated by UCI.

f. Non-UCI research collaborators when collaborative activities cannot be performed remotely and must be performed face-to-face in the same research space.

5. Administrative-like activities necessary or essential for conducting Research Activities performed by research personnel covered by an approved research plan (for example, obtaining and documenting human subject informed consent). **Phase 3 research <u>does not</u> include administrative functions or tasks in support of Research Activities performed by administrative/staff personnel as these functions are subject to unit <u>"Returning to Campus" plans</u>**.

<u>Safety and Mitigation Requirements</u>

1. All personnel performing In-Person Research Activities, including invited guests and visitors must follow:
    a. the Cal OSHA physical distancing requirement of at least six feet between people, except for:

        i. Personnel performing In-Person Research Activities in BSL 3 laboratories,

        ii. Personnel performing In-Person Research Activities in clinical space designated by UCI Health provided that they follow all safety protocols and protective measures implemented by UCI Health to comply with the requirements under section 5199 of the Cal OSHA Emergency Covid Regulations,

        iii. Personnel performing human subjects research where momentary in-person interactions at a distance of less than six feet are unavoidable

(please also see requirement 5, below),

iv. Life or safety emergencies or other situations in which physical distancing would create a hazard or impede an individual from receiving essential safety training, or

v. Very limited circumstances provided for under the Cal OSHA Emergency Covid Regulations for personnel working with aerosol transmissible pathogens (please contact Associate Vice Chancellor Bruce Morgan).

b. All federal, state, and local public health directives,

c. Applicable UCI Executive Directives,

d. The Framework for UCI Phased Research Activities, including the Guiding Principles,

e. All other applicable guidance issued by the Vice Chancellor for Research or the Office of Research, and

f. All other health, safety, and COVID-19 guidelines and requirements issued by Environmental Health & Safety and/or UCI Health (as applicable).

2. All Remote Research Activities must comply with:

a. All federal, state, and local public health directives applicable to the location/site where researchers will perform the Remote Research Activities,

b. All requirements, directives and guidance issued by the entity managing the location or site where researchers will perform the Remote Research Activities, and

3. Plan Owners may establish more restrictive requirements or safety protocols and measures for the spaces and Research Activities covered by their approved research plans.

4. All invited guests and visitors must follow the safety precautions and measures contained in the approved research plan covering the Research Activities in which they will participate. Plan Owners must inform invited guests and visitors about the following UCI Executive Directives, as well as where to find them:

a. Contact Tracing

b. Face Coverings, and

c. Daily Symptom Check

5. For the safety and well-being of researchers and human subjects, all human subject research must meet or exceed all public health and safety directives, as well as all guidelines and requirements issued by the Office of Research and the Institutional Review Board.

For additional guidance and information about conducting human subjects research during Phase 3, please visit the Guidance for Expanding Human Subjects Research Activities and the Human Research Protections pages on the UCI Research Continuity website.

Transition to Phase 3

As with Phases 1 and 2, UCI needs to document that Plan Owners have thoroughly considered and implemented the safety precautions and measures essential for complying with Phase 3 requirements. In particular, Plan Owners who wish to undertake human subject and/or undergraduate student Research Activities not covered by an approved Phase 1 or 2 plan must secure Authorized Official review and approval prior to commencing these activities.

Authorized Officials (AO) remain responsible for establishing and maintaining processes for reviewing and approving research plans, including plan modifications that will enable Plan Owners to conduct Phase 3 Research Activities. In fulfilling this responsibility, AOs may wish to consider the following optional guidelines for Phase 3 plan review and approval:

1. For previously approved Phase 1 and 2 plans, minimize burden and maximize efficiency by:

    a. Exempting from AO review and approval all research plans that do not require any modifications before transitioning to Phase 3.

    b. Implementing an administrative review and approval process (e.g., conducted by AO support staff) for minor plan modifications (for example, e.g., noting an increase research space population density, updating personnel covered by the plan, etc.).

    c. Implementing an expedited process for substantive changes to research plans (e.g., adding undergraduate students, expanding human subjects activities, changes in safety protocols and measures resulting from expanded research activities, etc.) where Plan Owners submit current plans with redline changes for AO review and approval.

2. For researchers without approved research plans, AOs should consider repurposing Phase 2 research plan approval forms and processes. Alternatively, they may wish to consider implementing a streamlined form and approval process. The following are optional points of consideration for doing so:

    a. Ensure that a Phase 3 approval form captures the data and information necessary for the AO (or their designee) to make informed decisions, such as

        i. Plan Owner name

        ii. The name of the Plan Owner's research program

        iii. The location of the Plan Owner's research space and/or spaces where their team will perform research

        iv. Layered safety precautions and measures used such as types of face coverings worn by research personnel, population control procedures to ensure six (6) feet of distance between occupants, routinely used personal protective equipment (PPE), special PPE used for higher-risk settings or circumstances, special procedures to protect the safety and well-being of human subject participants, personnel completing UCI Working Well symptom checker daily, etc.

        v. All personnel provided contact information for requesting accommodations (Wendy Pawling, Disability Management Specialist, People Services Human Resources, (949) 824-9756, wpawling@uci.edu, Andrew Berk ADA Coordinator, Equal Opportunity & Diversity, (949) 824-5594, anberk@uci.edu), and/or Karen L Andrews, Director, Student Disability Services Center, (949) 824-1633, klandrew@uci.edu.

Reversion to Earlier Phases

Pursuant to public health directives and current prevailing circumstances, the Vice Chancellor for Research may curtail or modify Phase 3 research activities on little or no notice.