UNIVERSITY OF OREGON

RESEARCH COMPLIANCE SERVICES

GUIDANCE ON SUBMITTING PROTOCOLS & MAINTAINING COMPLIANCE DURING OVPRI COVID-19 RECOVERY STAGES

Scope: The purposed of this document is to provide guidance to the UO research community when designing research and preparing submissions for review by Research Compliance Services (RCS) and the Institutional Review Board (IRB) during the institutional response to COVID-19. This guidance is published by RCS on behalf of the UO IRB. This guidance is intended to supplement the guidance made available by the Office of the Vice President for Research and Innovation (OVPRI) on their Staged Approach to Restarting Research Activity website. Questions regarding this guidance should be directed to researchcompliance@uoregon.edu.

I. INSTITUTIONAL RESPONSE TO COVID-19 AND HUMAN SUBJECT RESEARCH

The UO research enterprise has operated under State executive orders for higher education and has implemented a Staged Approach to Restarting Research Activity. The staged approach limits the types of research activities, including human subject research (HSR) activities, permitted in response to current public health guidance and safety considerations. The approach includes specific requirements for the conduct of face-to-face interactions with human subjects when permitted in the currently published recovery Stage/Phase.

The institutional response for research was led by the Research Incident Management Team (Research IMT) in consultation with Research Compliance Services (RCS) and the Institutional Review Board (IRB). As of July 13, 2021, the Research IMT group has disbanded. Communications regarding changes and updates during the Staged Recovery will be centrally communicated by OVPRI and/or the Research IMT group. The research community is invited to join town halls hosted by OVPRI when a new phase/stage is introduced.

A. Investigator Responsibilities & Applicability

- Investigators are responsible for monitoring the OVPRI research recovery website to understand the additional requirements and limitations on research activities for the currently published phase/stage of recovery.

- Only the activities permitted under the currently published phase/stage of recovery, or an earlier phase/stage of recovery, as published on the OVPRI Recovery website may be conducted. The following exceptions have been made:
    - Human subject research activities that can be facilitated remotely and that do not require human subject participants to travel and/or interact with individuals outside of their household are permitted without limitation under all OVPRI research recovery phases/stages, following the usual IRB protocol review process.
    - All human subjects research activities that study COVID-19 may be conducted following the usual IRB protocol review process.
- **Student-led research.** As of March 15, 2021, student-led research activities that are otherwise not affiliated with faculty-led research are subject to the same institutional restrictions as faculty-led research. Specifically:
    - Student investigators are expected to comply with the requirements of each Stage.
    - Student researchers continue to be expected to secure IRB approval or an exempt determination before initiating HSR activities and before implementing any changes to their currently approved protocols including changes to adapt previously approved research for COVID-19 considerations.

B. Contact Tracing Disclosure and Tracking

- Contact tracing is a public health requirement for the institution and includes limitations to confidentiality outside of research participation that must be disclosed to potential participants.
- Contact tracing requires disclosure of personally identifiable including names, contact information as well as date and location of exposure to public health officials in the circumstances where an individual with an identified case or exposure to COVID-19 has been in contact with others.
- Before an individual is consented to participate in face-to-face research, they must review and complete the Contact Tracing Disclosure Form.
- If an individual is unwilling or unable to complete the Contact Tracing Disclosure Form, they cannot be consented to participate in face-to-face research activities.
- A copy of the Contact Tracing Disclosure Form must be provided to the participant to supplement the IRB approved consent materials.
- The Contact Tracing Disclosure Form must be stored separately from other study records.

C. Stages/Phases of Recovery and Institutional Guidelines

Investigators are expected to conduct research activities according to the institutional guidelines for the current recovery Stage/Phase published on the research recovery website. All researchers are expected to follow the Research Activities and Safety Protocols guidelines. Additionally, guidelines for the following are published and are to be followed as applicable:

- On-campus research activities
- Fieldwork
- Face to Face Human Subjects Research

D. Research IMT Submission Requirements

- Previously, investigators were responsible for submitting a Research Recovery Plan to the Research Incident Management Team (Research IMT). The submission requirements for Research IMT have evolved and were updated July 13, 2021, 2021. Under the current Stage 3, investigators are no longer required to submit and secure approval from Research IMT.
- Investigators continue to be expected to secure IRB approval or an exempt determination from Research Compliance Services (RCS) before initiating HSR activities and before implementing any changes to their currently approved protocols. See **Sections II and III** below for more specific information and guidance on staying compliant and preparing submissions for IRB and RCS review.

II. MAINTAINING HUMAN SUBJECT RESEARCH COMPLIANCE DURING RESEARCH RECOVERY STAGES

RCS and the IRB continue to review and approve human subject research (HSR) during the Recovery Stages. Existing studies are expected to maintain compliance during the Recovery Stages. ***RCS and/or IRB approval is still required before implementing human subject research activities***.

A. New studies.

RCS and the IRB continue to accept application for new HSR activities.

B. Existing studies.

In general, investigators must adhere to their IRB approved protocol. Protocol approvals must be maintained.

- **Continuing Review Applications** need to be submitted at least 45-days in advance of a protocol expiration date.
- **Modification/Amendment Review Applications** and materials must be submitted, and approval secured before any changes to previously approved research are implemented.
- Timely submission of **Reportable New Information/Event Reports** continues to be expected.

C. Guidelines for submitting Modifications and Reportable New Information/Event Reports when changes are made to eliminate hazards and comply with institutional restrictions.

In general, investigators must adhere to their IRB approved protocol. Below are guidelines to help investigators understand when an amendment is required before making changes to face-to-face human subject research activities in response to the institutional research recovery plan.

- **No Submission Requirements**: IRB review and amendments to previously approved research is not required when:
  - Implementing or enhancing cleaning and disinfecting protocols and/or amending communication methods with research team members and human subjects to prevent the spread of illness.

- When the participants eligible for inclusion do not conflict with the IRB approved protocol materials.
- Addition of contact tracing procedures.
- Adding screening provisions to comply with UO self-check provisions for visitors to campus.

- **Protocol Deviation Requiring a Reportable New Information/Event Report Submission**: Investigators may implement temporary changes immediately and then submit an Event Report Form as soon as possible. A modification to the study may be necessary in follow-up to the report's submission. Temporary changes might include:
  - Adding or changing research procedures temporarily (e.g., from in-person to telephone)
  - Conducting a research visit outside of an established time frame in the approved protocol.
- **Protocol Change Requiring Amendment and Approval:** IRB review and approval of an amendment is required prior to making changes beyond a deviation, such as:
  - Making long-term or permanent changes to research methods that are designed to continue after COVID-19 restrictions are lifted.
  - Adding a sub-study and/or revised methods to study COVID-19 in ongoing research.
  - Adopting changes for future use, such as using online surveys for the remainder of study when they were not previously approved, or the research previously included in-person interviews only.
  - Updating inclusion/exclusion criteria beyond excluding those who are unable to comply with UO policies and additional screening criteria.
- **NOTE: In general, this initial response period has passed a study should be operating under circumstances that have eliminated immediate hazards. As researchers work to reintegrate activities or revert to previous procedures, modifications need to be submitted if changes are being made to previously approved studies. Implementing changes beyond those noted about without first securing approval is not appropriate unless the investigator can reasonably justify other hazards warranting immediate action to protect the rights and welfare of participants.**

III. PREPARING SUBMISSIONS TO RCS/IRB DURING RESEARCH RECOVERY

Investigators may continue to submit applications for human subject research (HSR) that include activities outside the scope of the currently published Recovery Stage. RCS and the IRB will consider these applications and issue any approval or determination with a contingency that limits the activities permitted under the protocol approval. Specifically, this will limit the activities that can be conducted to those allowable under the current Recovery Stage and as approved by Research IMT in any approved Research Recovery Plan.

Investigators <u>are typically not required</u> to submit documentation of Research IMT approval or approved Research Recovery Plans when requesting review of HSR applications. However, if an investigator has an approved Research Recovery Plan, they may elect to submit their plans when doing so may support their application. *The IRB may request an investigator provide an approved*

Recovery Plan if the IRB determines information within the plan is necessary to evaluate the IRB criteria for approval. If during pre-review, staff identify that the IRB may need to review an approved Recovery Plan to complete their review, staff may proactively request a copy of the approved plan along with any other pre-review requests.

When preparing protocols for review, investigators are asked to consider the following:

- **Initial Review Applications -** If the application includes proposed face-to-face interactions with participants, the investigator should explain within the applicable sections of the Research Plan:
    - Their plans for mitigating risks associated with COVID-19 consistent with the OVPRI published recovery Stage/Phase and applicable guidelines;
    - Whether and how activities may be adapted during Recovery Stages.

  The degree of explanation required within protocol materials is based on level of review and categories:

    - **Exempt Review (all categories) & Expedited Review Categories 5-8 -** If the study qualifies for Exemption or Expedited Review under Categories 5-8, it is likely that activities can be performed with little to no close contact with participants. Therefore, less information will be needed by RCS and the IRB to determine approval.
        - **Acknowledgement of Requirements**. Researchers are expected to simply state within the Research Plan that they intend to conduct the research in accordance with the currently published recovery Stage/Phase.
        - The IRB and/or RCS staff have discretion when evaluating the protocol materials for approval to determine whether a statement is sufficient given the research under consideration or if more detail is warranted in order to evaluate the study for approval.
    - **Expedited Review 1-4 & 9 or Full Board Review -** If the study qualifies for Expedited Review under Categories 1-4 & 9 or Full Board review, these studies are more likely to include invasive procedures and/or close contact that require modification in their standard approach to mitigate risks associated with COVID-19. For these studies, investigators will need to provide greater detail throughout relevant sections of the Research Plan and Informed Consent documents, regardless of whether the study has a Recovery Plan in place.
        - **Detailed Plans**. The IRB will need sufficient detail to assess the regulatory approval criteria.

          For example, in the Research Plan, as appropriate, describe:

            - any adjustments to methods in Section C. to demonstrate safety,
            - any additional inclusion/exclusion and screening considerations in Section D.,
            - additional consent procedures in Section E. and
            - risks/strategies to mitigate risks associated with COVID-19 in Section G.

An investigator may elect to create an appendix to the Research Plan to explain how the overall study will be adapted to address COVID-19 considerations. However, if an appendix is created, this must be included when the Research Plan is submitted for subsequent reviews until the appendix no longer applies.

The IRB and RCS staff will use their discretion when evaluating whether the description is sufficient given the research under consideration.

- **Modification/Amendment Review Applications** - If the application includes proposed changes in response to Recovery Stage requirements/limitations and includes face-to-face HSR activities, the investigator should explain:
  - That provisions have been made to mitigate the risks associated with COVID-19 consistent with the OVPRI published recovery Stage/Phase and applicable guidelines;
  - See notes above under Initial Review Applications regarding degree of explanation within protocol materials based on level of review and categories.
  - In addition, the investigator should explain whether activities are being temporarily revised or if the intent is to maintain these changes (i.e., would not revert to previously approved procedures once research activities can resume) and how activities may be adapted as Recovery Stages progress.
- **Continuing Review Applications** - If the currently approved protocol includes face-to-face HSR activities, the investigator is expected to submit the same materials as were previously approved. During pre-review, staff may reach out to investigators to ensure they are aware of the restrictions and appropriately set expectations for contingencies that will be issued at the time of the approval.
  - If the investigator is interested in making changes to the protocol to align with the current Recovery Stage, a separate amendment/modification needs to be submitted for review and approval once the continuation approval is finalized.

IV. ETHICAL AND SAFETY CONSIDERATIONS FOR CONDUCTING HUMAN SUBJECT RESEARCH DURING RESEARCH RECOVERY

In addition to institutional provisions in place to mitigate risks associated with COVID-19 when conducting human subject research activities, it is important for investigators to consider how their research is designed to address these risks while also attending to the ethical considerations for participants. Some considerations include:

A. Inclusion/Exclusion of Vaccinated Individuals

- The current research recovery stage defines different guidelines for mask wearing of vaccinated and unvaccinated individuals. Research teams will need to consider how mask wearing provisions will be implemented and determined with participants. It is important that participant expectations be clearly established during recruitment and prior to arrival for a study visit. If documentation of vaccination will be required, this needs to be clearly communicated.
- If investigators propose research that will only include vaccinated individuals, justification and rationale based on scientific and/or safety considerations will need to be provided for the IRB's consideration. The IRB will need to determine that exclusion of unvaccinated individuals is appropriate for the research. It is important to recognize that exclusion of

unvaccinated individuals without adequate justification is an equity issue and will be considered carefully by the IRB.

B. Additional Screening Procedures

- It may be appropriate to screen participants for symptoms of COVID-19 prior to and upon their arrival depending on the research methods employed and other measures in place to mitigate risks associated with COVID-19. If screening will be used, the study materials will need to describe the procedures for screening and ensuring participants are aware of the additional exclusion criteria. The OVPRI relies on current CDC guidance on symptoms associated with COVID-19. Investigators should monitor CDC guidance for new information.
    - We recommend that researchers use the standards outlined in the UO self-check procedures.

C. Supporting Compliance with Safety Provisions

- Ensure research personnel and participants are properly equipped to adhere to mask requirements on campus and in accordance with governing body mandates. If a participant is unwilling to comply with mask requirements, they should be excluded from participation and this needs to be made clear prior to their agreement to participate in the research.
- Ensure properly stocked hand-washing stations, hand sanitizer, tissues, and trash baskets are available to research team members and study participants.
- Increase frequency of hand washing by research staff and human participants.
    - Implement internal research procedures to increase routine cleaning and disinfecting of high-touch surfaces (e.g., door handles, equipment, materials, toys and supplies used during research studies, etc.).
    - Be mindful of your essential research team's own health. If they develop cold or flu-like symptoms they should not have contact with human subjects.