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 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. **NOTE: This guidance was updated to reflect Research IMT requirements as of March 15, 2021.**

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

The UO research enterprise is operating 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. A Guidance on Engaging in Human Subject Research during OVPRI COVID-19 Recovery Stages was developed by the UO Research Incident Management Team (Research IMT) in consultation with Research Compliance Services (RCS) and the Institutional Review Board (IRB).

- **Research IMT Submission Requirements.** The submission requirements for Research IMT have evolved and were updated March 15, 2021. Below reflects requirements for researchers who are newly initiating/re-instating research activities as of March 15, 2021. Researchers should refer to the Stage Approach for Restarting UO Research Activity website for the most recent information on specific activities permitted under each stage and to reference prior submission requirements.
    - **Stage 1 Research Registration Form.** To conduct activities under Stage 1, investigators will need to submit a Stage 1 Research Registration Form to Research IMT and agree to conduct research according the Stage 1 Research Protocol.
    - **Stage 2 Research Recovery Plan.** To conduct activities under Stage 2, investigators must submit a Research Recovery Plan to Research IMT and secure approval before engaging in research activities during the Recovery Stages.
- **Research Compliance Services/Institutional Review Board Submission Requirements.** 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.
    - The OVPRI Guidance on Engaging in Human Subject Research during OVPRI COVID-19 Recovery Stages outlines additional investigator responsibilities, contact tracing disclosure and tracking requirements, requirements for the conduct of face-to-face interactions, and guidelines for submitting amendments and event reports during the COVID-19 Recovery Stages.

- See **Sections II and III** below for more specific information and guidance on staying compliant and preparing submissions for IRB and RCS review.

- **Keeping the UO research community informed.** 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.
- **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 follow the OVPRI Guidance on Engaging in Human Subject Research during OVPRI COVID-19 Recovery Stages as applicable to their research and methods.
  - Student investigators are expected to register their research with Research IMT according to the requirements of the Stage in which their activities fall.
  - 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.

II. PROTOCOL REVIEWS & MAINTAINING COMPLIANT APPROVAL DURING RESEARCH RECOVERY STAGES

RCS and the IRB continues 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 still required <u>before</u> implementing human subject research activities**. Investigators are still required to submit protocols for review and secure approval before implementing HSR activities.
  - **New Studies**: RCS and the IRB continue to accept application for new HSR activities.
  - **Existing Studies**. Protocol approvals must be maintained.
    - Continuing Review Applications and Progress Reports 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.
- **Immediate changes to eliminate hazards and comply with institutional restrictions.** When institutional restrictions were placed in March 2020, investigators were initially guided to make immediate changes necessary to comply with the restrictions and to protect the rights and welfare of participants. If doing so required deviating from their approved protocols, investigators were guided to submit a Reportable New Information/Event Report detailing the actions taken. However, should these changes be maintained long-term and/or the study require modification to adapt

to COVID-19 circumstances, investigators must submit a modification and secure approval to maintain compliance.

NOTE: The initial period for which implementing immediate changes to a protocol has passed. Investigators should now submit an appropriate amendment/modification and await approval before implementing changes related to adapting their research for COVID-19 related restrictions and considerations. Implementing changes without first securing approval is no longer appropriate unless the investigator can reasonably justify other immediate hazards warranting immediate action to protect the rights and welfare of participants

III. PREPARING SUBMISSIONS 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 are typically not required 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 Guidance on Engaging Human Subject Research during OVPRI COVID-19 Recovery Stages;
    - Whether any necessary Stage 1 Registration or Research Recovery Plans have been submitted and approved as required by Research IMT;
    - 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 UO Research IMT Stage 1 Research Protocol or their approved Research Recovery Plan (for Stage 2 activities).

- 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 Guidance on Engaging Human Subject Research during OVPRI COVID-19 Recovery Stages;
  - Any necessary Stage 1 Registration or Research Recovery Plans have been submitted and approved as required by Research IMT;
  - 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.