

Guidance on Engaging in Human Subject Research during OVPRI COVID-19 Recovery Stages

The Office of the Vice President for Research (OVPRI) is implementing a staged recovery of research activities. The purpose of this guidance is to help the University research community understand when and how to safely and appropriately engage in human subject research activities as permitted in the [OVPRI staged research recovery plan](#). This is a living document and thus is subject to change.

I. Investigator Responsibilities

- 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 current phase/stage of recovery, or an earlier phase/stage of recovery, as published on the OVPRI Recovery website may be conducted.
 - NOTE: 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.
 - NOTE: All human subjects research activities that study COVID-19 may be conducted following the usual IRB protocol review process.
- Investigators are responsible for confirming if research is exempt from IRB or not human subjects research prior to submitting a recovery plan.

II. 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.

III. Requirements for the Conduct of Face-to-Face Interactions

Investigators must implement the following measures to protect the rights and welfare of research subjects.

A. Participant Inclusion/Exclusion Criteria

- Unless the research is directly studying COVID-19, research participants may only include those individuals who are symptom-free as determined by the procedures for screening (as detailed in Item B. below) and those individuals who are not at higher risk of severe illness per [CDC guidance \(i.e., exclusion of higher risk populations\)](#).
- If an investigator believes their research methods sufficiently mitigate risk for the safe inclusion of individuals at higher risk and is proposing activities permitted under the current recovery phase/stage, an [exception request may be submitted](#).
- To request an exception to the exclusion of higher risk populations, an investigator needs to include with their protocol amendment a narrative that addressed the following:
 - Justification that the research cannot be carried out without the inclusion of those individuals at higher risk of severe illness;
 - How the procedures proposed sufficiently mitigate risks for the higher risk population; and
 - How the benefits of the research justify any remaining risks.

NOTE: Both the Research IMT group and the IRB will need to approve the exception.

B. Modification of Research Activities

Investigators must modify research activities to provide significant provisions to prevent disease spread. Procedures must ensure physical distancing, screening for illness, and enhanced cleaning. Investigators will need to evaluate and revise research operating procedures as well as train research team members to ensure the following:

- Research participants may only include those individuals who are (1) not at higher risk of severe illness per [CDC guidance](#) and (2) are symptom-free as determined HSR guidelines. If a researcher wishes to request an exception to these criteria, use [the exception request form](#)
- All participants must be provided with notice regarding contact tracing requirements and limits of confidentiality associated with their participation using the [OVPRI Contact Tracing Disclosure Form](#).
- All participants must be screened for symptoms prior to visit and upon arrival. 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](#).
- Clean all surfaces and materials before and after research activities occur in the space. Diluted household bleach solutions, alcohol solutions, with at least 70 percent alcohol, and most common EPA-registered household disinfectants should be effective. See the CDC website for [a complete list of CDC recommendations on effective disinfectants and procedures](#).
- 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.
- 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 must not have contact with human subjects.
- Guidance on this topic is expected to change based on UO Stages. Please see our [website](#) for current procedures and policies that are permissible under each phase/stage.

IV. Guidelines for Submitting Amendments and Event Reports

In general, investigators must adhere to their IRB approved protocol. Below are guidelines to help investigators understand when an amendment is required before engaging in face-to-face human subject research activities. This is an overview, please see further details on the [OVRPI Research Recovery](#) and [FAQs](#) websites.

- **No Submission Requirements:** IRB review and amendments to previously approved research **are 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 as per Section III. A. and the modified activities required in Section III., B. do not conflict with the IRB approved protocol materials.
- **Protocol Deviation Requiring Event Report Submission:** Investigators may implement *temporary changes* immediately and then submit an [Event Report Form](#) as soon as possible. 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.
 - When participants for inclusion and/or the modified activities required above in Section III. B. conflict with the IRB approved protocol materials.