GUIDE FOR RETURNING TO IN-PERSON RESEARCH: HUMAN SUBJECTS RESEARCH

INTRODUCTION

The University respects and values the individuals who volunteer to participate in UW research, and accepts its responsibility for strong adherence to ethical principles and protection of participants’ rights and welfare. This occurs by reducing the risks of research participation, as feasible, and by only conducting research for which the participant risks are balanced or outweighed by the benefits of the research. The COVID-19 pandemic has introduced significant new risks for in-person human subjects research – that is, research in which participants and researchers interact in the same physical location.

WHAT DO I NEED TO KNOW?

Beginning March 23, some (but not all) in-person human subjects research was temporarily halted due to increased risks associated with the COVID-19 pandemic. Some of these studies were able to continue by converting to “remote” procedures.

The resumption of halted human subjects research will occur in phases that will typically be linked to the phases guiding the University’s resumption of research more generally. The COVID-19 webpage of the Human Subjects Division website will soon describe these stages for human subjects research. These phases may be more conservative than many researchers might prefer, because (1) research participants are volunteers; (2) many studies do not provide direct benefit to individual participants; and (3) it is difficult to ascertain risks due to COVID-19 at a location because there are so many unknowns.

The transition of human subjects research from one phase to another will likely occur at the same time as for non-human subjects research.

Like all UW research, human subjects research may need to return to an earlier, more restricted phase if warranted by epidemiological and healthcare utilization data.

The UW IRB expects to see some new types of information in IRB applications. This includes: (1) the possible sources of COVID-19 infection risk and how it will be managed for research participants and researchers who will conduct allowable research; (2) a description of the involvement of any public health authority in the design, direction, coordination, or conduct of the research as well as how a public health authority (if any) plans to use the data for any of its decision making; and (3) the specific rationale for selecting any remote video or audio technology for interacting with participants, including information about the vendor’s privacy practices and policy about selling information to third parties.

The UW IRB has adopted different priorities for which applications are reviewed first during the pandemic. Top priority is given to any COVID-19-related research and to modifications that are necessary to eliminate in-person research procedures or replace them with remote procedures. This is followed by non-COVID-related research that is allowed by the criteria of the current phase. Research that cannot occur in the current phase will be reviewed last.
WHAT DO I NEED TO DO?

1. Review the [HSD COVID-19](#) webpage to identify the current phase and what type of research is currently allowed.

2. Determine whether there are any restrictions or requirements for human subjects research at your specific research location. For example, research that is currently allowed on the UW campus or at UW Medicine facility may not currently be allowed in another country or in a different local institution.

3. Obtain the best available information about your specific study population and the risks of serious COVID-19 symptoms or COVID-19-related fatalities, compared with the general population in your general research location. Example sources: local health authorities webpages or news releases; scientific literature; CDC webpages. This may be difficult or impossible for research locations with little testing capacity, minimal mandatory reporting and other public health structures, and resource-challenged health care systems.

4. **Identify the specific sources of COVID-19-related risks for your research participants.** Specific issues to consider include:
   - Requirements for close interaction or physical contact of participants with your study team or with other participants (e.g., a blood draw or physical exam)?
   - The feasibility of social distancing.
   - The availability of appropriate personal protective equipment (PPE).
   - Likelihood that your study team members are infectious.
   - The availability of advance viral testing, symptom checks, and/or serological testing before participant interactions.
   - Equipment or other items that will be used with multiple participants (e.g., a virtual reality headset, a computer-administered questionnaire, or a sensing device).
   - What surfaces will be touched by participants, including items at the research location (e.g., chairs, desktop, research equipment & devices, elevator buttons, doorknobs).
   - The availability and frequency of disinfection and cleaning procedures for surfaces, hands, etc.
   - The number of times interaction is required for each participant.
   - The method of transportation that will be used by the participants to get to the research location (e.g., driving versus taking the bus).

5. **Develop plans for reducing or eliminating the risks,** as feasible for your research location. This should include consideration of any protections already available at the location.

6. Obtain documentation (e.g., email) that describes the specifics of any involvement of a public health authority, if you think your work is public health surveillance in addition to (or instead of research). This should include: a brief description of their role (e.g., design; coordination; direction); whether they plan to use the data to make decisions; and if yes, when and for what purpose. This is important because it has a significant impact on the type of IRB review required (if any). Note that NIH is rarely considered to be acting as a public health authority, even for research about COVID-19.

7. **If the research procedures includes testing participants for SARS-CoV-2 or serological antibodies,** identify any restrictions or requirements that apply. For example, Washington State has mandatory reporting of a positive or presumptive positive SARS-CoV-2 result to public health authorities but they may not accept results that come from a lab not certified by the federal CLIA program or state equivalent. If you obtain positive results, who must you tell? Who are you allowed to tell? Who is allowed/required to tell the participant?

8. Do not include information about the risks of COVID-19 in the consent form or process, unless the research involves intentionally exposing the participants to the virus or to individuals known to be infectious.

RESOURCES

> Human Subjects Division webpage: [COVID-19 and Human Subjects Research](#)
> [CDC COVID-19 webpage](#)
> [Public Health Seattle-King County COVID-19 webpage](#)