CHECKLIST for Human Subjects Research During the COVID-19 Pandemic

PURPOSE
This Checklist is a tool to assist researchers by listing all UW and Human Subjects Division requirements for actions to take before conducting research during the current stage of the COVID-19 pandemic. It applies to ongoing research as well as to halted research that is resuming. HSD will update this Checklist in near-real-time as new or revised HSD or campus-wide requirements are implemented. This is not intended to be part of an IRB application.

1. In-person interactions. Identify the minimal number of in-person interactions with participants that are essential for the research purpose and that cannot be postponed or occur in some other way. Example: Are all the originally-planned interim measurements during a clinical trial intervention necessary to adequately monitor safety or to assess the study endpoints or the effectiveness of the intervention?

2. Allowable research. Determine whether the research fits into one or more of the currently allowed categories described on the HSD COVID-19 webpage.

3. Location-specific restrictions and requirements. Identify any restrictions or requirements at the specific research location, and how to meet them. UW Medicine clinical facilities and settings: Researchers should review communications from UW Medicine and School of Medicine leadership for information about resuming research in clinical facilities and settings and/or check with specific clinic managers.

4. Participant population. Obtain the best available current information about the study population and the risks of serious COVID-19 symptoms or COVID-related impairments (e.g., kidney damage) and fatalities, compared with the general population. As appropriate while considering the research purpose, modify the nature of the participant population, or the inclusion/exclusion criteria, to reduce the number of high-risk participants. Examples: It may be possible (depending on the research purpose) to exclude individuals above a certain age, or with specific diagnosed medical conditions.

5. COVID-19-related risks. Identify the specific sources of COVID-19 related risk for the study participants. Issues to consider:
   - Participant interactions: How many? How long? Do any involve close interaction or touching?
   - Research equipment/devices that will be used by multiple participants: Extraordinary care should be taken to disinfect these items, if they are not disinfected as part of a clinical care facility procedure. Examples: Virtual reality headset, computer used to administer a questionnaire, a sensing or measurement device.
   - The research space (facilities/settings): Is physical distancing possible? Will there be individuals in the space who are not the participants or study team members? What surfaces will be touched by participants and will need to be disinfected after each participant? Examples: Chairs, desktop, research equipment and devices, doorknobs, elevator buttons.
   - Good hygiene: What is the availability of hygiene measures such as handwashing facilities?
   - Personal protective equipment (PPE): Will sufficient and appropriate PPE be available? NOTE: It is expected that study team members and research participants will all wear face coverings (“protective” level rather than cloth; see this GUIDE), except for the rare research procedures that are incompatible (e.g. dental exam).
   - Transportation of participants: How will they get to the research location? HSD strongly discourages studies from allowing participants to use mass transit. It should be allowed only under exceptional circumstances.
   - Consent form information: HSD strongly discourages putting COVID-related risk information in consent forms unless it is directly relevant to the study procedures (e.g., the study involves deliberate exposure of participants).
6. **Participant infection.** Avoid all participants with confirmed or presumptive positive COVID-19 or SARS-CoV-2 infection or requiring potentially aerosolizing procedures, unless this is the focus of the study. This requirement typically involves a screening protocol.

7. **Risk mitigation plan.** Develop and implement a plan for reducing or eliminating the COVID-19-related risks, as feasible for the research participants and location. This should include consideration of any protections already available at the location. The Office of Research has several GUIDES available that will be helpful (see item 13 below). Example: A face covering may be routinely handed out to anyone arriving at a clinical facility as part of the facility’s standard policy.

8. **Involvement of a public health authority.** If a public health authority is involved in the activity and you with the IRB to consider the possible regulatory effect of this involvement: Provide the IRB with documentation that describes the specifics of the involvement. 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 significant for the type of IRB review required (if any). Note that NIH is rarely considered to be acting as a public health authority, even for activities related to COVID-19.

9. **Testing for SARS-CoV-2 or serological antibodies.** If the participants will be tested for screening or research purposes: Identify any restrictions or requirements that apply. If there are positive results, who must you tell? Who are you allowed to tell? Who is allowed/required to tell the participants? This is a challenging issue that is subject to state mandatory reporting requirements as well as federal and state laboratory certification requirements.

10. **Face coverings and physical distancing.** Study team members and research participants must wear surgical/medical/procedure face coverings (not cloth coverings) during all in-person interactions, except when not possible due to the nature of a specific research procedure. All interactions must occur per standard physical distancing guidelines, except when not possible due to the nature of a specific research procedure. See this UW GUIDE for information about the proper use of face coverings. While the guide references a shortage of this type of covering, the UW has recently established supply arrangements.

11. **Other IRBs.** If the research is being reviewed by a non-UW IRB (external IRB) instead of the UW IRB: For local non-commercial IRBs, follow the requirements of the local IRB. Examples: Fred Hutch IRB, Seattle Children’s IRB. Otherwise, follow the requirements of the UW Human Subjects Division and IRB.

12. **Non-UW sites reviewed by the UW IRB.** If the UW IRB is reviewing non-UW sites in addition to the UW: The non-UW sites should follow the requirements of their own institution.

13. **Other applicable restrictions and requirements.** Identify and address any. Examples: ITHS COVID Portal review; Institutional Biosafety Committee review of handling COVID-positive specimens; UW travel restrictions.

14. **Complete the University’s generic requirements** for Returning to In-Person Research. Note that some of these elements are required by the state Department of Labor and Industries as part of allowing staff to resume work.
   1. Review the document entitled Requirements and Responsibilities for Returning to In-Person Research
   2. Complete the activities on the Checklist for Developing a Return to In-person Research Plan
   3. Make use of the topic-specific GUIDES available at the website. They include:
      - Plan for On-site Facilities and Social Distancing
      - PPE/Facemask Use
      - Cleaning and Disinfecting Your Workplace
      - Personal Hygiene and Hand-washing
      - Reporting of Infection and Exposure

15. **Fulfill any requirements of the dean-level unit** (e.g., School of Medicine, College of Arts & Sciences).