

PURPOSE

This tool is used by researchers to self-determine whether their (1) new or currently-halted IRB-approved or exempt human subjects research or (2) planned modification that might affect a study's COVID risks is allowable under current UW Office of Research and Human Subject Division (HSD) guidelines during the COVID-19 pandemic. It will be revised as information continues to develop and as pandemic conditions change. **Do not send this completed tool to HSD and do not upload it to your Zipline application.** Contact HSD at hsdinfo@uw.edu with any questions.

CONTEXT

The outcome of this tool is valid only if researchers follow all current [UW requirements and guidelines](#) about general infection control and risk mitigation AND the assumptions listed on the next page apply to your research.

INSTRUCTIONS

1. **Determine need for this tool.** Determine whether the study fits into the allowed Categories 1, 2, or 3 as described on the [HSD COVID-19 website](#). If yes, then this tool is not needed (even for modifications). If no, then use this tool.
2. **Calculate the COVID-19 risk score.** Use the table to rank the study or modification on each COVID-19 risk factor.
3. **Evaluate the Total Relative Risk score.** Sum the scores to create the Total Relative Risk Score. Compare it against the current allowed score range to determine whether the research or modification can proceed.
4. **Consider ways to reduce risk.** If the research or modification is not currently allowed, consider whether the research can be modified to reduce the score on any of the risk factors and thereby lower the total score into the currently allowable range. This will usually require a modification, if you are using this tool to assess an already-approved study that has been halted since mid-March.
5. **Requesting an exception.** Contact hsdinfo@uw.edu to request an exception if your score is above the allowable range and your research or modification will include additional participant protections not recognized by this scoring system.
6. **Save this for study records.** HSD recommends that this tool be completed and saved as part of the research records. It may be useful for responding to questions from funding agencies, journal reviewers, and conference organizers.
7. **Changes to the scores, risk factors, or threshold total score.** HSD does not intend to frequently revise this tool. Changes will be made only when there is significant new public health information or confirmed peer-reviewed scientific data. Any changes will be widely announced through the usual campus channels (e.g., HSD eNewsletter; MRAM meeting & newsletter; email to Associate/Vice Deans for Research). Researchers will then be expected to re-evaluate their research to determine whether the changes affect the allowability of their research. HSD recognizes the profound disruption caused by halting ongoing research and would require future halts only if truly warranted by changes in conditions or information that are also affecting other University operations.

UW RESEARCH REVIEWED BY AN EXTERNAL IRB

When the external IRB is a **local non-commercial IRB** (e.g., Fred Hutch, Seattle Children's): Follow the requirements and policies of that IRB as to which research can resume and under what conditions.

For **all other external IRBs**: For domestic research locations (i.e., U.S. locations), only research allowed by HSD as described in this tool may resume or begin.

INTERNATIONAL RESEARCH

For international research locations where a local IRB has provided review: The research may proceed if it is allowed by the local IRB. If a local IRB has not provided review, contact hsdinfo@uw.edu.

NON-UW INSTITUTIONS REVIEWED BY THE UW IRB

These sites should follow the policies and requirements of their own institution. This means that the research may be allowed at some locations but not at others.

COVID-19 RELATIVE RISK TOOL

Use this tool only if your study does not fit into [Categories 1, 2, or 3](#). See [important explanatory footnotes](#) below this page.

IMPORTANT ASSUMPTIONS: *First, make sure these assumptions apply to your research or modification*

- **Essential in-person interactions.** The only in-person interactions are those that cannot be adequately accomplished through a remote method such as a phone call, video conference (e.g., Zoom), email, etc.
- **Face coverings.** Study team members and participants wear face coverings throughout all procedures. HSD and UW infection control experts strongly recommend the use of surgical, medical/procedure, or N95 masks, instead of cloth coverings, during participant interactions. If cloth coverings are used, they should meet the [requirements](#) described by UW EH&S for effectiveness. [Good fit](#) of face coverings is vital.
- **COVID-19 screening.** All study staff and participants are screened for COVID-19 just prior to each research visit. This means: (1) questions about symptoms and/or attestation that [symptoms](#) have not been experienced recently or currently and (2) they are not under self-isolation for COVID-19, self-quarantine for COVID-19 exposure, or have pending testing for the SARS-CoV-2 virus. Temperature measurement alone is not considered an adequate screening method. **Just prior to** means upon arrival or in the preceding 24 hours.
- **Participant age.** No participants over the age of 85 years will be enrolled if their in-person participation is not connected with a clinical care visit. Contact hsdinfo@uw.edu if your research cannot comply with this requirement.

FACTOR 1 COVID-19 activity in the general geographic location of research, as measured by key indicators.¹ If your research will occur in both types of locations, complete this tool separately for each. Study score

Countries with upper-middle or high-income economies¹ (e.g., USA, Europe) For King County, see this [county data dashboard](#)

Decreasing (0) Flat (2) Increasing (4)

Countries with low or lower-middle income economies¹ (e.g., almost all African countries)

Decreasing (0) Flat (2) Increasing (6)

FACTOR 2 Participant age in years.² Click the age ranges that will collectively include most (say, 2/3 or more) of your population. The tool will automatically calculate the appropriate score. Study score

- 0 – 29 (0)
- 30 – 39 (1)
- 40 – 49 (2)
- 50 – 64 (3)
- 65 – 74 (4)
- 75 – 85 (6)

FACTOR 3 Research focuses on a medical condition that is associated with a higher risk of severe COVID-19 illness³ AND participants must make a research-specific trip to participate. Study score

- No (0)
- Risk evidence is limited (2)
- Risk evidence is stronger but mixed (3)
- Risk evidence is strong and consistent (6)

FACTOR 4 Physical distancing⁴ Study score

Note: Consult with HSD at hsdinfo@uw.edu if the study involves significant additional precautions (e.g., significant additional PPE) that may balance out this risk.

- During the entire visit, or for entire visit <15 minutes (0)
- Physical distancing not possible for 15 – 30 minutes total per visit (3)
- Physical distancing not possible for >30 minutes (6)

FACTOR 5 Number of people interacting with the participant at a distance of less than 6 feet for >15 minutes total during a visit.⁵ Study score

- 1 per visit (0)
- 2 per visit (2)
- 3 per visit (6)

TOTAL RELATIVE RISK SCORE⁶

Possible range: 0 – 30

Effective August 12, 2020: The research is allowed if the total score is **0 – 18⁶**

Requesting an exception. Contact hsdinfo@uw.edu to request an exception if your score is above the allowable range and there are participant protections that are not recognized by this scoring system.

FOOTNOTES

1. Risk factor 1: COVID-19 activity in general geographic location of the research, as measured by current key indicators

This refers to the current epidemiological status of the pandemic as assessed by public health authorities. Some areas or countries may have few current indicators. In these cases, researchers are expected to search for available data and to draw upon their knowledge and connections in the area to come up with the best possible understanding of the pandemic trend in the area.

Income of economies. The equivalent pandemic status is weighted more heavily for LMIC (low income and lower middle income countries) because they are less likely to have access to infection control procedures (e.g. widespread testing) and COVID treatments and advanced care (e.g., ventilators, extracorporeal mechanical oxygen), which increases the risk of poor COVID-related outcomes for participants. This [World Bank website](#) has a spreadsheet that categorizes the economy of each country.

Location could appropriately mean a city, county, state, or country, depending on the research.

Current means in the past two weeks or so. The intent is to understand the trend in the pandemic status currently and the recent past.

Key indicators are standard epidemiological measures of COVID-19 activity. The best measure is the trend in the Effective Reproductive Number (Re) or the trend in positivity rate of tested samples. If not available, other possibilities include: trends in number of reported cases (within the context of the amount of testing performed); percent of occupied hospital beds; proportion of hospital beds filled with COVID-19 patients. When there are multiple available key indicators, researchers should rely on the Effective Reproductive Number, trend in positivity rate of tested samples, and/or any general official statements about current pandemic trend from the relevant public health authorities. Phases of re-opening are not considered a key indicator.

2. Risk factor 2: Participant age

This information is drawn from the U.S. Centers for Disease Control & Prevention (CDC) COVID-19 website. The weights for each age range are based on the percentages of likely severe disease for each range.

Multiple age ranges in a study should be scored as follows: (1) identify the age ranges that are expected to include at 2/3 or more of the study population, based on the researcher's knowledge of the target population (e.g., local patients with chronic kidney disease; UW students; individuals at risk for HIV or who are HIV-positive in Kenyatta); (2) the tool will automatically average the scores for the age ranges you have identified.

Participants over 85 years of age. Select the range 75-85, if you will have participants over 85 but who are participating in connection with a clinical care visit.

3. Risk factor 3: Research focuses on a participant medical condition that is associated with a higher risk of severe COVID-19 illness AND participants must make research-specific trip to participate

The purpose of this factor is to consider the additional risk created when an individual with a medical condition known to be associated with an increased risk of serious COVID-19 symptoms must make a research-specific trip to a research location (as distinct from participating in research procedures conducted in association with a clinical hospitalization or outpatient care visit).

Medical condition means the [conditions identified by the CDC](#) as increasing the risk for severe COVID-19 symptoms. The CDC categories the conditions into three groups on the basis of the quality and consistency of the evidence for an increased risk. This list is complete and current as of July 28, 2020; consult the [CDC website](#) for the most up-to-date information.

Conditions for which the **evidence is limited:**

- Bone marrow transplantation
- HIV
- Immune deficiencies
- Inherited metabolic disorders
- Neurologic conditions not mentioned below
- Other chronic lung diseases not mentioned below

Conditions for which the **evidence is stronger but mixed:**

- Asthma
- Cerebrovascular disease
- Hypertension
- Pregnancy
- Smoking

Conditions for which the **evidence is strong and consistent:**

- Cancer

- Chronic kidney disease
- COPD (chronic obstructive pulmonary disease)
- Immunocompromised state (weakened immune system) from solid organ transplant
- Obesity (body mass index (BMI) of 30 or higher)
- Serious heart conditions, such as heart failure, coronary artery disease, or cardiomyopathies
- Sickle cell disease
- Type 2 diabetes mellitus

4. **Risk factor 4: Physical distancing.** This means a distance of at least 6 feet between the participants and other individuals. Note that physical barriers such as plexiglass shields have not been proven to prevent transmission in the absence of Personal Protective Equipment and short durations of interactions. These scores are based on current CDC recommendations that risk is elevated when individuals are separated by less than 6 feet for 15 minutes or more. *Remember, all participants should be wearing face coverings regardless of the physical distance.*

Visit means a set of research procedures that are linked together in time. Example: Three blood draws taken every 4 hours while a participant is in a room is considered a single visit.

5. **Risk factor 5: Number of people interacting with the participant at a distance of less 6 feet for >15 minutes total during a visit.** This risk factor and the scores are an approximation drawn from Appendix G of the JASON Report (reference provided below).

People means study team members, but it also includes other participants. Do not include individuals who are already interacting with participants for other reasons (e.g., clinical care providers; teachers) and who may also conduct research procedures

Visit means a set of research procedures that are linked together in time. Examples: Three blood draws taken every 4 hours while a participant is in a room is considered a single visit.

6. **Total Relative Risk Score**

The allowable range is necessarily a somewhat subjective value. HSD managers and IRB members evaluated the total score for dozens of possible research scenarios against collective public health recommendations, our collective detailed knowledge of the specific logistics of the scenarios, and group consensus of what made sense. HSD recognizes that it may be appropriate to conduct some research with a score above the allowable range if the researcher has implemented additional, specific participant protections; therefore, a mechanism for requesting an exception has been established. Contact hsdinfo@uw.edu.

A **Total Relative Risk Score** that is in the allowable range does not mean that there are no COVID-related risks. Instead, it means that the risks are being managed appropriately, based on current information and best practices.

How This Tool Was Developed

The University of Washington (UW) Human Subjects Division (HSD) drafted this tool, drawing upon recent peer-reviewed scientific consensus knowledge about COVID-19 and the SARS-CoV-2 virus. Key sources also included:

- The JASON Report “Managing the Risk from COVID-19 During a Return to On-Site University Research”, published online July 2, 2020 (JSR-20-NS1).
- “COVID-19 Literature Situation Report”, a daily newsletter prepared by the UW MetaCenter for Pandemic Preparedness and Global Health Security and the START Center, in collaboration with and on behalf of the Washington State Department of Health. One purpose of the report is to support evidence-based decision making throughout the region.
- The U.S. Centers for Disease Control & Prevention (CDC) COVID-19 website
- The UW COVID-19 resources website <https://www.washington.edu/coronavirus/coronavirus-resources/>
- The UW Environmental Health & Safety COVID-19 Health and Safety Resources website <https://www.ehs.washington.edu/covid-19-health-and-safety-resources>

Weights (the scores) were assigned by drawing inferences about the relative importance of virus transmission and disease morbidity factors; they are necessarily somewhat subjective and may change as additional information is published.

Feedback and vetting were provided by the UW Advisory Committee on Contagious Diseases, Office of Research leadership, and key faculty experts in infectious diseases and in research administration.

Contact Karen Moe kemoe@uw.edu with questions or comments.