

## Risk Matrix for Assessing In-person Human Subjects Research

Three dimensions of risk are considered: 1) population, 2) location and 3) activity. In the table below, population risk is on the X axis and location is on the Y axis. Activity is addressed in each cell of the matrix; characteristics of activity risk are provided below the matrix.

### Abbreviations:

SD – Social distancing

PPE – Personal Protective Equipment

CxC – Case by case

<p><b>POPULATION RISK CHARACTERISTICS</b> →</p> <p><b>LOCATION RISK CHARACTERISTICS</b> ↓</p>	<p><b>LOWEST RISK</b> <i>Healthy adults, 18-65</i> Not COVID vulnerable Understands SD Able to wear PPE Not reliant on assistance of others Not socio/eco disadvantaged Does not live in dense housing Has access to health care</p>	<p><b>MODERATE RISK</b> Some vulnerability</p>	<p><b>HIGHEST RISK</b> COVID-vulnerable Age, immune system, cognitive function, socio-eco disadvantaged, high-risk ethnic minority Not able to SD Not able to wear PPE Relies on assistance of others Lives in dense housing Uncertain health care</p>
<p><b>LOWEST RISK</b> KU-controlled space SD can be maintained Sufficient waiting areas Controllable entrance/exit Barriers available Surfaces can be disinfected Participants can get to and from location alone Local COVID incidence not greater than Douglas County</p>	<p><b>Low-Risk Population</b> <b>Low-Risk Location</b></p> <p>Low-Risk Activity <b>OK</b></p> <p>Moderate-Risk Activity <b>CxC</b></p> <p>High-Risk Activity <b>Not Phase 1</b></p>	<p><b>Moderate-Risk Population</b> <b>Low-Risk Location</b></p> <p>Low-Risk Activity <b>CxC</b></p> <p>Moderate-Risk Activity <b>CxC</b></p> <p>High-Risk Activity <b>Not Phase 1</b></p>	<p><b>High-Risk Population</b> <b>Low-Risk Location</b></p> <p>Low-Risk Activity <b>Not Phase 1 or 2</b></p> <p>Moderate-Risk Activity <b>Not Phase 1 or 2</b></p>
<p><b>MODERATE RISK</b></p>	<p><b>Low-Risk Population</b> <b>Moderate-Risk Location</b></p> <p>Low-Risk Activity <b>CxC</b></p> <p>Moderate-Risk Activity <b>CxC</b></p> <p>High-Risk Activity <b>Not Phase 1</b></p>	<p><b>Moderate-Risk Population</b> <b>Moderate-Risk Location</b></p> <p>Low-Risk Activity <b>CxC</b></p> <p>Moderate-Risk Activity <b>CxC</b></p> <p>High-Risk Activity <b>Not Phase 1</b></p>	<p><b>High-Risk Population</b> <b>Moderate-Risk Location</b></p> <p><b>NOT Phase 1 or 2</b></p>
<p><b>HIGHEST RISK</b> Area of high virus incidence Area of dense population Area of frequent public use Location not controlled by KU Difficult ingress/egress Poor ventilation Cramped facilities, SD not possible Space cleanliness uncertain Space difficult to disinfect</p>	<p><b>Low-Risk Population</b> <b>High-Risk location</b></p> <p>Low-Risk Activity <b>Not Phase 1</b></p> <p>Moderate-Risk Activity <b>Not Phase 1</b></p> <p>High-Risk Activity <b>NOT Phase 1 or 2</b></p>	<p><b>Moderate-Risk Population</b> <b>High-Risk Location</b></p> <p><b>NOT Phase 1 or 2</b></p>	<p><b>High-Risk Population</b> <b>High-Risk Location</b></p> <p><b>NOT Phase 1 or 2</b></p>

## ACTIVITY RISK CHARACTERISTICS

<b>LOWEST RISK</b>	<p>No direct contact required          KU or collaborating institution has approved building for increased occupancy, which meets CDC recommendations for SD and cleanliness          8-foot radius of SD can be maintained throughout activity, per person          Items can be exchanged asynchronously          Masks can be worn by all parties          No use of items handled by multiple people          No eating or drinking          No groups          Short duration per participant, &lt;15 min</p>
<b>MODERATE RISK</b>	
<b>HIGHEST RISK</b>	<p>Direct contact required          Building has not been approved for increased occupancy or space does not meet CDC recommendations for SD and cleanliness.          More than momentary close contact required          Specimen collection          Breathing hard or prolonged speaking at close range          Difficult-to-clean surfaces will be touched          Objects others have used will be touched          Eating or drinking is involved          Group activity          Long duration, &gt;30 minutes</p>

## PROPOSED Phase 1 minimum requirements for resumption of in-person human subjects research

### Study team preparation prior to conducting research

- All team members have taken Environment, Health & Safety (EHS) "COVID-19 Return to Work Safety 101" training on KU MyTalent site
- All team members trained on protocol safety and documentation procedures
- KU or local institution has approved space for increased occupancy, consistent with CDC guidelines for SD and cleanliness
- PI has adequate supply of masks, gloves, other PPE as required
- PI has adequate supply of disinfection agents and supplies, including soap/sanitizer
- Adequate space to maintain SD given number of individuals in the space has been checked/measured (including waiting/lobby areas)
- Plan to clean and disinfect objects and surfaces as well as flooring and soft surfaces
- Plan to control flow of participants/bystanders
- Plan for safe arrival and departure
- Plan for addressing team illness, participant illness

### On site

- CDC guidelines for SD and space maintenance are met
- All parties must wear cloth masks
- Appropriate PPE/hand washing/sanitizing for activity
- Must screen participants, team for COVID-19 symptoms and follow safety protocol for anyone with symptoms
- Frequent disinfection of high-touch areas and between-subjects cleaning as appropriate
- Groups are kept to minimum size necessary for research, 10 or fewer total researchers and participants, with appropriate PPE and SD
- Study team documents adherence to safety protocols