

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>POPULATION RISK CHARACTERISTICS →</p> <p>LOCATION RISK CHARACTERISTICS ↓</p>	<p>LOWEST RISK <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>MODERATE RISK Some vulnerability</p>	<p>HIGHEST RISK 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>LOWEST RISK 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>Low-Risk Population Low-Risk Location</p> <p>Low-Risk Activity OK</p> <p>Moderate-Risk Activity CxC</p> <p>High-Risk Activity Not Phase 1</p>	<p>Moderate-Risk Population Low-Risk Location</p> <p>Low-Risk Activity CxC</p> <p>Moderate-Risk Activity CxC</p> <p>High-Risk Activity Not Phase 1</p>	<p>High-Risk Population Low-Risk Location</p> <p>Low-Risk Activity Not Phase 1 or 2</p> <p>Moderate-Risk Activity Not Phase 1 or 2</p>
<p>MODERATE RISK</p>	<p>Low-Risk Population Moderate-Risk Location</p> <p>Low-Risk Activity CxC</p> <p>Moderate-Risk Activity CxC</p> <p>High-Risk Activity Not Phase 1</p>	<p>Moderate-Risk Population Moderate-Risk Location</p> <p>Low-Risk Activity CxC</p> <p>Moderate-Risk Activity CxC</p> <p>High-Risk Activity Not Phase 1</p>	<p>High-Risk Population Moderate-Risk Location</p> <p>NOT Phase 1 or 2</p>
<p>HIGHEST RISK 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>Low-Risk Population High-Risk location</p> <p>Low-Risk Activity Not Phase 1</p> <p>Moderate-Risk Activity Not Phase 1</p> <p>High-Risk Activity NOT Phase 1 or 2</p>	<p>Moderate-Risk Population High-Risk Location</p> <p>NOT Phase 1 or 2</p>	<p>High-Risk Population High-Risk Location</p> <p>NOT Phase 1 or 2</p>

ACTIVITY RISK CHARACTERISTICS

<p>LOWEST RISK</p>	<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, <15 min</p>
<p>MODERATE RISK</p>	
<p>HIGHEST RISK</p>	<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, >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