Risk matrix for assessing in-person human subjects research

(Based on the Risk Matrix developed at UC Santa Barbara and modified for our ramp-up tiers)

Risk assessment is based on 1) Participants + 2) Location + 3) Activity (see p.3 below). The combination of all three risk levels, determines if the study could take place during the Orange tier of UCR research ramp-up plan.

Table 1: Risk Matrix
(color code: allowed, allowed only if direct benefit to participant, not allowed)

<table>
<thead>
<tr>
<th>LOCATION RISK</th>
<th>PARTICIPANT RISK</th>
<th>HIGHER RISK = any of the following</th>
</tr>
</thead>
<tbody>
<tr>
<td>MINIMAL RISK</td>
<td>Lower Risk Activity OK in all ramp-up tiers</td>
<td>Lower-Risk Activity NOT ALLOWED in Orange Tier</td>
</tr>
<tr>
<td></td>
<td>Lower Risk Activity OK in all ramp-up tiers</td>
<td>Moderate-Risk Activity NOT ALLOWED in Orange Tier</td>
</tr>
<tr>
<td></td>
<td>Lower Risk Activity NOT ALLOWED in Orange Tier</td>
<td>Higher-Risk Activity NOT ALLOWED in Orange Tier</td>
</tr>
<tr>
<td>LOWER RISK</td>
<td>Lower-Risk Activity OK in Orange Tier</td>
<td>Lower-Risk Activity NOT ALLOWED in Orange Tier</td>
</tr>
<tr>
<td></td>
<td>Moderate-Risk Activity Allowed in Orange Tier only if there is a Direct Benefit to participants</td>
<td>Moderate-Risk Activity NOT ALLOWED in Orange Tier</td>
</tr>
<tr>
<td></td>
<td>Higher-Risk Activity NOT ALLOWED in Orange Tier</td>
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</tr>
</tbody>
</table>
### Table 2: Activity Risk Characteristics

<table>
<thead>
<tr>
<th>Minimal Risk</th>
<th>- Activity conducted entirely remotely</th>
</tr>
</thead>
</table>
| **Lower Risk** | - No direct contact required  
- One-on-one interaction, with no groups  
- Physical distancing can be maintained throughout activity (meaning at least 6 feet of separation, with 9 feet preferred)  
- Face coverings can be worn by all parties and at all times during the research activity  
- Short duration per participant, < 15 minutes with physical distancing;  
  - or long duration interventions of up to an hour where the subject stays in a room by themselves;  
  - or interventions requiring close contact (< 6 feet) with participant, with mask, and are only momentary |
| **Moderate Risk** | - Interaction is between 15 - 30 minutes with physical distancing  
- Interactions requiring close contact (< 6 feet) with participant, with mask and face shield required if more than momentary, but less than 10 minutes  
- Any other activity not clearly in Minimal/Low or High Risk categories  
- May involve small groups (< 10), with physical distancing and masking  
- No use of items handled by multiple people, without disinfection or 72 hrs between use |
| **Higher Risk** | - Close contact (< 6 feet) requires more than 10 minutes of interaction with participant  
- Specimen collection (with appropriate PPE and training, blood collection risk may be considered low)  
- Involves generation of aerosols, breathing heavy, or prolonged speaking, and physical distancing and masking cannot be maintained at all times (< 9 feet)  
- Difficult to clean surfaces will be touched  
- Objects others have used will be touched (excludes objects that have been disinfected or not handled for 72 hours between participants)  
- Eating or drinking is involved  
- Group activity (10 or more people)  
- Long duration per participant, > 30 minutes with physical distancing |

**Abbreviations:**  
PD - Physical Distancing  
FC - Face Covering/Mask  
PPE - Personal Protective Equipment
Tips on using the matrix

1. Minimal risk activities are always allowed (with regular IRB approval). For the rest use the following procedure.
2. Review the Participant Risk cells in Table 1 (top row) and identify the highest Participant Risk that applies to your study. For example, if your study involves working with children (moderate risk) who cannot wear facial coverings (high risk), the Participant Risk level for your study would be Higher Risk.
3. Review the Location Risk cells in Table 1 (first column) and identify the highest Location Risk that applies to your study. For example, if your study involves working inside a UCR building (low risk) but physical barriers are not available/practical, the Location Risk level for your study would be Moderate Risk.
4. Review the Activity Risk Characteristics in Table 2 (this page) and identify the highest risk that applies to your study. For example, if your study can be done without any direct contact with participants and you will spend less than 15 minutes with each participant, the Activity Risk level for your study would be Lower Risk.
5. Go back to Table 1 and find the cell that corresponds to the maximum Participant and Location risk level for your study. Based on the examples given in Steps 1 & 2, this would be the cell labeled as Higher-Risk Participant, Moderate-Risk Location.
6. Within the cell that you have identified, find the Activity Risk level that corresponds to the maximum Activity Risk level for your study. Based on the example given in Step 3, this would be the option labeled as Lower-Risk Activity. The wording under that risk level will indicate if that risk level is eligible for review in the current stage of the research ramp-up. In this example it says NOT ALLOWED in Orange Tier and, hence, this study will not be permitted as designed.