

# 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)

Revision in place starting June 29, 2021

Risk assessment is based on 1) Participants + 2) Location + 3) Activity (see p.2 below).

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

| LOCATION RISK*   | PARTICIPANT RISK  |   |   |
|--|---|---|---|
|  | <b>LOWER RISK = all of the following, if applicable</b><br>- Healthy adults, 18-65<br>- Fully vaccinated individuals**<br>- Not <a href="#">COVID-19 vulnerable</a><br>- Able to wear FC or PPE<br>- Able to consent on their own | <b>MODERATE RISK</b><br>- Some vulnerability (anything not clearly Low or High Risk)<br>- May involve asymptomatic, unvaccinated children under the age of 12                         | <b>HIGHER RISK = any of the following</b><br>- <a href="#">COVID-19-vulnerable</a> (age, immune system, etc.)<br>- Not able to wear FC or PPE<br>- Profession with high risk of exposure<br>- Adult unable to consent on their own<br>- Does not pass symptom self-screening survey |
| <b>MINIMAL RISK</b><br>- Shelter at home<br>- Only uses remote methods   | <b>Minimal Risk Activity</b><br>OK in all ramp-up tiers   | <b>Minimal Risk Activity</b><br>OK in all ramp-up tiers   | <b>Minimal Risk Activity</b><br>OK in all ramp-up tiers   |
| <b>LOWER RISK</b><br>- UCR indoor space<br>- Surfaces can be cleaned<br>- Sufficient waiting areas<br>- Participants can travel to and from location on their own<br>- Outdoor location where local COVID-19 incidence is no greater than Riverside County | <b>Lower-Risk Activity</b><br>Allowed<br><br><b>Moderate-Risk Activity</b><br>Allowed<br><br><b>Higher-Risk Activity</b><br>Allowed   | <b>Lower-Risk Activity</b><br>Allowed<br><br><b>Moderate-Risk Activity</b><br>Allowed<br><br><b>Higher-Risk Activity</b><br>Allowed   | <b>Lower-Risk Activity</b><br>NOT ALLOWED<br><br><b>Moderate-Risk Activity</b><br>NOT ALLOWED<br><br><b>Higher-Risk Activity</b><br>NOT ALLOWED   |
| <b>MODERATE RISK</b><br>- Anything not clearly Low or High Risk<br>- Indoor off-campus spaces where UCR researchers are working  | <b>Lower-Risk Activity</b><br>Allowed<br><br><b>Moderate-Risk Activity</b><br>Allowed<br><br><b>Higher-Risk Activity</b><br>Allowed   | <b>Lower-Risk Activity</b><br>Allowed<br><br><b>Moderate-Risk Activity</b><br>Allowed<br><br><b>Higher-Risk Activity</b><br>Allowed only if there is a Direct Benefit to participants | <b>Lower-Risk Activity</b><br>NOT ALLOWED<br><br><b>Moderate-Risk Activity</b><br>NOT ALLOWED<br><br><b>Higher-Risk Activity</b><br>NOT ALLOWED   |
| <b>HIGHER RISK</b><br>- Area of high virus incidence<br>- Area with no possibility of social distancing<br>- Indoor location with:<br>- Poor ventilation<br>- High occupancy<br>- Space difficult to disinfect   | NOT ALLOWED independently of Activity Risk Level being Lower, Moderate, or Higher   | NOT ALLOWED independently of Activity Risk Level being Lower, Moderate, or Higher   | NOT ALLOWED independently of Activity Risk Level being Lower, Moderate, or Higher   |

\*While this matrix is based on Cal/OSHA guidelines, researchers should be aware of and are subject to the guidelines of local health authorities in the region where they conduct their research.

\*\*People are considered fully vaccinated 2 weeks after the second dose in a 2-dose series, or 2 weeks after a single-dose vaccine.

**Abbreviations:**

**PD** - Physical Distancing      **FC** - Face Covering/Mask      **PPE** - Personal Protective Equipment

**Table 2: Activity Risk Characteristics**

|                      |   |
|----------------------|---|
| <b>Minimal Risk</b>  | - Activity conducted entirely remotely  |
| <b>Lower Risk</b>    | <ul style="list-style-type: none"> <li>- No direct contact required</li> <li>- One-on-one interaction, with no groups</li> <li>- Activity with only fully vaccinated individuals</li> <li>- Indoor activity with individuals not fully vaccinated in which everyone wears face coverings over the nose and mouth at all times and maintains six feet distance, except for momentary close contact interactions</li> <li>- Activities where the subject stays by themselves in a room or outdoors (no mask required if by themselves)</li> <li>- Outdoor activity with individuals not fully vaccinated and six feet distance maintained (no mask required outdoors if physical distance is maintained)</li> </ul>   |
| <b>Moderate Risk</b> | <ul style="list-style-type: none"> <li>- More than momentary, but less than 10-minute close contact interactions with non-fully vaccinated participants, with mask required</li> <li>- May involve small groups (&lt; 10), with masking</li> <li>- No use of items handled by multiple people, without cleaning between use</li> <li>- Any other activity not clearly in Minimal/Low or High Risk categories</li> </ul>   |
| <b>Higher Risk</b>   | <ul style="list-style-type: none"> <li>- Close contact (&lt; 6 feet) interactions with non-fully vaccinated participants requiring more than 10 minutes of interaction without masks</li> <li>- Specimen collection (with appropriate PPE and training, blood collection risk may be considered low)</li> <li>- Activities involving generation of aerosols, breathing heavy, or prolonged speaking, and physical distancing and masking cannot be maintained at all times (&lt; 9 feet)</li> <li>- Difficult to clean surfaces will be touched</li> <li>- Objects others have used will be touched (excludes objects that have been disinfected or not handled for 72 hours between participants)</li> <li>- Eating or drinking is involved with non-fully vaccinated people</li> <li>- Group activity with non-fully vaccinated people (10 or more people)</li> </ul> |

**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 under 12 years of age (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.
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 only involves fully vaccinated participants and researchers, 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.
6. Within the cell that you have identified, find the Activity Risk level that corresponds to the maximum Activity Risk level for your study. 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. For example if it says **NOT ALLOWED**, the study will not be permitted as designed.
7. This matrix is designed to provide baseline limits; researchers may request further restrictions based on their individual study protocols.