

Risk matrix for assessing in-person human subjects research

Stage 4b - Risk assessment is based on 1) Participants + 2) Location + 3) Activity (p. 2).

The combination of all three risk levels, determines if the study is eligible for review in Stage 4b.

Table 1: Risk Matrix

LOCATION RISK	PARTICIPANT RISK		
	LOWER RISK = all of the following, if applicable - Healthy adults, 18-65 - Not COVID vulnerable - Understands and complies with PD - Able to wear FC or PPE - Able to consent on their own	MODERATE RISK - Some vulnerability (anything not clearly Low or High Risk) - May involve healthy children who are accompanied by a healthy parent/guardian	HIGHER RISK = any of the following - COVID-vulnerable (age, immune system, etc.) - Not able to comply with PD - Not able to wear FC or PPE - Profession with high risk of exposure - Adult unable to consent on their own - Does not pass symptom self-screening survey
MINIMAL RISK - Shelter at home - Only uses remote methods	Minimal Risk Activity OK in all Stages	Minimal Risk Activity OK in all Stages	Minimal Risk Activity OK in all Stages
LOWER RISK - UCSB indoor space - Barriers available - Surfaces can be disinfected - Sufficient waiting areas - Space allows for PD - Participants can travel to and from location on their own - Outdoor location where local COVID incidence is no greater than Santa Barbara County	Lower-Risk Participant Lower-Risk Location Lower-Risk Activity OK Moderate-Risk Activity OK Higher-Risk Activity NOT in Stage 4b	Moderate-Risk Participant Lower-Risk Location Lower-Risk Activity OK Moderate-Risk Activity Only if Direct Benefit Higher-Risk Activity NOT in Stage 4b	Higher-Risk Participant Lower-Risk Location Lower-Risk Activity NOT in Stage 4b Moderate-Risk Activity NOT in Stage 4b Higher-Risk Activity NOT in Stage 4b
MODERATE RISK - Anything not clearly Low or High Risk	Lower-Risk Participant Moderate-Risk Location Lower-Risk Activity OK Moderate-Risk Activity Only if Direct Benefit Higher-Risk Activity NOT in Stage 4b	Moderate-Risk Participant Moderate-Risk Location Lower-Risk Activity Only if Direct Benefit Moderate-Risk Activity NOT in Stage 4b Higher-Risk Activity NOT in Stage 4b	Higher-Risk Participant Moderate-Risk Location Lower-Risk Activity NOT in Stage 4b Moderate-Risk Activity NOT in Stage 4b Higher-Risk Activity NOT in Stage 4b
HIGHER RISK - Area of high virus incidence - Area of dense population - Area of frequent public use - Indoor location with: - Poor ventilation - High occupancy prevents PD - Space difficult to disinfect	Lower-Risk Participant NOT in Stage 4b	Moderate-Risk Participant NOT in Stage 4b	Higher-Risk Participant NOT in Stage 4b

Abbreviations:

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

Table 2: Activity Risk Characteristics

Minimal Risk	- Activity conducted entirely remotely
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
Moderate Risk	- Interaction is between 15 - 30 minutes with physical distancing - Close contact (< 6 feet) with participant required, with mask, and is only momentary - Mask and Face Shield required if more than momentary and < 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 - 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

Tips on using the matrix

1. 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**.
2. 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 UCSB building (low risk) but physical barriers are not available/practical, the Location Risk level for your study would be **Moderate Risk**.
3. 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**.
4. 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**.
5. 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 in Stage 4b** and this study, as designed, would not be eligible for review in Stage 4b.