Identification of Activation Tier following Maximum Mitigation[1]

Activation Tier is identified based on combining the feature of the study that provides the highest Benefit Level to the individual participant in any study arm with the feature of the study that is in the highest Risk Category.

COVID-19 Community Transmission Risk Feature of Study	**Incremental Risk of COVID-19 Community Transmission Category[2]**			
	High	**Medium**	**Low[3]**	**None**
-Contact distance less than versus more than 6 feet -Contact duration less than versus more than 15 minutes -Participant wearing PPE versus not[4] *All UM personnel are required to wear appropriate PPE*	Contact distance is <u>less</u> than 6 feet ***AND*** contact duration is <u>more</u> than 15 minutes ***AND*** participant <u>cannot</u> wear PPE	Contact distance is <u>less</u> than 6 feet ***AND*** contact duration is <u>less</u> than 15 minutes (regardless of whether participant can or cannot wear PPE) ***OR*** Contact distance is <u>more</u> than 6 feet ***AND*** contact duration is <u>more</u> than 15 minutes (regardless of whether participant can or cannot wear PPE) ***OR*** Contact distance is <u>less</u> than 6 feet ***AND*** contact duration is <u>more</u> than 15 minutes ***AND*** participant is wearing PPE ***OR*** Contact distance is <u>more</u> than 6 feet ***AND*** contact duration is <u>less</u> than 15 minutes ***AND*** participant <u>cannot</u> wear PPE	Contact distance is <u>more</u> than 6 feet ***AND*** contact duration is <u>less</u> than 15 minutes ***AND*** participant is wearing PPE	No face-to-face interaction
# contacts between individuals per day[5]		More than 2	1-2	0
Participant characteristics[1]	-Immunocompromised ***OR*** -Known positive COVID-19 test result in past 14 days or new symptoms on COVID-19 health screen			
Benefit Level[6]				
1. Potential immediate benefit to the individual participant that is life-saving, including stabilization of a high risk psychological condition	Tier 0	Tier 0	Tier 0	Tier 0
2. Potential benefit to the individual participant for a condition with no current other intervention options	Tier 1	Tier 1	Tier 1	Tier 0
3. Potential benefit to the individual participant for a condition with existing intervention options	Tier 2	Tier 2	Tier 1	Tier 0
4. No benefit to the individual participant	Tier 3	Tier 2	Tier 1	Tier 0

1 Greater age is associated with greater vulnerability to severe COVID-19. All study activities must be as low risk as possible when with vulnerable participants. If possible, vulnerable individuals should not accompany participants to study visits.

[2] If all face-to-face interaction with study participants occurs *concurrent with* the clinical encounter in Michigan Medicine facilities, *entirely* with Michigan Medicine clinicians (no research staff), the study is classified as Tier 0, regardless of the Risk or Benefit Category.

[3] Studies taking place outdoors will be given special consideration with regard to risk assessment.

[4] All UM researchers ***MUST*** wear PPE. For interactions <6ft for >15min and/or with vulnerable participants , UM researchers must wear mask and face shield. All participants must wear PPE except children 24 months and individuals with health conditions precluding use of PPE. Brief unmasking (<2 min) is permissible if required for study procedures.

[5] Number of contacts includes staff-participant contacts and participant-participant contacts (for group behavior studies). One household is counted as one individual contact. Contact distance, duration, and whether or not the participant is wearing PPE does not change the risk of number of contacts.

[6] Observational, epidemiologic and data analysis-only studies that do not involve therapeutic interventions are classified as Benefit Level 4. Health Services or similar research on interventions intended to change group behavior (e.g., health care providers, teachers) to improve outcomes for individuals (e.g., patients, students) are Benefit Levels 1, 2 or 3.