Public Health Informed Human Research Re-engagement

Human Research Ramp up Committee:
UMOR AVP - Srijan Sen
RAD MED - Steve Kunkel
RAD ISR - Rich Gonzalez
SPH Expert - Emily Martin
MED AD/CTSU - Anna Lok
UMOR AVP and MED Clinical AD - Julie Lumeng
UMOR AVP - Tabbye Chavous
UMOR AVP - Lois Brako
IRB-MED - Judy Birk
IRB-HSBS - Cindy Shindledeker

Information contained within is considered PRELIMINARY and ADVISORY in nature and is not for public reference
U-M Human Research is occurring in a wide and diverse set of locations including but not limited to: MM health system, other health care locations in and out of MI, outdoors in many communities, shelters, schools, domestic, international.

- Clinical Trials
  - Treatment clinical trials
  - Prevention clinical trials
  - Diagnostic clinical trials
  - Screening clinical trials

- Observational studies
  - Cross sectional studies
  - Case-control studies
  - Cohort studies
  - Epidemiologic Studies

- Secondary data analysis

Thus a unifying framework & process to proceed in the time of COVID with Human research is needed
The safety of our researchers and participants is paramount
  ○ Study protocols will be optimized to reduce COVID-19 transmission risk
  ○ Activation (and potential future deactivation) of human research will be guided by infection rates and state guidance
  ○ No undergraduate researchers are allowed to participate in face to face human subjects research at this time
  ○ Graduate students cannot be compelled to participate in research

Tiered study prioritization
  ○ Potential benefit to individual participant
  ○ Incremental risk of COVID-19 transmission
  ○ Existing vs. new study
Benefit to Individual Participant

1. Potential immediate life saving benefit
   ● Subset of treatment clinical trials

2. Potential therapeutic benefit to the individual for conditions **without** current adequate options
   ● Subset of treatment clinical trials
   ● Subset of prevention clinical trials

3. Potential therapeutic benefit to the individual for a condition **with** existing options
   ● Subset of treatment clinical trials
   ● Subset of prevention clinical trials
   ● Subset of diagnostic clinical trials

4. No therapeutic benefit to individual research participant
   ● Subset of diagnostic, screening and clinical trials
   ● Cross-section, case-control, cohort studies
   ● Secondary data analysis studies
<table>
<thead>
<tr>
<th>COVID Community Transmission Risk Feature of Study</th>
<th>Incremental Risk of COVID Community Transmission Category</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Setting</strong></td>
<td>High</td>
</tr>
<tr>
<td>● Indoor without distancing or barriers possible</td>
<td></td>
</tr>
<tr>
<td>OR</td>
<td></td>
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<tr>
<td>● Small room (excluding in clinical setting) OR</td>
<td></td>
</tr>
<tr>
<td>● Indoor with social distancing <strong>OR</strong></td>
<td></td>
</tr>
<tr>
<td>● Indoor with barriers available</td>
<td></td>
</tr>
<tr>
<td>● Outdoor with social distancing <strong>OR</strong></td>
<td></td>
</tr>
<tr>
<td>● Participant alone</td>
<td></td>
</tr>
<tr>
<td><strong>Person-to-person contact type and duration for research purposes (close contact is &lt;6ft for &gt;15 min)</strong></td>
<td>High</td>
</tr>
<tr>
<td>● Close contact or direct contact without PPE. <strong>OR</strong></td>
<td></td>
</tr>
<tr>
<td>● Extended duration of contact (&gt;15min). <strong>OR</strong></td>
<td></td>
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<tr>
<td>● Participants are unable to wear face covering, including children &lt;2y</td>
<td></td>
</tr>
<tr>
<td>● Close contact) with appropriate PPE <strong>OR</strong></td>
<td></td>
</tr>
<tr>
<td>● Brief, direct contact (including phlebotomy) with appropriate PPE</td>
<td></td>
</tr>
<tr>
<td>● Contact from more than 6ft away <strong>OR</strong></td>
<td></td>
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<tr>
<td>● All contacts &lt;15 min or participant alone</td>
<td></td>
</tr>
<tr>
<td><strong>Contact frequency/density of research interactions</strong></td>
<td>High</td>
</tr>
<tr>
<td>● Groups of &gt;10 participants (not including household groups) <strong>OR</strong></td>
<td></td>
</tr>
<tr>
<td>● Staff in close contact with &gt;10 participants per day</td>
<td></td>
</tr>
<tr>
<td>● Groups of 3-10 participants (not including household groups) <strong>OR</strong></td>
<td></td>
</tr>
<tr>
<td>● Staff in close contact with 3-10 participants per day</td>
<td></td>
</tr>
<tr>
<td>● Groups of &lt;3 participants (not including household groups) <strong>OR</strong></td>
<td></td>
</tr>
<tr>
<td>● Staff in close contact with &lt;3 participants per day</td>
<td></td>
</tr>
<tr>
<td><strong>Vulnerable participants</strong></td>
<td></td>
</tr>
<tr>
<td>● Age &gt;65 years <strong>OR</strong></td>
<td></td>
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<tr>
<td>● Immunocompromised <strong>OR</strong></td>
<td></td>
</tr>
<tr>
<td>● Self-identify as being at higher risk of COVID</td>
<td></td>
</tr>
<tr>
<td><strong>COVID Status of Participant</strong></td>
<td></td>
</tr>
<tr>
<td>Known positive COVID test result in past 14 days or symptomatic</td>
<td></td>
</tr>
</tbody>
</table>
## Incremental Risk of COVID Transmission

<table>
<thead>
<tr>
<th>Benefit Level</th>
<th>High</th>
<th>Medium</th>
<th>Low</th>
<th>None</th>
</tr>
</thead>
<tbody>
<tr>
<td>1: Potentially immediately life-saving</td>
<td>Tier 0</td>
<td>Tier 0</td>
<td>Tier 0</td>
<td>Tier 0</td>
</tr>
<tr>
<td>2. Potential therapeutic benefit for a condition with no current other intervention options</td>
<td>Tier 1</td>
<td>Tier 1</td>
<td>Tier 1</td>
<td>Tier 0</td>
</tr>
<tr>
<td>3. Potential therapeutic benefit for a condition with existing intervention options</td>
<td>Tier 2</td>
<td>Tier 2</td>
<td>Tier 1</td>
<td>Tier 0</td>
</tr>
<tr>
<td>4. No benefit to the individual participant</td>
<td>Tier 3</td>
<td>Tier 2</td>
<td>Tier 1</td>
<td>Tier 0</td>
</tr>
</tbody>
</table>
What is the Benefit Level to the Individual Participant?

1: Potential immediate life-saving
2. Potential therapeutic benefit for a condition with no current other intervention options
3. Potential therapeutic benefit for a condition with existing intervention options
4. No benefit to the individual participant
An immunotherapy clinical trial for triple negative breast cancer

1. Potential immediate life saving

2. Potential therapeutic benefit for a condition with no current other intervention options

3. Potential therapeutic benefit for a condition with existing intervention options

4. No benefit to the individual participant

What is the incremental COVID community transmission risk?

Level of Benefit to Participant

Level of Incremental COVID Community Transmission Risk

Study is Existing or New

Tier for Activation

Tier 0 Tier 1 Tier 2 Tier 1 Tier 0 Tier 2 Tier 1 Tier 0 Tier 2 Tier 1 Tier 0 Tier 3 Tier 2 Tier 1 Tier 2 Tier 0
Clinical trial for a medication for treatment-resistant anxiety

1: Potential immediate life saving

2. Potential therapeutic benefit for a condition with no current other intervention options

3. Potential therapeutic benefit for a condition with existing intervention options

4. No benefit to the individual participant

What is the incremental COVID community transmission risk?

Level of Benefit to Participant

Level of Incremental COVID Community Transmission Risk

Study is Existing or New

Tier for Activation
Behavioral task study with undergraduate students as participants

Level of Benefit to Participant

1: Potentially life saving
2. Potential therapeutic benefit for a condition with no current other intervention options
3. Potential therapeutic benefit for a condition with existing intervention options
4. No benefit to the individual participant

Level of Incremental COVID Community Transmission Risk

What is the incremental COVID community transmission risk?

High | Medium | Low | None
---|---|---|---
Existing | New | Existing | New | Existing | New | Existing | New

Study is Existing or New

Tier for Activation

Tier 0 | Tier 1 | Tier 2 | Tier 1 | Tier 2 | Tier 1 | Tier 0 | Tier 2 | Tier 1 | Tier 2 | Tier 0 | Tier 3 | Tier 2 | Tier 1 | Tier 2 | Tier 0
Study on group dynamics between aging adults with dementia

Level of Benefit to Participant

1: Potentially life saving
2. Potential therapeutic benefit for a condition with no current other intervention options
3. Potential therapeutic benefit for a condition with existing intervention options
4. No benefit to the individual participant

Level of Incremental COVID Community Transmission Risk

- High
- Medium
- Low
- None

Study is Existing or New

- Tier 0
- Tier 1
- Tier 2
- Tier 3

Tier for Activation

- New
- Existing

What is the incremental COVID community transmission risk?
Timeline of Human Research Reactivation

- **June 22** – Reactivation Checklist and Training Module released to researchers
- **June 22** – Reactivation Committees open to Tier 0,1 applications
- **June 22 week** – Human Research Reactivation Town Hall
- **July 13 (est.)** – Reactivation Committees open to Tier 2 applications
PI/Team Actions to Activate Studies

- Complete Human Research Training Module
- Complete Human Research Activation Checklist
  - Identify study benefit level
  - Identify COVID-19 Community Transmission Risk and mitigation plans
  - Review Human Research Reactivation Tier Flowchart and determine study tier
  - Verify school/dept agreement on any necessary space and resource needed for reactivation
- Prepare research space to adhere to local COVID-19 regulations
Committees will review, approve and confirm tier for studies and plan for activation.

Two Human Research Activation Committees

- CTSU committee (Chair: Anna Lok)
  - Non-CTSU committee (Co-Chairs: Julie Lumeng and Tabbye Chavous)

Goal turnaround time from Activation Checklist submission to approval is one week.
Toolkit and Resources Provided to Prepare

- Human Research Activation Checklist
- Human Research Activation Tier Framework
- Human Research During COVID-19 Training Module
- Human subjects FAQ
- Questions to Domain-specific Activation Committee Chairs

https://research.umich.edu/covid-19/research-reengagement