Human Research Activation Checklist

Q1
Human Research Activation Checklist

Review the Activation Tier Framework, Activation Tier Flowchart and Human Research Guidelines before completing this checklist.

Incomplete Activation Checklists will be returned and will not be reviewed.

Tier 2 studies will not be reviewed until after July 13, 2020
Tier 3 studies will not be reviewed until an activation date for Tier 3 is determined.

Q2 Activation Tier Requested:

- Tier 0 (potential immediate benefit that is life saving) (1)
- Tier 0 (studies which are remote and will remain remote) (6)
- Tier 1 (2)
- Tier 2 (3)
- Tier 3 (5)

Display This Question:
If Activation Tier Requested: = Tier 0 (studies which are remote and will remain remote)

Q3
You've selected Tier 0 (for remote studies). If this study will stay remote, you do not need to complete the checklist. Please exit the survey.
Q4 Is the study under the oversight of the Clinical Trials Support Office?

- Yes (1)
- No (2)

Display This Question:
If Is the study under the oversight of the Clinical Trials Support Office? = Yes

Q5 Select the CTSU that administers this study:

- ACCST - Acute, Critical Care, Surgery & Transplant (1)
- ACD - Ambulatory & Chronic Disease (2)
- BFP - Behavior, Function & Pain (3)
- CHILD - Children's (4)
- HVB - Heart, Vessel, Blood (5)
- NSS - Neurosciences & Sensory (6)
- O-CTSU - Oncology (7)
- Unsure (8)

Q6 Does the study include fMRI (functional magnetic resonance imaging)?

- Yes (1)
- No (2)

Q7 Study Title (eResearch 1.1):

________________________________________________________________
Q8 Principal Investigator First Name:

________________________________________________________________

Q9 Principal Investigator Last Name:

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Q10 PI School/College/Unit

▼ Architecture & Urban Planning (1) ... Other (25)

Q11 PI Department

________________________________________________________________

Q12 HUM# from eResearch (include the leading zeros):

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Q13 Provide a brief description of this study and how it interacts with human participants (<300 words). For example, does it include face to face interactions for procedures, assessment with equipment, administration of consent and drug therapy, etc?

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Q14
Assessment of Tier: Study Benefit Level and COVID Transmission Risk Category

Human Research Activation Framework and Human Research Activation Tier Flowchart

Q15 Study Benefit Level to the individual participant. Select the highest level of Direct Benefit to an individual participant of any element of the study:

- Benefit Level 1: Potential immediate benefit to the individual participant that is life-saving, including stabilization of a high risk psychological condition (1)
- Benefit Level 2: Potential benefit to the individual participant for a condition with no current other intervention options (2)
- Benefit Level 3: Potential benefit to the individual participant for a condition with existing intervention options (3)
- Benefit Level 4: No benefit to the individual participant (including observational studies which may result in additional information being provided to the participant) (4)

Display This Question:

If Study Benefit Level to the individual participant. Select the highest level of Direct Benefit to... = Benefit Level 1: Potential immediate benefit to the individual participant that is life-saving, including stabilization of a high risk psychological condition

Or Study Benefit Level to the individual participant. Select the highest level of Direct Benefit to... = Benefit Level 2: Potential benefit to the individual participant for a condition with no current other intervention options

Or Study Benefit Level to the individual participant. Select the highest level of Direct Benefit to... = Benefit Level 3: Potential benefit to the individual participant for a condition with existing intervention options

Q16 Describe the benefit to the individual participant (<200 words)

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Q17 At the time of activation, including your mitigation approaches, will the study have any of these high COVID-19 Community Transmission Risks? Select all that apply.

- Indoons without PPE possible OR the ability to social distance (1)
- Close contact, direct contact, or extended duration of contact (>15 min) without PPE (e.g., participants are unable to wear face covering, except children) (2)
- Groups of >10 participants (not including household groups) (3)
- Staff in close contact with >10 participants per day (4)
- Vulnerable participants (>65 years, immunocompromised, or other risks) (5)
- Participants with known positive COVID-19 test result in past 14 days (6)
- Participants with unknown COVID-19 status, with new symptoms on COVID-19 health screen and/or have had close or household contact in last 14 days with someone diagnosed with COVID-19 (7)
- None of the above (8)
Q18 At the time of activation, including your mitigation approaches, will the study have any of these medium COVID-19 Community Transmission Risks? Select all that apply.

☐ Indoors with social distancing or barriers (1)
☐ Indoors with PPE (2)
☐ Close contact with appropriate PPE (3)
☐ Brief, direct contact (e.g., phlebotomy) with appropriate PPE (4)
☐ Groups of 3-10 participants (not including household groups) (5)
☐ Staff in close contact with 3-10 participants per day (6)
☐ None of the above (7)

Q19 Study status:

☐ Existing - IRB approval obtained and study activities may have started prior to ramp down (1)
☐ New - IRB approval not yet obtained prior to ramp down (2)

Q20 Which IRB is this project reviewed by?

☐ IRB-HSBS (1)
☐ IRBMED (2)
Q21
Safe Research Plan
U-M Guidelines for Human Research During COVID-19

Q22 Is the consent process changing due to COVID-19 (e.g., change from in-person to remote)?

- Yes (1)
- No (2)

Display This Question:
If Is the consent process changing due to COVID-19 (e.g., change from in-person to remote)? = Yes

Q23 Describe how the consent process is changing (<100 words):

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Q24 Is the study taking place in a health care setting?

- Yes (1)
- No (2)
Display This Question:
If Is the study taking place in a health care setting? = Yes

Q25 Attestation

☐ I confirm I have reviewed the PPE requirements of the health care setting and all team members will adhere to them. (1)

Display This Question:
If Is the study taking place in a health care setting? = No

* Q26 Does the incremental research activity require close contact (<6 feet apart for >15 min)?

☐ No (1)

☐ Yes and I confirm the study will be compliant with the PPE requirements of the setting (for example the current Governor’s Executive Orders indicate that close contact requires a face shield if < 3 feet of contact for a prolonged period). Refer to EHS guidance on PPE and close contact. (2)

☐ Yes but I cannot confirm that the study will be compliant with the PPE requirements of the setting (for example the current Governor’s Executive Orders indicate that close contact requires a face shield if < 3 feet of contact for a prolonged period). Refer to EHS guidance on PPE and close contact. (3)
Q27 Confirm that the following requirements will be implemented to mitigate risk of COVID-19 community transmission:
There will not be more than one staff member per 144 sq ft space. If the space is smaller than 144 sq feet only one person may be present. (16)

Masks will be provided to participants and individuals accompanying the study participant if they don't bring their own. (17)

Individuals accompanying participants who are vulnerable to severe COVID-19 or are unable to wear masks will not be permitted to accompany the participant to the study visit. (7)

Hand sanitizer or a handwashing station will be available and will be used before and after each participant encounter. (8)

Participants with known positive COVID-19 test results in the past 14 days or new symptoms on covid health screen will be excluded except studies specifically of COVID-19. (9)

The study will log dates and contact information for all participants and any individual(s) accompanying the participant to the study visit in case contact tracing is needed. (10)
All study procedures that can be conducted remotely will be conducted remotely (if allowed by study sponsor(s)).

Note: In some situations, such as obtaining informed consent in the clinical setting, spending incremental research time with the participant is acceptable and does not need to be moved remotely. (19)

All work that does not require staff/personnel to be on site will remain remote, including analysis and study team meetings. (20)

Prior to presenting to work each day, all study team members complete the U-M Daily Health Screen and follow the next steps provided by the Health Screen. (21)

Participants and any individual(s) accompanying the study participant to the study visit will be screened for a COVID-19 diagnosis, risk factors, or symptoms (refer to the U-M Health Screen questions available at U-M Daily Health Screen for the most up-to-date health screen), to prevent them from arriving at or engaging in the study visit. (Note that the screen is employee- and not participant-facing; participants with positive screens should not be directed to call OHS). If participants screen positive, staff should defer the study visit and refer the participant to their health care provider. (22)
Research personnel will remain home if ill. Supervisors will insist on employees not reporting to work when ill regardless of impending deadlines. (23)

Research space and any shared equipment (incremental to clinical care activities) will be disinfected twice daily and before and after each participant interaction. (24)

Q28 Describe how this study has been modified to mitigate the risk of COVID-19 community transmission per the U-M Human Subject Safe Research Plans for incorporating a **daily health screen** for study participants, those accompanying them to the study visit, and research staff.

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Q29 Describe how this study has been modified to mitigate the risk of COVID-19 community transmission per the [U-M Human Subject Safe Research Plans](#) for **social distancing**.

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Q30 Describe how this study has been modified to mitigate the risk of COVID-19 community transmission per the U-M Human Subject Safe Research Plans for **hygiene and disinfection procedures including shared equipment**.

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Q31 Describe how this study has been modified to mitigate the risk of COVID-19 community transmission per the U-M Human Subject Safe Research Plans for **masks and personal protective equipment (PPE)**.

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Q32 Describe how this study has been modified to mitigate the risk of COVID-19 community transmission per the U-M Human Subject Safe Research Plans for **density of work area**.

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Q33 Describe how this study has been modified to mitigate the risk of COVID-19 community transmission per the U-M Human Subject Safe Research Plans by maintaining contact tracing logs of participants and those accompanying them to the study visit.

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End of Block: Risk Mitigation

Start of Block: Research Location

Q34 Will any of the research interactions occur outside of Ann Arbor or U-M property?

○ Yes (1)

○ No (2)

Display This Question:

If Will any of the research interactions occur outside of Ann Arbor or U-M property? = Yes

Q35 Where will the research interactions occur? Select all that apply.

☐ In Michigan but outside Ann Arbor (3)

☐ Outside the state of Michigan but in the United States and US territories (1)

☐ Outside of the United States and US territories (note: most international studies will not restart at this time) (6)

☐ In a location which has separate requirements of individuals for being in the space or interacting with individuals under its oversight in order to adhere to the governor’s executive orders (Whitmer - Executive Orders) in that venue (e.g., a school, child care, prison, etc)? (5)
Q36 You indicated that research interactions will occur in area(s) in Michigan other than Ann Arbor. Describe the current COVID-19 public health guidance specific to that region if it is different than in Ann Arbor and how you will adhere (Whitmer - Executive Orders) (<200 words):

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Q37 You indicated that research interactions will occur outside of the state of Michigan, but in the United States and U.S. territories. Describe the current COVID-19 public health guidance specific to that state and how you will adhere (<100 words):

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Q38 You indicated that research interactions will occur outside of the United States and US territories (note: most international studies will not restart at this time)
Q38 You indicated that research interactions will occur outside of the United States and U.S. territories. Describe the current COVID-19 public health guidance specific to that location outside of the US and how you will adhere (<100 words):

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Display This Question:

If Where will the research interactions occur? Select all that apply. = In a location which has separate requirements of individuals for being in the space or interacting with individuals under its oversight in order to adhere to the governor’s executive orders (Whitmer - Executive Orders) in that venue (e.g., a school, child care, prison, etc)?

Q39 You indicated that research interactions will occur in a location which has separate requirements of individuals for being in the space or interacting with individuals under its oversight in order to adhere to the governor’s executive orders (Whitmer - Executive Orders) in that venue (e.g., a school, child care, prison, etc). Describe the current COVID-19 public health guidance specific to that location and how you will adhere (<100 words):

○ Yes (1)
○ No (2)

End of Block: Research Location

Start of Block: Attestation

Q40
Provide attestation confirming responsibility for items on this checklist.
Q41 I attest that:

- I, as the Study Principal Investigator have reviewed this checklist with every member of my study team OR (1)

- I am submitting on behalf of the Study PI, and I attest that the Study PI has reviewed this checklist with me and every member of the study team. (2)
Q42 I attest that:
<table>
<thead>
<tr>
<th></th>
<th>Yes (1)</th>
<th>No (2)</th>
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<tbody>
<tr>
<td>I have reviewed with my study team the PPE requirements specific</td>
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<td>to the study setting that are compliant with the specific</td>
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<td>setting and state or local regulations. (4)</td>
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<td>I am minimizing the number of staff present in the workplace to</td>
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<td>only those necessary. (6)</td>
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<td>I have modified and implemented all feasible mitigation tactics</td>
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<td>to reduce COVID-19 transmission (e.g., installation of plexiglass</td>
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<td>barriers, use of larger rooms, conducting study activities</td>
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<td>outdoors, and limiting the number of people present). (7)</td>
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<td>Prior to restarting, I will obtain IRB (including non-UM IRB if</td>
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<td>applicable) and/or sponsor approval as needed for any study</td>
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<td>modifications that were necessary to meet the identified Study</td>
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<td>Benefit Level and COVID-19 Community Transmission Risk Category.</td>
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<td>(8)</td>
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<td>All staff work space (including both that which is participant-</td>
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<td>facing and not participant-facing) is (or has been modified to</td>
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<td>be) compliant with density and social distancing requirements.</td>
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<td>(9)</td>
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I understand that it is my responsibility to work with my school/college/unit to ensure that my research space is available and open for research. I confirm I will not begin work in U-M spaces until my school/college/unit has approved it. (10)

Everyone engaging with this research study has completed the Human Research During COVID-19 Training Module. (11)

I have considered the impact to the study, the participants, and the science if this study needed to be ramped down again. (5)

I have read the human research COVID guidelines and this study is compliant with all of the human research COVID guidelines. (12)

End of Block: Attestation

Start of Block: PI Determination

Q43 Are you the PI on this project?

- Yes (1)
- No (2)
Q44 Are you a faculty member?

- Yes (1)
- No (2)

End of Block: PI Determination

Start of Block: Contact Info

Display This Question:
If Are you a faculty member? = No

Q45 Your name:

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Display This Question:
If Are you a faculty member? = No

Q46 Your email:

________________________________________________________________

Display This Question:
If Are you a faculty member? = No

Q47 Email of faculty member who oversees this project:

________________________________________________________________

Display This Question:
If Are you a faculty member? = Yes

Q48 Your email:

________________________________________________________________
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