Human Research Activation Checklist

Incomplete request forms will be returned to the PI and not reviewed.

1. Submission date
2. Activation Tier Requested:
   a. Tier 0
   b. Tier 1
   c. Tier 2 (checklist not reviewed until after Julu 13th)
   d. Tier 3 (checklist will not be reviewed until an activation date for Tier 3 is determined)
3. Is the study under the oversight of the Clinical Trials Support Office?: Yes/No
   a. If yes, select the CTSU that administers the study
4. Does the study include fMRI (functional magnetic resonance imaging)? Yes/No
5. Study Title (eresearch 1.1):
6. Principal Investigator (eresearch 1.2):
7. Principal Investigator Last Name
8. School/college/unit
9. Department
10. HUM# (in eresearch):
11. How does this study interact with human participants (<200 words) For example is the face to face interaction a procedure, an assessment with equipment, administration of consent and drug therapy etc), :

Assessment of Tier: Study Benefit Level and COVID Transmission Risk Category (refer to: Human Research Activation Tier Framework and Human Research Reactivation Docs)

12. Study Benefit Level to the individual participant (eResearch 6.0). Select the highest level of Direct Benefit to an individual participant of any element of the study.
   a. Benefit Level 1: Potential immediate benefit to the individual participant that is life-saving, including stabilization of a high risk psychological condition
   b. Benefit Level 2: Potential benefit to the individual participant for a condition with no current other intervention options
   c. Benefit Level 3: Potential benefit to the individual participant for a condition with existing intervention options
   d. Benefit Level 4: No benefit to the individual participant

13. At the time of activation, including your mitigation approaches, will your study have any of these high COVID Community Transmission Risks (refer to Framework)? Select all that apply.
   i. Indoor without PPE possible OR the ability to social distance.
   ii. Close contact, direct contact, or extended duration of contact (>15min) without PPE. (eg. Participants are unable to wear face covering, except children <2y)
   iii. Groups of >10 participants (not including household groups)
   iv. Staff in close contact with >10 participants per day
   v. Vulnerable participants (>65, immunocompromised, or other)
   vi. Participants with known positive COVID test result in past 14 days
vii. Participants with unknown COVID-19 status who have had exposure to a known COVID-19 positive person in last 14 days, or new symptoms on covid health screen

14. At the time of activation, including your mitigation approaches, will your study have any of these medium COVID Community Transmission Risks (refer to Framework)? Select all that apply.
   i. Indoors with social distancing or barriers
   ii. Indoor with PPE
   iii. Close contact- with appropriate PPE
   iv. Brief, direct contact (eg. phlebotomy) with appropriate PPE
   v. Groups of 3-10 participants (not including household groups) OR
   vi. Staff in close contact with 3-10 participants per day

15. Study Status (Select one)
   a. Existing - the study has started collecting data
   b. New - the study has not started collecting data

Safe Research Plan (refer to U-M Guidelines for Human Research During COVID-19)

16. Is the consent process changing due to COVID? (e.g., change from in-person to remote) Yes or No
   a. If yes, describe how it has changed (<100 words)

17. Is the study taking place in a health care setting?
   a. If yes, qualtrics pops up attestation: I confirm I have reviewed the PPE Requirements of the health care setting and all team members will adhere to them.
   b. If no, does the incremental research activity require close contact (< 6 feet apart for > 15 min)?
      i. No
      ii. 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 currently requires a face shield if < 3 feet of contact for a prolonged period).
      iii. 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 currently requires a face shield if < 3 feet of contact for a prolonged period).

18. Confirm that the following requirements will be implemented to mitigate risk of COVID-19 community transmission?
   a. 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.
   b. Masks will be provided to participants and individuals accompanying the study participant if they dont bring their own.
   c. Individuals accompanying participants who are vulnerable to severe COVID or are unable to wear masks will not be permitted to accompany the participant to the study visit
   d. Hand sanitizer or a handwashing station will be available and will be used before and after each participant encounter.
   e. Participants with known positive COVID test results in the past 14 days or new symptoms on covid health screen will be excluded except studies specifically of COVID-19.
   f. The study will keep a log of dates of participation and contact information of all participants and those accompanying them to face-to-face research interactions with dates if contact tracing is needed.
g. All study procedures that can be conducted remotely will be conducted remotely (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.)

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

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

j. Study 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 COVID-19 Daily Check In / healthscreen.umich.edu for the most up-to-date health screen), to prevent them from arriving at or engaging in the research 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.

k. Research personnel will remain home if ill. Supervisors will insist on employees not reporting to work ill regardless of impending deadlines.

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

19. Will the research interactions occur outside of Ann Arbor or not on University of Michigan property?
   a. If yes, qualtrics pops up, stating, “Where will the research interactions take place?” (Select all that apply)
      1. In Michigan but outside Ann Arbor
         a. 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):
      2. Outside the state of Michigan but in the United States and US territories
         a. Describe the current COVID-19 public health guidance specific to that state and how you will adhere (<100 words):
      3. Outside of the United States and US territories- (Note most international studies will not restart at this time)
         a. Describe the current COVID-19 public health guidance specific to that location outside of the US and how you will adhere (<100 words):
      4. 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)?
         a. Describe the current COVID-19 public health guidance specific to that location and how you will adhere (<100 words):

Provide attestation confirming responsibility for items on this checklist.

I attest that:

- I, as the Study Principal Investigator, have reviewed this checklist with every member of my study team. OR
- I am submitting this 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.

I also attest that
● I have reviewed with my study team the PPE requirements specific to the study setting that are compliant with the specific setting and state or local regulations.
● I am minimizing the number of staff present in the workplace to only those necessary.
● I have modified and implemented all feasible mitigation tactics to reduce COVID-19 transmission (e.g., installation of plexiglass barriers, use of larger rooms, conducting study activities outdoors, and limiting the number of people present).
● Prior to restarting, I will obtain IRB (including non-UM IRB if applicable) and/or sponsor approval as needed for any study modifications that were necessary to meet the identified Study Benefit Level and COVID Community Transmission Risk Category.
● All staff work space (including both that which is participant-facing and not participant-facing) is (or has been modified to be) compliant with density and social distancing requirements.
● 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 University of Michigan spaces until my school/college/unit has approved it.
● Everyone engaging with this human research study has completed the training module.
● I have considered the impact to the study and the participants and the science if this study needed to be ramped down again.