

This is only a preview of the checklist. Answers will only be accepted if submitted via the online link.

Human Research Activation Checklist

9.30.20

Q1

Human Research Activation Checklist

Review the [Activation Tier Framework](#) and [Human Research Guidelines](#) before completing this checklist.

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

Q2 What are you seeking to do? Select all that apply.

- Conduct face-to-face interactions with participants (including research-related interactions with clinical care providers during clinical encounters) (1)
- Return to U-M facilities (2)
- Return to contact among staff members in any setting (3)
- None of the above (4)

Display This Question:

If What are you seeking to do? Select all that apply. = None of the above

Q3

Your response has indicated that you do not need to complete the Human Research Activation Checklist at this time. Please exit the Checklist.

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Q4 Do you currently have initial IRB approval for this study?

- Yes (1)
- No (2)

Display This Question:

If Do you currently have initial IRB approval for this study? = No

Q5

Initial IRB approval of your study is needed before completing the Human Research Activation Checklist. Please exit at this time.

Q6 Which IRB is this project reviewed by?

- IRB-HSBS (1)
- IRBMED (2)

Q7 HUM# from eResearch (include the leading zeros):

Q8 Is this a multi-site study where U-M is the IRB of record overseeing other site(s)?

- Yes (1)
- No (2)

Display This Question:

If Is this a multi-site study where U-M is the IRB of record overseeing other site(s)? = Yes

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Q9

Multi-site studies where U-M is the IRB of record overseeing other site(s) should first consult with the UM IRB about their overall plans to reactivate. Include in your responses in the Checklist the overall plan for how you will obtain local site activation approval as the individual sites are ready to activate.

Q10 Study Title (eResearch 1.1):

Q11 Principal Investigator First Name:

Q12 Principal Investigator Last Name:

Q13 PI School/College/Unit

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

Q14 PI Department

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Q15 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

Q16 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)

Q17 Does the study include fMRI (functional magnetic resonance imaging) at the Bonisteel Interdisciplinary Research Building on North Campus?

- Yes (1)
 - No (2)
-

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Q18 Provide a brief description of the study, including the study goals, study design and the interactions that occur with human participants.
(<300 words)

Q101 Is this a study of COVID diagnosis, prevention, treatment or outcomes?

- Yes (1)
- No (2)

Q20 Will ALL interactions with participants for research purposes be remote?

- Yes (1) → Complete only questions below that are highlighted in yellow
- No (2) → Move to Q27

End of Block: Intro Question

Start of Block: Remote Path

Display This Question:

If Will ALL interactions with participants for research purposes be remote? = Yes



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Q21 Confirm that the following requirements will be implemented to mitigate risk of COVID-19 community transmission:

	Yes (9)	No (10)
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)	<input type="radio"/>	<input type="radio"/>
All work that does not require staff/personnel to be on site will remain remote, including analysis and study team meetings. (20)	<input type="radio"/>	<input type="radio"/>
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)	<input type="radio"/>	<input type="radio"/>
Research personnel will remain home if ill. Supervisors will insist on employees not reporting to work when ill regardless of impending deadlines. (23)	<input type="radio"/>	<input type="radio"/>
Research space and any shared equipment (incremental to clinical care activities) will be disinfected twice daily and before and after each participant interaction. (24)	<input type="radio"/>	<input type="radio"/>

Display This Question:

If Will ALL interactions with participants for research purposes be remote? = Yes

Q22 Describe the plan 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 research staff.**

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Display This Question:

If Will ALL interactions with participants for research purposes be remote? = Yes

Q23 Describe the plan to mitigate the risk of COVID-19 community transmission per the U-M Human Subject Safe Research Plans for social distancing.

Display This Question:

If Will ALL interactions with participants for research purposes be remote? = Yes

Q24 Describe the plan 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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Display This Question:

If Will ALL interactions with participants for research purposes be remote? = Yes

Q25 Describe the plan 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).

Display This Question:

If Will ALL interactions with participants for research purposes be remote? = Yes

Q26 Describe the plan to mitigate the risk of COVID-19 community transmission per the U-M Human Subject Safe Research Plans for density of work area.

End of Block: Remote Path

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Start of Block: Clinical Encounter Question

Display This Question:

If Will ALL interactions with participants for research purposes be remote? = No

Q27 Will ALL interactions with participants for research be completed entirely by clinical care providers during a Michigan Medicine clinical encounter?

In order to respond YES, the study must meet ALL of the following additional criteria below.

- a) There are NO interactions with research staff;
- b) Clinical care providers who are conducting study-specific activities (e.g. consent or study procedures) are listed on the study IRB;
- c) The study-specific activities will not unduly prolong the clinical encounter (i.e., lengthen the visit by more than 15 minutes);
- d) The clinical encounter would have occurred regardless of the individual's participation in a research study.

If the criteria above are NOT met, choose NO.

Yes (1) → Complete only questions below that are highlighted in green

No (2) → Complete only questions below that are highlighted in blue

End of Block: Clinical Encounter Question

Start of Block: Non Remote or Clinical Path

Display This Question:

If Will ALL interactions with participants for research purposes be remote? = No

Q28

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

[Human Research Activation Framework](#)

Display This Question:

If Will ALL interactions with participants for research purposes be remote? = No

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Q29 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

And Will ALL interactions with participants for research purposes be remote? = No



Q30 Describe the benefit to the individual participant (<200 words)

Page Break

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Display This Question:

If Will ALL interactions with participants for research purposes be remote? = No

Q31 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.

- Person-to-person contact distance is less than 6 feet AND contact duration is more than 15 minutes AND participant cannot wear PPE (1)
- The study includes participants who are immunocompromised (16)
- The study includes participants self-identify as higher risk of severe COVID-19 (14)
- The study includes participants who have known or suspected COVID-19 (as indicated by a positive COVID-19 test result in past 14 days or COVID-19 symptoms on health screen) (15)
- None of the above (8)

Display This Question:

If Will ALL interactions with participants for research purposes be remote? = No

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Q32 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.

- Person-to-person contact distance is less than 6 feet AND contact duration is less than 15 minutes (regardless of whether participant can or cannot wear PPE) (5)
- Person-to-person contact distance is more than 6 feet AND contact duration is more than 15 minutes (regardless of whether participant can or cannot wear PPE) (8)
- Person-to-person contact distance is less than 6 feet AND contact duration is more than 15 minutes AND participant is wearing PPE (9)
- Person-to-person contact distance is more than 6 feet AND contact duration is less than 15 minutes AND participant cannot wear PPE (10)
- There are contacts between more than 2 individuals per day for the study. This includes contacts between researchers and participants, as well as between participants (as in a group study) (6)
- None of the above (7)

Display This Question:

If Will ALL interactions with participants for research purposes be remote? = No

Q33 At the time of activation, including your mitigation approaches, will the study have any of these low COVID-19 Community Transmission Risks? Select all that apply.

- Person-to-person contact distance is more than 6 feet AND contact duration is less than 15 minutes AND Participant is wearing PPE (1)
- There are contacts between 1-2 individuals per day for the study. This includes contacts between researchers and participants, as well as between participants (as in a group study) (2)
- Study takes place outdoors (3)
- None of the above (4)

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Display This Question:

If Will ALL interactions with participants for research purposes be remote? = No

Q34

Safe Research Plan

[U-M Guidelines for Human Research During COVID-19](#)

(Click on +Safe Research Plans)

Display This Question:

If Will ALL interactions with participants for research purposes be remote? = No

Q35 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

And Will ALL interactions with participants for research purposes be remote? = No

Q36 Describe how the consent process is changing (<100 words):

Display This Question:

If Will ALL interactions with participants for research purposes be remote? = No

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Q37 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

And Will ALL interactions with participants for research purposes be remote? = No

Q38 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

And Will ALL interactions with participants for research purposes be remote? = No

Q39 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)

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Display This Question:

If Will ALL interactions with participants for research be completed entirely by clinical care provi... =
No



PREVIEW

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Q40 Confirm that the following requirements will be implemented to mitigate risk of COVID-19 community transmission:

PREVIEW

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	Yes (9)	No (10)
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)	<input type="radio"/>	<input type="radio"/>
Masks will be provided to participants and individuals accompanying the study participant if they don't bring their own. (17)	<input type="radio"/>	<input type="radio"/>
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)	<input type="radio"/>	<input type="radio"/>
Hand sanitizer or a handwashing station will be available and will be used before and after each participant encounter. (8)	<input type="radio"/>	<input type="radio"/>
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)	<input type="radio"/>	<input type="radio"/>
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)	<input type="radio"/>	<input type="radio"/>

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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)

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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)



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Display This Question:

If Will ALL interactions with participants for research be completed entirely by clinical care provi... =
No

Q41 Describe the plan 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.

Display This Question:

If Will ALL interactions with participants for research be completed entirely by clinical care provi... =
No

Q42 Describe the plan to mitigate the risk of COVID-19 community transmission per the U-M Human Subject Safe Research Plans for **social distancing**.

Display This Question:

If Will ALL interactions with participants for research be completed entirely by clinical care provi... =
No

Q43 Describe the plan 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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Display This Question:
If Will ALL interactions with participants for research be completed entirely by clinical care provi... =
No

Q44 Describe the plan 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).

Display This Question:
If Will ALL interactions with participants for research be completed entirely by clinical care provi... =
No

Q45 Describe the plan 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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Display This Question:

If Will ALL interactions with participants for research be completed entirely by clinical care provi... =
No

Q46 Describe the plan 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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PREVIEW

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Display This Question:

If Will ALL interactions with participants for research be completed entirely by clinical care provi... = No

Q47 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
And Will ALL interactions with participants for research be completed entirely by clinical care provi... = No*

Q48 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)

Display This Question:

*If Will any of the research interactions occur outside of Ann Arbor or U-M property? = Yes
And Will ALL interactions with participants for research be completed entirely by clinical care provi... = No*

Q49 Describe the current COVID- 19 public health guidance specific to the location where the research interaction will occur and how you will adhere (<200 words):

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End of Block: Non Remote or Clinical Path

Start of Block: Attestation

Q62

Provide attestation confirming responsibility for items on this checklist.

Q63 I attest that:

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



PREVIEW

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Q64 I attest that:

PREVIEW

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	Yes (1)	No (2)
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. (4)	<input type="radio"/>	<input type="radio"/>
I am minimizing the number of staff present in the workplace to only those necessary. (6)	<input type="radio"/>	<input type="radio"/>
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). (7)	<input type="radio"/>	<input type="radio"/>
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-19 Community Transmission Risk Category. (8)	<input type="radio"/>	<input type="radio"/>
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. (9)	<input type="radio"/>	<input type="radio"/>

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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)

Q65 Are you the PI on this project?

Yes (1)

No (2)

Q66 Are you a faculty member?

Yes (1)

No (2)

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Display This Question:

If Are you a faculty member? = No

Q67 Your name (first and last):

Display This Question:

If Are you a faculty member? = No

Q68 Your email:

Display This Question:

If Are you a faculty member? = No

Q69 Email of faculty member who oversees this project:

Display This Question:

If Are you a faculty member? = Yes

Q70 Your email:

Display This Question:

If Q66 = Yes

Q71 If you would like to include a secondary contact to receive the review notification, please include the email address here:

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Click the "NEXT" button to submit your Checklist for review

PREVIEW