Guidance for "Request to Initiate or Resume Face-to-Face Human Subject Research" Form

- <u>Until July 5</u>, no face-to-face research may be conducted except critical research with the potential for direct therapeutic benefit to the participant with VP approval.
- On July 6, face-to-face research may resume with Associate Dean for Research (ADR)/Center Director (CD) and ORC approval. Approval is contingent upon there being no remote alternative to this method, and safety guidelines in place.
- All ongoing and new protocols should incorporate safety precautions and indicate that face-to-face activities will cease if the University moves back into a more restrictive phase in the future.

What is this form?

Within this form, you will be asked to explain why the research cannot be conducted remotely. Please indicate any additional safety precautions that will be implemented to protect the participants and the researchers before, during, and after in-person research activities by checking the appropriate boxes. If you plan to include additional safety measures, please inform us of those plans as well in the space provided.

Who needs to complete this form?

If your study is current/ongoing and either halted all in-person research activity or moved to online methods and you wish to go back to conducting in-person research activities, OR

If you are submitting a new study that plans to include in-person research activities.

I've completed the form, what do I need to do?

Once the form has been signed by your ADR/CD, please send it to <u>IRB@research.msstate.edu</u> for ORC review. We will communicate with you as to whether your request was approved, if more information is needed, or if it is denied. You will receive an email with the determination and the signed form, with the understanding that if the University goes back to more restrictive measures at any point, then in-person research will cease until you are notified otherwise. The final document will be uploaded by your IRB administrator as an attachment in the protocol.

Contact Information

If you have questions about the form, please contact us at <u>IRB@research.msstate.edu</u>. Any updates to the status of in-person research will be made on the <u>Continuity for Researchers</u> page on our website.



Request to Initiate or Resume Face-to-Face Human Subject Research Activities

Beginning July 6, 2020, MSU will be allowing face-to-face interactions with participants with Associate Dean for Research/Center Director and Office of Research Compliance approval. Approval is contingent upon there being no remote alternative and with safety precautions in place. Please complete this form and route it to your ADR/CD for approval and then to ORC (irb@research.msstate.edu) for final review and approval.

Principal Investigator:

Protocol ID#:

Study Title:

Describe why this study cannot be conducted remotely:

Below each statement, please answer each question about how you will adjust your study protocols to accommodate MSU social distancing guidelines. (Please indicate N/A if a question is not applicable to your study and why):

1. Describe how you will promote and enforce physical distancing (individuals staying 6 feet apart) in the areas where your study will be held:

2. Who will be responsible for managing these guidelines for the research study?

3. If physical distancing is not possible due to the nature of the research study, facial coverings will be required. How will you ensure that participants will have proper facial coverings?

4. How will you provide proper handwashing and sanitizing available to your participants?

5. Who will oversee disinfecting high touch areas during the study?

6. How will you adjust and minimize the risk for participants in high-risk categories?

7. How will you implement participant screening for COVID-19 symptoms in order to minimize exposure risks to your participants? Attached is an example checklist.

8. Is there a way that you can schedule appointments to not overlap between participants participating in this study?

Describe additional safety precautions that will be put in place:

Approvals:

Associate Dean for Research/Center Director

Date

Date

Office of Research Compliance

CDC information regarding COVID- 19 : https://www.cdc.gov/coronavirus/2019-ncov/index.html Mississippi State University information regarding COVID-19: https://www.msstate.edu/coronavirus

Participant screening checklist:

Participant ID#: _____

YES NO

□ □ In the past 2 weeks, have you been in close contact with anyone with confirmed COVID-19 virus who is still in their isolation period or still has symptoms?

□ □ In the last 2 weeks, have you been in close contact with anyone who is currently awaiting their COVID-19 test results?

Have you had a fever and cough within the last 24 hours that you cannot attribute to another known health condition?

□ □ Have you had a shortness of breath within the last 24 hours that you cannot attribute to another known health condition?

Do you feel generally unwell for any reason? For example, do you have a new unexplained muscle aches, new sore throat, new GI distress or other new changes in your health that you cannot attribute to another known health condition or specific activity?

Disclaimer: The results of the screening questions should NOT be added to research records.

If a potential participant answers "Yes" to any of these questions, you may recommend that they contact their medical provider or primary care physician.