Human Subject Research (HSR) Resumption Form

The IRB will be gradually reopening in-person HSR activities that are currently on hold as a result of the pandemic. PIs cannot resume any in-person research activities without the approval from the IRB. If you have any questions, please contact Sena Lim at slim2@bsu.edu.

If information requested below is also included in the materials submitted to the Vice Provost for Research as part of the request to re-enter research/lab spaces (part of the health and safety plan), you may simply state “See Provost approved plan”.

1. Investigator(s) Information

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<tr>
<th>PI Name (Last, First)</th>
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<tr>
<td>College/Department</td>
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<td>Email Address</td>
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<td>BSU Affiliation</td>
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<tr>
<td>Faculty Advisor (Last, First)</td>
<td>*If a student research project</td>
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2. IRB Protocol

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<tr>
<th>IRBNet Number</th>
<th>Protocol Title</th>
<th>Review Level</th>
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Check all that are applicable:

[ ] This is a multi-site/multi-state study

[ ] Approved protocol, but on hold

[ ] Approved protocol, with a post pandemic start date

[ ] Graduate research project

[ ] Undergraduate research project

[ ] Funded research project

[ ] Time sensitive research project; Please describe/provide additional information:

[ ] Other; Please describe/provide additional information:

3. Initial Checklist:

If all of these items are not complete, please do not submit this Application at this time.

[ ] I am seeking or have received approval by the Provost for research space access (and have attached the approval notice and safety plan if approval is in place or will send separately if received).
My research team and I have completed a current Employee Health Screening and Self-Certification Assessment form.

For research taking place at other sites, institutions, states, etc., I have checked with the applicable party(s) about any special requirements they have and have built those requirements into my plan or modified my IRB protocol accordingly. Whichever institution (BSU or non-BSU) has the most stringent requirements, the most stringent are the requirements included in my protocol, including but not limited to requirement for cloth facemask and physical distancing of at least 6 feet.

For funded research, I have checked with SPA about any specific requirements the funder may require and have built those requirements into my plan or modified my IRB protocol accordingly.

4. Estimated/Requested Start Date Click or tap to enter a date):  
   [ ] Check here if the study will need to continue uninterrupted into 2021.  
   [ ] Check here if the in-person interactions portion of the study can be completed by the 2020 Thanksgiving break.

5. Please describe the location where the research will be performed.  
   Study location is:  
   [ ] Within BSU facility  
   [ ] Non-BSU facility, but within Indiana  
   [ ] Both  
   [ ] The study will take place (or will also take place) in another state.  
   [ ] The study will take place (or will also take place) in another country.  
   Note: At this time, no BSU PI may travel to another country to conduct HSR. This option is only for studies that involve Co-PIs that are already in country and can conduct the research while meeting applicable health and safety requirement if BSU IRB approval is achieved via this application process.

Please specify all applicable building/floor/room numbers and any non-BSU sites.

6. Please describe the study population.  
   • Age Range:  
   Please also review the CDC’s information about risk increasing by age:  [CDC Guidance for Older Adults]  
   • Are BSU students included?  [ ] Y  [ ] N
• Study includes participants in other states:  [ ] Y  [ ] N
• Study includes participants in other countries:  [ ] Y  [ ] N
• Study includes a protected population:  [ ] Y  [ ] N

Please check the one that best applies:

[ ] Target population have self-certified that they meet the CDC’s “People of Any Age with Underlying Medical Conditions”.

[ ] Target population have self-certified that they are not within CDC’s “People of Any Age with Underlying Medical Conditions” as they are being screened out (ex. via a health screening questionnaire, precluded by inclusion/exclusion criteria, etc.).

[ ] Target population may include people who have an underlying medical condition as per the CDC’s list.

7. Will recruitment screening informed consent, and Pre-Visit Screening, take place remotely?
   a. Yes [ ]
   b. No. [ ] Please explain why.

8. Will close interactions (less than 6 feet) and/or personal contact be required?
   a. No [ ]
   b. Yes. [ ] Please describe what interaction(s) will be required and what safety precautions will be in place

9. Will participants and research team members be able to wear cloth facemasks for the entire duration of the study visit?
   a. Yes [ ]
   b. No. [ ] Please explain why and how this will be managed.

10. What shared surfaces will be touched by participants or researchers as part of the visit?

11. Describe how you plan to manage density, including participants coming to visit.
    • How many study team members will be present at the same time? ________
    • How many people, at the same time, will be in the space where the study is being performed? ________

   Please describe your plan to manage density and to keep social distancing.
12. In the event a study team member or participant tests positive for COVID-19, Please outline the plans for managing the situation and for safely pausing/shutdown the study.
   a. Any study team member and/or participant that are known to be COVID-19 positive must not be allowed into the research area at all. This item is aimed at plans for discovery after the fact.

13. Are there any extenuating circumstances that the IRB should consider as part of their review and that may impact the review level determination, or which phase your study is actually allowed to start in?
   a. No [ ]
   b. Yes. [ ] Please describe below.

14. By signing below, I confirm that:
   ___ I, as the study’s Principal Investigator, have reviewed the Guidance for Resumption of In-Person Human Subject Research and the BSU Return to Campus Plans with every member of the research team and will abide by these requirements;
   ___ I am minimizing the number of staff present in the workplace/research site to only those necessary;
   ___ For studies that involve an international Co-PI that is working in the applicable country, I will ensure that the Co-PI will follow all applicable guidance and requirements (see Guidance for Resumption of In-Person Human Subject Research);
   ___ When and where possible, I am using virtual/online means for conducting my research and limiting, to the best of my ability, in-person HSR;
   ___ I have modified or implemented all feasible mitigation options 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 and/or sponsor approval, as needed, for any study modifications that are necessary to safely restart in-person HSR or as may be needed due to changing circumstances;
   ___ All staff workspaces and research areas within BSU and non-BSU facilities are compliant with BSU density and social/physical distancing requirements;
   ___ I understand that it is my responsibility to work with my school/college/unit to ensure that my research space continues to meet applicable BSU and CDC requirements;
   ___ I and my research team can, and will, follow all applicable BSU health and safety requirements, plus those that may be required by the VPR and IRB;
   ___ I understand that the final decision to allow the restart of in-person HSR will be made regardless of funding or funding source and will be made on health and safety needs, and ethical considerations; and
I understand the procedure to take in the event a study team member or participant tests positive for COVID-19.

PI signature:                                      Date:    / 7/21/2020

Faculty Advisor Signature:                          Date   / 7/21/2020

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Final Risk Level determination:

[ ] Low Risk
[ ] Medium Risk
[ ] High Risk

Protocol is:

[ ] Approved to restart
[ ] Approved to restart earlier than Risk Level Phase, based on extenuating circumstances
[ ] Not approved to restart at this time

Approved restart date: 7/21/2020

Additional health and safety requirements required by the IRB

Additional Notes

Signature of HRPP Mgr

Signature of IRB Chair

Signature of ORI Director

Signature of VPR