COVID-19 Related Guidance for In-Person Human Subject Research – Fall 2021
Updated: June 30, 2021

I. Introduction
The Ball State University (BSU) Institutional Review Board (IRB) will continue to respond to the COVID-19 pandemic to protect the health and safety of our research community, which includes human participants and researchers. Accordingly, researchers who wish to conduct in-person activities will be required to submit the COVID-19 Safety Plan (also referred to in this guidance as the Safety Plan) in Fall 2021.

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This guidance provides up-to-date guidelines and procedures for in-person human subjects research (HSR) projects. **This guidance may change at any time in response to new information, governmental requirements, and so forth.**

**Note to our researchers:** Recent changes from the CDC and to BSU’s guidance concerning mask use and physical distancing requirements for those who are fully vaccinated have provided us with greater flexibility in resuming and conducting research on campus. The guidance below represents a response to that flexibility and reflects the IRB’s primary charge to protect research participants.

II. **Summary of Change**

- The Lab Access for Research (Space Access Approval) will no longer be required.
- Phased approaches will no longer be applied to assess in-person HSR resumption plans.
- The COVID-19 Safety Plan will replace the HSR Resumption Form considering current HSR guidance and BSU guidance. No separate Resumption Form will be required any longer.
- All research team members who will have in-person contacts with participants are required to be fully vaccinated.
- If participants who are deemed to be at increased risk for severe illness are fully vaccinated, they may be allowed to participate in the in-person HSR projects.
- Based on the research design and/or safety plan, the IRB may require participants to be fully vaccinated or require additional safety measures.
- The review process will be changed. Researchers need to submit the Safety Plan with their IRB application or IRB modification form via IRBNet.org.
- Researchers who still have a protocol on hold or with a delayed start date may begin their study(s) by contacting the IRB and submitting a Safety Plan as described below.

III. **General Requirements**

To protect participants and researchers and to reduce the risk of COVID-19 in our research community, the following are required for all in-person HSR projects.

1. **Researchers**

- All researchers working with human subjects must familiarize themselves with up-to-date IRB guidance and BSU guidance. Researchers must also consider the risk to research participants, the community, and the research team members of transmitting the virus causing COVID-19.
- All researchers and research team members who will have in-person contact with participants are required to be fully vaccinated by the time the in-person research portion of a study begins.
  - The exception is allowed only if researchers are unable to be fully vaccinated based on a medically documented condition(s) or pregnancy where the vaccination is contraindicated for use. In this situation, researchers must follow masking and social distancing requirements.
- All researchers are expected to abide by the CDC’s quarantine guidance. Currently, the CDC recommends a 14-day quarantine period as the safest strategy for those who test positive for COVID-19.
- Researchers who will be in physical (or close) contact with research participants must be screened/self-screened daily prior to contact with subjects using the [Health Assessment Questionnaire](#) (see Appendix A).
- If any IRB-reportable events occur, including COVID-19-related events, the PI of record should submit an adverse event/unanticipated problem report form to the IRB.
2. **Participants and Procedures**
   - Prior to each in-person activity/meeting/visit, each participant should fill out the Health Assessment Questionnaire (see Appendix A).
   - The health and safety plan and/or instructions, including screening procedure and mask requirement, should be provided to participants before the in-person activities occur.
   - Participants under 65 years old are strongly recommended to be fully vaccinated before participating in the projects. Those who cannot be fully vaccinated due to health conditions (medical condition(s), pregnancy, etc.) are strongly encouraged to follow masking and social distancing requirements.
   - Participants over 65 are still recognized as a high-risk group, and thus they must be fully vaccinated before participating in any projects. Participants over 65 who are unable to be fully vaccinated based on a medically documented condition(s) must follow masking and social distancing requirements.
   - Depending on the research design/safety plan, the IRB may require all participants to be fully vaccinated or follow additional safety procedures.
   - Fully vaccinated participants are allowed to participate in research activities without wearing a mask. However, depending on the research design, the IRB may require participants to wear masks regardless of vaccination status.
   - The equipment and rooms must be sanitized between each session.
   - Regardless of vaccination status, a physical distance of 6 feet is strongly recommended.

IV. **Risk Assessment**
The IRB will perform a risk assessment on every HSR protocol that has an in-person component and may require additional steps to mitigate potential risks. The IRB will consider the following factors when reviewing the Safety Plan. The consideration of these factors will assist both the IRB and researchers themselves in the generation of a holistic risk profile that will guide resumption decisions. The lists are not all-inclusive.

1. **Availability of Alternative Options**
   If the IRB determines that the project can be conducted virtually, the IRB may recommend doing the study virtually.

2. **Participant Age, Heath Condition, and Characteristics**
   The CDC guidelines suggest that the risk for severe illness with COVID-19 increases with age. In addition, certain medical conditions can also increase the risk of severe illness. Thus, the IRB will consider the participants’ age, health condition, and characteristics to assess the risk. The IRB will also carefully evaluate the risk of a project that will recruit participants from vulnerable populations (e.g., children, persons with disabilities, etc.).

3. **Participant Vaccination Status**
   If all participants are vaccinated, it will lower the risk. PIs will need to provide an outline to the IRB as to how they are determining/confirming immunization status.

   **Note:** Asking a participant directly about their immunization status does not violate HIPAA. Asking for access to a participant’s medical records to confirm immunization status is a HIPAA issue and will require signed authorization.

4. **Number of People**
The total number of individuals interacting at one time or in each session is one of the primary considerations to assess the risk. The more individuals who will be at the project location, the higher the risk will be. The IRB recommends a minimal number of researchers and participants to be present at a time. Including social distancing requirements in the Safety Plan for projects involving larger groups (ex. focus groups) will be considered a mitigation strategy.
5. **Location and Space Characteristics, Proximity**  
The project locations will be evaluated in terms of two factors: whether appropriate physical distance can be maintained and whether the site strictly implements COVID-19 prevention strategies.

6. **Procedures**  
The IRB will examine if the procedures are conducive to spreading the contagious virus. If necessary, the IRB may recommend using virtual research means as much as possible in lieu of in-person methods. Please refer to the table below for study types for each category.

<table>
<thead>
<tr>
<th>Low risk</th>
<th>Medium risk</th>
<th>High risk</th>
</tr>
</thead>
</table>
| - No invasive procedures are required as part of the research  
- One-to-one interview, participant observation without interaction, or observation in a public setting | - No invasive procedures are required as part of the research, but some minimal contact procedures may be involved (blood pressure test, headset fitting for eye trackers, etc.)  
- Focus group with 5 or fewer participants, classroom observation without interaction or intervention | - Invasive and physical procedures are required as part of the research (e.g., blood draws, biopsies,)  
- Group activities in an enclosed room or group physical/athletic activities. |

7. **Duration of Activities and Number of Sessions**  
The IRB will consider the project to be high risk if the duration of activities takes more than 2 hours and multiple visits are necessary. The researchers may be asked to provide the duration of each session and the number of sessions (visits).

8. **Precautions**  
The IRB may recommend researchers have additional COVID 19-related health and safety precautions and/or include more stringent inclusion/exclusion criteria as a part of their study.

V. **Approval Procedures**

1. **IRB-Approved Study**  
For projects that have been previously approved by the IRB (including those protocols approved with post-pandemic start date),  
a. PI of record needs to fill out the Safety Plan and submit it to the IRB via IRBNet. 

b. If the project is conducted off-site, supplementary documents like COVID-19 guidance from the site, a letter of support, and/or an additional health screening document may be required. 

c. If the project requires a permanent modification of the IRB application in response to COVID-19 restrictions, a modification form must be submitted to the IRB. 

d. The IRB will review the Safety Plan at the appropriate review level.

2. **New Study**  
For a new study that has not been previously approved by the IRB,  
a. PI of record needs to fill out the Safety Plan and submit it with the IRB application on IRBNet.org.
b. If the project is conducted off-site, supplementary documents like COVID-19 guidance of the site, a letter of support, and/or an additional health screening document may be required.

c. The IRB will review the Safety Plan with the IRB application at the appropriate review level.

VI. Additional Considerations

1. Sponsored Project

If the study is a funded project, the researcher needs to reach out to the funding agency and/or the SPA Grant Manager to see if any special requirements are necessary to restart the project.

If any specific requirements may impact the approved IRB protocol, PI must contact the ORI for additional guidance.

Funding status does not ensure that the project will be approved for the resumption of in-person HSR. A final decision will be made about health and safety needs and ethical considerations regardless of funding or funding source.

2. Off-Site Study

a. Restrictions and Limitations

Some researchers may be collecting data outside of BSU facilities, including in the greater Muncie area, other states, and other countries. To ensure safety, research conducted at an off-site location(s) must comply with BSU’s guidelines and any requirements specified by the non-BSU institution/organization.

The BSU IRB will not override a site’s restrictions or limitations on research being conducted at their location but will require at least the same level of stringency as those in place within BSU facilities. When in doubt, the strongest protections and/or the more restrictive elements will apply.

b. Letter of Support

For the approved studies, a new letter of support is not required, but PI must confirm with the IRB that they have been in contact with the site and will comply with any health and safety requirements the site may stipulate. For new projects, PI must obtain a letter of support before submitting the IRB application and Safety Plan.

c. Cardinals Care Partner Pledge

If the project is conducted in the Muncie community, the community organization(s) or business(es) where the project will be conducted must take the Cardinals Care Partner Pledge. Please visit the Cardinals Care Partner Pledge site for more information.

3. International Study

Researchers must check the COVID-19 Travel Standards for the most up-to-date information. If BSU researchers are partnered with a Co-PI working in the host country, the safety of participants, community, and researchers remains paramount.

Researchers will need to make sure that, at a minimum, the safety requirements in place for BSU facilities are adhered to at the international site, including facemask standards, vaccination requirements, and physical distancing.

VII. Resources

Please consult the University’s COVID-19 Website for more information on the University’s response to this pandemic. In addition, other general resources include:

- CDC Coronavirus Disease 2019 (COVID-19)
- Latest Guideline and updates from the CDC
- Indiana State Department of Health
VIII. **Contact Information**
If you have any questions or need more information, please contact the following for assistance related to the IRB and HSR:

<table>
<thead>
<tr>
<th>Name</th>
<th>Title</th>
<th>Email</th>
<th>Phone</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sena Lim</td>
<td>Human Research Protection Program Manager</td>
<td><a href="mailto:slim2@bsu.edu">slim2@bsu.edu</a></td>
<td>765-285-5034</td>
</tr>
<tr>
<td>Chris Mangelli</td>
<td>Director, Office of Research Integrity</td>
<td><a href="mailto:cmmangelli@bsu.edu">cmmangelli@bsu.edu</a></td>
<td>765-285-5070</td>
</tr>
</tbody>
</table>

If the research is supported through internal or external sponsored funding, please contact the following to receive guidance on working out terms and conditions with sponsors:

<table>
<thead>
<tr>
<th>Name</th>
<th>Title</th>
<th>Email</th>
<th>Phone</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jackie Davis</td>
<td>Director, Sponsored Projects Administration Development</td>
<td><a href="mailto:jsdavis@bsu.edu">jsdavis@bsu.edu</a></td>
<td>765-285-1607</td>
</tr>
</tbody>
</table>
Appendix A: Health Assessment Questionnaire

Health Assessment Questionnaire

To reduce the risk of COVID-19 exposure, all BSU researchers and participants must complete the following screening questionnaire prior to each in-person meeting. This form is to be used uniformly by all BSU researchers (no modification is allowable). Questionnaires are to be retained by the BSU Office of Research Integrity following the conclusion of the study.

Name (first and last): __________________________ Researcher OR Research Participant

**Vaccination Status**

<table>
<thead>
<tr>
<th></th>
<th>YES</th>
<th>NO</th>
<th>Received 1st Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Have you been fully vaccinated against COVID 19?</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Health Assessment**

<table>
<thead>
<tr>
<th></th>
<th>YES</th>
<th>NO</th>
</tr>
</thead>
<tbody>
<tr>
<td>Have you been advised by a health care practitioner or government official to stay home/self-quarantine or have traveled outside the United States within the last 14 days?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Have you had close contact (same household or within 6 feet) with someone testing positive for COVID or having symptoms of COVID-19 within the last 14 days?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Have you experienced any cold or flu-like symptoms in the last 14 days, including fever, cough, shortness of breath or difficulty breathing, a new loss of taste or smell, sore throat, chills with or without shaking, muscle pain, headaches, vomiting, or diarrhea?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Temperature measurement ______ ° F</td>
<td>&gt;100.0°F,</td>
<td></td>
</tr>
</tbody>
</table>

Anyone answering “YES” to any of the above questions will not be permitted access to the research facility.

- BSU employees for whom the answer is “yes” to any of these screening questions are to follow the BSU instructions in the Return to Campus plan for employees and immediately depart the BSU facility.
- BSU students who answer “yes” to any of these screening questions are to follow the instructions in the Return to Campus plan for students and immediately depart the BSU facility.
- Researchers or participants who are not BSU employees or students who answer “yes” to any of the screening questions should be encouraged to contact a healthcare provider and immediately depart the BSU facility.
For Internal Use Only:

Access to facility (circle one): Approved Denied

Researcher signature: ___________________________ Date: ___________________________