COVID-19 Related Guidance for In-Person Human Subjects Research – Fall 2021
Updated: Aug 18, 2021

Table of Contents
I. Introduction .................................................................................................................................... 2
II. Summary of Change ...................................................................................................................... 2
III. General Requirements ............................................................................................................. 2
   1. Researchers ............................................................................................................................. 2
   2. Participants and Procedures .................................................................................................... 3
   3. Informed consent requirements ............................................................................................... 3
IV. Risk Assessment ..................................................................................................................... 3
   1. Availability of Alternative Options ............................................................................................ 4
   2. Participant Age, Health Condition, and Characteristics ............................................................ 4
   3. Participant Vaccination Status ................................................................................................. 4
   4. Number of People .................................................................................................................... 4
   5. Location and Space Characteristics, Proximity ....................................................................... 4
   6. Procedures ............................................................................................................................... 4
   7. Duration of Activities and Number of Sessions ........................................................................ 5
V. Approval Procedures ............................................................................................................... 5
   1. IRB-Approved Study ................................................................................................................ 5
   2. New Study ................................................................................................................................ 5
VI. Additional Considerations ........................................................................................................ 5
   1. Sponsored Project ................................................................................................................... 5
   2. Off-Site Study .......................................................................................................................... 5
      a. Restrictions and Limitations ............................................................................................... 5
      b. Letter of Support ................................................................................................................. 6
      c. Cardinals Care Partner Pledge ......................................................................................... 6
   3. International Study ................................................................................................................... 6
VII. Resources ................................................................................................................................ 6
VIII. Contact Information .................................................................................................................. 6
Appendix A: Health Assessment Questionnaire ................................................................................. 8
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.

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.

UPDATES (August 12, 2021): BSU modified the mask requirements on August 9, 2021, thus ALL researchers and participants must wear masks on the BSU campus, regardless of vaccination status.

For the studies conducted off-campus, the IRB requires ALL researchers and participants wear masks as well. Very limited exceptions may be allowed depending on the study design and circumstances at the sites.

All researchers who will have in-person contacts are still strongly encouraged to be fully vaccinated.

II. Summary of Changes
- 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 CDC guidance and BSU guidance. No separate Resumption Form will be required any longer.
- All research team members who will have in-person contact with participants are strongly encouraged to be fully vaccinated.
- All research team members who will have in-person contacts with participants are required to wear protective masks regardless of vaccination status.
- 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.
- 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.
- Informed consent requirements have been updated.

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 wear protective masks regardless of vaccination status during the in-person sessions and while in BSU buildings, in accordance with current BSU guidelines.
Social/physical distancing is strongly encouraged when and where possible.

- All researchers are expected to abide by the CDC’s quarantine guidance.
- 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 are strongly encouraged to be fully vaccinated before participating in the research projects. Participants over 65 are still recognized as a high-risk group, and thus should be fully vaccinated before participating in any projects.
  - All participants taking part in research on the BSU campus or other properties, must follow the current BSU COVID-19 policies, including mandatory masking inside of BSU buildings, regardless of vaccination status.
- As part of the research design, PIs may require participants be fully vaccinated before taking part in the in-person component. This would be considered along with other research-based inclusion/exclusion criteria.
- The equipment and rooms must be sanitized between each session.
- Regardless of vaccination status, a physical distance of 6 feet is strongly recommended.

3. Informed consent requirements

As part of the informed consent process:

- For researchers/research teams that are not fully vaccinated:
  - The informed consent must include a statement that the researcher and/or members of the research team may not be fully vaccinated at the time of the in-person session. This must be followed by a statement as to what steps they will be taking to help protect participants.
  - For research involving minors, this language must be in the parental consent. Language in the child assent can vary based on age, reading comprehension, etc. The IRB will review child assent language on a per-protocol basis.
  - Sample language: “Please be advised that the researcher and/or members of the research team may or may not be fully vaccinated at the time of the in-person session. The researcher and research team members will remain fully masked during the in-person session and will use the following safety precautions [add items that apply].

- For researchers/research teams that are fully vaccinated:
  - You may include a statement to this effect, but only if all researchers and team members are, and remain, fully vaccinated.
  - If full vaccination status cannot be maintained for the duration of the in-person portions of the study, then PIs need to follow the requirement above.

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.

   As part of the research design, PIs may require participants be fully vaccinated before taking part in the in-person component. This would be considered part of the inclusion/exclusion criteria.

   **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>Risk Level</th>
<th>Study Types</th>
</tr>
</thead>
</table>
| Low risk   | • No invasive procedures are required as part of the research  
            • One-to-one interview, participant observation without interaction, or observation in a public setting |
| Medium risk| • 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, |
| High risk  | • 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.

In some situations, researchers are not able to ask participants to wear masks due to research designs or masking policies at these sites. In such cases, limited exceptions may be allowed depending on the study design and circumstances at the off-campus sites. Researchers must address the circumstances and provide reasonable justifications. For example, classroom observations without intervention in a school where masks are not mandatory may be allowed if no more than minimal risk is involved.

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 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
- Delaware County Indiana Coronavirus Hub
- OHRP (Office of Human Research Protections) Guidance on Coronavirus

VIII. Contact Information
If you have any questions or need more information, please contact the following for assistance related to the IRB and HSR:

| Sena Lim, Human Research Protection Program Manager | slim2@bsu.edu or 765-285-5034 |
| Chris Mangelli, Director, Office of Research Integrity | cmmangelli@bsu.edu or 765-285-5070 |

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:
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

<table>
<thead>
<tr>
<th>Health Assessment</th>
<th>YES</th>
<th>NO</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. 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>2. 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>3. 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>4. If your response to #3 was Yes, do you have a known/diagnosed reason other than COVID?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Temperature measurement ______ ° F &gt;100.0 °F.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Anyone answering “YES” to any of the above questions will not be permitted access to the research facility. (This does not apply to fully vaccinated people who are asymptomatic after exposure to close contact)

- BSU employees for whom the answer is “yes” to any of these screening questions are to follow the BSU instructions in the [COVID-19 Response Plan](#) and immediately depart the BSU facility.
- BSU students who answer “yes” to any of these screening questions are to follow the instructions in the [COVID-19 Response 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: ___________________________