

COVID-19 Related Guidance for In-Person Human Subjects Research

Updated: March 21, 2022

Major changes are marked as green.

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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.

The purpose of this guidance is to provide up-to-date guidelines and procedures for in-person human subjects research (HSR) projects. Specifically, this version contains updates regarding mask policy and IRB review procedures in accordance with the discontinuation of the requirement to wear face masks on campus.

This guidance may change at any time in response to new information, governmental requirements, and so forth.

UNIVERSITY FACE MASK POLICY UPDATES (March 4, 2022): Effective March 4, 2022, at 5:00 p.m., face masks are optional on campus. However, they may still be required in

certain locations, such as health care settings and laboratory settings. Determinations for these settings will be made by the area supervisor.

Individuals who are at greater risk for infection, or the consequences of infection, are encouraged to continue wearing a mask if they prefer to do so.

Summary of Changes

- The review process has changed. A separate COVID-19 Safety Plan will no longer be required. Researchers will be required to describe their in-person activities in the IRB application (Study Design, Methods, and Procedures page and Potential Risks/ Discomforts Information page, if applicable).
 - Researchers who still have a protocol on hold or with a delayed start date may begin their study(s) by contacting the Office of Research Integrity.
- All research team members who will have in-person contact with participants are still strongly encouraged to be fully vaccinated.
- All research team members who will have in-person contacts with participants are not required to wear protective masks on campus. However, they may still be required in certain locations if the area supervisor(s) or principal investigator(s) require wearing masks.
- Any research team members or participants who are at greater risk for infection or the consequences of infection are encouraged to continue wearing a mask.
- Researchers and participants are not required to fill out the [Health Assessment Questionnaire](#) (see Appendix 1), but the form is still available for research teams that wish to follow stricter precautions or work with high-risk populations.
- Informed consent requirements have been updated (March 21, 2022).
- For studies conducted off-campus, all researchers and participants must comply with BSU's guidelines and any requirements specified by the non-BSU institution/organization(s).

II. 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 research team members who will have in-person contact with participants are still strongly encouraged to be fully vaccinated.
- While it is not required to wear a mask on the BSU campus, researchers may still be required in certain locations if the area supervisor(s) require wearing masks or principal investigators (PIs) decide to do so considering the risk of studies.
- For studies conducted off-campus, all researchers must comply with BSU's guidelines and any requirements specified by the non-BSU institution/organization(s).
- All researchers are expected to abide by the CDC's Isolation and Quarantine Guidance.
- Researchers who will be in physical (or close) contact with research participants are encouraged to be self-screened daily prior to contact with participants.
Note: The [Health Assessment Questionnaire](#) (see Appendix A) is no longer required, but the form is still available for those who wish to use it.
- Social/physical distancing is strongly encouraged when and where possible.
- 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, participants are encouraged to self-monitor their symptoms before coming to the research locations. If they experience symptoms of COVID-19 (without a separate diagnosed cause, e.g., asthma, allergies, etc.), they should contact the PI or research team member(s) for further guidance.
Note: The Health Assessment Questionnaire (see Appendix A) is no longer required, but the form is still available for those who wish to use it.
- If applicable, the health and safety plan and/or instructions, including screening procedure and mask policy, 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 and requirements of labs or locations.
- As part of the research design, PIs may require participants to be fully vaccinated before taking part in the in-person component and wear masks during the in-person activities. 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 or mask requirement, a physical distance of 6 feet is strongly recommended when and where possible.

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.”
- 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.
- If participants are asked to wear masks during an in-person session, it is recommended to indicate the requirement in the consent form.

III. Procedures

1. IRB-Approved Study

For projects that have been previously approved by the IRB (including those protocols approved with post-pandemic start date),

2. New Study

a. For a new study that has not been previously approved by the IRB, PIs of record need to describe the in-person activities in the IRB application (Study Design,

Methods, and Procedures page and Potential Risks/ Discomforts Information page, if applicable) in a detailed manner. You may include the following items, but not limited to:

- Mask requirement
- Vaccine requirement
- Description of location
- Number of researchers participants in one session
- Possible risks and discomforts

- 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 activities described in the IRB application and may ask the research team to take some actions to ensure safety.

IV. 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 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

A new letter of support is not required for the approved studies, 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 as usual.

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.

V. 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](#)

VI. 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:

Jackie Davis, Director, Sponsored Projects Administration Development | jsdavis@bsu.edu or 765-285-1607

Appendix A: Health Assessment Questionnaire (Optional form)

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

Health Assessment	YES	NO
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?		
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?		
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?		
4. If your response to #3 was Yes, do you have a known/diagnosed reason other than COVID?		
Temperature measurement _____ ° F	>100.0°F.	.

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: _____