COVID-19 Human Subjects Research Guidelines

In accordance with the BSU COVID-19 Safe Return guidelines, guests are not allowed on campus during the fall 2020 semester. Therefore, research subjects would need to have all face to face contact outside of BSU or they would have to be a regular part of our community, such as students or staff. Contact Tracing Guidelines require documentation of any BSU students or staff, if they must enter spaces they do not have access to, such as access for classes or residential purposes. Research models that use distance mediating technologies are strongly encouraged during the fall 2020 semester. Faculty and students proposing new or resuming approved human subjects research are required to first obtain approval from the dean of their college who is responsible for attesting that COVID-19 risk assessment has been completed. The Institutional Review Board will only review new research protocols that have completed the attestation process.

Guiding Principles for Restarting Human Subject Research (HSR)

The COVID-19 pandemic has introduced unique challenges to research studies involving human subjects. This document is to provide additional guidance for a range of research in order to protect the health and safety of researchers, research participants, and students. Given that a one-size fits-all set of guidelines may not capture the risks and benefits across all types of human subject research, individual colleges, departments, and laboratories may need to tailor their plans for mitigating risk to fit the specific circumstances and scope of their research activities. Since research may be conducted off-campus, research teams should also be familiar with and follow the guidelines, procedures and timelines developed by those entities. As new information about COVID-19 becomes available and its prevalence within our environment changes, these guidelines will be periodically re-evaluated and adjusted, and researchers may need to modify their safety plans.

1. All investigators are required to complete the COVID-19 Human Subjects Research Checklist for resuming or beginning research operations (see instructions below).
2. Researchers and participants must follow the safety principles listed in the BSU Code of Public Health Pledge for every visit to a lab or interaction with other researchers or participants.
3. Researchers should use the table at the end of this document to determine the highest potential level of COVID-19 Exposure Risk for both research personnel and participants.
4. The COVID-19 Exposure Risk table provides guidance on the minimum required strategies for mitigating risk for each level of COVID-19 exposure risk. Some situations may require additional mitigation strategies (such as COVID-19 testing), which should be assessed by the principle investigator and research unit.
5. For studies that include in person participants or research staff with elevated risk for COVID-19, additional safeguards should be considered. Based on current CDC guidelines, elevated risk is defined as all persons age 65 or older, or persons of any age with a medical condition including lung disease or moderate-severe asthma, serious heart condition, immune system compromise, obesity (BMI >39), diabetes, or chronic kidney or liver disease.
6. Whenever possible, research involving human subjects should be conducted using methods that remove or diminish contact between researchers and participants. Research models that use distance mediating technologies are strongly encouraged during the fall 2020 semester.
7. Some studies may require more than one research participant to be present in the study area at a given time. In accordance with BSU COVID-19 Prevention Mask and Face Shield Guidance, all researchers and research participants must wear masks at all times. For participants who reside together (e.g., a parent accompanies a child, or spouses), no additional precautions are necessary. For participants who do not reside together, social distancing at a minimum of 6 ft between participants must be strictly maintained and participants should wear an approved face covering at all times.
8. Studies requiring more than one research visit may use mitigation strategies that are appropriate to each visit. For example, the requirements for behavioral testing may be different than a visit for blood draw.
9. Adequate social distancing (minimum 6 ft) between all participants and research personnel should be maintained unless person-to-person contact is necessary for a study (see examples in the table below). Plans for maintaining social distancing should consider additional factors, such how participants will travel to and from the research setting, ingress/egress from the laboratory and building, use of waiting areas, and scheduling additional time between visits to allow for disinfecting of spaces.
10. All research staff should review CDC guidance on handwashing and the use of hand sanitizer. Researchers should wash their hands before/after each research visit, and immediately before/after any direct physical contact with a research participant.
11. All research staff should self-screen daily. Researchers who are experiencing COVID-19 symptoms or have been exposed to individuals with COVID-19 should refrain from engaging in face-to-face human research activities for 14 days.
12. Participants should be screened by phone using the Wellness Screen prior to attending a face-to-face research visit. Additionally, the Wellness Screen should be repeated in-person at the beginning of each research visit. Participants who
are experiencing COVID-19 symptoms or have been exposed to individuals with COVID-19 should be rescheduled at least 14 days later.

13. Participants must be fully informed of the COVID-19 risks and the mitigation strategies that will be employed during the study (see suggested consent language later in this document). Researchers should document that each participant has indicated that they understand the information and accept the risk.

14. Training for personnel engaged in research in the MEDIUM, HIGH, or HIGHEST COVID-19 exposure risk categories (see COVID-19 Exposure Risk table below) should include detailed training on the correct procedures for hand washing, donning and doffing PPE, as well as adequate cleaning and disinfecting protocols. It is strongly encouraged that laboratories use a “buddy system” to ensure that correct PPE procedures and disinfecting protocols are followed by all personnel. **Research in the Medium/High/Highest risk level are to be avoided until university guidelines allow.**

15. Community-based studies or studies that take place at affiliated facilities should follow these same guidelines with the addition of any guidance and/or rules imposed by the community partners and/or other facilities.
COVID-19 Human Subjects Research Checklist

Click here to access the link to complete the checklist.

The purpose of this checklist is to: 1) Ensure all researchers evaluate and plan for the health and safety of researchers, participants, and potentially impacted communities prior to resuming in person research or beginning new research; 2) Assist researchers to review their critical operations, plans, approvals, and equipment before resuming or beginning new operations following the BSU temporary closure.

Principal investigators are ultimately responsible for:
1. Ensuring all research operations are accounted for, and that any hazardous materials/equipment are appropriately introduced/reintroduced safely into operations.
2. Planning and modifying any research methods and procedures to enhance human safety and reduce risk.
3. Identifying and training personnel able to safely perform any required opening procedures, modified research procedures, any critical operations, and effective closing procedures (should they be necessary).
4. Meeting specific requirements for physical distancing and other protective measures in place during the COVID-19 pandemic and ensuring that all research is conducted efficiently to minimize in-person contact between researchers, researchers and human subjects, the general public, and/or support personnel.
5. Empowering any research-related faculty, staff, or students to issue “stop work” orders should an unsafe condition emerge.
6. Providing all research personnel with appropriate contact information for all key research contacts and safety-related services.

In order to meet these responsibilities, Principal Investigators must complete this checklist. All research personnel should be properly trained in research and procedures and safe equipment use. Researchers should remain flexible to changing circumstances and remain postured and prepared to safely/securely ramp down operations in the future, as necessary.

Instructions: The following checklist questions will help determine if your research is adequately prepared to meet COVID-19 related health, safety, and compliance needs.
“Yes” certifies that you are confirming a research requirement and/or have performed a specific action;
“No” certifies that you are denying a research requirement and/or have not performed a specific action;
“N/A” certifies the particular item is not present in your research.

Once all boxes are checked, your form will be routed accordingly. If you indicate that there is no exposure risk, your form will be sent directly to the BSU IRB. If you indicate low, medium, high, or highest risk, your form will be routed to your Dean or Director for approval. Do not begin (or resume) research before receiving confirmation that your completed checklist has been received and approved by the Dean.

Please note that while completion of this checklist is required to begin or resume research, it is not a substitute for complete IRB applications, including clear and thorough methods and materials. The IRB may require more details regarding study benefits, risks and risk mitigation.
Suggested consent language for COVID 19:

**Important Information about COVID-19 and Research Participation**
At Bridgewater State University our primary responsibility related to research is to protect the safety of our research participants.

If you are considering joining an in-person study at this time or are currently enrolled in a study, it is important that you consider the following information to determine if study participation is right for you at this time.

**How is COVID-19 spread?** COVID-19 is a respiratory virus spread by respiratory droplets, mainly from person-to-person. This can happen between people who are in close contact with one another (less than 6 feet). It is also possible that a person can get COVID-19 by touching a surface or object (such as a doorknob or counter surface) that has the virus on it, then touching their mouth, nose, or eyes.

**Can COVID-19 be prevented?** Current ways to minimize the risk of exposure to COVID-19 include “social distancing” which is a practice to decrease the potential for direct exposure to others who may have been exposed to COVID-19, for example by avoiding large gatherings or refraining from shaking hands with others. It is important to understand that since study participation may include increased travel outside of your home and increased exposure to others within a clinical care environment or research site it may increase your exposure to COVID-19. At this time there is no vaccination to prevent COVID-19 infection.

**What are the risks of COVID-19?** For most people, the new coronavirus causes only mild or moderate symptoms, such as fever and cough. For some, especially older adults and people with existing health problems, it can cause more severe illness, including pneumonia. While we are still learning about this virus, the information we have right now suggests that about 3 of 100 people who are infected might die from the virus.

**Who is most at risk?** Individuals over 60 and with chronic conditions such as cancer, diabetes and lung disease have the highest rates of severe disease from the infection.

**How could your participation in this research change as a result of COVID-19?** There are several ways we try to minimize your risk. If possible, we limit the number of times you have to come to a clinical care or research site. We ask every research participant if they have the symptoms of COVID-19 or have been in close contact with anyone who has or had COVID-19. During your research visits, we try to reduce the time you are exposed to other people as much as possible. If you are suspected to be positive for COVID-19, there may be last minute changes to how research procedures are performed [such as a change from an in-person visit to a telephone call] or cancellations of research tests or procedures to ensure your safety. It is even possible that your research procedures will be put on hold or stopped because of COVID-19.

The information related to risks of COVID-19 changes every day. The leaders at BSU are monitoring these risks and deciding how these risks should change our research. If you have questions about COVID-19 and your participation in research, please talk to your study team.
<table>
<thead>
<tr>
<th>CV-19 Exposure Risk</th>
<th>Study Activities and Examples</th>
<th>Mitigation Strategies</th>
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| None                | • Studies conducted using fully online/distance methods or remote activities  
Example Activities: Online surveys, web-based experimental tasks, virtual interviews and focus groups, phone interviews, telehealth, remote chart review | N/A |
| Low                 | • In-person interactions and procedures that require no physical contact and that can maintain social distancing, minimum 6 ft, between all individuals  
• Can be conducted with limited number of research team members (max 2)  
Example Activities: Behavioral experiments or clinical interventions without physical contact, computerized tasks, onsite chart review | • Personnel training on handwashing, face coverings, disinfection  
• COVID-19 symptom screening for researchers and participants  
• Social distancing plan to maintain 6 ft between all individuals  
• Face coverings for researchers and subjects  
• Increased cleaning/disinfecting |
| High                | • In-person non-invasive interactions and procedures that require minimal physical contact but can otherwise maintain social distancing  
• Physical contact with the participant limited to one research team member  
• Can be conducted with limited number of research team members (max 2)  
Example Activities: Instrument setup including MRI, TMS, ERP, DEXA, eye tracking, physical examinations such as balance testing and neurological exam, blood pressure measurements, sleep evaluations, audiology assessment, studies with infants and young children that are not anxiety-provoking | • Personnel training on handwashing, wearing PPE, disinfection  
• COVID-19 symptom screening for researchers and participants  
• Social distancing plan to minimize physical contact and otherwise maintain 6 ft between all individuals  
• Surgical grade mask, gloves for researchers  
• Increased cleaning/disinfecting |
| Highest             | • In-person interactions, interventional activities and procedures that require physical contact less than 15 mins and involve collection of biofluid samples through non-aerosolizing methods  
Example Activities: Collection of blood, urine, saliva samples, contact with mucosa | • Personnel training on handwashing, wearing PPE, disinfection  
• Personnel training on procedures for safe handling of biofluid samples  
• COVID-19 symptom screening for researchers and participants  
• Social distancing plan to minimize physical contact time  
• Surgical grade mask, gloves for researchers  
• Additional PPE including gown and eye protection may be required for post-collection processing of biofluid samples  
• Increased cleaning/disinfecting |
|                     | • In-person interactions, interventional activities and procedures that may or may not require physical contact but likely produce aerosols  
• Activities and procedures that require direct or close physical contact lasting more than 15 mins  
• COVID-19 studies involving patients with current diagnosis, under investigation, or those with active symptoms consistent with COVID-19  
Example Activities: Studies involving exercise, cardiovascular stress testing, pulmonary function tests, infant-child studies that may induce crying, medical procedures including but not limited to intubation, anesthesia, interventional and basic research studies involving COVID-19 patients | • Personnel training on handwashing, donning/doffing full PPE, disinfection  
• Procedures for safe handling of biofluid samples where required  
• COVID-19 symptom screening for researchers and participants  
• Social distancing plans to minimize physical contact time  
• Full PPE for researchers including N-95 grade mask, gloves, gown, eye protection  
• Increased cleaning/disinfecting  
• Consider COVID-19 testing of study participants prior to intervention  
• Adequate ventilation¹ |

¹Adequate ventilation: Where possible, research in the HIGHEST exposure category should be conducted in spaces with negative-pressure ventilation. If negative-pressure ventilation is not available, pauses between participants should be included to allow for adequate air circulation, air replacement, and disinfecting. Guidance can be obtained through Facilities Management. Revised August 28, 2020