

Human Subject Research Guidance

SAFEGUARDING THE HEALTH OF RESEARCH PARTICIPANTS

EFFECTIVE DATE: March 23, 2022

INTRODUCTION

In accordance with the University's updates to required COVID-19 measures on campus, the guidance in this document has been designed to provide Principal Investigators (PIs) more discretion in assessing and mitigating the risk of research participant exposure to COVID-19 and transmissible diseases in general.

GENERAL GUIDELINES

1. Newly approved IRB protocols do not need to submit a Research Resumption Application and those studies that have received a modification approval, do not need to update, or submit new Research Resumption Applications.
2. Newly approved IRB protocols do not need to develop and implement a specific COVID Safety Plan and those studies that have received a modification approval do not need to submit updated COVID safety planning to the AVPERS. However, the below expectations and requirements with respect to transmissible disease must still be followed.
3. For existing projects, it will be the responsibility of the PI to evaluate if significant reduction in COVID protections for existing projects will alter or influence the study outcome before changes are made.
4. Taking a more universal approach towards transmissible diseases in general, PIs will still be required to assess the risk of transmissible disease spread between participants and researchers and university staff and students and incorporate steps that reduce the risk of disease transmission between researchers and participants to as low as reasonable as well as report any actual or suspected exposures or outbreaks to the Office of Academic and Research Safety at ehs@northeastern.edu. Below you will find guidance on assessing the risk of transmissible disease spread.
5. PIs must be prepared to quickly implement additional protection measures to reduce the risk of transmissible disease in the community should governmental agencies or university leadership require additional measures be put in place to reduce community risk.
6. When PIs incorporate transmissible disease reduction measures as a part of their research study, they must inform participants as well as others (including researchers, students, staff and others who may be exposed) of infectious disease protective measures to be followed when the participant is involved with face to face contact with researchers.
7. Regardless of the risk associated with the project or the status of transmissible disease spread in the city, PIs must ensure that participants and researchers can voluntarily wear face coverings or take advantage of other risk reduction strategies as long as it does not interfere with the research. If voluntary protection measures interfere with the study, the PI should collaborate with the participant or researcher on alternative solutions.

8. Regardless of the risk associated with the project, the PI should require that researchers who are feeling unwell not participate in any in-person research activities, especially with study participants, until they are well or medically cleared of transmissible disease.
9. Regardless of the risk associated with the project, the PI should encourage participants to cancel their scheduled visit if they are feeling unwell.
10. Participants and researchers should be encouraged to discuss their concerns with the PI or an assigned focal point for the project.
11. For project tasks that will take place off of the Boston campus, it will be the PIs responsibility to determine federal, state, local, and organizational requirements for reducing the risk of transmissible disease and to implement applicable requirements into their research protocol. This information is often available on the federal CDC website, state websites, and city/town websites. PIs should also contact the focal point at any non-Northeastern facility where participants meetings will occur to ensure compliance with the facility's rules and requirements.
12. Personal hygiene and research space cleanliness are a best practice under all circumstances. Therefore, PIs must maintain adequate supplies of the following
 - Hand sanitizer or hand-washing sink with soap
 - Disinfectant wipes, or similar cleaning supplies, to clean equipment and surfaces on a regular basis
 - Appropriate closed waste containers

RISK ASSESSMENT GUIDELINES

Factors to consider when assessing risk:

1. Status of transmissible disease within the community

- i. Has the local health department or community leaders communicated an increase in rate of transmissible disease circulating in the community? This information would be available on the local department of health's website in the city or town where the research will occur.
- ii. Has the local health department or community leaders issued warnings concerning a transmissible disease circulating in the community that is shown to have a negative impact on certain members of the population or the community in general? his information would be available on the local department of health's website in the city or town where the research will occur.

2. Person to person contact with human subject participants:

- i. Will the participant pool include people vulnerable to severe outcomes from contracting a transmissible disease? To determine if the participant pool is susceptible to a transmissible disease of concern, it is recommended that PIs consult available information on the CDC website.
- ii. Will the participant pool include people who may be at risk of transmitting a communicable disease, such persons positive for tuberculosis?
- iii. What activities is the participant being asked to complete (e.g., MRI, sputum test, nasal swab) and do these activities expose themselves or others to increased risk of a transmissible disease.

- NOTE: Exposure to human blood, bodily fluids, unfixed tissues or organs, tissue cultures, organ cultures, or other potentially infectious human materials is regulated under federal and state safety standards. PIs working with these types of materials must contact the Office of Academic and Research Safety prior to project approval to determine specific compliance requirements to be met.

3. Research location:

- Will any research activities take place in the participant's home?
- Will research occur in any other high-risk setting such as a hospital, clinic, congregate housing/living facilities, day care facilities, or other locations considered to be at higher than average risk of disease transmission?

RISK MITIGATION GUIDANCE

If, based on the assessment of risk, the PI determines that additional measures are needed to reduce the chance of transmissible disease spread, the following guidance is offered to assist the PI. While not an exhaustive list, the mitigation steps below represent commonly accepted measures that the PI can follow based on the outcome of the risk assessment.

NOTE: The mitigation practices identified below represent common recommendations from recognized authorities such as the CDC, the Commonwealth of Massachusetts, and other publicly available resources. It does not represent an all-inclusive list and additional measures may be needed depending on identified risk and community requirements in place at the time research will take place. It is, therefore, the responsibility of the PI and researchers to stay informed concerning best practices to reduce the risk of transmissible disease spread and to recognize that transmissible disease experts may recommend different and unique control measures for mitigating risk based on the specific disease of concern. Other sources that may be of assistance are the Northeastern Office of Academic and Research Safety as well as the Northeastern Office of Risk Management.

1. Risk Elimination

- Eliminate in-person contact with human subject research participants wherever possible.

2. Engineering Control Recommendations:

- Evaluate the ability to modify research space layout to reduce instances of participant close contact that will last longer than 15 minutes – especially if the participant will not be using a face mask.
- Work with Facilities Services personnel to ensure the ventilation in the on-campus research space is in optimal working order.
- Consider additional air filtering or air handling devices
- Evaluate waste containment and disposal

3. Administrative Controls and Safe Work Practice Recommendations:

- Limit the number of people in the research space to reduce any potential viral load.

- b. Schedule time for allowing the research space to “air out” in between scheduled research participant appointments. For on campus research, use a space that is served by a building HVAC system, where possible. It is recommended that a minimum of two air exchanges occur within the space between participant visits. Departmental safety officers or Facilities Services can assist with identifying the air exchange rate in the space.
 - c. When meeting with participants, minimize the time to as low as possible that researchers must be in close contact (less than 6 feet) with participants.
 - d. Establish a cleaning program for research personnel to sanitize all fomite locations (equipment controls, devices, table surfaces,) daily or as needed before and after each use and especially between research participant visits/use.
 - e. Train researchers on applicable risk reduction steps to be followed before, during, and after engaging with research participants.
 - f. Provide an information sheet to each study participant outlining the protocol and protective measures to be taken by researchers while the participant is present. Include the requirements the research participant will be expected to follow while participating in the study(including not showing up for in person visits if the participant is symptomatic, has been recently exposed or is diagnosed with a transmissible infection/disease
- 4.** Based on risk, the use of face masks by participants and researchers may be warranted. If face masks will be required to be worn, KN95 masks are recommended and participants should be provided a clean KN95 mask upon each arrival to the research location. Contact your departmental safety office or college safety officer to determine the most efficient way to obtain KN95 masks for use in your study.

For questions, please contact:

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