



## **HUMAN SUBJECT RESEARCH GUIDANCE**

### **Additional COVID-19 Protection Requirements for On-Campus Research**

#### **INTRODUCTION**

Due to the variables associated with human subject research, Northeastern will require the Principal Investigators (PIs) to develop individual COVID-19 notifications and protective measures for each Institutional Review Board (IRB) protocol that involves human to human contact.

#### **I. COVID-19 PROTECTION PLAN REQUIREMENTS**

- Provide an architectural layout of the research location where human subjects will be engaged. Using the space layout, identify where researchers will be positioned and where subjects will be positioned. Include all spaces where the subject may visit, including waiting areas.
- Develop a detailed written plan of compensating controls where standard COVID-19 protective measures cannot be maintained that incorporates best practice into lowering the risk of COVID-19 spread while ensuring other regulatory requirements are met (see Item II, COVID-19 Protection Plan Guidelines and Considerations).
- An informational rider to address COVID-19 risks has been developed for distribution to subjects. Researchers must provide subjects with this informational rider as an addendum to the consent process. The informational rider should be provided at the same time as the consent document. If the consent document has already been signed and returned, subjects must be given a copy of the informational rider at their next visit. The completed rider must be collected and filed accordingly. The informational rider is available from the IRB.
- Train research staff on COVID-19 protection, to include a self-audit after the completion of a subject visit to ensure protocols are being followed and are effective.
- Update the plan as COVID-19 information evolves. Regularly monitor federal, state, local, and Northeastern requirements and update your plan and train researchers accordingly.
- Ensure protocols address all IRB requirements and are approved as required by the IRB.
- Ensure all researchers participating in human subject research participate in the Northeastern COVID-19 Testing program and follow the “primarily in-person” schedule of testing every 3 days, even if the researcher is primarily remote.

#### **II. COVID-19 PROTECTION PLAN GUIDELINES AND CONSIDERATIONS: Specific considerations to be addressed based on research activities**

##### **1. General COVID-19 precaution awareness:**

- Provide initial and periodic information or otherwise update research personnel on guidelines/restrictions while attending research sessions.
- Provide initial orientation or refresher information to human subjects at the beginning of each session to review guidelines and restrictions. Clearly articulate requirements to be followed.
- Provide written information sheet to each study participant outline the protocol and protective measures to be taken.
- Establish a cleaning program for lab/office personnel to sanitize all fomite locations (equipment controls, devices, table surfaces,) daily or as needed before and after each use.
- Co-ordinate with Building Services and DSO to access lab suite (as needed), and nearby areas such as bathrooms, for cleaning communal areas, empty trash, or restock handwashing supplies.

## **2. Public Health Protective Equipment (PHPE) and Personal Protective Equipment (PPE)**

- Face coverings (PHPE) to be worn always by all research personnel. Face shields must be worn with the face covering when closer than 6 ft to others unless the research protocol provides other controls to mitigate exposure risk during the testing procedures.
- Research subjects must always wear a face covering with a face shield when closer than 6 ft to others, unless the covering interferes with the research protocol itself. If this is the case, the research protocol must provide other controls to mitigate exposure risks during the testing procedure.
- Laboratory maintains adequate supply of PHPE for research personnel:
  - Face covering (procedure mask, cloth mask)
  - Face shield
  - Disposable non-latex gloves (nitrile)
  - Lab coats: single-use (then launder) or disposable
  - Non-contact thermometers and Oxygen meters
- Provide human subjects with disposable or properly sanitized PHPE as needed.
- Laboratory maintains adequate supply of cleaning supplies:
  - Hand sanitizer or hand-washing sink with soap
  - Disinfectant wipes, or similar cleaning supplies, to clean equipment and surfaces between different subjects.

## **3. COVID-19 Controls:** The following considerations should be addressed within your written plan, if applicable.

- At what points in each protocol will there be human to human contact? What is involved with that contact? How long will the contact last? What is the number of people who will be involved with the contact at any given time?
- What percentage of the day will researchers spend in close contact with human subjects?
- How can you eliminate or reduce human to human contact time?
- What protective equipment will be used to reduce the risk of viral spread? Will barriers be erected to limit close contact?

- What sanitization plans will be used before and after human subject visits? How long will sanitization take? What materials will you use?
- How will you schedule? Is there a waiting room for human subjects? Will they be in this room alone or with others?
- How will you communicate requirements the subject must follow while on campus?
- Who is in your human subject population? Is there a chance a human subject could be in the high-risk category for developing the severe form of COVID-19?
- What is your expectation for the subject? Will you provide a mask and face shield for their use? Will you have them wash their hands before beginning and before leaving?

**4. Additional precautions for human subject research on campus:**

- Confirm pre-visit health screening or other pre-visit clearance procedure. On the day of a scheduled visit, the human subject should confirm that none of the following symptoms or conditions exist:
  - Extreme difficulty breathing
  - Blue-colored lips or face
  - Severe pain or pressure in the chest
  - Severe constant dizziness or light-headedness
  - Fever or feeling feverish
  - Chills
  - Shortness of breath
  - Cough
  - Body Aches
  - Sore Throat
  - New loss of taste or smell
  - New gastrointestinal symptoms
  - In the past 14-days have you had close contact with someone who is confirmed as having COVID-19?
- Confirm on-campus parking availability and/or other transportation matters for their visit to campus
- Research subjects must always be greeted by the PI or his/her designee at the building entrance and escorted when in the building.
- Review the location of emergency fire egress, restrooms, as well as food/drink breaks or other procedures that facilitate their visit.

For questions, please contact:

Marné Smith  
 Associate Vice Provost for Education and Research Safety  
 Email: [marn.smith@northeastern.edu](mailto:marn.smith@northeastern.edu)