HUMAN SUBJECT RESEARCH GUIDANCE

Additional COVID-19 Protection Requirements for Research Performed in Subject's Homes

INTRODUCTION

Due to the variables associated with human subject research performed in the subject's home, 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 within the subject's home.*

I. COVID-19 PROTECTION PLAN REQUIREMENTS

1. Develop a detailed written plan of compensating controls to augment standard COVID-19 protective measures and that incorporates best practice for lowering the risk of COVID-19 spread while ensuring other regulatory requirements are met (see Item II, COVID-19 Protection Plan Guidelines and Considerations).
2. Ensure the subject (or subject's guardian) reads, understands, and agrees to the Northeastern consent addendum notification associated with COVID-19. For your records, ensure the subject (or guardian) signs the consent. An unsigned copy of the consent can be left with the subject (or guardian). If applicable, the Northeastern consent may be read to the subject with verification, preferably in writing, that the participant understands and agrees to it.
3. 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.
4. Update the plan as COVID-19 information evolves. Regularly monitor federal, state, local, and Northeastern requirements and update your plan and train researchers accordingly.
5. Ensure protocols address all IRB requirements and are approved as required by the IRB.

6. Ensure all researchers involved with human subject research participate in the Northeastrn in-person COVID-19 testing program 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 precautions and awareness activities to be completed prior to the visit:

a) Provide initial and periodic information or otherwise update research personnel on guidelines/restrictions while attending research sessions.
b) Work with the subject to:
    i. Determine an appropriate room in the home where the research can be conducted.
    ii. Confirm the subject is physically able to wear a mask and will consent to wearing a clean surgical mask provided by the researcher.
    iii. Discuss requirements for other members of the household. (i.e. other members of the household must not enter the room where the researcher is working with the participant unless the household member is the legal guardian of a minor subject and wearing appropriate PHPE and PPE.)
c) Provide information to human subjects as a of review guidelines and restrictions. Clearly articulate requirements to be followed.
d) Prepare equipment to be used in the home per the requirements below in Section 3.
a) Complete pre-visit health screening or other pre-visit clearance procedure for the subject and all other members in the household on the day of the visit to include all members of the household.
b) If the participant or any member in the household exhibits symptoms, the visit must be cancelled and scheduled for another day once the participant or household are free of symptoms for 14 days. The minimum screening questions should include:
    i. Are you experiencing any of the following symptoms?
        - New loss of smell or taste
        - New or worsened muscle aches
        - Fever, feeling feverish or shaking chills
        - New or worsened cough
        - New or worsened shortness of breath
        - New or worsened sore throat
        - Diarrhea/vomiting

- In the past fourteen (14) days, have you had close contact with someone who is confirmed as having COVID-19?

ii. A close contact is defined as a person who:

- Provided care for the individual, including healthcare workers, family members or other caregivers, or who had similar close physical contact without consistent and appropriate use of personal protective equipment or,
- who lived with or otherwise had close prolonged contact (within 6 feet/2 meters) with the person while they were infectious or,
- had direct contact with infectious bodily fluids of the person (e.g., was coughed or sneezed on) while not wearing recommended personal protective equipment.

2. Upon arriving for the visit

a) Provide initial orientation or refresher information to human subjects as a review guidelines and restrictions. Clearly articulate requirements to be followed.

b) Provide and use sanitizer that has been approved by the CDC. Both the participant and research must use the sanitizer at the start of work and at the end of work as well as any time in between when hands may become contaminated.

i. Clean nitrile gloves are also appropriate for use and will require hands to be sanitized before donning and after doffing the gloves.

ii. Change gloves any time contamination of the outer surface has occurred.

c) Provide the required PHPE and PPE as described in Section 4 below.

i. Safety glasses, goggles, or face shields must be wiped down before putting them on and after taking them off. Hands will be sanitized before donning or removing any safety gear used on the face or head, including donning and doffing facial coverings

d) Provide written information sheet to each study participant outlining the protocol and protective measures to be taken.

i. Include a summary of the Northeastern COVID-19 testing program, when the last time the researcher was tested, the results of the test with the understanding that a researcher who has received a positive test is prohibited to participate in human subject research until cleared to do so as required by a Northeastern's Return To Work Policy.

e) Complete the research as required.

3. Shipping or delivering research equipment to the participant's home

a) Establish a cleaning program (based on vendor recommendations) to sanitize all equipment and materials to be brought or shipped to the home and include the following:
    i. Obtain a sanitizer that is appropriate for use with your equipment. Ensure you have the safety data sheet available and review it for applicable precautions.
    ii. Follow the manufacturer instructions for sanitizer use to include contact time of the sanitizer with the surface it has been applied to.
    iii. Wear required PPE as specified by the manufacturer to include gloves and sanitize all equipment in advance of shipment or in-person delivery to the home. Place equipment in a sealed bag with the date that it was sanitized. It is recommended to let this sealed bag sit for 72-96 hours before shipment to the participant.
    iv. Ship or deliver the sanitized equipment to the participant in the bag with the sanitization date.
    v. If the participant is to use equipment without a researcher present, include instructions explaining to the participant how to use the equipment and instruct them to place equipment back in the bag after use. The participant can mail equipment back to your lab or the researcher can decide to pick up the package in person.
        i. In person pick up will require that prescreening as defined below has been completed and the researcher and participant are wearing appropriate PHPE while in contact with each other.

d) It is recommended that the returned equipment to sit for 72-96 hours (for viral decay) before opening it up. Don appropriate PPE including gloves to open the bag and sanitize the equipment before use. However, if access to the equipment is needed immediately, thorough sanitization must occur prior to use.
    i. Under all circumstances requiring equipment sanitization, a sanitization protocol must be developed and submitted with your application. Follow all manufacturer instructions for appropriate and effective use.

e) Ensure appropriate cleaning and sanitizing supplies are available for use off site as needed.

4. Public Health Protective Equipment (PHPE) and Personal Protective Equipment (PPE)

a) A new, clean surgical mask and face shield are to always be worn by all research personnel when engaging participants in their homes. Gloves are also be worn and changed after potential contamination.
b) Research subjects must always wear a clean surgical mask provided by the researcher and face shield when the researcher is in the home unless the shield and/or face 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 research visit.
c) Researcher brings adequate supply of PHPE as appropriate for research personnel and participants:
    i. Surgical mask
    ii. Face shield
    iii. Disposable non-latex gloves (nitrile)
    iv. Lab coats: single-use (then launder) or disposable
    v. Non-contact thermometers and Oxygen meters
    vi. Provide human subjects with disposable or properly sanitized PHPE as needed.
    vii. Hand sanitizer
    viii. Disinfectant wipes, or similar cleaning supplies, to clean equipment and surfaces as needed.

5. ADDITIONAL HYGIENE MEASURES

a) Frequent hand washing is required. Hands must be washed after touching common surfaces outside of the lab such as in bathrooms and pantry areas.
b) Shared equipment/supplies will be wiped down before and after each use of the equipment. This includes pens and other incidental items. Wash hands after using and disinfecting shared equipment.
c) Personal equipment that is not shared with others must be sanitized daily.
d) DISINFECTANTS: The United States Environmental Protection Agency (USEPA) has created a list of effective disinfectants to be used. Only disinfectants listed on the USEPA N List. If a non-listed disinfectant is to be used, proof will be available to show that it meets USEPA criteria for use against COVID-19. Researchers responsible for disinfecting equipment and surfaces will be provided an SDS and instructions for the disinfectant to be used and will follow all manufacturer requirements for use. More information is available here: https://www.epa.gov/pesticide-registration/list-n-disinfectants-use-against-sars-cov-2-covid-19

6. **Additional COVID-19 Controls:** The following considerations should be addressedwithin your written plan, if applicable.

    a) At what points in each protocol will there be human to human contact, including physical contact with the participant as well as in-person interviews with the participant ?
        i. What is involved with that contact?
        ii. How long will the contact last?
        iii. What is the number of people who will be involved with the contact at any given time?
        iv. For in person interviews, what physical distance will be maintained?
    b) What amount of time will researchers spend in the subject's home?
    c) What amount of time with researchers and participants spend in close contact with human subjects in their home?
    d) What locations other than the home can be used for the research?
    e) What location at the home can be used to minimize indoor contact (covered porch, patio, sunroom with open windows
    f) How can you eliminate or reduce human to human contact time?
    g) How can you eliminate or reduce time spent in the subject's home?
    h) What sanitization plans will be used before and after human subject visits? How long will sanitization take? What materials will you use?
    i) How will you schedule the visit?
    j) How will you communicate requirements the subject must follow while participating in the study?
    k) Who is in your human subject population?
    l) Is there a chance a human subject could be in the high-risk category for developing the severe form of COVID-19?
    m) What is your expectation for the subject?

For questions, please contact:

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