**Guidelines for Restarting Human Participant Research**

**State University of New York at New Paltz**

Introduction

On April 3, 2020, Jason Wrench, the interim Human Protections Administrator for SUNY New Paltz, suspended all human subjects research conducted face-to-face due to the COVID-19 pandemic. This document sets forth guidelines that serve as a plan for restarting human subjects research at SUNY New Paltz.

Key Principles

* Protect the health and safety of human research participants, research personnel, and others involved in the research enterprise.
* Re-opening must be consistent with all applicable government mandates.
* Follow guidance from New York State, SUNY, the Office of Human Research Protections (OHRP), the Centers for Disease Control and Prevention (CDC), and our local requirements here at SUNY New Paltz.
* Resume research activities as public health conditions and campus resources permit.

All researchers should consider conducting research online or remotely whenever possible.

If face-to-face interaction is necessary, then the researcher must provide a rationale (cost/benefit) and must create a COVID-19 Plan and submit it to the HREB for review.

Elements of a COVID-19 Plan.

1. Lab Specific Procedures

Each research lab must submit a detailed description of their lab specific procedures to address COVID-19 issues and how the original procedures were adjusted. A key to this will be a description of the interactions the lab personnel will have with the research participants including: setting up equipment, giving instructions, using physiological monitoring devices, monitoring progress, and debriefing.

2. Training

All researchers, research assistants, and research staff will need to complete COVID-19 practices training. All SUNY New Paltz employees and student researchers will need to complete NYForward Employee Training.

3. Health Screening

You must have a plan to conduct a health screening for both participants and research personnel. You may want to consider a pre-screening the night before the research session and a screening when the participants and research personnel arrive for the study.

You must conduct both a temperature screen and a health question screening. The HREB recommends touchless thermometers. How will you conduct temperature screens? When and how will you document that individuals passed the health screening.

You should specify the contingencies for the case when someone fails the screening.

4. Contact Log

You must keep a log of everyone who enters and interacts in your research lab space. You need to record the time (of entry and departure) and date for everyone who enters and interacts in your research lab space. You should also record any researchers or other personnel participants may have had contact with.

5. COVID-19 Information Sheet

You must provide an information sheet about COVID-19 and its related risks to research participants.

6. Social Distancing --6 feet apart

You must detail your plan for keeping a minimum of 6 feet between participants and researchers.

* How many people will share the space at a time?
* How will informed consent and instructions be given?
* How will equipment be set up?
* Where will participants wait for the study to begin?
* How will you stagger start times?
* How much time will be scheduled between participant appointments?

All interactions should maintain the 6 feet of physical distance, except when not possible due to the nature of specific research procedures. When this occurs, participants and research staff must wear masks.

When designing protective measures for safe distancing, researchers must consider the amount of time between participant interventions. Researchers should take into consideration the space and its contents, air flow and exchange, and prevailing guidelines from the CDC, such as: <https://www.cdc.gov/coronavirus/2019-ncov/community/office-buildings.html> and OSHA: <https://www.osha.gov/SLTC/covid-19/>.

All researchers should consult the Office of Emergency Management:  <https://www.newpaltz.edu/emergency/> and the Office of Environmental Health and Safety: <https://newpaltz.edu/ehs/> to understand the needs of their lab space.

7. Masks

Study team members and research participants must wear face coverings during all in-person interactions, except when not possible due to the nature of a specific research procedure. In these cases, physical distancing guidelines must be adhered to.

8. COVID Personal Protective Equipment (PPE)

Your plan should include a description of the PPE that will be used in your research for participants and research personnel. You should also indicate what PPE the research lab will provide and what PPE participants and research personnel will be expected to bring with them. For example, will you provide masks for participants and research personnel? If they fail to bring their face masks, will you provide them or will you ask them to leave? Will you require gloves? Will research personnel use face shields? Will there be plexiglass barriers set up between the participant and researcher?

Requests for supplies such as PPE, no-touch thermometers, and disinfectants, may be made directly through the College online request form: <https://www.newpaltz.edu/emergency/return-to-work-requests/>. Supplies will be provided at no cost to the researcher or their Department.

Note, for projects with more than one investigator or study team member, only one person should be designated to submit the request. If you have multiple research projects, please consolidate your needs into one request. This person must have knowledge regarding the spaces where supplies will be needed.

9. Common Equipment

You must include your procedures for disinfecting equipment used in your research study. Equipment includes, computers, electrodes, equipment to measure physiological responses, eye tracking equipment, etc... Who will be responsible for disinfecting the equipment? How will this be done after each participant?

10. Sanitizing Lab Space/Rooms

You will be responsible for cleaning and sanitizing your lab space between participants. This includes cleaning desks, chairs, door knobs, light switches, etc... Air exchange requires temporally spacing sessions.

11. Handwashing/Hand Sanitizer

Your plan must include a description for handwashing and providing hand sanitizer. Will you require participants and research personnel to wash their hands prior to beginning the research study? All research labs should have hand sanitizer that is approved by SUNY New Paltz available in the area. In addition, research personnel should be able to direct participants to the nearest place to wash their hands before and after the research study.

NOTE: As stated above, if these guidelines are in conflict with the SUNY New Paltz campus guidelines, the campus guidelines take precedence.