Supplemental Guidance for the Return to In-person Research with Human Study Subjects
(This guidance is for research whereby social distancing can be maintained)

In order to resume in-person research with human study subjects, all safety processes set forth by the University must be strictly followed. Principal Investigators (PI) must regularly check updates by the CDC and the NYSDOH screening guidelines to ensure that information is current including any supplemental guidelines for certain populations.

It is highly likely that human subject protocols with in-person interactions will require study modifications to address the safety procedures related to COVID (i.e. adjustment in location, addition or removal of an activity, change of subject pool). All modification requests must be submitted by the PI via PACS and be approved by the IRB. It is best practice to contact the IRB office to discuss the modification(s) before submitting via PACS.

In addition to submitting modifications to the IRB, each Principal Investigator (PI) will be required to complete and submit a Return to In-Person Research with Human Subjects Request Form (R2R-HS) for review and approval via the University Return to Research (R2R) process before research can commence. Careful planning is critical to reduce opportunities for exposure.

Note: Investigators seeking to engage in any on-campus research that requires the use of lab space(s) must first complete the general Return to Research Application Form (R2R) and receive approval before the Return to In-person Research with Humans Subjects process can occur. This is a separate step in the approval process for PIs with dedicated lab spaces.

Return to Research forms and all related information and guidance can be found at: https://www.binghamton.edu/research/vp/returntoresearch.html

Online activities (interviews with individual and/or focus groups, questionnaires, surveys) previously approved by the IRB, and the analysis of data when performed remotely, can be conducted without additional restrictions and do not require additional approval. NOTE: Best practice will be to adapt to online platforms for any research for which this approach is reasonably possible.

Please follow these supplemental guidelines, as applicable to your protocol, to promote a safe environment when conducting in-person human subject research.

- **Modify protocols** to conduct research online whenever possible and/or remove non-essential steps in protocols that require in-person interactions. If possible, any of the ordinary screening, consent, and survey documents should be filled out online before the study subject arrives.
- **COVID-vulnerable populations:** Researchers and study subjects who are over age 65 and/or have health conditions that make them vulnerable to experiencing serious complications should be precluded from participating in in-person data collection.
(especially in research with no direct benefits to the study subjects or no near-term benefit to health and well-being).

- **A screening protocol** for all study subjects and study team members for COVID symptoms and exposure is to be followed. Advise all to evaluate their health and potential risk for COVID-exposure before their engagement. If they have any symptoms of illness, they should discuss them with a healthcare provider and the engagement should be postponed until the study subject and/or the study member is symptom free for 14 days. Ideally, study subjects and study team members will be screened prior to entering the research facility (e.g. phone, email, or web-based assessment on the day of the visit). If a prior screen is not proposed, a justification will be required. The following screening questions are to be considered in the screening protocol:
  - Have you or someone you live with been tested for or diagnosed with COVID-19 in the last four weeks?
  - Have you traveled out of state or country recently?
  - Are you experiencing any of the following?
    - Fever (100 degrees or higher)
    - Chills
    - New or worsening shortness of breath or difficulty breathing
    - New or worsening cough
    - Muscle or body aches
    - Sore throat
    - Congestion or runny nose
    - Nausea, vomiting, and/or diarrhea
    - New loss of smell or taste

If anyone screens positive for any symptoms, then their participation must be cancelled or rescheduled and the individual should be encouraged to contact their primary care physician. Temperature screening is not required, but PIs may choose to adopt this measure.

- **Informed Consent:** At the time of consent (online or in-person), the study subject should be given a brief description of the health risk mitigation procedures. Encourage subjects to bring their own pen if the IC requires a signature (preferentially, complete this step online). Request a waiver of signature to the IRB when appropriate/allowable as part of a modification of the protocol.

- **Post alerts** such as signs and posters at entrances and in strategic places around the facility with instructions for study subjects with COVID symptoms to go home and contact their health care provider.

- **Schedule** one-on-one appointments only. Consider having study subjects text or call you when they have arrived so you can be waiting for them to minimize time in waiting areas. The PI is to maintain a daily log of project activities and check-in and check-out schedules. Schedule appointment times to avoid overlap/contact with other study subjects and to permit time for any necessary disinfection between tests. Note that any log must not refer to the subject’s participation in any way. Multiple study subjects waiting in a waiting area is not permitted.
• Social distancing of 6 feet apart is to be maintained during the research activities (i.e. interviews, computer activities, observations. This includes waiting areas. When possible, the study subject should come to the site alone. If another person accompanies the study subject, the accompanying person should wait outside or in the car if feasible. If that is not feasible, make sure that your site can provide an appropriate waiting area that ensures social distancing. Meeting rooms are to be scheduled and arranged in advanced.

• Minimize the number of study team members engaging with study subjects during the research activities. Schedule appropriately to avoid an overlap of study team members. Consider the use of web cameras or baby monitors where possible if testing rooms are small.

• Facial Coverings/PPE: A facial covering must be worn by study team members and study subjects during in-person interactions. Furthermore, study team members must keep facial coverings in place regardless of whether study subjects are present. Advise study subjects that they should put on a facial covering before arriving for their visit. If the study subject arrives and is not already wearing a facial covering, provide one. The PI is to provide the necessary and appropriate safety equipment and PPE to all study team members. The use of gloves, face shields, and physical structural barriers (i.e. plexiglass) should be considered as additional measures, if appropriate.

• Hand Washing/Sanitizing: Frequently sanitize hands during activities (before and after at a minimum). Ensure that all study team members are trained in the execution of sanitization procedures (with documentation of training completion). Research procedure areas, data collection areas, and equipment must be carefully cleaned and disinfected prior to and following use by study team members and/or subjects. This process includes a regular wipe down of shared research equipment and spaces (e.g., desk and table tops, chairs, keyboard/mouse, tablets, clipboards, pens, door handles) after each visit plus a wipe down of shared research equipment and spaces at the end of the day. If a study subject wishes to also wipe down an area they will come in contact with, they are to be provided with disinfectant wipes. Please note that any cleaning done by study subjects does not substitute for the required cleaning by the study team. If study subjects are using keyboards, study personnel should put a smooth covering over them or detail a procedure for disinfection. Contact the EH&S Office for guidance. Study subjects using a shared piece of equipment (e.g., keyboard, mouse, touch screen) should also be offered hand sanitizer containing at least 60% alcohol or access to a sink for hand-washing and gloves for optional use during the visit. Hand sanitizer should be available to study subjects throughout their study visit. Contact EH&S or the OH&S Specialist should you have any questions or need guidance.

• Contingency plans should be developed in the event that there is a second surge of a COVID outbreak. This instance may require in-person research to be ramped down. During safety planning, consider which studies/aspect of the research can be easily halted or delayed.

• Off-site facilities where the research will be conducted may have specific requirements or policies related to COVID. The policies of the external entity in combination with those enclosed in this document (whichever are most restrictive)
must be followed. Research visits to study subjects’ homes should only be conducted if they can be “contactless,” such as deliveries and/or pickups of samples or devices. Recommendations for study team and subjects regarding the wearing of facial covering, maintaining social distancing, and frequent handwashing must always be followed. No private in-home visits to conduct in-person human subjects research are allowed at this time. If traveling to an off-campus study site, there should only be one study team member per vehicle, however exceptions may be made under certain circumstances (consult the IRB).

**Note:** The IRB will require a current letter of cooperation/collaboration with the off-site entity(s) to ensure all safety measures required at the site(s) are understood and can be adhered to by the PI and study team.

If you have any questions, please contact Nancy Lewis, Assistant Vice President for Research Compliance at nlewis@binghamton.edu or at (607) 777-3532 or Linda Reynolds, IRB Associate Director at lreynold@binghamton.edu. You can also contact the Department of Health and Safety at (607) 777-2222 or visit their website at [https://www.binghamton.edu/ehs/contact_us.html](https://www.binghamton.edu/ehs/contact_us.html) for the EH&S staff listing.

Additional guidance can be found at
[https://www.binghamton.edu/research/vp/covid19.htm](https://www.binghamton.edu/research/vp/covid19.htm)
[https://www.rfsuny.org/About-Us/COVID-19/](https://www.rfsuny.org/About-Us/COVID-19/)