May 20, 2020

We are emerging from the ‘pause’ that the COVID-19 pandemic has brought to the University’s research community. As restrictions surrounding coronavirus begin to ease, we are planning to incrementally expand human subject research activities. However, a return to “normal” activity is unlikely for many months or longer.

There will be a new era of precautions, which we expect to last for many months, and possibly longer. Social distancing, masking, increased cleaning precautions, and other modifications will become common.

The gradual expansion of human subject research at UB will be tied to the corresponding expansion of clinical operations including regular clinic/office visits and elective surgeries and procedures in our affiliate institutions and, on the North, South and Downtown Campuses, opening up the laboratory research areas.

\*\**Additional limitations to restarting some individual projects may be imposed by sponsors of the research or through Local, State or Federal direction.*

*\*\* Refer to the* [*UB COVID-19 Information*](http://www.buffalo.edu/coronavirus/dashboard.html) *page for UB updates*

Please also note that study ramp up will likely take time. We suggest that each PI and department assess start-up capacity and stagger the restart.

This document provides guidance to research teams who conduct or manage human subjects research in the COVID-19 era.

**The following factors should be used to determine restarting studies involving human subjects:**

* Potential clinical benefit to patients
* Ability to maintain social distancing during in-person visits
* Availability of appropriate personal protective equipment and other supplies necessary to conduct in-person visits safely (see below)
* Approval by the IRB of any protocol changes necessitated by social distancing and hygiene requirements
* Permission from the sponsor to restart sponsored studies
* Studies with “time-sensitive” considerations
* Ensuring that each point in the next section “**Before you restart any study, make sure that you have:”** is in place:

**Before you restart any study, make sure that you have:**

* a study visit area that can accommodate social distancing in both the study treatment/visit area and the waiting area
* the ability to screen study subjects by phone prior to the study visit and at the time of the onsite study visit.
	+ The study subject should be questioned regarding symptoms of COVID-19 including: fever, cough, shortness of breath, sore throat, fever, muscle aches, headache, new loss of taste or smell, repeated or shaking chills.
* adequate personal protective equipment (PPE) and hand washing supplies for both study subjects and staff
	+ Note: UB will provide cloth face masks to all UB employees. PPE required for study participants and extra PPE for research teams necessitated by the study will be the responsibility of the Principal Investigator (PI). The PI should work with purchasing to buy their own face masks and gloves and other PPE as required for their studies to provide to their employees.
* a thermometer to take each participant’s temperature upon arrival for the visit
* cleaning supplies on hand to clean furniture and study equipment that come in contact with study subjects (see below)
* examined the study protocol and contacted the study sponsor and the IRB, where appropriate, about any modifications, including changes in protocol, remote/virtual/tele-research visits, new risks to study subjects, or any other study protocol issues.
* Approval of the Institutional Biosafety Committee for studies that require collection of biological samples that may cause an increased COVID-19 exposure risk to study staff;
	+ for example procedures that may generate aerosols (e.g., pulmonary function tests, exercise testing, bronchoscopy). The CRO will be able to assist with this.
* a plan developed by the PI, for how your clinical studies will be conducted. The plan should be in compliance with UB, state, sponsor, DHHS, FDA and IRB regulations and should be submitted to the PI’s department chair who will send to the associate dean for research of the PI’s school. The plan should be available if it is requested by UB, state, sponsor, or regulatory agencies. The human subject research plan should be compatible with the check list outlined in the University at Buffalo: Research Ramp-up Plan developed by the Office of the Vice President for Research and Economic Development.

Note that for study visits that are conducted at Kaleida, Erie County Medical Center or practice sites, the conduct of the visits should also adhere to policies and procedures of those sites.

We strongly advise conducting several mock study visit practice sessions so that study staff can practice the new workflow.

**General Guidance**

* Modifications in study procedures and study conduct need to be approved by the IRB and the study sponsor.
* Physical visits should be replaced with phone or video sessions where possible. This may include using an alternate consent process for enrollment.
* For studies that have safety monitoring, alternate methods for study safety assessments should be evaluated, as research subjects may not be able to get to the study site. However, the alternate methods must be sufficient to assure the safety of study subjects. Study sponsors should determine if in-person visits are necessary to fully assure the safety of subjects. This may require a modification to the existing study.
* Consider if study subjects can be provided investigational medicinal products at home if they cannot get to the study site. Verbal consent from the subject to provide shipping information, as well as all necessary posting/storage requirements must be provided. Additionally, a risk assessment must be completed by the study team. If the study subject is unable to sign for the package, a follow up phone call is required to ensure the products were successfully delivered.
* Comprehensive guidance on clinical trials and research conduct can be found in the document: [FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Public Health Emergency](https://www.fda.gov/media/136238/download).
* Develop a plan to safeguard subjects and investigators in the event of potential disruption of the study as a result of COVID-19 (e.g. cross train research staff to fill in for others who may be out sick or unable to come to work; create a unique identifier for participants affected by COVID-19; assess the availability of clinical trial supplies and continued operations of vendors, etc.)

**Research Personnel**

**Personnel Screening:** Any study personnel with COVID-19 symptoms should **not** report to work.

**PPE Training:**All study personnel who will have direct subject contact should review the training provided free by the World Health Organization (WHO): [Health and safety briefing for respiratory diseases](https://openwho.org/courses/eprotect-acute-respiratory-infections) even if you do not expect to have studies with COVID-19 positive subjects with active infection. This is important, as you may need to do follow up visits with subjects who have tested positive for COVID-19, or who are less than 28 days out from a COVID-19 infection.

Additional training provided by WHO : [Hand hygiene](https://openwho.org/courses/IPC-HH-en)

 [COVID-19:How to put on and remove PPE](https://openwho.org/courses/IPC-PPE-EN)

[UB Environmental Health and Safety](http://www.buffalo.edu/administrative-services/managing-facilities/environment-and-safety.html) offers excellent safety training resources.

**Human Subject Visits to UB or Clinic Sites**

**Screening:**All subjects, and support persons, who will have a contact visit should be screened for symptoms of COVID-19. Study coordinators or staff should make sure triage procedures are compliant with HIPAA guidance and consider a multi-step screening process to ensure subjects with symptoms are not missed prior to entering the research study area. While the process for screening depends on facility layout and staffing, the general steps include:

* **Pre-screen** study subjects, and their support person(s), to check their temperature and gather information about COVID-19 symptoms the day prior to their visit. They may not have a thermometer, and this should not preclude a study visit. Ask if they have felt feverish.
* **Advise** study subjects to check their temperature at home before leaving for their research study visit (if they have a thermometer). Advise them they should put on a cloth face covering, regardless of symptoms, before leaving their home.
* **Post alerts** such as signs and posters at clinic entrances and in strategic places around the facility with instructions for subjects with fever or symptoms of respiratory infection to go home and contact their health care provider.
* **Instruct** subjects to notify the study coordinator before arriving if they have fever or symptoms of COVID-19. If they have symptoms, they should discuss them with a healthcare provider and you should postpone the study visit until the subject is symptom free for 14 days.
* **Schedule**study subject arrival to be staggered. Consider having study subjects text or call you when they have parked so you can be waiting for them to avoid or minimize time in waiting areas.
* **Protect:**If the study subject and the subject’s support person arrive and are not already wearing a cloth face covering, provide a cloth face covering or a face mask (see below). When possible, the study participant should come to the site alone.  If another person accompanies the participant,  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.
* **Screen all study subjects and their support person on arrival** by asking about symptoms of COVID-19 including: cough or shortness of breath, sore throat, fever, muscle aches, headache, new loss of taste or smell, repeated or shaking chills. Take each study subject’s temperature.
* **Triage**patients who have COVID-19 symptoms or fever to see their healthcare provider, unless they are known COVID-19 positive study subjects specifically enrolled in a research study for treatment of COVID-19. For more seriously ill subjects, consider sending them to the Emergency Room.
* **Social Distance:** Make sure all individuals in waiting areas are separated by at least six feet as per the [NY State Executive Order](https://coronavirus.health.ny.gov/new-york-state-pause) and recommended by the [CDC.](https://www.cdc.gov/coronavirus/2019-ncov/hcp/ambulatory-care-settings.html)
* **Minimize** the number of individuals in close contact with participant even if over 6 feet.
* **Separate**study subjects that are COVID-19 positive or recovering from COVID-19 as part of the study. They should wait and be seen in a separate, high risk study area that isolates them from other study subjects and staff to the extent possible.

**Masking:** All research subjects who arrive without a mask will need to be provided one, along with their support person. Cloth masks are acceptable protection if the subject (and/or their support person) arrives wearing one.

**Social Distancing:** Research subject interviews or contact with research staff must adhere to social distancing guidelines. Subjects should be seen in areas that allow six feet of separation during periods where physical examination, procedures, or other contact is not performed. Signs promoting social distancing should be prominently displayed.

**Hand washing/sanitizing:** All areas where study subject visits will take place should have an approved hand sanitizer available in the area. When wall-mounted dispensers are available, please use these to sanitize hands.

**Cleaning Research Subject Rooms and Equipment:** **Contact EH&S**

Current recommendations are to follow the clinical guidelines for cleaning rooms and equipment that has been in contact with study subjects. Only gloves are needed to clean the room.

* ***For NON-COVID-19-suspected study subjects,*** continue using your current approved disinfectant for routine cleaning between visits or subjects.
* ***For COVID-19-suspected or positive study subjects,*** especially those with unknown respiratory illness, please use CaviWipes, Clorox Healthcare Hydrogen Peroxide wipes or bleach wipes.

**Study Subject Contact:**

Research staff members who are screening study subjects should remain six feet away from the subject until screening determines they are symptom-free and afebrile (by patient report or active temperature monitoring).

* Screening staff should wear a facemask but do not need to wear PPE if they are separated from study subjects by a physical barrier such as a glass or plastic window. Screening staff should make these interactions as brief as possible by limiting the interaction to screening questions only.
* If a staff member must be within six feet of a study subject, they should use appropriate PPE, including a face mask, gloves and eye protection. A gown could be considered if extensive contact with the subject is anticipated. Cloth face coverings are not considered PPE and should not be worn by the study team member or health care professional when PPE is indicated.
* If a study subject is known to have COVID-19 (as part of the study), full PPE should be used, including a fitted N95 respirator, gloves, eye protection and a gown.

**Visits With Known COVID-19 Positive Subjects**

A small number of studies and clinical trials will involve outpatient studies of subjects with active COVID-19 infection. These studies will require a greater degree of vigilance. For these study subjects to come to the study site for their visit, the following steps will be taken:

1. The study team and staff will be notified of the subject’s arrival time.
2. The study subject will be directed to a designated entry point at the facility - *separate from the primary study subject entrance/check-in desk*.
3. A surgical mask will be placed onto the study subject upon entering the building.
4. The study subject will be accompanied directly to an isolation room by a designated staff member donning the required PPE. *A negative pressure room is****not****required unless you are conducting high-risk, aerosolizing procedures.*
5. Isolation practices will be maintained at all times.

**Additional Approvals required for COVID-19 Research**

For any study proposing to enroll subjects with active COVID-19 infection approval from the Institutional Biosafety Committee is required. Your study must be registered in [Central Study Registration (CSR).](https://www.research.buffalo.edu/studyregistration/main/login) We will review the study with Safety and if needed, a Safety module submission will be started in CLICK for you to complete and submit for committee review.