

August 12, 2020

**STANDARD OPERATING PROCEDURES FOR MEASURES TO BE TAKEN WITH PATIENTS/PARTICIPANTS
IN UNIVERSITY RESEARCH DURING COVID-19 CONDITIONS**

Accessing Clinical Research Units – Protection of Building Tenants

1. All scheduled patients are to be advised in advance not to come to the research center/building if they feel ill. Study participants are encouraged to come to the study visit alone if possible. But if someone does accompany them, these instructions will apply to the participant and their companion. All scheduled patients will be provided with instructions regarding these public health measures and if the patient's scheduled visit is in a building without a guard station contact information about who to call upon arrival for an escort to the research unit.
2. All patients who arrive at the research center must wear a mask or will be provided with a mask and instructed that a mask must always be worn while in the building.
3. Patients who are scheduled for appointments should report to the guard station, usually on the first floor of the building. Security guards will refer to a list provided by the research center to see that the patient is expected. If the patient is on the list of expected research patients, security will call the number provided by that research clinic and a staff member from the clinic should come to the guard station to meet the patient and escort the patient to the research unit.
4. If the patient is not on the list of expected patients, security should call the number provided by that research clinic and a staff member from the clinic should come to the guard station to meet the patient, perform the assessment in the lobby if possible, and escort the patient to the research center.
5. All patients are escorted through the building for any reason, whether to go to the bathroom, to move to another unit, or upon discharge for the day, will be escorted out of the building.

Protection of TU staff while in the building

6. All patients are screened during the reminder call one day before their clinic visit and upon their visit to the clinic using the COVID-19 Screening Questionnaire provided below. While the temperature cannot be taken during the phone call, the other questions are important to assess whether the patient should come into the clinic.
7. At the patient's actual clinic visit, the full assessment, including temperature will be taken. If the temperature exceeds 100.4 Fahrenheit or 38 Celsius, the patient is sent home with a recommendation to contact their healthcare provider. If the patient's answer to any of the assessment questions is "YES" the patient is to be sent home with a recommendation to see their healthcare provider.
8. Face masks will be provided to staff members and all staff are required to wear face masks in common areas and during patient visits. It is recommended that clinic and clinical trial staff, who interact with patients be provided with surgical masks routinely.
9. Each office and examination room only allows one staff at any one time, along with one patient, for a maximum of two in a room at any time. Exceptions will be made, based on needs related to appropriate patient care, only.

10. Study participants may sit in waiting area if they remain six (6) foot apart, maintaining social distancing always.
11. Cleaning protocols for examination rooms are based on a risk assessment and depend on the type of facility. Research staff should consult with the Office of Biosafety to obtain recommendations for cleaning and disinfection of examination rooms. Decontamination between visits should include, at a minimum, a wipe-down of all hard surfaces with EPA approved products effective against COVID-19 and a 15 minute interval between use of the examination room.
12. For any patient visit that exceeds 15 minutes and all blood draws, a face shield is required for all staff, in addition to masks.

COVID-19 SCREENING QUESTIONNAIRE – to be assessed at the door with each patient who wishes to enter a University building:

Patient Name:

Date:

TEMPERATURE:

Do you have any of the following symptoms?

- | | | |
|--|---------------------------|--------------------------|
| ▪ Fever greater than 100.4? | <input type="radio"/> Yes | <input type="radio"/> No |
| ▪ Chills? | <input type="radio"/> Yes | <input type="radio"/> No |
| ▪ New cough not related to allergies or COPD? | <input type="radio"/> Yes | <input type="radio"/> No |
| ▪ Difficulty breathing/ shortness of breath? | <input type="radio"/> Yes | <input type="radio"/> No |
| ▪ Sore Throat? | <input type="radio"/> Yes | <input type="radio"/> No |
| ▪ Nasal congestion unrelated to allergies? | <input type="radio"/> Yes | <input type="radio"/> No |
| ▪ Body aches and pains? | <input type="radio"/> Yes | <input type="radio"/> No |
| ▪ New headache? | <input type="radio"/> Yes | <input type="radio"/> No |
| ▪ Nausea or vomiting? | <input type="radio"/> Yes | <input type="radio"/> No |
| ▪ Diarrhea? | <input type="radio"/> Yes | <input type="radio"/> No |
| ▪ Loss of or reduction in sense of taste or smell? | <input type="radio"/> Yes | <input type="radio"/> No |

In the past 14 days, have you been exposed to individuals who have tested positive or presumed positive for COVID-19? Yes No

Have you been tested previously for COVID-19? Yes No

Have you tested positive for COVID-19 previously? Yes No

In the past 14 days have you traveled outside of the U.S.? Yes No

Research Staff Name and Signature: _____