Protocol for Bringing Human Subjects to IIT (Illinois Tech) for Research Studies

In an effort to support research involving human subjects during the COVID-19 re-opening of the state of Illinois and Illinois Tech, the Office of Research has developed procedures to re-start human subjects research. Our primary goal is to minimize risks to our research participants and the research team members, while preserving the highest level of scientific integrity of the research protocols. Please note that in order to bring human subjects to campus, you must have an active, IRB-approved protocol. Our goal is to restart research activity involving human participants in a phased, systematic approach, while creating a work environment where social distancing, appropriate use of personal protective equipment (PPE) and frequent sanitation protocols can be practiced.

Each PI must develop a safety plan before restarting research that involves bringing human subjects to campus. The plan should be customized to the research protocol. (A template is attached as Exhibit A).

The plan will be evaluated and approved by the Office of Research and IRB. Some guidelines are given below. In addition to these guidelines, you must follow the ongoing University safety committee guidelines (https://www.iit.edu/COVID-19) as well as applicable public health guidance from the CDC and state and local public health departments. Please make sure to submit a protocol modification through Cayuse system if your research protocol needs to be changed due to COVID-19 related actions.

All plans are to include the below components.

PRESCREEN

These questions are to be asked, on the phone prior to face-to-face meeting, of the participant.

- In the past two weeks have you come in close contact with someone who has tested positive for COVID-19?
- Have you or someone who lives with you traveled out of state/country in the last 30 days?
- Do you live in a high-populated area/apartment complex that is exposed to COVID-19?
- In the past two weeks, have you experienced any of the following symptoms: fever or chills, cough, shortness of breath or difficulty breathing, fatigue, muscle or body aches, headache, new loss of taste or smell, sore throat, congestion or runny nose, nausea or vomiting, diarrhea?

In general, participants that answer yes to any of the questions should not be invited to come to campus to participate until two weeks have passed since the date of the triggering event.

UPON ARRIVAL

- Assess body temperature.
- Re-ask questions related Covid-19 symptoms and possible close contracts.
• Participants need to be wearing masks; researchers need to provide masks to those participants that do not have masks.
• Schedule one human subject per defined time period based on your protocol. No other person should be allowed to come to Illinois Tech unless that person is required caretaker (i.e., when children are the human subject). Do not to overlap schedules.
• Have subjects complete all possible forms via online. This will help to minimize their time in your facility.
• Human subjects should not be staying in waiting room/waiting area. Investigators should be ready to take them directly to assigned lab or test room upon arrival.

For all staff and subjects entering your facility:
• PPE must be worn by all staff, and given to all presenting human subjects who do not have one.
• Each room should be occupied by the minimum number of people required to do the testing and should, to the extent feasible, stay at least 6 feet apart during testing.
• Temperatures should be taken for all subjects presenting to the Illinois Tech before they entering the building/your facility.
• If the subject is symptomatic and in distress, the principal investigator should be notified immediately and make arrangements to assist the subject with promptly leaving the facility.

Rooming Functions: Upon Arrival, During Visit and After the Visit
• If social distance is not possible due to the protocol (i.e. taking a blood sample/taking blood pressure). The research staff should wear a face shield and a disposable gown/lab coat.
• Exam room furniture along with any door handles or any devices used during a test must be cleaned with recommended disinfecting wipes before the subject enters and after the subject leaves the room.
• Research staff should follow all CDC and state and local public health protocols related to washing hands, changing masks, changing gloves (if needed to wear gloves during the testing), changing or cleaning face shield, changing lab coat - before and after the visit.

All individuals are required to complete and submit “Exhibit A”. The plan will be evaluated and approved by the Office of Research and IRB before any studies can begin.