**In-Person Research Activity Protocol during the COVID-19 Pandemic**

**Effective 19 June 2020**

**Purpose:** This In-Person Research Activityprotocol will be **required** for all studies that will include in-person research activities, such as in-person consent, recruitment, data collection, treatments, or interventions. This protocol is intended for participants who do not have COVID-19 and are not suspected of having COVID-19.

* If you are **submitting a new IRB application that will include in-person research activities** this protocol must be included where appropriate in the application. If your study does not include in-person research activities and you are conducting these activities remotely only this does not apply.
* If you are currently conducting a **study that has IRB approval** **and includes in-person research activities** you must sign the In-Person Research Activity Agreement form and submit to the IRB to be kept on file with your IRB approved application.

**All in-person research activities must conduct remote COVID-19 screenings 24 hours prior to in-person research activities and also conduct COVID-19 on-site screenings when the participant arrives on-site for their research activity (assuming they screen negative during the remote screening within 24 hours in advance). Keeping in mind face masks or facial coverings, hand washing, and social distancing (6ft). Hand sanitizer should be freely available.**

**IRB application submission**: All IRB applications that intend to include in-person research activities **must** include the following steps outlined below in the protocol. You may copy and paste the steps below and add to form 1 in the IRB application. This would include sections pertaining to How Subjects Will Be Selected and Recruited, Procedures for Attaining Informed Consent or Assent, Description of Procedure. Take into consideration if recruitment and obtaining consent are conducted in-person.

**In-Person Research Activity Protocol:**

1. **Remote COVID-19 screening** (via phone or teleconference) on participants **must** take place within 24 hours before each in-person study visit. Remote screening must include:
	1. Inquire if the participant has been diagnosed with COVID-19 or has been in the presence of someone diagnosed with COVID-19. If yes, then they are not permitted to participate.
	2. A temperature may be taken with a thermometer or noted subjectively by the participant to the research personnel. Body temperature should read <100.4°.
	3. Subjective symptom assessment: inquire about COVID-19 symptoms (cough, shortness of breath or difficulty breathing, fever, chills, muscle pain, sore throat, new loss of taste or smell).
	4. During the remote 24-hour screening, research personnel should instruct participants to wear a mask or face covering to the study visit.
		1. If they do not have a mask or face covering, research personnel may provide a mask or face covering. If not available, the in-person screening and study visit cannot proceed.
		2. Consider providing information to the participant so they know what to expect during the remote screening and prior to engaging in the study activities.
	5. Upon completion of the remote pre-screening:
		1. If a participant screens positive for COVID-19 on any criteria, the in-person screening and research visit must be postponed.
		2. Research personnel should instruct the participant to contact their primary care provider for further screening and testing.
2. **On-Site Screening:** COVID-19 screenings must be conducted when the participant arrives on-site (assuming they screen negative during the remote screening within 24 hours in advance).
	1. Instruct the participant to call the research staff upon on-site arrival to be **greeted and screened outside of the building or in their car.** Research personnel may consider bringing a mask or face covering for the participant in the event the participant does not have a mask or face covering.
	2. Research personnel and participant(s) should wear face masks or face coverings, and stringent handwashing and social distancing (6ft) are to be followed.
	3. Personnel can wear gloves and a gown (if available) if the visit requires close contact due to necessary research procedures or facility constraints.
	4. Hand sanitizer should be freely available.
	5. **In-person screenings must include the following:**
		1. A tympanic or forehead thermometer should be used for measuring body temperature. Body temperature should read <100.4°.
		2. Subjective symptom assessment: inquire about COVID-19 symptoms (cough, shortness of breath or difficulty breathing, fever, chills, muscle pain, sore throat, new loss of taste or smell).
3. **Upon completion of the in-person screening:**
	1. If a participant screens negative and is afebrile (<100.4°), he or she can be directed to a waiting area or directly to a research room but should maintain social distance (6ft) with other participants and personnel at all possible times, and continue to wear their mask or face covering.
	2. **If a participant screens positive for COVID-19,** the participant will not enter the building and be instructed to contact their primary care provider for further screening and testing.
		1. If participant is tested and there is positive test result, the participant should be informed to follow the guidelines of their primary care provider.
		2. Participants who screen positive but then test negative should be instructed to conduct a subjective symptom assessment and check their temperature with a thermometer and document screening negative for 8 additional days following the negative test.
		3. If the self-assessment screenings have remained negative for 8 days the participant will notify the research personnel and proceed with the remote screening procedure and on-site screenings before proceeding with in-person research activities.
4. **Conducting in-person research activities**
	1. Following a negative on-site COVID-19 screening the following procedures **must** be in place for participants to proceed with the in-person research activities:
		1. Waiting areas should be arranged to allow for 6 feet of social distancing between seating.
		2. Hand sanitizer should be freely available in all waiting and research areas.
		3. Attention must be given to following the facility disinfection and cleaning protocol after the presence of an individual known or suspected of being COVID-19 positive.
		4. If participants and researchers are physically able, encourage stairs rather than elevators.
		5. Participant visits should be scheduled to stagger visits and minimize waiting room occupancy. This will promote social distancing and allow time between visits to clean spaces appropriately.
		6. When conducting focus groups or educational sessions as part of the study:
			1. Participants and research personnel must wear mask or a face covering
			2. The space must be able to accommodate for social distancing (6ft) with other participants and personnel at all possible times.
			3. Hand sanitizer should be freely available.
		7. For in-person research activities occurring in the hospital or ambulatory clinic setting the participants and the research personnel will also follow the policies and guidance in place for those areas.
5. **Completion of all in-person research activities**
	1. Participants who have complete all in-person research activities will be asked to notify research personnel if they receive a COVID-19 positive test following their participation in the study.