APPENDIX 2A: Protocols and Policies for Clinical Trials and Human Subjects Research

Screening Protocols for Study Participants

Pre-Screening

All subjects attending a scheduled appointment for clinical or research related purposes must be pre-screened via telephone prior to their appointment. Using the pre-screening checklist below, if the subject answers “No” to all questions, the in-person visit may proceed.

If the subject responds “Yes” to one or more of the questions, the subject may still attend the in-person visit based if the benefit to the subject outweighs the risks posed to the staff and other subjects as determined by the study PI and formally approved by them. However, the study participant will be required to have additional in-person screening upon arrival and all risk mitigation protocols must be adhered to.

Study personnel are responsible for maintaining a record of completed pre-screening checklists for all study participants. Audits to ensure compliance may occur.

Pre-Screening Checklist for Research Subjects by phone (or telehealth) prior to AND at the time of arrival on campus – each individual subject

In the last 30 days, have you had a positive COVID-19 test? ☐ Yes ☐ No

In the last 14 days, have you had sustained close contact (such as a household contact) with a person with a positive COVID-19 test? ☐ Yes ☐ No

In the last 14 days, have you had a fever, cough or diarrhea? ☐ Yes ☐ No

In the last 14 days, have you had cold or flu like symptoms? ☐ Yes ☐ No

In the last 14 days, do you have concerns regarding other potential symptoms (loss of taste, loss of smell, eye redness or discharge, confusion, dizziness, unexplained muscle aches) related to COVID 19? ☐ Yes ☐ No

If all responses are NO, the research subject is eligible for in-person visit.

If YES to any of the above, but subject has approval from the PI for an in-person visit:

PI/Sub PI who is providing approval: ________________________________

Enter the date approval received for in-person visit: ________________________________
Outpatient Research Visits

Goal: To transition to a hybrid model for the conduct of clinical trials and human subjects research, including a combination of in-person and virtual visits, that allows appropriate adherence to study specific requirements for all study subjects regardless of the type of study, while at the same time adhering to recommended physical distancing guidelines and considering the necessity of PPE conservation. This applies to all research and clinical space across the health system and campus. Study teams must be aware of and comply with policies and strategies for physical distancing and PPE utilization.

1. Scheduling
   - **Offices at the local level may change any visit type as deemed appropriate by the PI.**
   - For subjects **without** COVID symptoms, offer subjects the option of a video visit or an in-person visit with the PI. **Coordinators must specifically note that subjects are required to have an in-person visit if required by the protocol.**
   - For subjects **with** COVID symptoms, PI must be notified and the subject should have a video visit.

2. Personal Protective Equipment (PPE)
   - Use of PPE should follow all guidance provided by UCLA, the Los Angeles County Department of Public Health, and the CDC.
   - Masks will be provided to all upon entry into clinical care buildings during the screening process. Staff who work in off-site clinics should receive masks from their manager.
   - In clinical areas where there is no direct patient contact, cloth face coverings may be worn in lieu of masks. Cloth face coverings should be laundered with warm water and detergent daily or whenever they are visibly soiled.
   - Masks or cloth face coverings should be worn ALL DAY when inside clinical care or other University buildings. Masks or cloth face coverings should also be worn when traveling between buildings on campus.
   - Masks or cloth face coverings should be changed whenever soiled, wet, or damaged.
   - The mask or cloth face covering may be removed when eating/drinking or when in private (single person) offices, single restrooms, or lactation rooms.
   - Use of other PPE (e.g., face shields, safety goggles/glasses, gowns, gloves) should be in accordance with policies in effect at each location (i.e., UCLA Health clinical facility policies).

3. Clinical Areas
   - Clinics employ an “air traffic controller” position to optimize flow of subjects safely through the clinic from check in to check out.
   - For each clinic, assess in-person maximum capacity that will allow for appropriate physical distancing. Use the tactics described below to ensure volume does not exceed this number at any given time.
     - PIs will have staggered blocks of virtual visits and in-person visits scheduled each day to minimize the number of subjects waiting in the waiting room at any point in time.
     - Implement extended hours (in the early morning or evening) for all visit types to minimize the number of subjects waiting in the waiting room at a given time.
● Schedule vulnerable patients (e.g., elderly, immunocompromised) at the beginning of the day, if possible.
● Although discouraged, if any subjects with an upper respiratory infection or COVID symptoms need to be seen, schedule them at the end of the day, if possible and safe.

4. Physical Space and Workspaces
● Utilize additional office space in other locations to ensure physical distancing.
● Consider plexiglass partitions to facilitate infection prevention.
● Ensure that all computers (exam rooms and work rooms) have necessary software (i.e. syngo, Muse, Zoom, CareConnect Video, etc.).
● Ensure all computers have webcams.
● Consider noise cancelling headphones or headsets with directed microphones (individual use only).

5. Check-in/Waiting
● Ask subjects to check in via phone call to the study team who will coordinate the subjects’ entry into the facility.
● When subjects call to check in, let them know that they have the option of waiting in their car until the exam room is available. Study team will call the subject when the room is ready.
● Continue symptom and temperature screening at door.
  ○ Greeters will check temperatures and symptoms on arrival.
  ○ Those with a positive screen will be roomed immediately (or, as an option, consider video visit from the car).
  ○ Every subject (> 2 yrs old) will be asked to wear a mask upon arrival, and will be provided one if needed. Visitors will also follow the same policy.
● Gloves are not to be worn within the department to prevent cross contamination. Study subjects/patients/visitors who present with gloves on from outside will be asked to remove gloves to prevent cross contamination. Hand sanitizer needs to be available, as well as soap and water.
● Arrange waiting room seating to allow for proper physical distancing.
● Utilize separate entrances and exits as possible.
● Adhere to PPE Guidelines.
● Continue to limit visitors per current Ambulatory and Hospital Visitor Policies.

6. Rooming and Exit Coordination
● Room subjects as soon as an exam room is available.
● Cleaning and Disinfection of Exam Rooms: Once the subject has left the exam room, the room may be immediately disinfected following standard precautions. If level 1 PPE was worn during patient care, wear level 1 PPE to disinfect the room. PDI Sani-Prime wipes, PDI Super-Sani wipes, Clorox Hydrogen Peroxide wipes may be used to disinfect the patient exam room. Surfaces include but are not limited to: exam table, chair where subject sat, research workstation, sink area, door handles.
● New gloves should be provided AS SUBJECTS EXIT if requested.
Outpatient COVID-19 Visitor Guidelines

*Essential visitors are identified as those who will be providing physical assistance to the non-ambulatory subjects in a research area.*

Every UCLA research subject can bring one person with them to appointments in the outpatient research setting. This person can be a family member or support person who is necessary to help the study participant during the visit or with the return home.

Note: Visitors presenting with visible signs of fever, cough or other flu-like symptoms will be politely asked to wait outside the research building.

Remote Monitoring for Research Studies during COVID19

Remote monitoring options are being piloted:

Option A. Use of Zoom for “over the shoulder” remote monitoring.

Option B. Healthlink Access via CareConnect. This pathway requires appropriate contractual and budgeting language and approval from the study sponsor or CRO. Please contact the CTSI Office of Regulatory Affairs at ctsiora@mednet.ucla.edu.