

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: _____