

School TLC Study - Phase I Testing Preference Study

Study Protocol

This protocol pertains to the phase 1 testing preference study only. Study protocols for the formative needs assessment (also to occur during Phase 1) and future study phases will be submitted separately.

Study Enrollment

A study information form will be emailed to all staff and parents of students to invite participation in the study. After reading the form, staff and parents can choose to enroll (self/child) in the study by completing and submitting an enrollment form. The enrollment form will collect identifying information for each participant necessary to provide testing results to the participant/family and school.

Study Team Training

The principal investigators will train up to six study staff members to follow the study protocol for phase 1 testing preference study. Dr. Goldman and Dr. Schuster will provide training on protocols for recruitment, consent, and administering the COVID-19 tests for students, staff, and family members. Dr. Keener Mast and Dr. Isabela Lucas will provide training on the protocol for administering the test preference survey to students, staff, and family members. The training will take place over two meetings totally 2-3 hours and will include the following components: 1) introduction and background to the study; 2) how to approach school staff, students and families at the three schools and introduce the study; 3) how to gather consent and conduct the testing; 4) how to administer the COVID-19 tests; 5) how to pull up research records and enter data into REDCap; 6) how to administer the test preference survey and enter responses into REDCap; 7) study logistics; 8) how to protect all study information; and 9) practice sessions.

Protocol for COVID-19 Testing and Test Preference Survey (for surveillance testing of students and staff)

- COVID-19 testing will be offered to all students and school staff in participating schools who choose to enroll in the study by submitting the enrollment form.
- Each participant will be offered at least one COVID-19 surveillance test during this school year. In addition, diagnostic testing will be offered to registered students and staff with COVID-19 symptoms or with an exposure to COVID-19.
- At least one study staff member from Children's Mercy Hospital will be on site at the school during surveillance testing.
- Study staff may be assisted by the school nurse or school administrator to help coordinate the test administration.
- Study staff will have printed lists of registered students by grade or classroom.
- The timing and specific location of testing will be determined by each school.
- The testing and survey are expected to take less than 5 minutes per student.
- If more than one study staff member is on site, multiple test stations may be set up for simultaneous testing.
- When a student arrives at the test station, the study staff member will ask their name and month and day of birth to pull up their research record on a tablet.
- The study staff member will follow the script on the tablet to collect and label two COVID-19 test samples—one nasal swab and one saliva test—from the participants.

- The study staff member will follow the script on the tablet to administer the test preference survey out loud and record responses into the participants research record using the tablet.
- The study staff will thank and dismiss the participant.
- Study staff will package the samples and delivery them to the hospital laboratory for processing.
- All test results will be shared with the school within 48 hours. Positive test results will be reported directly to the family within 48 hours.

Protocol for At-Home COVID-19 Testing and Preference Survey (for diagnostic testing of family members)

- At-home COVID-19 diagnostic testing will be offered to family members of enrolled students who are symptomatic or with a known exposure to COVID-19.
- The school nurse will help contact family members of students who tested positive for COVID-19 or were exposed to COVID-19. Family members can also call the nurse to request a test kit.
- COVID-19 test kits will be mailed or sent by courier to family members. The first 50 at home test kits will include two sample kits. Instructions will be provided to collect two samples per family member and apply provided labels and return to package for delivery.
- Test packages will be picked up via courier and delivered directly to the hospital laboratory for processing.
- Within 24 hours of completing the at home test kit, adult family members will receive an email or text with a link to the test preference survey for at home participants.
- Test results will be reported directly to the family within 48 hours.