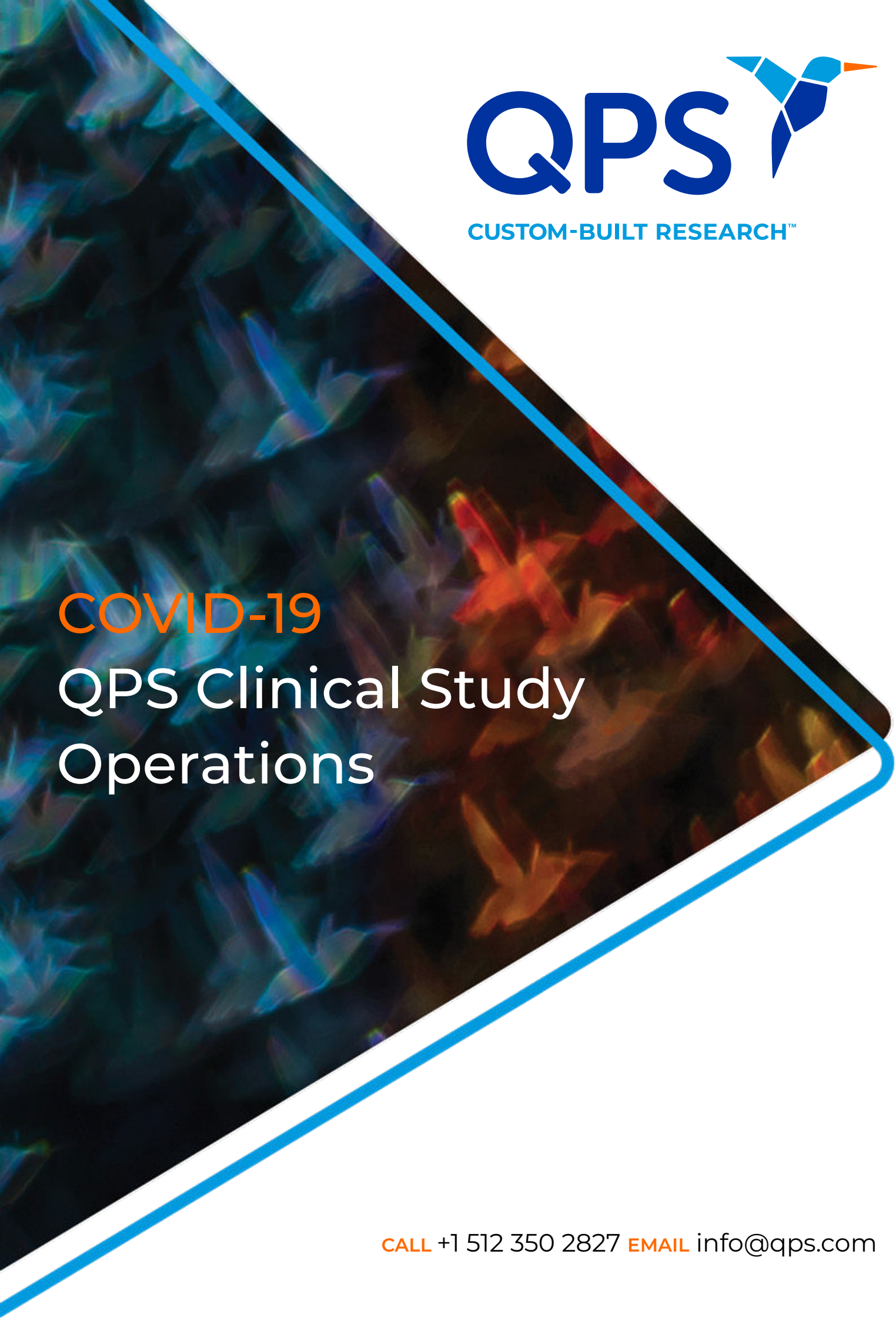

QPS

CUSTOM-BUILT RESEARCH™

COVID-19
QPS Clinical Study Operations

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QPS Clinical Study Site Operations: COVID-19

GENERAL INFORMATION

This document outlines and reviews the plans that QPS is implementing to run global clinical study sites and facilities during the later stages of the COVID-19 pandemic. Planning for each study will be conducted on a study-by-study basis, in conjunction with each study sponsor, and adjustments will be made as needed. QPS follows guidelines provided by the WHO, FDA and EMA. Adherence to local regulations for each site will always be the highest priority and QPS local businesses will defer to local and national regulations and guidelines as needed, and as appropriate.

SCREENING STUDY SUBJECTS

Telephone Screening Of Subjects

All volunteers, study subjects and potential study subjects are screened over the phone with (IRB-approved) questionnaires prior to participation. It is QPS standard practice for phone screens to include questions on current health issues, regardless of current events. QPS has also implemented questions directed toward COVID-19 symptoms, recent contacts, and travel history. When appropriate, QPS will not invite those individuals, who are identified as a risk, to visit our clinics until cleared via their health care professional. Call logs and source documents will be maintained for applicable subjects screened.

On-Site Screening of Subjects

Upon arrival and entry into clinic, each volunteer/study subject will complete a questionnaire to determine if they are exhibiting any characteristics that could be associated with COVID-19, including a body temperature check. Hand sanitation will be encouraged upon entering the clinic.

We will direct individuals who meet the criteria for persons who could be infected away from the site, in a manner consistent with local regulations. All visibly ill individuals will be turned away and will not continue in the screening process.

Screening activities will be conducted once characteristics of COVID-19 have been ruled out and will be conducted in designated areas. COVID-19 testing at screening is optional and will only be conducted as a result of a discussion between the site and sponsor.

If testing were to be done at screening, it would be to catch asymptomatic carriers and pre-symptomatic subjects, to avoid their coming back for admission and exposing others. This would be an “extra” precaution, which the sites and/or sponsors may, or may not, feel is necessary. For that reason, we have decided to leave it as optional, and open to discussion between the site and the sponsor.

If deemed necessary by the site or the sponsor, the volunteer would be tested for COVID-19 utilizing a polymerase chain reaction (PCR) assay or FDA approved for emergency use POC SARS COVID test kit. QPS will deliver test results within 48 hours or less, and possibly as soon as 8-12 hours. We will conduct screening as planned, during which time, the study subject will be treated as if they are infected with COVID-19, which is explained in the section “Contingency Planning”. If the site tests subjects during screening, the subjects will go home after the screening. The site will inform the subjects about the test later when the results are available.

QPS staff will wear appropriate personal protective equipment (PPE) and the ICF will be explained in person by the site. Answering questions and signing the ICF will be performed with 1.5m (or 6 feet) between the subject and the physician or delegated staff member wearing a mask. To avoid contact between subjects, screening will take place on an individual basis. Screening areas will be cleaned between subjects.

QPS Clinical Study Site Operations: COVID-19

CLINICAL STUDY EXECUTION

Admission

Only subjects that are eligible for the relevant study, and if applicable have tested negative for COVID-19 at screening, will be invited back to the clinic to participate in the study. Just as during screening, each study subject will be assessed upon arrival and entering the QPS building to determine if they are exhibiting any characteristics that could be associated with COVID-19, including a body temperature check. We will direct individuals who meet the local government criteria for persons who could be infected away from the site, in a manner consistent with local regulations. Arrival of subjects will only be conducted in designated areas.

Upon completion of the questionnaire and safety checks, the study subject will be tested for COVID-19 utilizing a PCR Assay and/or a FDA approved for emergency use POC SARS COVID test kit. As the test results will be available within 48 hours or less, and possibly as soon as 8-12 hours, the subjects will be invited within ample time before the start of the study. Subjects will stay in the clinic until the results are available, and they will be treated as if they are infected, which is explained in the next paragraph. If the test is positive, subjects will not continue with the study. The subjects may be paid for the extra day(s)/hours that they are in the clinic, which will be described in the Informed Consent process.

Study subjects will be asked to observe all applicable social distancing guidelines, including wearing QPS provided masks and maintaining 1.5m, or 6 feet, distance from other study subjects and QPS staff will wear appropriate PPE at all times. All efforts will be made to limit contact between QPS staff and the subjects.

Direct and clear communication between QPS and each sponsor will be maintained at all times. Discussions will be held related to any potential study changes due to COVID-19 precautions, including changes in scope, timelines and cohort assignments. Each study will be reviewed with each sponsor, on a case-by-case basis, and changes will be implemented as necessary and as agreed.

Clinical Study Execution

Study subjects who have no symptoms, or who have negative COVID-19 test results, will be allowed into the clinical trial unit where the actual conduct of the study will take place.

As observed during the Admission period, subjects will be asked to observe all applicable social distancing guidelines, including wearing QPS provided masks and maintaining 1.5m, or 6 feet, distance from other study subjects at all times. QPS will make sure there is 1.5m, or 6 feet, between the beds and all other applicable scenarios managing distance between volunteers as well as maintaining a strict cleaning policy at all times. The QPS staff will wear appropriate PPE. All efforts will be made to limit contact between QPS staff and the subjects.

Outpatient Visits

Each volunteer/study subject will be screened during telephone confirmation of the visit and upon arrival and entering the QPS building to determine if they are exhibiting any characteristics that could be associated with COVID-19, including a body temperature check. Hand sanitation will be encouraged upon entering the site, in a manner consistent with the clinic guidelines. We will direct individuals who meet the criteria for persons who could be infected to act in accordance with local regulations. These subjects will not continue in the study. Initially, each study subject will be treated as if they are infected with COVID-19.

CONTINGENCY PLANNING

Clinical Study Volunteer Isolation

QPS will abide by the guidance communicated by global and local health authorities. In the event that a volunteer falls ill while at a QPS facility, and is suspected of having COVID-19, QPS will work with local health authorities and follow their direction for next steps. Follow-up actions (testing, drop-out) will be determined on a case-by-case basis, depending on study duration, seriousness of symptoms, and other factors as determined by local regulations and consultation with the study sponsor.

QPS Clinical Study Site Operations: COVID-19

QPS clinical sites are of a design similar to medical facilities, with exam rooms dedicated to volunteers and study subjects. Exam rooms are available to isolate sick individuals. Any room used in this manner will be thoroughly cleaned and disinfected once the sick individual has left.

Caring for Volunteers Who Fall Ill at a QPS Site

Employees at QPS clinical sites are trained to follow SOP's to address any volunteer who becomes ill while at a QPS facility. When there are study subjects on site, there are also employees, including medical staff, on site at QPS clinics to care for them.

SAMPLE TRANSPORT AND TESTING

Study Sample Transport

Sample shipment for bioanalysis is a concern of QPS, and we intend to use only highly qualified vendors for these shipments.

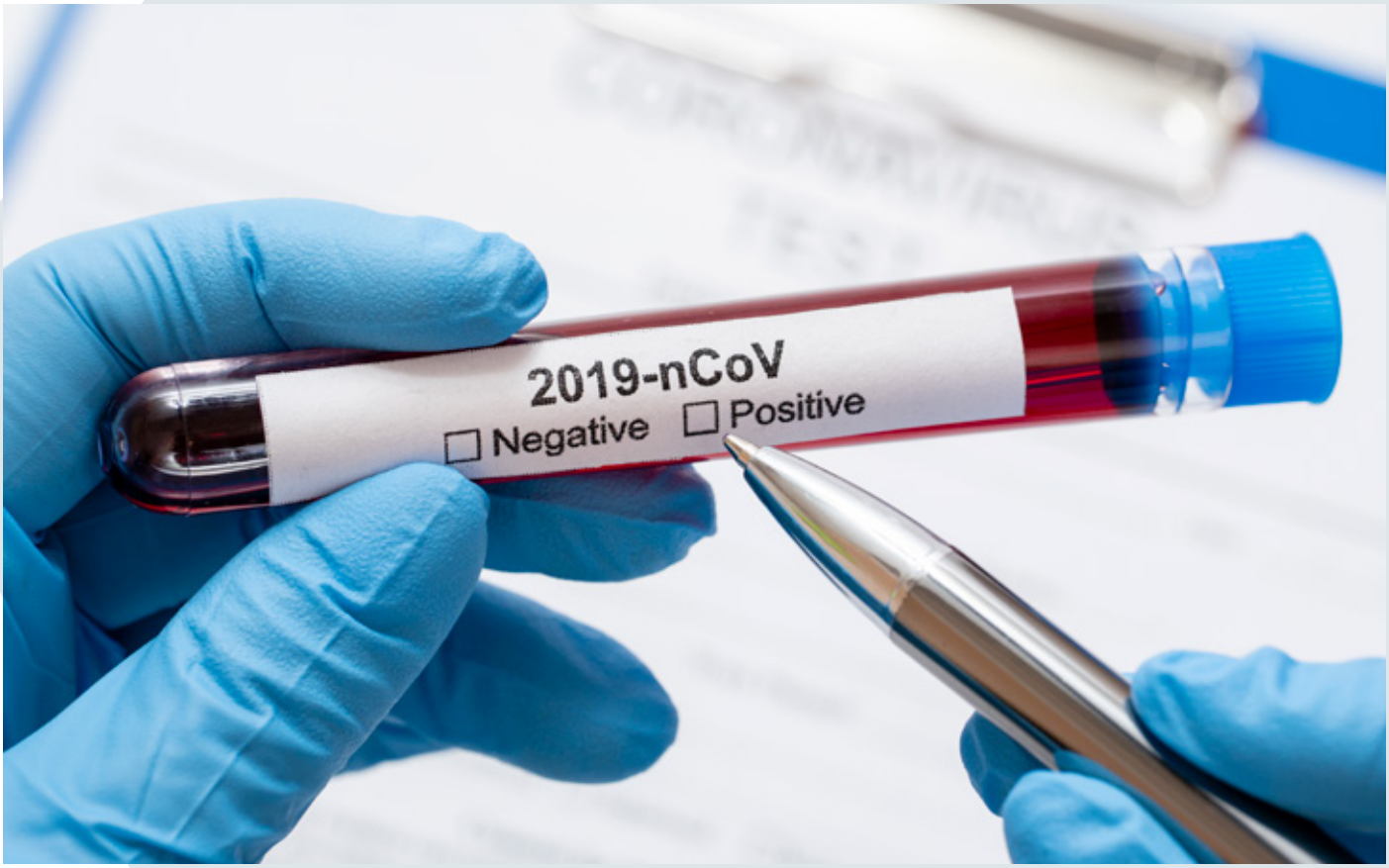
Each study site will select the most appropriate vendor for study sample shipment, carefully considering reliability and cost. For example, QPS Netherlands prefers to use World Courier during the travel restrictions. World Courier has been qualified by QPS NL and our contract stipulates that, if samples cannot be shipped directly, World Courier will ensure that the level of dry ice is checked and refilled as needed in order to keep the temperature storage of the samples within specifications at all times.

Study Sample Analysis

QPS tests study subjects using polymerase chain reaction (PCR) testing. A PCR test can detect coronavirus RNA in a patient's nasal (and/or throat) swab so its presence can be confirmed. PCR is incredibly sensitive and specific for the target

that it seeks, but care must be taken in recovering a good sample as the use of collection swabs can vary from clinician to clinician. Viral DNA or RNA can be found in the body as soon as an infection begins, even if you're asymptomatic (typically 48 hours before onset of symptoms). However, RNA declines gradually over the next 30 days as the immune system clears the infection out. So, this type of test is useful to find out who is currently infected, but not who once was infected. This PCR test will also identify subjects who have already recovered and are not contagious, but have yet to completely eliminate the virus.

There is another type of test called an antibody test, also known as a serology test that analyzes a patient's serum (the liquid portion of blood that excludes cells and clotting factors but includes antibodies).This type of test uses a technique like ELISA (enzyme-linked immunosorbent assay), looking for antibodies made in response to the large protein that sticks out of the coronavirus's surface. It is important to note that there are many different coronaviruses and this test is designed to look specifically for antibodies to the novel coronavirus that causes COVID-19.
Antibody tests play an important role in identifying individuals who may have been exposed to the SARS-CoV-2 virus or have had COVID-19 and recovered.



Frequently Asked Questions

COVID-19 STUDY FAQ

Information contained in this Q&A document has been adapted to the recommendations from international, national and local governmental health authorities. QPS will also work closely with each sponsor, on a case-by-case basis, to ensure that their needs are met with regards to each individual study.

COVID-19 TESTING

What kinds of testing will be performed on upcoming clinical trials?

QPS uses COVID-19 PCR testing for study subjects coming into our clinics during the conduct of a study. The PCR test is the most appropriate test (vs a serology test), as it identifies the presence of an active novel coronavirus infection, in individuals presenting with or without symptoms. QPS may also use a FDA approved for emergency use POC SARS COVID test kit. This does not take the place of the PCR, however, offers an emergency quick test for staff and volunteers.

Is QPS performing antibody testing for study participants/staff?

The safety of our study participants and our staff is our primary concern and the COVID-19 PCR test is the most accurate and reliable way to identify individuals with an active novel coronavirus infection. We are regularly evaluating the latest information and will consider the addition of antibody testing, as warranted, in the future.

How will COVID-19 testing be implemented for study participants?

Study participant screening and admissions procedures, including any necessary testing, will be performed in designated locations, away from the clinic that is used for active study participants. QPS will perform COVID-19 PCR testing at check-in for each confinement period.

What is the turnaround time for COVID-19 Testing results?

The turnaround time for results is 48 hours or less. Specific turnaround times are clinic and location specific, and will be explained in advance to all potential study participants. Upon admission, study participants will be required to remain in the clinic while

they are awaiting test results, and if negative, will be guided directly to the active study clinic area.

Will QPS test staff for COVID-19?

The health and safety of our staff are of utmost importance. QPS tests staff at certain locations, when appropriate and will continue to do so. QPS staff follow strict procedures to protect themselves and others, using Personal Protective Equipment (PPE) while on site and following all applicable local guidelines while not at a QPS facility. In addition, all QPS sites, including clinics, laboratories and offices, fully comply with all local regulations regarding testing staff for COVID-19.

CLINICAL TRIAL SITE INFORMATION

Is QPS experiencing any disruptions to clinic activity?

The QPS clinics in Miami and Missouri in the USA, Groningen and Leeuwarden in the Netherlands, Taipei in Taiwan and Hyderabad in India, are all fully operational, screening and enrolling patients on a normal schedule. QPS continues to closely monitor the global and local COVID-19 situation and will make all necessary changes to our operational procedures as needed.

What are QPS' policies on clients visiting the sites as the pandemic begins to resolve?

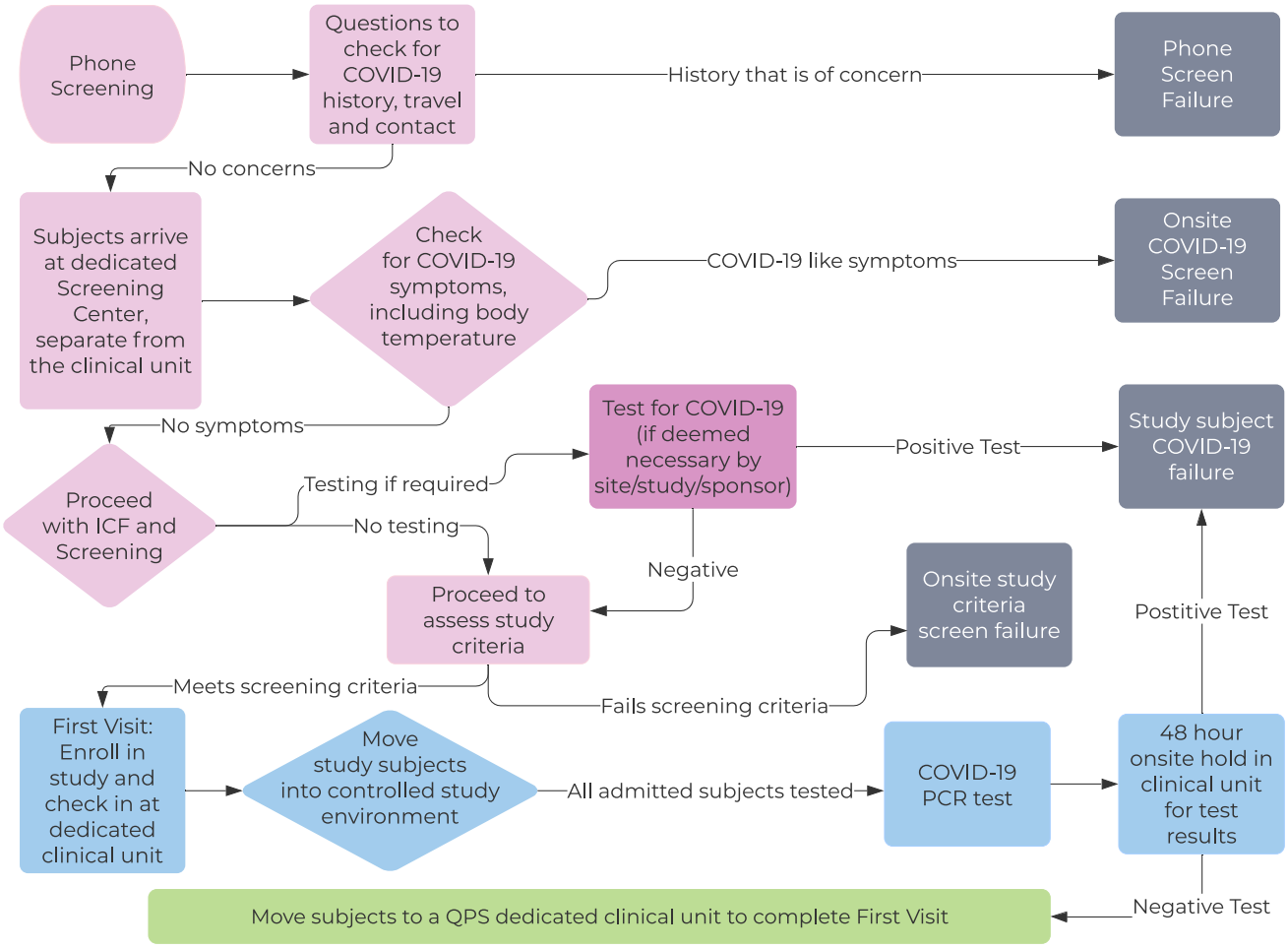
Travel and visitation policies will vary by site, and depend on the national and local guidance at the time. In general, QPS is limiting the number of people at each site to only those required to run operations smoothly. In addition, QPS clinical trials sites have buildings and areas that are separated from the clinical trial units. When visits are conducted, we invite visitors into those separate buildings/areas. Visitors will only be invited into a clinical trial unit when necessary. Sponsors and vendors, in general, are required to follow same guidelines as study participants when coming for any study visits. PPE will be provided to sponsor representatives while on site (for example: Clinical Research Associates and Study Monitors).

Is the Covid-19 Testing Informed Consent included in the study specific Informed Consent?

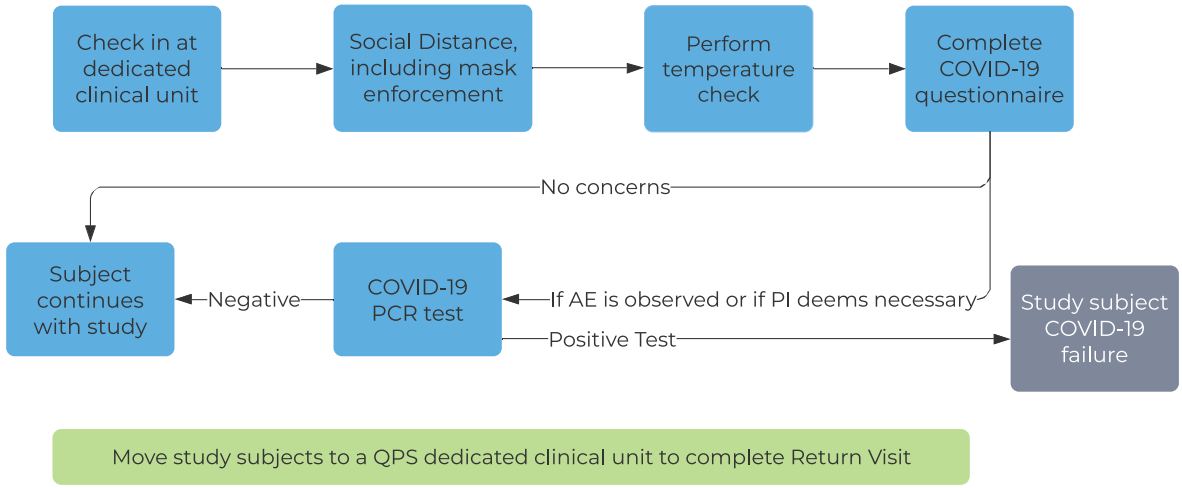
QPS utilizes a separate COVID-19 Testing Informed Consent as part of the process of consenting all study subjects. If needed, this wording can be incorporated into the main Informed Consent based on sponsor and Central IRB's requests and requirements. The final decision on how to obtain this consent for each study will be made on a study-to-study basis, in conjunction with the study sponsor and the IRB's.

CLINICAL STUDY SUBJECT FLOW THROUGH CLINIC

QPS LLC MARCH 2021



Ambulatory/Return/Follow up visits to, or stays in, a QPS dedicated clinical unit



COVID-19 (CORONA VIRUS DISEASE)
FACT SHEET FOR PATIENTS

CUSTOM-BUILT RESEARCH™

YOU ARE BEING GIVEN THIS FACT SHEET BECAUSE YOUR SAMPLE(S) WAS TESTED FOR THE VIRUS THAT CAUSES CORONAVIRUS DISEASE 2019 (COVID-19). THIS FACT SHEET CONTAINS INFORMATION TO HELP YOU UNDERSTAND THE RISKS AND BENEFITS OF USING THIS TEST FOR THE DIAGNOSIS OF COVID-19. IF YOU HAVE QUESTIONS OR WOULD LIKE TO DISCUSS THE INFORMATION PROVIDED AFTER YOU READ THIS FACT SHEET, PLEASE TALK TO YOUR HEALTHCARE PROVIDER.

What is COVID-19?

COVID-19 is caused by the SARS-CoV-2 virus and can cause mild to severe respiratory illness. There is limited information available about the spectrum of illness associated with COVID-19, but it likely spreads to others when a person shows signs or symptoms of being sick (e.g., fever, coughing, difficulty breathing, etc.).

What is the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel?

The test is designed to detect the virus that causes COVID-19 in respiratory specimens, via nasal or oral swabs.

Why was my sample tested?

You were tested because your healthcare provider believes you may have been exposed to the COVID-19 virus based on your signs and symptoms (e.g., fever, cough, difficulty breathing), and/or because:

- You live in or have recently traveled to a place where COVID-19 is known to occur, and/or
- You have been in close contact with an individual suspected of or confirmed to have COVID-19.

What are the known and potential risks and benefits of the test?

Potential risks include:

- Possible discomfort or other complications that can happen during sample collection.
- Possible incorrect test result. For more information, please see below.

Potential benefits include:

- The results, along with other information, can help your healthcare provider make recommendations about your care.
- The results of this test may help limit the spread of COVID-19.

What does it means if I have a positive test result?

If you have a positive test result, it is very likely that you have COVID-19. Therefore, it is also likely that you may be placed in isolation to avoid spreading the virus. There is a very small chance that this test can give a positive result that is wrong (a false positive result). Your healthcare provider will work with you to determine how best to care for you based on the test results, medical history, and your symptoms.

What does it means if I have a negative test result?

A negative test result means that the virus that causes COVID-19 was not found in your sample. For COVID-19, a negative test result for a sample collected while a person has symptoms usually means that COVID-19 did not cause your recent illness.

However, it is possible for this test to give a negative result that is incorrect (false negative) in some people with COVID-19. This means that you could possibly still have COVID-19 even though the test is negative. If this is the case, your healthcare provider will consider the test result together with your symptoms, possible exposures, and geographical location of places you have recently traveled in deciding how to care for you.

It is important that you work with your healthcare provider to help you understand the next steps you should take.

Is this test FDA-approved or cleared?

No. This test is not yet approved or cleared by the United States FDA. The FDA can make tests available under an emergency access mechanism called an Emergency Use Authorization (EUA). The EUA for this test is supported by the Secretary of Health and Human Service's (HHS's) declaration that circumstances exist to justify the emergency use of *in vitro* diagnostics (IVDs) for the detection and/or diagnosis of COVID-19. This will remain in effect (meaning this test can be used) for the duration of the COVID-19 declaration justifying emergency use of IVDs, unless it is terminated or revoked by FDA (after which the test may no longer be used).

Need more information? The most up-to-date information on COVID-19 is available at the CDC General webpage: **https://www.cdc.gov/COVID19**. In addition, please also contact your healthcare provider with any questions/concerns.

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Time is of the essence in drug development. Contact the QPS business development team today!

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