

Form: Concomitant Medications

Log Page #: _____

Medication name	_____
Indication	_____
Route	Oral <input type="checkbox"/>
	Intramuscular <input type="checkbox"/>
	Intravenous <input type="checkbox"/>
	Topical <input type="checkbox"/>
	Inhalation <input type="checkbox"/>
	Vaginal <input type="checkbox"/>
	Rectal <input type="checkbox"/>
	Subcutaneous <input type="checkbox"/>
	Subdermal <input type="checkbox"/>
	Sublingual <input type="checkbox"/>
	Intrauterine <input type="checkbox"/>
	Nasal <input type="checkbox"/>
	Intraocular <input type="checkbox"/>
	Other <input type="checkbox"/>
If "Other", specify:	_____

Form: COVID-19 Symptoms

Did the participant experience any COVID-19 symptoms? Yes
No

If "No", end of form.

What was the date of onset of symptoms? _____

Total duration of acute symptoms Fixed Unit: # days

During the illness, did the participant experience any of the following?

Fever Yes
No

If "No" or "Unknown", go to Dyspnea with exertion
Unknown

Duration of symptom Fixed Unit: # days

Maximum temperature Fixed Unit: C

Respiratory/Cardiac

Dyspnea with exertion Yes

If "No" or "Unknown", go to Dyspnea at rest
No
Unknown

Does symptom persist after COVID-19 resolution? Yes
No

Duration of symptom Fixed Unit: # days

Dyspnea at rest Yes

If "No" or "Unknown", go to Cough
No
Unknown

Does symptom persist after COVID-19 resolution? Yes
No

Duration of symptom Fixed Unit: # days

Cough Yes

If "No" or "Unknown", go to Hemoptysis
No
Unknown

Does symptom persist after COVID-19 resolution? Yes
No

Duration of symptom Fixed Unit: # days

Hemoptysis Yes

If "No" or "Unknown", go to Sputum production
No

Form: COVID-19 Symptoms

Unknown

Does symptom persist after COVID-19 resolution? Yes

No

Duration of symptom Fixed Unit: # days

Sputum production Yes

If "No" or "Unknown", go to Chest pain No

Unknown

Does symptom persist after COVID-19 resolution? Yes

No

Duration of symptom Fixed Unit: # days

Chest pain Yes

If "No" or "Unknown", go to Unable to sleep lying down No

Unknown

Does symptom persist after COVID-19 resolution? Yes

No

Duration of symptom Fixed Unit: # days

Unable to sleep lying down Yes

If "No" or "Unknown", go to Rhinorrhea/nasal congestion No

Unknown

Does symptom persist after COVID-19 resolution? Yes

No

Duration of symptom Fixed Unit: # days

HEENT

Rhinorrhea/nasal congestion Yes

If "No" or "Unknown", go to Sore throat No

Unknown

Does symptom persist after COVID-19 resolution? Yes

No

Duration of symptom Fixed Unit: # days

Sore throat Yes

If "No" or "Unknown", go to Anosmia (loss of smell) No

Unknown

Form: COVID-19 Symptoms

Does symptom persist after COVID-19 resolution? Yes
No

Duration of symptom Fixed Unit: # days

Anosmia (loss of smell) Yes
If "No" or "Unknown", go to Ageusia (loss of taste) No
Unknown

Does symptom persist after COVID-19 resolution? Yes
No

Duration of symptom Fixed Unit: # days

Ageusia (loss of taste) Yes
If "No" or "Unknown", go to Anorexia No
Unknown

Does symptom persist after COVID-19 resolution? Yes
No

Duration of symptom Fixed Unit: # days

Gastrointestinal
Anorexia Yes
If "No" or "Unknown", go to Nausea or vomiting No
Unknown

Does symptom persist after COVID-19 resolution? Yes
No

Duration of symptom Fixed Unit: # days

Nausea or vomiting Yes
If "No" or "Unknown", go to Diarrhea No
Unknown

Does symptom persist after COVID-19 resolution? Yes
No

Duration of symptom Fixed Unit: # days

Diarrhea Yes
If "No" or "Unknown", go to Abdominal pain No
Unknown

Does symptom persist after COVID-19 resolution? Yes

Form: COVID-19 Symptoms

_____ No

Duration of symptom Fixed Unit: # days

Abdominal pain Yes

If "No" or "Unknown", go to Fatigue No

Unknown

Does symptom persist after COVID-19 resolution? Yes

No

Duration of symptom Fixed Unit: # days

General

Fatigue Yes

If "No" or "Unknown", go to Myalgia No

Unknown

Does symptom persist after COVID-19 resolution? Yes

No

Duration of symptom Fixed Unit: # days

Myalgia Yes

If "No" or "Unknown", go to Headache No

Unknown

Does symptom persist after COVID-19 resolution? Yes

No

Duration of symptom Fixed Unit: # days

Headache Yes

If "No" or "Unknown", go to Confusion/mental status changes No

Unknown

Does symptom persist after COVID-19 resolution? Yes

No

Duration of symptom Fixed Unit: # days

Confusion/mental status changes Yes

If "No" or "Unknown", go to Chills No

Unknown

Does symptom persist after COVID-19 resolution? Yes

No

Form: COVID-19 Symptoms

Duration of symptom Fixed Unit: # days

Chills Yes

If "No" or "Unknown", go to New skin findings attributable to No

COVID-19 Unknown

Does symptom persist after COVID-19 resolution? Yes

No

Duration of symptom Fixed Unit: # days

Dermatological

New skin findings attributable to COVID-19 Yes

If "No", go to Other No

Unknown

Specify (max 200 characters): _____

Does symptom persist after COVID-19 resolution? Yes

No

Duration of symptom Fixed Unit: # days

Other

Other COVID-19 symptom Yes

If "Yes", specify up to 3 symptoms below. No

If "No", end of form.

Specify (max 200 characters): _____

Does symptom persist after COVID-19 resolution? Yes

No

Duration of symptom Fixed Unit: # days

Specify (max 200 characters): _____

Does symptom persist after COVID-19 resolution? Yes

No

Duration of symptom Fixed Unit: # days

Specify (max 200 characters): _____

Does symptom persist after COVID-19 resolution? Yes

No

Duration of symptom Fixed Unit: # days

Form: COVID-19 Treatment and Hospitalization

Treatment/Diagnostic Information

Did the participant receive supplemental oxygen? Yes
No

Did the participant have pneumonia on radiologic imaging (e.g.,
chest x-ray or CT scan)? Yes
No
Unknown

Was the participant enrolled in any experimental treatment trials? Yes
No

If "Yes", specify: _____

Did the participant receive any of the following medications?

Complete below AND record on the Concomitant Medications log, as applicable.

Remdesivir Yes
No
Unknown

Chloroquine/hydroxychloroquine +/- azithromycin Yes
No
Unknown

Tocilizumab or other IL-6 pathway inhibitors Yes
No
Unknown

Convalescent plasma Yes
No
Unknown

Corticosteroids Yes
No
Unknown

Hospitalization Information

Was the participant hospitalized? Yes
No

If "No", end of form.

Did the participant receive intensive care? Yes
No

If "Yes", was the participant intubated? Yes
No

If "Yes", did the participant receive ECMO? Yes
No
Unknown

Form: COVID-19 Treatment and Hospitalization

Was the participant discharged on supplemental oxygen?

Yes

No

Form: Demographics

Thank you for being a part of our research. As you know, the virus SARS-CoV-2 and the disease it can cause, COVID-19, affect many people. People live in different places, with different customs, cultures, sexual practices, and beliefs. We hope to include people from different communities in our research. We respect all people. Not all questions we ask in our research will apply to you. Because we do not want to make assumptions, we ask the same questions of everyone. We want you to be comfortable in speaking with us. You do not have to answer any question that makes you uncomfortable.

Now I am going to ask you some questions about yourself. The answers to these questions will tell us more about who you are, such as your age and race. I will also ask you about your sex and gender. Please feel free to ask any questions about things that you don't understand. All of your answers will be kept private.

Region Americas
Africa (South Africa)
Africa (other African countries)

Date of birth. _____

Age. _____

Fixed Unit: yrs

The next question is about your sex. When I ask about your sex, I am asking about what sex you were determined to be at birth, which is generally done by looking at a baby's genitals (sex organs).

Sex assigned at birth Male
Female

Ethnicity. Hispanic or Latino.
Not Hispanic or Latino.

Race

Mark all that apply.

American Indian or Alaska Native.

Asian.

Black or African American.

Native Hawaiian or other Pacific Islander.

White.

Other.

.If "Other", specify: _____

.Do you currently have health insurance/coverage or medical aid? Yes.
No.
Don't know.
Prefer not to answer.

.If Region is "Americas", what is the highest level of formal schooling you have completed? No formal education.
Did not graduate from high school.
High school graduate or GED.

Form: Demographics

	Some college/AA degree/technical school training.	<input type="radio"/>
	Undergraduate college degree (BS/BA).	<input type="radio"/>
	Some graduate school.	<input type="radio"/>
	Master's degree.	<input type="radio"/>
	Doctorate/medical degree/law degree.	<input type="radio"/>
	Don't know.	<input type="radio"/>
	Prefer not to answer.	<input type="radio"/>

.If Region is "Africa (South Africa)" or "Africa (other African countries)", what is the highest level of formal schooling you have completed?

	No formal education.	<input type="radio"/>
	Some primary school.	<input type="radio"/>
	Completed primary school.	<input type="radio"/>
	Some secondary/high school.	<input type="radio"/>
	Completed secondary/high school.	<input type="radio"/>
	Some university/technical education (associates/bachelors/technical degree).	<input type="radio"/>
	Completed university/technical education (associates/bachelors/technical degree).	<input type="radio"/>
	National certificate/trade certificate/national diploma/occupational certificate.	<input type="radio"/>
	Some graduate school (doctorate/masters/honours/higher education degree).	<input type="radio"/>
	Completed graduate school (doctorate/masters/honours/higher education degree).	<input type="radio"/>
	Prefer not to answer.	<input type="radio"/>

.If Region is "Africa (other African countries)", end of form.

Gender.

Mark all that apply.

Gender is the social part of being male or female, and relates to your self-identity. I am asking whether you consider yourself to be transgender male, transgender female, gender queer, gender variant or gender non-conforming, female, or male or if you identify yourself in an additional category. How do you identify your gender?

Male.	<input type="checkbox"/>
Female.	<input type="checkbox"/>
Transgender Male.	<input type="checkbox"/>
Transgender Female.	<input type="checkbox"/>
Gender Nonconforming/Gender Variant.	<input type="checkbox"/>
Gender Queer.	<input type="checkbox"/>

Form: Demographics

Self-identify.

.If "Self-identify", specify: _____

Prefer not to answer.

The next question asks about your sexual orientation. By sexual orientation, I mean who are you sexually attracted to.

- .How do you identify your sexual orientation?
- Gay/Lesbian/Homosexual.
 - Bisexual.
 - Queer.
 - Two Spirit.
 - Straight/Heterosexual.
 - Additional category.
 - Not sure.
 - Prefer not to answer.

.If "Additional category", specify: _____

Form: Interim Visit

Interim visit code _____

Date of visit _____

What is/are the reason(s) for this interim visit?

Mark all that apply.

Participant missing part or all of a scheduled study visit and is outside of visit window.

Participant contacted site to report updated Medical History.

Update Medical History log.

Repeat specimen collection

Other reason

If "Other reason", specify (max. 200 characters): _____

Did the participant exit/terminate the study at this visit? Yes

If "Yes", complete Termination form. No

FORMS COMPLETED AT INTERIM VISIT:

COVID-19 Symptoms

COVID-19 Treatment and Hospitalization

Nasal Specimen for SARS-CoV-2 PCR

Participant Transfer

Participant Receipt

SARS-CoV-2 Exposure

Specimen Collection - Blood

Form: Medical History

Log Page #: _____

Participant Information

Height _____ Fixed Unit: cm

Weight _____ Fixed Unit: kg

Targeted Conditions

Does the participant have any of the following conditions?

If "Yes", record details in Medical History log below and/or on Concomitant Medications log, as applicable.

Hypertension Yes No

COPD/emphysema/asthma Yes No

Congestive heart failure Yes No

Myocarditis/pericarditis Yes No

Diabetes Yes No

If "Yes", does the participant have renal disease, eye disease or peripheral neuropathy? Yes No

Record any medication use, including insulin, on the Concomitant Medications log.

Chronic kidney disease Yes No

Immune system disorders Yes No

Record any immunosuppressant medications on the Concomitant Medication log.

Has the participant ever smoked cigarettes? Yes No

If "Yes", does the participant currently smoke cigarettes? Yes No

Has the participant ever smoked marijuana? Yes No

If "Yes", does the participant currently smoke marijuana? Yes No

Medical History

Description of condition/event _____

Start date of condition/event _____

Form: Medical History

Log Page #: _____

Is the condition ongoing? Yes

No

Is condition/event gradable? Yes

No

Severity grade Grade 1 (Mild)

Grade 2 (Moderate)

Grade 3 (Severe)

Grade 4 (Potentially
life-threatening)

Comments (max. 450 characters): _____

Form: Nasal Specimen for Antibodies

Use this form to document nasal wash/swab collection for antibody testing.

Was specimen collected? Yes

No

If "No", end of form.

Specimen collection date _____

Specimen collection time _____

Specimen collection location Clinical research site

Elsewhere (e.g. Home)

If "Clinic", was the procedure performed by participant or by clinic staff? Participant

Clinic staff

Specimen collection type Nasal Wash

Nasal Swab

Were all requirements of the specimen collection met per the SSP? Yes

No

If "No", provide explanation in Comments. Report any nasal product use on the Concomitant Medications log.

Comments (max. 600 characters): _____

Form: Nasal Specimen for SARS-CoV-2 PCR

Use this form to document nasopharyngeal/nasal swab collection for RT-PCR testing.

Was specimen collected? Yes
No

If "No", end of form.

Specimen collection date _____

Specimen collection time _____

Specimen collection location Clinical research site
Elsewhere (e.g. Home)

If "Clinic", was the procedure performed by participant or by clinic staff? Participant
Clinic staff

Swab type Nasopharyngeal
Nasal

Were all requirements of the specimen collection met per the SSP? Yes
No

If "No", provide explanation in Comments. Report any nasal product use on the Concomitant Medications log.

Comments (max. 600 characters): _____

Form: Participant Receipt

Name of receiving study site	Atlanta - Hope Clinic	<input type="checkbox"/>
	Atlanta - Ponce de Leon Center	<input type="checkbox"/>
	Baltimore - Johns Hopkins University	<input type="checkbox"/>
	Birmingham - Alabama	<input type="checkbox"/>
	Boston - Brigham and Women's Hospital Vaccine	<input type="checkbox"/>
	Boston - Fenway Health	<input type="checkbox"/>
	Chapel Hill	<input type="checkbox"/>
	Chicago - AYAR at CORE	<input type="checkbox"/>
	Cleveland - Case	<input type="checkbox"/>
	Los Angeles - UCLA CARE Center	<input type="checkbox"/>
	Nashville - Vanderbilt Vaccine	<input type="checkbox"/>
	New Orleans - Adolescent Trials Unit	<input type="checkbox"/>
	New York - Bronx Prevention Center	<input type="checkbox"/>
	New York - Harlem Prevention Center	<input type="checkbox"/>
	New York - NY Blood Center	<input type="checkbox"/>
	New York - Physicians & Surgeons	<input type="checkbox"/>
	Newark - New Jersey Medical School	<input type="checkbox"/>
	Philadelphia - Penn Prevention	<input type="checkbox"/>
	Rochester - Univ. of Rochester Vaccines to Prevent HIV Infection	<input type="checkbox"/>
	San Francisco - Bridge HIV	<input type="checkbox"/>
	Seattle Vaccine Trials Unit	<input type="checkbox"/>
	Washington, DC - George Washington University	<input type="checkbox"/>
	Iquitos - Asociacion Civil Selva Amazonica	<input type="checkbox"/>
	Lima - Barranco	<input type="checkbox"/>
	Lima - San Marcos/CITBM	<input type="checkbox"/>
	Lima - San Miguel	<input type="checkbox"/>
	Lima - Via Libre	<input type="checkbox"/>
	Bloemfontein	<input type="checkbox"/>
	Cape Town - Emavundleni	<input type="checkbox"/>
	Cape Town - Groote Schuur	<input type="checkbox"/>
	Cape Town - Khayelitsha	<input type="checkbox"/>
	Durban - Botha's Hill	<input type="checkbox"/>
	Durban - Chatsworth	<input type="checkbox"/>
	Durban - eThekweni	<input type="checkbox"/>
	Durban - Isipingo	<input type="checkbox"/>

Form: Participant Receipt

	Durban - Tongaat	<input type="checkbox"/>
	Durban - Verulam	<input type="checkbox"/>
	Harare - Seke South	<input type="checkbox"/>
	Harare - St. Mary's	<input type="checkbox"/>
	Harare - Zengeza	<input type="checkbox"/>
	Klerksdorp	<input type="checkbox"/>
	Ladysmith	<input type="checkbox"/>
	Lilongwe - Malawai	<input type="checkbox"/>
	Lusaka - Matero	<input type="checkbox"/>
	Lusaka - ZHERP	<input type="checkbox"/>
	Mamelodi	<input type="checkbox"/>
	Maputo	<input type="checkbox"/>
	Masiphumelele	<input type="checkbox"/>
	Mbeya	<input type="checkbox"/>
	Mthatha	<input type="checkbox"/>
	Ndola	<input type="checkbox"/>
	Rustenburg	<input type="checkbox"/>
	Soshanguve	<input type="checkbox"/>
	Soweto - Bara	<input type="checkbox"/>
	Soweto - Kliptown	<input type="checkbox"/>
	Tembisa - Clinic 3	<input type="checkbox"/>
	Tembisa - Clinic 4	<input type="checkbox"/>
	Vulindlela	<input type="checkbox"/>

Name of transferring study site

	Atlanta - Hope Clinic	<input type="checkbox"/>
	Atlanta - Ponce de Leon Center	<input type="checkbox"/>
	Baltimore - Johns Hopkins University	<input type="checkbox"/>
	Birmingham - Alabama	<input type="checkbox"/>
	Boston - Brigham and Women's Hospital Vaccine	<input type="checkbox"/>
	Boston - Fenway Health	<input type="checkbox"/>
	Chapel Hill	<input type="checkbox"/>
	Chicago - AYAR at CORE	<input type="checkbox"/>
	Cleveland - Case	<input type="checkbox"/>
	Los Angeles - UCLA CARE Center	<input type="checkbox"/>
	Nashville - Vanderbilt Vaccine	<input type="checkbox"/>
	New Orleans - Adolescent Trials Unit	<input type="checkbox"/>
	New York - Bronx Prevention Center	<input type="checkbox"/>

Form: Participant Receipt

New York - Harlem Prevention Center	<input type="checkbox"/>
New York - NY Blood Center	<input type="checkbox"/>
New York - Physicians & Surgeons	<input type="checkbox"/>
Newark - New Jersey Medical School	<input type="checkbox"/>
Philadelphia - Penn Prevention	<input type="checkbox"/>
Rochester - Univ. of Rochester Vaccines to Prevent HIV Infection	<input type="checkbox"/>
San Francisco - Bridge HIV	<input type="checkbox"/>
Seattle Vaccine Trials Unit	<input type="checkbox"/>
Washington, DC - George Washington University	<input type="checkbox"/>
Iquitos - Asociacion Civil Selva Amazonica	<input type="checkbox"/>
Lima - Barranco	<input type="checkbox"/>
Lima - San Marcos/CITBM	<input type="checkbox"/>
Lima - San Miguel	<input type="checkbox"/>
Lima - Via Libre	<input type="checkbox"/>
Bloemfontein	<input type="checkbox"/>
Cape Town - Emavundleni	<input type="checkbox"/>
Cape Town - Groote Schuur	<input type="checkbox"/>
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Durban - Verulam	<input type="checkbox"/>
Harare - Seke South	<input type="checkbox"/>
Harare - St. Mary's	<input type="checkbox"/>
Harare - Zengeza	<input type="checkbox"/>
Klerksdorp	<input type="checkbox"/>
Ladysmith	<input type="checkbox"/>
Lilongwe - Malawai	<input type="checkbox"/>
Lusaka - Matero	<input type="checkbox"/>
Lusaka - ZHERP	<input type="checkbox"/>
Mamelodi	<input type="checkbox"/>
Maputo	<input type="checkbox"/>
Masiphumelele	<input type="checkbox"/>
Mbeya	<input type="checkbox"/>

Form: Participant Receipt

	Mthatha	<input type="checkbox"/>
	Ndola	<input type="checkbox"/>
	Rustenburg	<input type="checkbox"/>
	Soshanguve	<input type="checkbox"/>
	Soweto - Bara	<input type="checkbox"/>
	Soweto - Kliptown	<input type="checkbox"/>
	Tembisa - Clinic 3	<input type="checkbox"/>
	Tembisa - Clinic 4	<input type="checkbox"/>
	Vulindlela	<input type="checkbox"/>

Date informed consent signed at receiving site _____

Form: Participant Transfer

Name of transferring study site	Atlanta - Hope Clinic <input type="checkbox"/>
	Atlanta - Ponce de Leon Center <input type="checkbox"/>
	Baltimore - Johns Hopkins University <input type="checkbox"/>
	Birmingham - Alabama <input type="checkbox"/>
	Boston - Brigham and Women's Hospital Vaccine <input type="checkbox"/>
	Boston - Fenway Health <input type="checkbox"/>
	Chapel Hill <input type="checkbox"/>
	Chicago - AYAR at CORE <input type="checkbox"/>
	Cleveland - Case <input type="checkbox"/>
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	Rochester - Univ. of Rochester Vaccines to Prevent HIV Infection <input type="checkbox"/>
	San Francisco - Bridge HIV <input type="checkbox"/>
	Seattle Vaccine Trials Unit <input type="checkbox"/>
	Washington, DC - George Washington University <input type="checkbox"/>
	Iquitos - Asociacion Civil Selva Amazonica <input type="checkbox"/>
	Lima - Barranco <input type="checkbox"/>
	Lima - San Marcos/CITBM <input type="checkbox"/>
	Lima - San Miguel <input type="checkbox"/>
	Lima - Via Libre <input type="checkbox"/>
	Bloemfontein <input type="checkbox"/>
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	Durban - Botha's Hill <input type="checkbox"/>
	Durban - Chatsworth <input type="checkbox"/>
	Durban - eThekweni <input type="checkbox"/>
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Form: Participant Transfer

	Durban - Tongaat	<input type="checkbox"/>
	Durban - Verulam	<input type="checkbox"/>
	Harare - Seke South	<input type="checkbox"/>
	Harare - St. Mary's	<input type="checkbox"/>
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	Vulindlela	<input type="checkbox"/>

Name of receiving study site

	Atlanta - Hope Clinic	<input type="checkbox"/>
	Atlanta - Ponce de Leon Center	<input type="checkbox"/>
	Baltimore - Johns Hopkins University	<input type="checkbox"/>
	Birmingham - Alabama	<input type="checkbox"/>
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Form: Participant Transfer

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Lusaka - ZHERP	<input type="checkbox"/>
Mamelodi	<input type="checkbox"/>
Maputo	<input type="checkbox"/>
Masiphumelele	<input type="checkbox"/>
Mbeya	<input type="checkbox"/>

Form: Participant Transfer

	Mthatha	<input type="checkbox"/>
	Ndola	<input type="checkbox"/>
	Rustenburg	<input type="checkbox"/>
	Soshanguve	<input type="checkbox"/>
	Soweto - Bara	<input type="checkbox"/>
	Soweto - Kliptown	<input type="checkbox"/>
	Tembisa - Clinic 3	<input type="checkbox"/>
	Tembisa - Clinic 4	<input type="checkbox"/>
	Vulindlela	<input type="checkbox"/>
Visit of last completed contact with participant	V1.0 - Enrollment	<input type="checkbox"/>
	V2.0 - Follow-up	<input type="checkbox"/>
	V3.0 - Follow-up	<input type="checkbox"/>
	V4.0 - Follow-up	<input type="checkbox"/>
	Interim Visit	<input type="checkbox"/>

If "Interim visit", specify Interim visit code _____

Date participant's records were sent to receiving study site _____

Form: SARS-CoV-2 Exposure

Log Page #: _____

Household Exposure

At the time of, or just before, their positive SARS-CoV-2 test, did the participant live with any other individuals in their household? Yes No

If "Yes", please provide the below information for all individuals in the participant's household

Age _____ Fixed Unit: yrs

Did the person have confirmed SARS-CoV-2 infection by a laboratory test? Yes No

If "Yes", was the laboratory test performed prior to the study participant's symptoms or test results? Yes No

Did the person develop symptoms consistent with COVID-19? Yes No

If "Yes", did the symptoms develop before the study participant's symptoms or test results? Yes No

Other Exposure

What is the participant's OSHA risk of occupational exposure? Lower exposure risk Medium exposure risk High exposure risk Very high exposure risk Not applicable

Does the participant have regular exposure to young children (<5 years old)? Yes No

Did the participant have exposure to any other individuals with confirmed SARS-CoV-2 infection or COVID-19 outside the home setting? Yes No

If "No", end of form.

Date of last contact with individual _____

Exposure description (max. 200 characters): _____

Form: SARS-CoV-2 Test Results

Log Page #: _____

Approximate date of test _____

Test result

Detected

Not Detected

Indeterminate

Where was the specimen collection done?

Inpatient

Outpatient

Employer

Urgent Care

Emergency Room

Home

Other

If "Other", specify: _____

Test type

RT-PCR

Antibody/serology

Other

If "Other", specify: _____

Specimen collection type

Nasal or Nasopharyngeal Swab

Nasal Wash

Oropharyngeal Swab

Saliva

Blood

Other

If "Other", specify: _____

Form: Screening Outcome

Informed consent date _____	
Is the participant eligible to enroll in the study?	Yes <input type="radio"/>
	No <input type="radio"/>
If "No", go to "Eligibility status".	
Group	Group 1 - not previously hospitalized, without specific clinical spectrums or outcomes <input type="radio"/> Group 2 - previously hospitalized, without specific clinical spectrums or outcomes <input type="radio"/> Group 3 - with specific clinical spectrums or outcomes <input type="radio"/>
If "Group 3", specify:	Recovered after intubation <input type="radio"/> Prolonged viral shedding <input type="radio"/> Myocarditis/pericarditis <input type="radio"/> Rapid recovery from COVID-19 <input type="radio"/> Second positive SARS-CoV-2 RT-PCR test result after a negative result <input type="radio"/> Other <input type="radio"/>
If "Other", specify: (max. 200 characters) _____	
Eligibility status	Eligible and enrolled <input type="radio"/> Ineligible <input type="radio"/> Incomplete Screening <input type="radio"/>
If "Ineligible", select reason(s) why participant is ineligible.	Inclusion Criterion 1 - Age 18 or older. <input type="radio"/> Inclusion Criterion 2 - Reports having had a positive test for SARS-CoV-2. <input type="radio"/> Inclusion Criterion 3 - Reports resolution of COVID-19 within 1-8 weeks of enrollment OR, if asymptomatic infection, reports positive SARS-CoV-2 test within 2-10 weeks of enrollment. <input type="radio"/> Inclusion Criterion 4 - Access to a participating HVTN or HPTN CRS and willingness to be followed for the planned duration of the study. <input type="radio"/> Inclusion Criterion 5 - Ability and willingness to provide informed consent. <input type="radio"/> Inclusion Criterion 6 - Assessment of understanding: volunteer demonstrates understanding of this study. <input type="radio"/>

Form: Screening Outcome

-
- Inclusion Criterion 7 - Volunteers who were assigned female sex at birth: negative urine or serum beta human chorionic gonadotropin (β -HCG) pregnancy test within 4 days of enrollment visit (ie, prior to enrollment blood draw or nasal collections).
 - Exclusion Criterion 1 - Reports current COVID-19.
 - Exclusion Criterion 2 - Pregnant.
 - Exclusion Criterion 3 - Receipt of SARS-CoV-2 specific antibodies (eg, convalescent plasma or sera, monoclonal antibodies, hyperimmune globulin).
 - Exclusion Criterion 4 - SARS-CoV-2 vaccine(s) received in a prior vaccine trial.
 - Exclusion Criterion 5 - Any medical, psychiatric, occupational, or other condition that, in the judgment of the investigator, would interfere with, or serve as a contraindication to, protocol adherence or a volunteer's ability to give informed consent.
 - Volunteer inappropriate for enrollment in the judgement of the investigator.
-

Form: Specimen Collection - Blood

Do NOT use this form for any local lab specimens. Use this form ONLY to document the collection of blood specimens that will be sent to the site processing lab.

Was specimen collected? Yes
No

If "No", end of form.

Specimen collection date _____

Specimen collection time _____

EDTA Collected
Not collected

ACD Collected
Not collected

SST Collected
Not collected

SST - Clinical SARS-CoV-2 IgG Antibody Results Collected
Not collected

Mark if a new Specimen Collection form is needed to complete specimen collection requirements for this visit.

Form: Study Termination

Date of study exit _____

Primary reason for completion/discontinuation

Scheduled exit visit/end of study

Death

Participant refused further participation

Participant is unwilling or unable to comply with required study procedures

Investigator decision

Unable to contact participant

Early study closure

Protocol deviation

Pregnancy

Study terminated by sponsor

Participant unable to adhere to visit schedule

Participant relocated, no follow-up planned

Other, specify

If "Other", specify (max. 200 characters): _____

If "Death", enter date of death. _____
