Form: Concomitant Medications Log Page #:_____

Medication name	
Indication	
Date started	
Date stopped	
Or	
Continuing at final clinic visit	☐
Route	
	Oral ☐
	Intramuscular ☐
	Intravenous ☐
	Topical ☐
	Inhalation ☐
	Vaginal ☐
	Rectal ☐
	Subcutaneous ☐
	Subdermal ☐
	Sublingual ☐
	Intrauterine ☐
	Nasal ☐
	Intraocular ☐
	Other ☐
If "Other", specify:	

Form: COVID-19 Symptoms - Enrollment

Did the participant experience any COVID-19 symptoms prior to or at enrollment?
- Yes ☐
- No ☐

If "No", end of form.

Fever
- Yes ☐
- No ☐

If "No", go to Fatigue/Malaise

Onset date _____

Maximum temperature Fixed Unit: C

_____

Overall

Fatigue/Malaise
- Yes ☐
- No ☐

If "No", go to Myalgia

Onset date _____

Maximum severity
- Mild ☐
- Moderate ☐
- Severe ☐

Myalgia
- Yes ☐
- No ☐

If "No", go to Chills

Onset date _____

Maximum severity
- Mild ☐
- Moderate ☐
- Severe ☐

Chills
- Yes ☐
- No ☐

If "No", go to Headache

Onset date _____

Maximum severity
- Mild ☐
- Moderate ☐
- Severe ☐

Head

Headache
- Yes ☐
- No ☐

If "No", go to Nausea/Vomiting

Onset date _____

Maximum severity
- Mild ☐
- Moderate ☐
- Severe ☐

Gastrointestinal

Nausea/Vomiting
- Yes ☐
- No ☐

If "No", go to Diarrhea/Abdominal pain

Onset date _____

Form: COVID-19 Symptoms - Enrollment

Maximum severity	Mild ☐ Moderate ☐ Severe ☐
Diarrhea/Abdominal pain	Yes ☐
If "No", go to Cough	No ☐
Onset date	_____
Maximum severity	Mild ☐ Moderate ☐ Severe ☐
Lungs	
Cough	Yes ☐
If "No", go to Chest congestion/Shortness of breath	No ☐
Onset date	_____
Maximum severity	Mild ☐ Moderate ☐ Severe ☐
Chest congestion/Shortness of breath	Yes ☐
If "No", go to Pharyngitis/Rhinorrhea	No ☐
Onset date	_____
Maximum severity	Mild ☐ Moderate ☐ Severe ☐
ENT	
Pharyngitis/Rhinorrhea	Yes ☐
If "No", go to Anosmia/Ageusia	No ☐
Onset date	_____
Maximum severity	Mild ☐ Moderate ☐ Severe ☐
Anosmia/Ageusia	Yes ☐
If "No", end of form.	No ☐
Onset date	_____
Maximum severity	Mild ☐ Moderate ☐ Severe ☐

Form: COVID-19 Hospitalization

Was the participant hospitalized? Yes ☐ No ☐

If "No", end of form.

Baseline independence with activities of daily living
Requires no assistance ☐
Some assistance needed ☐
Complete assistance needed ☐

Date of admission _____

Did the participant receive intensive care? Yes ☐ No ☐

If "No", go to "Did the participant receive supplemental oxygen?"

ICU start date _____

Number of days in ICU Fixed Unit: # days _____

Did the participant receive supplemental oxygen? Yes ☐ No ☐

If "Yes", mark all that apply.

If "No", go to "Did the participant experience hypotension requiring vasopressors?"

High-flow oxygen (e.g., >15L/min) ☐

Non-invasive ventilation (e.g., CPAP, BiPAP) ☐

Invasive ventilation ☐

ECMO ☐

Any other oxygen (e.g., 2L/min nasal cannula) ☐

Days of invasive ventilation (including ECMO) Fixed Unit: # days _____

Did the participant experience hypotension requiring vasopressors? Yes ☐ No ☐

Did the participant experience kidney injury? Yes ☐ No ☐

If "Yes", did the participant receive renal replacement therapy (e.g., dialysis)? Yes ☐ No ☐

Did the participant experience thrombosis or other vascular event, including stroke? Yes ☐ No ☐

Did the participant experience myocarditis or pericarditis? Yes ☐ No ☐

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

Form: COVID-19 Hospitalization

	Unknown, chest imaging not performed ☐
Was the participant enrolled in any experimental treatment trials?	Yes ☐ No ☐
If "Yes", specify treatment (max. 200 characters):	
Record any medications on the Concomitant Medications log.	_____
Did the participant receive any of the following medications?	
Complete below AND record on the Concomitant Medications log.	
Remdesivir	Yes ☐ No ☐
Chloroquine/hydroxychloroquine +/- azithromycin	Yes ☐ No ☐
Tocilizumab or other IL-6 pathway inhibitors	Yes ☐ No ☐
Anti-SARS-CoV-2 monoclonal antibody	Yes ☐ No ☐
Convalescent plasma	Yes ☐ No ☐
Corticosteroids	Yes ☐ No ☐
Off-label immunomodulatory therapy (not in the context of a clinical trial)	Yes ☐ No ☐
If "Yes", specify (max. 200 characters):	_____
Off-label antiviral therapy (not in the context of a clinical trial)	Yes ☐ No ☐
If "Yes", specify (max. 200 characters):	_____
Other COVID-19 specific therapy	Yes ☐ No ☐
If "Yes", specify (max. 200 characters):	_____
Discharge Information	
Has the participant been discharged?	Yes ☐ No ☐
If "No", end of form.	
Date of discharge	_____
What is the participant's vital status?	Alive ☐
If "Deceased", complete Study Termination CRF and end of form.	Deceased ☐

Form: COVID-19 Hospitalization

Discharge independence with activities of daily living	Requires no assistance ☐ Some assistance needed ☐ Complete assistance needed ☐
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. ☐ Undergraduate college degree (BS/BA). ☐ Some graduate school. ☐ Master's degree. ☐ Doctorate/medical degree/law degree. ☐ Don't know. ☐ Prefer not to answer. ☐
.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. ☐ Some primary school. ☐ Completed primary school. ☐ Some secondary/high school. ☐ Completed secondary/high school. ☐ Some university/technical education (associates/bachelors/technical degree). ☐ Completed university/technical education (associates/bachelors/technical degree). ☐ National certificate/trade certificate/national diploma/occupational certificate. ☐ Some graduate school (doctorate/masters/honours/higher education degree). ☐ Completed graduate school (doctorate/masters/honours/higher education degree). ☐ Prefer not to answer. ☐

.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.	☐
Female.	☐
Transgender Male.	☐
Transgender Female.	☐
Gender Nonconforming/Gender Variant.	☐
Gender Queer.	☐

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: Dietary Information

This form should only be completed for participants who provide a stool sample.

In the last 6 months, did the participant follow a special diet? Yes ☐ No ☐

If "No", go to "Does the participant limit or avoid any food or food groups (such as meat, dairy, carbs)?"

What kind of special diet did the participant follow? Specify: _____

Does the participant limit or avoid any food or food groups (such as meat, dairy, carbs)? Yes ☐ No ☐

If "No", go to "Did the participant eat fermented milk products...in the last 24 hours prior to sample collection?"

What food groups does the participant limit or avoid?

Mark all that apply.

- Meat ☐
- Wheat/Grains ☐
- Fish ☐
- Carbohydrates ☐
- Dairy ☐
- Other ☐

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

Did the participant eat fermented milk products (such as yogurt, amahewu if made with milk, etc.) in the last 24 hours prior to sample collection? Yes ☐ No ☐

Did the participant eat fermented milk products (such as yogurt, amahewu if made with milk, etc.) in the last 6 months prior to day of sample collection? Yes ☐ No ☐

Did the participant take any probiotic supplements in the last 24 hours prior to sample collection? Yes ☐ No ☐

Did the participant take any probiotic supplements in the last 6 months prior to day of sample collection? Yes ☐ No ☐

Did the participant take any antibiotics in the last 24 hours prior to sample collection? Yes ☐ No ☐

If "Yes", record on the Concomitant Medications log.

Did the participant take any antibiotics in the last 6 months prior to day of sample collection? Yes ☐ No ☐

If "Yes", record on the Concomitant Medications log.

Form: Health Contact

Was the health contact completed?	Yes ☐
If "No", end of form.	No ☐
Contact date	_____
What is the participant's vital status?	Alive ☐
If "Deceased", complete Study Termination CRF and end of form.	Deceased ☐
What is the participant's current independence with activities of daily living?	Requires no assistance ☐
	Some assistance needed ☐
	Complete assistance needed ☐
Does the participant require supplemental oxygen?	Yes ☐
	No ☐
Does the participant require dialysis?	Yes ☐
	No ☐
Since the study began, did the participant ever develop blood clots?	Yes ☐
	No ☐
Does the participant consider themselves to be recovered?	Yes ☐
If "Yes", end of form.	No ☐

Symptom Assessment

Mark all ongoing symptoms.

Fever	☐
Fatigue/Malaise	☐
Myalgia	☐
Chills	☐
Headache	☐
Nausea/Vomiting	☐
Diarrhea/Abdominal pain	☐
Cough	☐
Chest congestion/Shortness of breath	☐
Pharyngitis/Rhinorrhea	☐
Anosmia/Ageusia	☐
Other	☐

If "Other", specify up to 3 symptoms below.

Specify (max 200 characters):	_____
Specify (max 200 characters):	_____
Specify (max 200 characters):	_____

Form: Hematology

HEMOGRAM	
Was a hematology sample collected?	Yes ☐ No ☐
Hematology collection date	
Hemoglobin	Fixed Unit: g/dL
Hematocrit	Fixed Unit: %
MCV	Fixed Unit: fL
Platelets	Fixed Unit: cells/mm3
WBC	Fixed Unit: cells/mm3
DIFFERENTIAL	
Was a differential done?	Yes ☐ No ☐
Differential collection date	
Neutrophils	Fixed Unit: cells/mm3
Lymphocytes	Fixed Unit: cells/mm3
Monocytes	Fixed Unit: cells/mm3
Eosinophils	Fixed Unit: cells/mm3
Basophils	Fixed Unit: cells/mm3
Atypical lymphocytes	Fixed Unit: cells/mm3
Comments (max. 450 characters):	

Form: Informed Consent

Informed consent date _____

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.	
Participant contacted site to report updated Concomitant Medications.	☐
Update Concomitant Medication 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:

Hematology	☐
Participant Transfer	☐
Participant Receipt	☐
Pregnancy Test Results	☐
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 ☐
Diabetes	Yes ☐ No ☐
If "Yes", does the participant have renal disease, eye disease or peripheral neuropathy consistent with diabetic neuropathy?	Yes ☐ No ☐

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

Chronic kidney disease	Yes ☐ No ☐
If "Yes", does the participant require dialysis?	Yes ☐ No ☐
Autoimmune disease (e.g., rheumatoid arthritis, lupus) or immunodeficiency (e.g., low antibody levels, hypogammaglobulinemia)	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 #:_____

Comments (max. 450 characters):

Form: Participant Receipt

Name of receiving study site

- ☐ Atlanta - Hope Clinic
- ☐ Atlanta - Ponce de Leon Center
- ☐ Baltimore - Johns Hopkins University
- ☐ Birmingham - Alabama
- ☐ Boston - Brigham and Women's Hospital Vaccine
- ☐ Boston - Fenway Health
- ☐ Chapel Hill
- ☐ Cleveland - Case
- ☐ Miami - University of Miami IDRU
- ☐ New Orleans - Adolescent Trials Unit
- ☐ New York - NY Blood Center
- ☐ New York - Physicians & Surgeons
- ☐ Newark - New Jersey Medical School
- ☐ Philadelphia - Penn Prevention
- ☐ Rochester - Univ. of Rochester Vaccines to Prevent HIV Infection
- ☐ San Francisco - Bridge HIV
- ☐ Seattle Vaccine Trials Unit
- ☐ Belo Horizonte - FUMG
- ☐ Buenos Aires - Almagro
- ☐ Buenos Aires - Balvanera, Ramos Mejia
- ☐ Iquitos - Asociacion Civil Selva Amazonica
- ☐ Lima - Barranco
- ☐ Lima - San Marcos/CITBM
- ☐ Lima - San Miguel
- ☐ Lima - Via Libre
- ☐ Merida
- ☐ Mexico City
- ☐ Rio de Janeiro - IPEC-Fiocruz
- ☐ Rosario - Instituto CAICI
- ☐ Cape Town - Groote Schuur
- ☐ Durban - Botha's Hill
- ☐ Durban - Chatsworth
- ☐ Durban - Isipingo
- ☐ Durban - Tongaat
- ☐ Durban - Verulam

Form: Participant Receipt

Durban-eThekwini ☐
Elandsdoorn ☐
Gaborone ☐
Harare - Parirenyatwa ☐
Harare - Seke South ☐
Harare - St. Mary's ☐
Khayelitsha ☐
Kisumu ☐
Klerksdorp ☐
Ladysmith - QM ☐
Lilongwe - Malawi ☐
Lusaka - Matero ☐
Lusaka - ZEHRP ☐
Maputo, Polana Canico Health Research and Training Center Network ☐
Masiphumelele ☐
Mbeya ☐
Medunsa ☐
Mthatha ☐
Ndola ☐
Rustenburg ☐
Soshanguve - Setshaba RC ☐
Soweto – Bara ☐
Soweto - Kliptown ☐
Tembisa - Clinic 4 ☐
Vulindlela ☐

Name of transferring study site

Atlanta - Hope Clinic ☐
Atlanta - Ponce de Leon Center ☐
Baltimore - Johns Hopkins University ☐
Birmingham - Alabama ☐
Boston - Brigham and Women's Hospital Vaccine ☐
Boston - Fenway Health ☐
Chapel Hill ☐
Cleveland - Case ☐
Miami - University of Miami IDRU ☐
New Orleans - Adolescent Trials Unit ☐
New York - NY Blood Center ☐

Form: Participant Receipt

- ☐ New York - Physicians & Surgeons
- ☐ Newark - New Jersey Medical School
- ☐ Philadelphia - Penn Prevention
- ☐ Rochester - Univ. of Rochester Vaccines to Prevent HIV Infection
- ☐ San Francisco - Bridge HIV
- ☐ Seattle Vaccine Trials Unit
- ☐ Belo Horizonte - FUMG
- ☐ Buenos Aires - Almagro
- ☐ Buenos Aires - Balvanera, Ramos Mejia
- ☐ Iquitos - Asociacion Civil Selva Amazonica
- ☐ Lima - Barranco
- ☐ Lima - San Marcos/CITBM
- ☐ Lima - San Miguel
- ☐ Lima - Via Libre
- ☐ Merida
- ☐ Mexico City
- ☐ Rio de Janeiro - IPEC-Fiocruz
- ☐ Rosario - Instituto CAICI
- ☐ Cape Town - Groote Schuur
- ☐ Durban - Botha's Hill
- ☐ Durban - Chatsworth
- ☐ Durban - Isipingo
- ☐ Durban - Tongaat
- ☐ Durban - Verulam
- ☐ Durban-eThekwini
- ☐ Elandsdoorn
- ☐ Gaborone
- ☐ Harare - Parirenyatwa
- ☐ Harare - Seke South
- ☐ Harare - St. Mary's
- ☐ Khayelitsha
- ☐ Kisumu
- ☐ Klerksdorp
- ☐ Ladysmith - QM
- ☐ Lilongwe - Malawi
- ☐ Lusaka - Matero

Form: Participant Receipt

Lusaka - ZEHRP	☐
Maputo, Polana Canico Health Research and Training Center Network	☐
Masiphumelele	☐
Mbeya	☐
Medunsa	☐
Mthatha	☐
Ndola	☐
Rustenburg	☐
Soshanguve - Setshaba RC	☐
Soweto – Bara	☐
Soweto - Kliptown	☐
Tembisa - Clinic 4	☐
Vulindlela	☐

Date informed consent signed at receiving site _____

Form: Participant Transfer

Name of transferring study site

- ☐ Atlanta - Hope Clinic
- ☐ Atlanta - Ponce de Leon Center
- ☐ Baltimore - Johns Hopkins University
- ☐ Birmingham - Alabama
- ☐ Boston - Brigham and Women's Hospital Vaccine
- ☐ Boston - Fenway Health
- ☐ Chapel Hill
- ☐ Cleveland - Case
- ☐ Miami - University of Miami IDRU
- ☐ New Orleans - Adolescent Trials Unit
- ☐ New York - NY Blood Center
- ☐ New York - Physicians & Surgeons
- ☐ Newark - New Jersey Medical School
- ☐ Philadelphia - Penn Prevention
- ☐ Rochester - Univ. of Rochester Vaccines to Prevent HIV Infection
- ☐ San Francisco - Bridge HIV
- ☐ Seattle Vaccine Trials Unit
- ☐ Belo Horizonte - FUMG
- ☐ Buenos Aires - Almagro
- ☐ Buenos Aires - Balvanera, Ramos Mejia
- ☐ Iquitos - Asociacion Civil Selva Amazonica
- ☐ Lima - Barranco
- ☐ Lima - San Marcos/CITBM
- ☐ Lima - San Miguel
- ☐ Lima - Via Libre
- ☐ Merida
- ☐ Mexico City
- ☐ Rio de Janeiro - IPEC-Fiocruz
- ☐ Rosario - Instituto CAICI
- ☐ Cape Town - Groote Schuur
- ☐ Durban - Botha's Hill
- ☐ Durban - Chatsworth
- ☐ Durban - Isipingo
- ☐ Durban - Tongaat
- ☐ Durban - Verulam

Form: Participant Transfer

Name of receiving study site

- Atlanta - Hope Clinic
- Atlanta - Ponce de Leon Center
- Baltimore - Johns Hopkins University
- Birmingham - Alabama
- Boston - Brigham and Women's Hospital Vaccine
- Boston - Fenway Health
- Chapel Hill
- Cleveland - Case
- Miami - University of Miami IDRU
- New Orleans - Adolescent Trials Unit
- New York - NY Blood Center
- Durban-eThekwini
- Elandsdoorn
- Gaborone
- Harare - Parirenyatwa
- Harare - Seke South
- Harare - St. Mary's
- Khayelitsha
- Kisumu
- Klerksdorp
- Ladysmith - QM
- Lilongwe - Malawi
- Lusaka - Matero
- Lusaka - ZEHRP
- Maputo, Polana Canico Health Research and Training Center Network
- Masiphumelele
- Mbeya
- Medunsa
- Mthatha
- Ndola
- Rustenburg
- Soshanguve - Setshaba RC
- Soweto – Bara
- Soweto - Kliptown
- Tembisa - Clinic 4
- Vulindlela

Form: Participant Transfer

- ☐ New York - Physicians & Surgeons
- ☐ Newark - New Jersey Medical School
- ☐ Philadelphia - Penn Prevention
- ☐ Rochester - Univ. of Rochester Vaccines to Prevent HIV Infection
- ☐ San Francisco - Bridge HIV
- ☐ Seattle Vaccine Trials Unit
- ☐ Belo Horizonte - FUMG
- ☐ Buenos Aires - Almagro
- ☐ Buenos Aires - Balvanera, Ramos Mejia
- ☐ Iquitos - Asociacion Civil Selva Amazonica
- ☐ Lima - Barranco
- ☐ Lima - San Marcos/CITBM
- ☐ Lima - San Miguel
- ☐ Lima - Via Libre
- ☐ Merida
- ☐ Mexico City
- ☐ Rio de Janeiro - IPEC-Fiocruz
- ☐ Rosario - Instituto CAICI
- ☐ Cape Town - Groote Schuur
- ☐ Durban - Botha's Hill
- ☐ Durban - Chatsworth
- ☐ Durban - Isipingo
- ☐ Durban - Tongaat
- ☐ Durban - Verulam
- ☐ Durban-eThekwini
- ☐ Elandsdoorn
- ☐ Gaborone
- ☐ Harare - Parirenyatwa
- ☐ Harare - Seke South
- ☐ Harare - St. Mary's
- ☐ Khayelitsha
- ☐ Kisumu
- ☐ Klerksdorp
- ☐ Ladysmith - QM
- ☐ Lilongwe - Malawi
- ☐ Lusaka - Matero

Form: Participant Transfer

	Lusaka - ZEHRP ☐
	Maputo, Polana Canico Health Research and Training Center Network ☐
	Masiphumelele ☐
	Mbeya ☐
	Medunsa ☐
	Mthatha ☐
	Ndola ☐
	Rustenburg ☐
	Soshanguve - Setshaba RC ☐
	Soweto – Bara ☐
	Soweto - Kliptown ☐
	Tembisa - Clinic 4 ☐
	Vulindlela ☐
Visit of last completed contact with participant	V1.0 - Enrollment ☐
	V2.0 - Follow-up ☐
	V3.0 - Follow-up ☐
	V4.0 - Follow-up ☐
	V5.0 - Follow-up ☐
	V6.0 - Follow-up ☐
	V7.0 - Health Contact ☐
	Interim Visit ☐
If "Interim visit", specify Interim visit code	_____
Date participant's records were sent to receiving study site	_____

Form: Pregnancy Test Results

Was a pregnancy test done?	Yes ☐
	No ☐
If no, why?	Not of reproductive potential ☐
Add details to Comments.	Participant is pregnant ☐
	Other ☐
Collection date	_____
Collection time	_____
Pregnancy test result	Positive ☐
	Negative ☐
Comments (max. 450 characters):	_____

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 household member 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 household member 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 #:_____

Specimen collection date	_____
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 ☐
	Antigen ☐
	Other ☐
If "Other", specify:	_____
Specimen collection type	Nasal or Nasopharyngeal Swab ☐
	Nasal Wash ☐
	Oropharyngeal Swab ☐
	Saliva ☐
	Blood ☐
	Other ☐
If "Other", specify:	_____

Form: Screening Outcome

Is the participant eligible to enroll in the study?	Yes ☐
If "No", go to "Eligibility status".	No ☐
Enrollment date	_____
Group at Enrollment	Group 1 - asymptomatic ☐
	Group 2 - mild symptoms, not hospitalized ☐
	Group 3 - hospitalized ☐
Eligibility status	Eligible and enrolled ☐
	Ineligible ☐
	Incomplete screening ☐
If "Ineligible", select reason(s) why participant is ineligible.	Inclusion Criterion 1 - Age 18 or older. ☐
	Inclusion Criterion 2 - Test result indicating presence of SARS-CoV-2 virus. ☐
	Inclusion Criterion 3 - Ability and willingness to provide informed consent. ☐
	Inclusion Criterion 4 - Willingness to have clinical research staff come to place of residence or hospital if needed. ☐
	Inclusion Criterion 5 - Willingness to be followed for the planned duration of the study. ☐
	Inclusion Criterion 6 - Assessment of understanding: volunteer demonstrates understanding of this study. ☐
	Inclusion Criterion 7 - Agreement to allow access to medical records. ☐
	Inclusion Criterion for Group 1 - No current symptoms. ☐
	Inclusion Criterion for Group 1 - No symptoms consistent with COVID-19 within 2 weeks prior to positive test. ☐
	Inclusion Criterion for Group 1 - Positive SARS-CoV-2 RNA test or antigen test within six days prior to enrollment (target time) up to 10 days prior to enrollment (upper allowable window). ☐
	Inclusion Criterion for Group 2 - Onset of mild symptoms consistent with COVID-19 within six days prior to enrollment (target time) up to 14 days prior to enrollment (upper allowable window). ☐

Form: Screening Outcome

	☐ Inclusion Criterion for Group 2 - Positive SARS-CoV-2 RNA test or antigen test within six days prior to enrollment (target time) up to 10 days prior to enrollment (upper allowable window).
	☐ Inclusion Criterion for Group 3 - Participant hospitalized for COVID-19 within 3 days prior to enrollment.
	☐ Exclusion Criterion 1 - 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 investigator's judgement

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	_____
ACD or NaHep (sodium heparin)	Collected ☐ Not collected ☐
SST - room temperature	Collected ☐ Not collected ☐
SST - on wet ice for serum cytokines (innate immunity)	Collected ☐ Not collected ☐
SST - Clinical SARS-CoV-2 IgG Antibody Results	Collected ☐ Not collected ☐
Tempus	Collected ☐ Not collected ☐
Mark if a new Specimen Collection form is needed to complete specimen collection requirements for this visit.	☐

Form: Specimen Collection - Nasal Wash

Was specimen collected?	Yes ☐ No ☐
If "No", provide reason and end of form.	
Primary reason specimen was not collected	Participant declined ☐ Participant unable to provide sample ☐ Other ☐
If "Other", specify (max. 200 characters):	_____
Specimen collection date	_____
Specimen collection time	_____
Specimen collection location	Clinical research site ☐ Elsewhere (e.g. Home) ☐
Was the procedure performed by participant or by staff?	Participant ☐ Staff ☐
Has the participant recently experienced nosebleeds?	Yes ☐ No ☐
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: Specimen Collection - NP/Nasal Swab

Was specimen collected?	Yes ☐
	No ☐
If "No", provide reason and end of form.	
Primary reason specimen was not collected	Participant declined ☐
	Participant unable to provide sample ☐
	Other ☐
If "Other", specify (max. 200 characters):	_____
Specimen collection date	_____
Specimen collection time	_____
Specimen collection location	Clinical research site ☐
	Elsewhere (e.g. Home) ☐
Was the procedure performed by participant or by staff?	Participant ☐
	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: Specimen Collection - Saliva

Was specimen collected?	Yes ☐ No ☐
If "No", provide reason and end of form.	
Primary reason specimen was not collected	Participant declined ☐ Participant unable to provide sample ☐ Other ☐
If "Other", specify (max. 200 characters):	_____
Specimen collection date	_____
Specimen collection time	_____
Specimen collection location	Clinical research site ☐ Elsewhere (e.g. Home) ☐
Does the participant have a mouth injury or infection that might cause there to be blood in the sample?	Yes ☐ No ☐
Were all requirements of the specimen collection met per the SSP?	Yes ☐ No ☐
If "No", provide explanation in Comments.	
Comments (max. 600 characters):	_____

Form: Specimen Collection - Stool

Was a specimen collected? If "No", provide reason and end of form.	Yes ☐ No ☐
Primary reason specimen was not collected	Participant declined ☐ Participant unable to provide sample ☐ Other ☐
If "Other", specify (max. 200 characters):	_____
Date of stool collection	_____
Time of stool collection	_____
How many swabs were collected?	One ☐ Two ☐
Method of swab collection	Swabbing the rectum ☐ Swabbing stool ☐ Swabbing used toilet paper ☐
Brand name of saline vial	_____
Lot number of saline vial	_____
Was the stool collected when the participant was in the clinic or elsewhere? If "Clinical research site", go to "Was the procedure performed by participant or by staff?"	Clinical research site ☐ Elsewhere (e.g. Home) ☐
Date swab(s) arrived at clinic	_____
Time swab(s) arrived at clinic	_____
Was the procedure performed by participant or by staff?	Participant ☐ Staff ☐
Did the participant use any intrarectal products within 48 hours prior to specimen collection? If "Yes", specify type of intrarectal products (mark all that apply):	Yes ☐ No ☐
Douches	☐
Lubricants	☐
Enemas	☐
Anti-inflammatory creams	☐
Cleaning product	☐
Other	☐
If "Other", specify (max. 200 characters):	_____
For participants assigned female sex at birth, is menstruation occurring?	Yes ☐ No ☐ Not applicable ☐
Comments (max. 450 characters):	_____

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 ☐ 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.	