7 Point Ordinal Scale Days 0-15

Record ID _____

7-Point Ordinal Scale of Treatment Severity.
Select the most severe value applicable per study day hospitalized.
Day 0 = randomization/baseline.

	Death	Hospitalized, on invasive mechanical ventilation or ECMO	Hospitalized, on non-invasive mechanical ventilation or high flow devices	Hospitalized, on any oxygen therapy	Hospitalized, not requiring oxygen therapy	Not hospitalized, limitation of activities of daily living	Not hospitalized, no limitations of activities of daily living
Day 0 (Baseline)	◯	◯	◯	◯	◯	◯	◯
Day 1	◯	◯	◯	◯	◯	◯	◯
Day 2	◯	◯	◯	◯	◯	◯	◯
Day 3	◯	◯	◯	◯	◯	◯	◯
Day 4	◯	◯	◯	◯	◯	◯	◯
Day 5	◯	◯	◯	◯	◯	◯	◯
Day 6	◯	◯	◯	◯	◯	◯	◯
Day 7	◯	◯	◯	◯	◯	◯	◯
Day 8	◯	◯	◯	◯	◯	◯	◯
Day 9	◯	◯	◯	◯	◯	◯	◯
Day 10	◯	◯	◯	◯	◯	◯	◯
Day 11	◯	◯	◯	◯	◯	◯	◯
Day 12	◯	◯	◯	◯	◯	◯	◯
Day 13	◯	◯	◯	◯	◯	◯	◯
Day 14	◯	◯	◯	◯	◯	◯	◯
Day 15	◯	◯	◯	◯	◯	◯	◯

7 Point Ordinal Scale Days 16-28

Record ID _____

7-Point Ordinal Scale of Treatment Severity.
Select the most severe value applicable per study day hospitalized.
Day 0 = randomization/baseline.

	Death	Hospitalized, on invasive mechanical ventilation or ECMO	Hospitalized, on non-invasive mechanical ventilation or high flow devices	Hospitalized, on any oxygen therapy	Hospitalized, not requiring oxygen therapy	Not hospitalized, limitation of activities of daily living	Not hospitalized, no limitations of activities of daily living
Day 16	○	○	○	○	○	○	○
Day 17	○	○	○	○	○	○	○
Day 18	○	○	○	○	○	○	○
Day 19	○	○	○	○	○	○	○
Day 20	○	○	○	○	○	○	○
Day 21	○	○	○	○	○	○	○
Day 22	○	○	○	○	○	○	○
Day 23	○	○	○	○	○	○	○
Day 24	○	○	○	○	○	○	○
Day 25	○	○	○	○	○	○	○
Day 26	○	○	○	○	○	○	○
Day 27	○	○	○	○	○	○	○
Day 28	○	○	○	○	○	○	○

12 Health Survey

Record ID	_____
Is the patient able to complete the 12 Health Survey on this study day?	◯ Yes ◯ No (It is permissible to complete this survey +/- 1 day if the patient is unable to complete the survey on the indicated study day)
Why was the patient unable to complete the 12 Health Survey?	☐ Patient intubated ☐ Patient with Altered Mental Status ☐ Patient in procedure or operating room ☐ Other
Explain other reason for the 12 Health Survey not being completed	_____
Date & Time of Completion	_____

12 Health Survey

In general, would you say your health is:	◯ Excellent ◯ Very Good ◯ Good ◯ Fair ◯ Poor

The following questions are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

	YES - Limited a lot	YES - Limited a little	No - Not limited at all
Moderate activities such as moving a table, a vacuum cleaner, bowling, or playing golf	◯	◯	◯
Climbing several flights of stairs	◯	◯	◯

During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

	Yes	No
Accomplished less than you would like	◯	◯
Were limited in the kind of work or other activities	◯	◯

During the past 4 weeks, how much did pain interfere with your normal work (including work outside the home and housework)?

- ◯ Not at all
- ◯ A little bit
- ◯ Moderately
- ◯ Quite a bit
- ◯ Extremely

These questions are about how you have been feeling during the past 4 weeks.
For each question, please give the one answer that comes closest to the way you have been feeling.

How much of the time during the past 4 weeks...

	All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time
Have you felt calm & peaceful?	◯	◯	◯	◯	◯	◯
Did you have a lot of energy?	◯	◯	◯	◯	◯	◯
Have you felt down-hearted and blue?	◯	◯	◯	◯	◯	◯

During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting friends, relatives, etc.)?

- ◯ All of the time
- ◯ Most of the time
- ◯ Some of the time
- ◯ A little of the time
- ◯ None of the time

Baseline Vitals Data

Record ID _____

Vitals Closest to Enrollment and Prior to Study Drug Initiation

Systolic Blood Pressure _____ (mmHg)

Diastolic Blood Pressure _____ (mmHg)

Mean Arterial Pressure _____ (mmHg)

Blood Pressure Method
◯ Cuff
◯ Arterial Line

Temperature _____ (Celsius)

Heart Rate _____ (Beats per minute)

Respiratory Rate _____ (Breaths per minute)

Oxygen saturation (Sp02) _____ (%)

WORST Vital Signs from Baseline (Day 0)

Systolic Blood Pressure _____

Diastolic Blood Pressure _____

Mean Arterial Pressure _____

Temperature _____ (Celsius)

Heart Rate

_____
(Beats per minute)

Respiratory Rate

_____
(Breaths per minute)

Oxygen Saturation (%)

_____

Ventilatory Status at Time of Enrollment

Is the Patient on Supplemental Oxygen or Intubated

◯ Yes
◯ No

What Type of Supplemental Oxygen is the Patient Receiving?

☐ Nasal Cannula
☐ High Flow Nasal Cannula
☐ BiPAP
☐ CPAP
☐ Face Mask / Non Re-Breather
☐ Endotracheal Intubation
☐ ECMO

What is the FiO2?

If not measured, estimate FiO2 as 0.21 + 0.03 x liters per minute oxygen

_____

What is the Ventilator FiO2

_____

What is the Ventilator Tidal Volume?

_____

What is the Peak End Expiratory Pressure?

_____

Is the participant in the prone position?

◯ Yes
◯ No

Daily Imaging & Cardiac Monitoring

Record ID	_____
Were any of the Following Imaging Studies Performed on this Study Day?	☐ Chest X-Ray ☐ Chest Computed Tomography ☐ Echocardiogram ☐ Electrocardiogram (EKG) ☐ None (select all that apply)
Chest X-Ray Impression	_____
Chest CT Impression	_____
Echocardiogram Impression	_____
Electrocardiogram (EKG) QTc Interval (ms)	_____ (If multiple, list the longest QTc interval from this study day)

Daily Inpatient Medications

Record ID _____

Was the patient receiving any of the below medications on this study day?

	No	Yes	Unknown
Oral / Orogastric fluids	○	○	○
Intravenous fluids	○	○	○
Antiviral medications	○	○	○
Corticosteroids	○	○	○
Antibiotics	○	○	○
Antifungal agents	○	○	○
Antimalarial agents	○	○	○
Experimental agents	○	○	○
Non-steroidal anti-inflammatory Drugs (NSAIDs)	○	○	○
Vasopressors	○	○	○
Inhaled beta agonists	○	○	○
500cc fluid bolus for hypotension	○	○	○
Remdesivir	○	○	○
Interleuken Inhibitors	○	○	○
Vitamin C	○	○	○
Convalesent Plasma	○	○	○
Heparin	○	○	○

What Vasopressor(s) is the Patient on this Study Day?

- ☐ Norepinephrine
- ☐ Epinephrine
- ☐ Phenylephrine
- ☐ Vasopressin
- ☐ Dobutamine
- ☐ Dopamine
- ☐ Isoproterenol
- ☐ Milrinone

(select all that apply)

Maximum Norepinephrine Infusion Rate on this Study Day? _____

Maximum Epinephrine Infusion Rate on this Study Day? _____

Maximum Phenylephrine Infusion Rate on this Study Day? _____

Maximum Vasopressin Infusion Rate on this Study Day? _____

Maximum Dobutamine Infusion Rate on this Study Day?

_____

Maximum Dopamine Infusion Rate on this Study Day?

_____

Maximum Isoproterenol Infusion Rate on this Study Day?

_____

Maximum Milrinone Infusion Rate on this Study Day?

_____

What antiviral medication(s) is the patient taking?

- ☐ Ribavirin
- ☐ Lopinavir/Ritonavir
- ☐ Neuraminidase inhibitor
- ☐ Interferon Alpha
- ☐ Interferon Beta
- ☐ Other

(Select all that apply)

What other antiviral medication is the patient receiving?

_____

What type of corticosteroids is the patient receiving?

- ☐ Oral
- ☐ Intravenous
- ☐ Inhaled

(Select all that apply)

List the corticosteroid(s) that the patient is receiving

_____

What is the daily maximum dose (w/ units) of the corticosteroid?

_____

List the antifungal medication(s) that the patient is taking

_____

List the antimalarial medication(s) that the patient is taking

_____

List the experimental agent(s) that the patient is receiving

_____
(Not including ALPS study drug)

What type of heparin is the patient receiving?

- ◯ UFH
- ◯ LMWH
- ◯ Full Dose Heparin
- ◯ Prophylaxis

Daily Laboratory Data

Record ID _____

Record the Values as Close to 7:00AM as possible

White Blood Cell Count (WBC)

_____
(k/cmm)

☐ Check if White Blood Cell Count (WBC) NOT DONE

Hemogobin

_____
(g/dL)

☐ Check if Hemoglobin NOT DONE

Platelets

_____
(k/cmm)

☐ Check if Platelets NOT DONE

INR

_____

☐ Check if INR NOT DONE

Sodium

_____
(mEq/L)

☐ Check if Sodium NOT DONE

Potassium

_____
(mEq/L)

☐ Check if Potassium NOT DONE

Chloride

_____
(mEq/L)

☐ Check if Chloride NOT DONE

Glucose

_____
(mg/dL)

☐ Check if Glucose NOT DONE

Creatinine

_____ (mg/dL)

☐ Check if Creatinine NOT DONE

Lactate

_____ (mmol/L)

☐ Check if Lactate NOT DONE

Procalcitonin

_____ (ng/mL)

☐ Check if Procalcitonin NOT DONE

Erythrocyte Sedimentation Rate (ESR)

_____ (mm/hr)

☐ Check if Erythrocyte Sedimentation Rate (ESR) NOT DONE

C Reactive Protein

_____ (mg/L)

☐ Check if C Reactive Protein NOT DONE

D-Dimer

_____ (mg/L)

☐ Check if D-Dimer NOT DONE

Ferritin

_____ (ng/mL)

☐ Check if Ferritin NOT DONE

Albumin

_____ (g/dL)

☐ Check if Albumin NOT DONE

AST (SGOT)

_____ (IU/L)

☐ Check if AST (SGOT) NOT DONE

ALT (SGPT)

_____
(IU/L)

☐ Check if ALT (SGPT) NOT DONE

Bilirubin (total)

_____
(mg/dL)

☐ Check if Bilirubin NOT DONE

Troponin

_____
(ng/mL)

☐ Check if Troponin NOT DONE

BNP or ProBNP

_____
(pg/mL)

☐ Check if BNP/ProBNP NOT DONE

Blood Gases

Arterial Blood Gases Drawn

◯ Yes
◯ No

Arterial pH

_____

Arterial PCO2

_____
(mmHg)

Arterial PO2

_____
(mmHg)

Arterial Bicarbonate

_____
(mEq/L)

Venous Blood Gases Drawn

◯ Yes
◯ No

Venous PCO2

_____
(mmHg)

Venous PO2

_____
(mmHg)

Venous pH

_____

Venous Bicarbonate

_____
(mEq/L)

Day 15

Record ID	_____
Is the patient still receiving supplemental oxygen therapy?	◯ Yes ◯ No (Not including OSA treatments or baseline O2 needs)
What supplemental oxygen is the patient receiving	☐ Nasal Cannula ☐ High Flow Nasal Cannula (≥30lpm) ☐ BiPAP ☐ CPAP ☐ Facemask ☐ Invasive mechanical ventilation ☐ Tracheostomy w/ supplemental oxygen (Not including OSA treatments or baseline O2 needs)
What is the FiO2? If not measured, estimate FiO2 as 0.21 + 0.03 x liters per minute oxygen	_____
What is the Ventilator FiO2	_____
What is the Ventilator Tidal Volume?	_____
What is the Peak End Expiratory Pressure (PEEP)?	_____

Day 28

Record ID	_____
Was the patient able to complete the 28-day follow up call?	◯ Yes ◯ No
Why was the patient unable to complete the 28-day follow up?	☐ Patient refused ☐ Patient with Altered Mental Status ☐ Patient still hospitalized ☐ Patient is deceased ☐ Other
Please explain the other reason that the patient was unable to complete the 28-day follow up	_____
Date of 28-day follow up	_____
Has the patient been able to return to their baseline activities yet?	◯ Yes ◯ No
How many days following hospital discharge did it take the patient to return to their baseline activities?	_____
Is the patient still receiving supplemental oxygen therapy?	◯ Yes ◯ No (Not including OSA treatments or baseline O2 needs)
What supplemental oxygen is the patient receiving?	☐ Nasal Cannula ☐ High Flow Nasal Cannula (≥30lpm) ☐ BiPAP ☐ CPAP ☐ Facemask ☐ Invasive mechanical ventilation ☐ Tracheostomy w/ supplemental oxygen (Not including OSA treatments or baseline O2 needs)

Day 90

Record ID	_____
Is the Patient Alive at Day 90?	◯ Yes ◯ No
Date of 90 Day Follow Up	_____
What was the Patient's Date of Death?	_____
Study complete?	◯ Yes ◯ No

Early Discharge

Record ID

_____

Was the participant discharged home prior to study day 7?

◯ Yes
◯ No

Ensure that the patient is discharged home with a pulse oximeter for the day 7 assessment

What was the participant's oxygen saturation on study day 7 after discharge?

_____
(%)

If the participant is on oxygen, enter the dose

_____
(Liters per minute. For those not on oxygen, enter 0.)

Calculated Fi02

_____

Calculated Sp02/Fi02

_____

Early Withdrawal

Record ID	_____
Did the participant withdraw early?	◯ Yes ◯ No
Date of early withdrawal notification	_____
Please describe why the participant withdrew	☐ Due to adverse event ☐ Consent withdrawn ☐ Lost to follow up ☐ Removed by investigator ☐ Other (Select all that apply)
If other was selected, please explain.	_____
Does the participant consent to partial withdrawal?	◯ Yes ◯ No (Defined as stopping all contact with investigators but allow for continued access to EMR to capture outcomes.)
Does the study participant still consent to future research with collected bio-specimens?	◯ Yes ◯ No

Eligibility

Record ID _____

Inclusion Criteria

Presumptive positive laboratory test for SARS-CoV-2 or upper respiratory infection with recent exposure to laboratory proven (presumptive) SARS-CoV-2 and a negative influenza and respiratory virus panel

◯ Yes ◯ No

Is the patient 18+ years old

◯ Yes ◯ No

Is the patient being admitted to the hospital via the Emergency Department?

◯ Yes ◯ No

Respiratory SOFA Scoring Chart Want a calculator? Use this link here.

Respiratory SOFA Score	PaO2/FiO2	SaO2/FiO2				
	No Positive Pressure		Positive Pressure			
			PEEP<8	PEEP 8-12	PEEP>12	
0	>=400	>400	>=502	>=515	>=425	Ineligible values for IP enrollment
1	<400	<=400	<502	<515	<425	
2	<300	<=315	<370	<387	<332	
3	<200	<=235	<240	<259	<234	
4	<100	<=150	<115	<130	<129	

Respiratory SOFA greater than or equal to 1 and increased oxygen requirement compared to baseline

This includes all patients who have a room air SpO2 of 97% or lower.

◯ Yes ◯ No
(Please confirm with the calculator above)

Can the patient be randomized within 48 hours of admission to the hospital or positive COVID-19 test, whichever is later?

◯ Yes ◯ No

It Appears that the Patient DOES NOT Meet Inclusion Criteria Do not Proceed with Enrollment!

Exclusion Criteria

Will randomization take place greater than 48 hours after hospital admission order is placed OR from positive test result, whichever is later?

◯ Yes ◯ No

Is the patient currently taking an angiotensin converting enzyme inhibitor (ACEi) or Angiotensin receptor blocker (ARB)?

◯ Yes ◯ No

Does the patient have a history of prior reaction or intolerance to an ARB or ACEi?	◯ Yes ◯ No
Is the patient pregnant? (must have negative urine or serum pregnancy test if less than 60 years old)	◯ Yes ◯ No (If male, select no)
Is the patient breastfeeding?	◯ Yes ◯ No (If male, select no)
If the patient is of childbearing age and potential, are they unwilling to use contraception or practice abstinence for the duration of the study? Study Approved Contraception Methods: Hormonal pill, IUD, implant, injection, condom use, prior history of hysterectomy or commitment of abstinence.	◯ Yes ◯ No
Does the patient have any reported history or electronic medical record history of kidney disease, defined as: 1. Any history of dialysis 2. History of chronic kidney disease stage IV 3. Estimated Glomerular Filtration Rate (eGFR) of LESS THAN 30ml/min/1.73 m2 at the time of randomization 4. Other kidney disease that in the opinion of the investigator, would affect losartan clearance	◯ Yes ◯ No
Does the patient have any reported history or electronic medical record history of liver disease, defined as: 1. Cirrhosis 2. History of hepatitis B or C 3. Other liver disease that in the opinion of the investigator, would affect losartan clearance 4. Documented AST or ALT >3 times the upper limit of normal. Measured within 24 hours prior to randomization.	◯ Yes ◯ No
Was the patient's most recent mean arterial pressure (MAP) less than 65 before enrollment?	◯ Yes ◯ No
Does the patient have severe volume depletion or dehydration that, in the opinion of the investigator, would preclude administration of losartan?	◯ Yes ◯ No
Was there a potassium level greater than 5.0 within 24 hours prior to randomization?	◯ Yes ◯ No

Was there a repeat potassium less than or equal to 5.0 within the 24 hours prior to enrollment?	◯ Yes ◯ No
Is the patient being concurrently treated with Aliskiren (Brand names Tekturna or Rasilez)?	◯ Yes ◯ No
Is there an inability to obtain informed consent?	◯ Yes ◯ No
Is the patient currently enrolled in another blinded, randomized, drug trial? (open label drug trials are okay)	◯ Yes ◯ No (open label drug trials are eligible)

It Appears that the Patient Meets Study Exclusion Criteria Do not Proceed with Enrollment!

Stratification information

Admitting hospital	◯ M Health Bethesda ◯ M Health Southdale ◯ M Health Ridges ◯ Hennepin ◯ M Health St Joes ◯ Cincinnati ◯ North Memorial ◯ U Florida ◯ U Michigan ◯ U Mississippi ◯ Temple ◯ Wayne State ◯ KUMC ◯ MCW ◯ Henry Ford
What is the participant's age?	◯ 18-59 years old ◯ 60 years old or older (For randomization)

Randomization Link

Calculate eligible

_____
(19 = eligible)

Based on the submitted data, the participant appears eligible for randomization. Please proceed to the randomization system.

PI Attestation

As PI of this site, I attest that I have review the inclusion and exclusion criteria for this patient and confirm that they are an appropriate candidate for randomization.

_____
(Can be completed retrospectively)

Site PI Name

_____

Enrollment Data

Record ID

_____

Pre-Admission Course

Date & Time of First Healthcare Provider Contact

_____
(Healthcare provider = physician, physician's assistant, or nurse ED working at an ED, hospital, urgent care, clinic, or virtual health visit)

Was the participant evaluated at the study site emergency department?

◯ Yes
◯ No

What was the Date & Time of Admission to the Study Hospital?

_____

When Did the Patient First Arrive to the Study Site ED?

_____

Total ED Length of Stay

_____
(Minutes)

Medications Prior to Enrollment

Did the patient receive any immunomodulator medications between arrival to the study hospital and enrollment?

◯ Yes
◯ No

Has the patient been taking any other prescribed COVID-19 outpatient medications prior to enrollment?

◯ Yes
◯ No

What COVID-19 medications was the patient taking as an outpatient?

☐ Hydroxychloroquine
☐ Acetaminophen (Tylenol)
☐ Ibuprofen
☐ Azithromycin
☐ Other(s)

If other, list the other medication(s) the patient was taking to treat COIVD-19 prior to hospital admission?

_____

Has the patient taken any of the following medications within 14 days of hospital admission?

☐ Angiotensin converting enzyme inhibitors (ACE inhibitors)
☐ Angiotensin II receptor blockers (ARBs)
☐ Non-steroidal anti-inflammatory (NSAID)
☐ Unknown
☐ None

COVID-19 Symptoms

What was the first date that the patient had upper respiratory symptoms of COVID-19 (cough, rhinorrhea) or a fever >101.5F?

If patient can not recall the exact date, use a estimated date

_____

How many days did the patient have symptoms before seeking care?

_____
(Days. For those who are asymptomatic, enter zero.)

What COVID-19 Signs & Symptoms did the participant experience

	No	Yes	Unknown
Fever	○	○	○
Cough (dry)	○	○	○
Cough (with sputum production)	○	○	○
Cough (with hemoptysis)	○	○	○
Sore Throat	○	○	○
Runny Nose (rhinorrhea)	○	○	○
Wheezing	○	○	○
Chest Pain	○	○	○
Muscle Aches (myalgias)	○	○	○
Joint Pain	○	○	○
Abdominal Pain	○	○	○
Fatigue / Malaise	○	○	○
Shortness of Breath	○	○	○
Inability to Walk	○	○	○
Headache	○	○	○
Altered mental status	○	○	○
Seizures	○	○	○
Vomiting / Nausea	○	○	○
Diarrhea	○	○	○
Conjunctivitis	○	○	○
Skin Rash	○	○	○
Skin Ulcers	○	○	○
Lymphadenopathy	○	○	○
Bleeding (Hemorrhage)	○	○	○
Loss of smell	○	○	○
Loss of taste	○	○	○
Other	○	○	○

Where did the patient experience bleeding from?

_____

What other symptom(s) did the patient experience?

_____

COVID-19 Sample

What location was the patient's COVID-19 sample obtained at?

◯ Emergency Department
◯ Outpatient Clinic
◯ Drive through Testing Center
◯ Hospital Inpatient
◯ Unknown

Date & Time of First Positive COVID-19 Sample Collection

_____

Date & Time of COVID-19 Sample Result

_____
(Time of result in study site EHR, not time of patient notification)

Time of COVID-19 Testing

_____

At the time of enrollment, was the patient receiving any of the following medications?

	No	Yes	Unknown
Oral / Orogastric Fluids	◯	◯	◯
Intravenous Fluids	◯	◯	◯
Antiviral medications	◯	◯	◯
Corticosteroids	◯	◯	◯
Antibiotics	◯	◯	◯
Antifungal Agents	◯	◯	◯
Antimalarial Agents	◯	◯	◯
Experimental Agents	◯	◯	◯
Non-steroidal Anti-inflammatory Drugs (NSAIDs)	◯	◯	◯
Angiotensin converting enzyme inhibitors (ACE inhibitors)	◯	◯	◯
Angiotensin II receptor blockers (ARBs)	◯	◯	◯
Remdesivir	◯	◯	◯
Interleukin inhibitors	◯	◯	◯
Vitamin C	◯	◯	◯
Convalescent Plasma	◯	◯	◯

What antiviral medication(s) is the patient taking?

☐ Ribavirin
☐ Lopinavir/Ritonavir
☐ Neuraminidase inhibitor
☐ Interferon Alpha
☐ Interferon Beta
☐ Other
(Select all that apply)

What other antiviral medication is the patient receiving at the time of enrollment?	_____
What type of inhaled corticosteroids is the patient receiving on enrollment?	☐ Oral ☐ Intravenous ☐ Inhaled (Select all that apply)
List the corticosteroid(s) that the patient is receiving at the time of enrollment?	_____
What is the daily maximum dose (w/ units) of the corticosteroid?	_____
List the antifungal medication(s) that the patient is taking	_____
List the antimalarial medication(s) that the patient is taking	_____
List the experimental agent(s) that the patient is receiving on enrollment	_____

Event Reporting

Record ID

_____

Any events to be reported for this study day?

◯ Yes
◯ No

What Type of Event is Being Reported?

☐ Note to File
☐ Adverse Event (AE)
☐ Protocol Deviation
(AEs Include (but are not limited to): New hypotension due to study drug, electrolyte abnormalities, acute kidney injury, difficulty breathing, significant changes to urination, myalgias)

Name of Person(s) Filing

_____

Note to File

Date & Time of Note to File

_____

Note to File Details

_____

Adverse Event

Date and Time of AE Report

_____

Which organ system(s) is affected?

☐ Nervous
☐ Respiratory
☐ Renal
☐ Circulatory
☐ Digestive
☐ Excretory
☐ Reproductive
☐ Muscular
☐ Skeletal
☐ Integumentary
☐ Immune
☐ Endocrine
☐ Unsure - PI will be prompted for input
(select all that apply)

Expected Adverse Events include (but are not limited to) :
Worsening fatigue Syncope Angioedema Worsening cough Dyspnea Decreased urine output Expected Serious Adverse Events include (but are not limited to) :
Respiratory distress requiring supplemental, or increased supplemental, oxygen New cardiac arrhythmia Any kidney injury requiring treatment New rental replacement therapy

AE of special interest?

◯ Yes
◯ No

SAE of special interest?	◯ Yes ◯ No
Is this a serious adverse event? These include any event that results in any of the following: 1. Fatal 2. Life threatening 3. Requires or prolongs the hospital stay 4. Results in significant disability or incapacity 5. A congenital anomaly or birth defect 6. An important medical event	◯ Yes ◯ No
Did AE continue for >1 day?	◯ Yes ◯ No
Discontinue study drug for related Serious Adverse Event	
Discontinue study drug for related Adverse Event lasting >1 day	
Reduce study drug for related Adverse Event	
Was study drug reduced or discontinued due to this AE?	◯ No ◯ Reduced ◯ Discontinued
Which of the following drug reduction/discontinuation procedures was followed?	◯ Decrease in study drug from twice a day to once a day if currently dosing twice daily ◯ Discontinuation of study drug if only taking once daily ◯ Discontinuation of study drug at the discretion of the investigator
When was the study drug reduced?	_____
When was the study drug discontinued?	_____
Adverse Event Details	_____ (Please include start time, disposition (if continuing or resolved), clinical context surrounding the adverse event, and any corrective actions (treatment, withdrawal, etc) that occurred as a result)
List ICD10 code associated with this adverse event	_____ (Keyword search)

PI Attestation - (For PI Completion ONLY)

According to the PI, which organ system(s) is affected?

- ☐ Nervous
- ☐ Respiratory
- ☐ Renal
- ☐ Circulatory
- ☐ Digestive
- ☐ Excretory
- ☐ Reproductive
- ☐ Muscular
- ☐ Skeletal
- ☐ Integumentary
- ☐ Immune
- ☐ Endocrine

(Select all that apply)

Scales Used Attribute Adverse Events: The Principal Investigator will assess the relationship of all AEs to any drug or study procedure: Definitely Related: There is clear evidence to suggest a causal relationship, and other possible contributing factors can be ruled out. The clinical event, including an abnormal laboratory test result, occurs in a plausible time relationship to study agent/intervention administration and cannot be explained by concurrent disease or other drugs or chemicals. The response to withdrawal of the study agent/intervention (de-challenge) should be clinically plausible. The event must be pharmacologically or phenomenologically definitive, with use of a satisfactory re-challenge procedure if necessary.
Probably Related: There is evidence to suggest a causal relationship, and the influence of other factors is unlikely. The clinical event, including an abnormal laboratory test result, occurs within a reasonable time sequence to administration of the study agent/intervention, is unlikely to be attributed to concurrent disease or other drugs or chemicals, and follows a clinically reasonable response on withdrawal (de-challenge). Re-challenge information is not required to fulfill this definition.
Possibly Related: There is some evidence to suggest a causal relationship (e.g., the event occurred within a reasonable time after administration of the trial medication). However, the influence of other factors may have contributed to the event (e.g., the subject's clinical condition, other concomitant events). Although an adverse drug event may rate only as "possible" soon after discovery, it can be flagged as requiring more information and later be upgraded to probable or certain as appropriate.
Unlikely: A clinical event, including an abnormal laboratory test result, whose temporal relationship to study agent/intervention administration makes a causal relationship improbable (e.g., the event did not occur within a reasonable time after administration of the trial medication) and in which other drugs or chemicals or underlying disease provides plausible explanations (e.g., the subject's clinical condition, other concomitant treatments).
Not related: The AE is completely independent of study agent/intervention administration, and/or evidence exists that the event is definitely related to another etiology. There must be an alternative, definitive etiology documented by the clinician.

In the opinion of the PI, was the AE related to the study drug or procedures?

- ◯ Not related
- ◯ Unlikely related
- ◯ Possibly related
- ◯ Probably related
- ◯ Definitely related

Scales Used to Grade Severity of Adverse Events: All AEs will be graded in the following manner: Grade 1 (Mild): Events require minimal or no treatment and do not interfere with the participant's daily activities.
Grade 2 (Moderate): Events result in a low level of inconvenience or concern. Moderate events may cause some interference with functioning.
Grade 3 (Severe): Events interrupt a participant's usual daily activity and may require systemic drug therapy or other treatment. Severe events are usually incapacitating.
Grade 4 (Life-threatening): Any adverse drug experience that places the participant, in the view of the Investigator, at immediate risk of death from the reaction as it occurred (i.e., it does not include a reaction that had it occurred in a more severe form, might have caused death).
Grade 5 (Death)

What grade is this Adverse Event?

◯ Grade 1 - Mild
◯ Grade 2 - Moderate
◯ Grade 3 - Severe
◯ Grade 4 - Life-threatening
◯ Grade 5 - Death

Expected Adverse Events include (but are not limited to) :
Worsening fatigue Syncope Angioedema Worsening cough Dyspnea Decreased urine output Expected Serious Adverse Events include (but are not limited to) :
Respiratory distress requiring supplemental, or increased supplemental, oxygen New cardiac arrhythmia Any kidney injury requiring treatment New rental replacement therapy

Was the adverse event unexpected?

◯ Yes
◯ No

PI Name

_____

PI Signature of Attestation

_____

Time of Attestation

_____

Protocol Deviation

Date of Protocol Deviation

_____

Please provide details of the protocol deviation

_____
(Include details of: what happened, when was it discovered, what was done after the protocol deviation was discovered, was the protocol deviation resolved (if so, what was done), was patient harm caused as a result of this, and did the protocol deviation cause data collection to stop or the patient to be withdrawn early from the study.)

Please provide a corrective action plan to prevent this protocol deviation from repeating in the future, if applicable

_____

Hospital Discharge

Record ID _____

Please complete this CRF for every hospital admission through day 90.

Length of Stay

Did the Patient Survive to Hospital Discharge?
◯ Yes
◯ No

Date & Time of Hospital Admission _____

Date & Time of Hospital Discahrge _____

Total Hospital Length of Stay _____

What was the Date & Time of Death? _____

What was the Presumed Cause of Death? _____

Intensive Care Unit Admission

Was the Patient Admited to the ICU During the Hospitalization?
◯ Yes
◯ No
(at any time)

First ICU Admit Date & Time _____

First ICU discharge or transfer out time _____

First ICU total length of stay _____

Was the patient transferred out of the ICU and then readmitted to the ICU during their hospitalization?
◯ Yes
◯ No

Second ICU admit date & time _____

Second ICU discharge or transfer out date & time _____

Second ICU total length of stay _____

Total ICU days

_____

Invasive Mechanical Ventilation

Was the patient on invasive mechanical ventilation at any time during the hospitalization?
◯ Yes
◯ No

Intubation Date & Time

_____

Extubation Date & Time

_____

Total Length of Intubation

_____

Was the patient extubated and reintubated during their hospitalization?
◯ Yes
◯ No

Date & Time of Second Intubation

_____

Date & Time of Second Extubation

_____

Second Intubation Length

_____

Total Intubation Time (if multiple intubations)

_____

Ventilator Free Days

_____

Ventilator Free Days

_____

Other Supplemental Oxygen Therapy

Was the patient on regular nasal cannula oxygen between between admission and discharge or day 28 (whichever comes first)?
◯ Yes
◯ No

If yes, was the nasal cannula oxygen discontinued prior to death, discharge or day 28?
◯ Yes
◯ No

First date of nasal cannula oxygen therapy?

_____

Last date of nasal cannula oxygen therapy?

_____

Was the patient on high flow nasal cannula between between admission and discharge or day 28 (whichever comes first)? High flow nasal cannula flow rate ≥ 30 liters per minute	◯ Yes ◯ No
If yes, was the high flow nasal cannula oxygen discontinued prior to death, discharge or day 28?	◯ Yes ◯ No
First date of high flow nasal cannula oxygen therapy?	_____
Last date of high flow nasal cannula oxygen therapy?	_____
Was the patient on BiPAP between between admission and discharge or day 28 (whichever comes first)?	◯ Yes ◯ No
If yes, was the BiPAP discontinued before death, discharge or day 28?	◯ Yes ◯ No
First date of BiPAP oxygen therapy?	_____
Last date of BiPAP oxygen therapy?	_____

ECMO

Was the Patient on Extracorporeal Membrane Oxygenation (ECMO) During the Hospitalization?	◯ Yes ◯ No
Date & Time of ECMO Flow Start	_____
Date & Time of ECMO Flow End	_____
Total Time on ECMO Flow	_____

Medications Received During Admission

Immunomodulator medications	◯ Yes ◯ No
Azithromycin	◯ Yes ◯ No
Hydroxychloroquine	◯ Yes ◯ No
Antiviral medicaitons	◯ Yes ◯ No

Microbiology

Did the patient test POSITIVE for the flu during the hospitalization ?	◯ No ◯ Yes ◯ Not Tested
Date & Time of Positive Influenza Sample Collection	_____
What influenza strain did the patient test positive for?	◯ Influenza A ◯ Influenza B ◯ Both
Did the patient have a POSITIVE respiratory virus panel during the hospitalization?	◯ No ◯ Yes ◯ Not Tested
Date & Time of positive viral respiratory panel sample collection	_____
List positive findings from viral respiratory panel	_____
Did the patient have a POSITIVE blood culture between admission and day 7 of hospitalization?	◯ No ◯ Yes ◯ Not Tested
Date & Time of positive blood culture sample collection	_____
List positive findings from blood culture	_____
Did the patient have a POSITIVE respiratory culture between admission and day 7 of hospitalization?	◯ No ◯ Yes ◯ Not Tested
Date & Time of positive respiratory culture sample collection	_____
List positive findings from respiratory culture	_____

Complications at Any Time During Hospitalization

	No	Yes	Unknown
Shock	○	○	○
Seizure	○	○	○
Meningitis	○	○	○
Anemia	○	○	○
Cardiac arrhythmia	○	○	○
Cardiac arrest	○	○	○
Secondary bacterial pneumonia	○	○	○
Acute Respiratory Distress Syndrome (ARDS)	○	○	○
Bacteraemia	○	○	○
Bleeding	○	○	○
Endocarditis	○	○	○
Myocarditis/Pericarditis	○	○	○
Acute renal injury	○	○	○
Pancreatitis	○	○	○
Liver dysfunction	○	○	○
Cardiomyopathy	○	○	○
New renal replacement therapy or dialysis	○	○	○

Was the patient discharged home with any of the following medications?

	No	Yes	Unknown
Oral / Orogastric Fluids	○	○	○
Intravenous Fluids	○	○	○
Antiviral medications	○	○	○
Corticosteroids	○	○	○
Antibiotics	○	○	○
Antifungal Agents	○	○	○
Antimalarial Agents	○	○	○
Experimental Agents	○	○	○
Non-steroidal Anti-inflammatory Drugs (NSAIDs)	○	○	○
Angiotensin converting enzyme inhibitors (ACE inhibitors)	○	○	○
Angiotensin II receptor blockers (ARBs)	○	○	○

What antiviral medication(s) is the patient being discharged with?

- ☐ Ribavirin
- ☐ Lopinavir/Ritonavir
- ☐ Neuraminidase inhibitor
- ☐ Interferon Alpha
- ☐ Interferon Beta
- ☐ Other

(Select all that apply)

What other antiviral medication is the patient being discharged with?	_____
What type of corticosteroids is the patient being discharged wtih?	☐ Oral ☐ Intravenous ☐ Inhaled (Select all that apply)
List the corticosteroid(s) that the patient is being discharged home with	_____
What is the daily maximum dose (w/ units) of the corticosteroid?	_____
List the antifungal medication(s) that the patient is being discharged with	_____
List the antimalarial medication(s) that the patient is being discharged with	_____
List the experimental agent(s) that the patient is being discharged with	_____

Discharge Functional Assessment

Where was the patient discharged to?	◯ Home ◯ Transfer to other hospital ◯ Discharge to skilled nursing facility ◯ Discharge to subacute rehabilitation facility ◯ Death ◯ Unknown

Loss to Follow Up

Record ID

_____

Loss to Follow Up

This form is to document attempts to contact the participant for their day 15 safety and bio-specimen testing if there was failure to follow-up.

15 Day Follow Up Status Instructions:

1. Participants will be contacted for follow up status.
2. Research staff will document all attempts to contact participants below.

	No	Yes
1st Attempt: Were you able to contact the participant?	◯	◯
2nd Attempt: Were you able to contact the participant?	◯	◯
3rd Attempt: Were you able to contact the participant?	◯	◯

Date of 15 Day Follow Up: 1st Attempt

_____

Date of 15 Day Follow Up: 2nd Attempt

_____

Date of 15 Day Follow Up: 3rd Attempt

_____

Write down notes about the results of this follow up attempt (e.g., whether phone answered, message left):

_____

Write down notes about the results of this follow up attempt (e.g., whether phone answered, message left):

_____

Write down notes about the results of this follow up attempt (e.g., whether phone answered, message left):

_____

Patient Information

Record ID	_____
Patient location at time of enrollment?	◯ Emergency Department ◯ Inpatient - Floor ◯ Inpatient - Step-down Unit or Intermediate Unit ◯ Inpatient - Intensive Care Unit ◯ Other location
Describe other location	_____
Local site MRN	_____
Participant first name	_____
Participant last name	_____
Sex	◯ Male ◯ Female
Patient date of birth	_____
Is the patient between the ages of 18-89?	◯ Yes ◯ No
Patient age	_____
Patient age (>89)	_____
Stated Patient Weight	_____ (lb)
Weight (kg)	_____ (kg)
Stated Patient Height	_____ (inch. 5 foot = 60 inches.)
Patient height (cm)	_____ (cm)

BMI	_____
Race	◯ Caucasian ◯ Black or African American ◯ Native American or Alaskan Native ◯ Asian ◯ Native Hawaiian or Pacific Islander ◯ Hispanic ◯ Other / Unknown
Ethnicity	◯ Non-Hispanic or Latino ◯ Hispanic or Latino ◯ Unknown
Does the patient have medical insurance?	◯ Yes ◯ No
What type of medical insurance does the patient have?	☐ Medicaid ☐ Medicare ☐ Private Insurance (select all that apply)
Where did the patient reside prior to this hospitalization?	◯ Home independently ◯ Home with assistance (family or professional) ◯ Skilled nursing facility ◯ Long-term acute care rehabilitation facility ◯ Outside hospital ◯ Outside ICU ◯ Other
Describe other prior living facility	_____

Contraception - For Women of Child-Bearing Age

Date of Negative Pregnancy Test	_____
Patient's Method of Contraception	☐ Hormonal Pill ☐ Condom ☐ IUD ☐ Subcutaneous Implant (Nexplanon) ☐ Injection (Depo-provera) ☐ Commitment to Abstinence ☐ Prior History of Hysterectomy (select all that apply)
Pregnancy within the past 1 year?	◯ Yes ◯ No

Past Medical History

Organ transplant	◯ Yes ◯ No
What organ transplant(s) has the patient had?	☐ Kidney ☐ Liver ☐ Heart ☐ Lung ☐ Other
What other organ transplant?	_____
History of prior cardiothoracic surgery?	◯ Yes ◯ No
What Prior Cardiothoracic Surgery?	☐ Coronary Artery Bypass Graft (CABG) ☐ Valve Replacement ☐ Pacemaker ☐ Heart Transplant ☐ Other (select all that apply)
Describe other cardiothoracic surgery	_____
Coronary Artery Disease (CAD)	◯ Yes ◯ No
Hypertension	◯ Yes ◯ No
Is the patient taking medication for treatment of their hypertension (NOT including study drug)	◯ Yes ◯ No
Pacemaker or AICD in place	◯ Yes ◯ No
Congestive heart failure (CHF)	◯ Yes ◯ No
Is the patient's ejection fraction	◯ Reduced ◯ Preserved ◯ Both ◯ Unknown
Atrial fibrillation	◯ Yes ◯ No
Stable angina	◯ Yes ◯ No
Myocardial infarction (MI)	◯ Yes ◯ No
Pulmonary hypertension	◯ Yes ◯ No
Asthma	◯ Yes ◯ No

Has the patient been evaluated in the ED or admitted to the hospital for asthma in the past year?	☐ ED Evaluation ☐ Hospital Admission ☐ None
Chronic obstructive pulmonary disease (COPD)	◯ Yes ◯ No
Chronic bronchitis	◯ Yes ◯ No
Tuberculosis	◯ Yes ◯ No
Obstructive sleep apnea (OSA)	◯ Yes ◯ No
What does the patient use to treat their obstructive sleep apnea?	☐ CPAP ☐ BiPAP ☐ Home O2 ☐ Nothing ☐ Unknown
Other pulmonary disease	◯ Yes ◯ No (Emphysema, cystic fibrosis, etc)
Describe other pulmonary disease(s)	_____
Diabetes mellitus	◯ Yes ◯ No
What type of diabetes?	◯ Insulin Dependent (Type I) ◯ Non-Insulin Dependent (Type II)
Chronic neurologic disorder (e.g. ALS, Parkinson's, Alzheimer's, multiple sclerosis, Huntington's, epilepsy, etc.)	◯ Yes ◯ No
Human immunodeficiency virus infection and acquired immune deficiency syndrome (HIV/AIDS)?	◯ Yes ◯ No
Previous or current diagnosis of any cancer	◯ Yes ◯ No
If history of cancer is YES, please describe which organ(s) affected.	☐ Brain ☐ Ear/Nose/Throat ☐ Heart ☐ Lung ☐ Stomach ☐ Liver ☐ Kidney ☐ Bone ☐ Muscle ☐ Blood/lymphoma/leukemia ☐ Other (Select all that apply)
If other is selected, please explain	_____

Medication History

Home oxygen use	◯ Yes ◯ No (Not for Sleep Apnea)
What is the flow rate of the patient's home oxygen	_____ (Liters Per Minute)
What medication(s) is the patient taking for hypertension?	☐ Beta-adrenergic blockers (-olol name suffix) ☐ Calcium channel blockers (amlodipine, diltiazem, verapamil) ☐ Diuretics (furosemide, hydrochlorothiazide) ☐ Alpha-adrenergic blockers (doxazosin, prazosin, terazosin) ☐ Alpha-beta adrenergic blockers (Carvedilol, labetalol) ☐ Vasodilators (hydralazine, minoxidil) ☐ Aldosterone receptor blockers (eplerenone, spironolactone) (Select all that apply)
Chronic corticosteroid use, including inhaled or pills	◯ Yes ◯ No (Inhaled or Systemic)
What type of steroids	☐ Inhaled ☐ Systemic (select all that apply)
Chronic NSAID Use	◯ Yes ◯ No (Aspirin, Ibuprofen, Naproxen, etc)
If yes to HIV, Is the patient on antiretroviral therapy (ART)?	◯ Yes ◯ No ◯ Unknown
Baseline Antiviral Use	◯ Yes ◯ No
Describe the patient's antiviral use	◯ Chronic ◯ Acute (since current illness onset)
Immunosuppressant medications	◯ Yes ◯ No

Social History

Does the patient use tobacco or nicotine?	◯ Yes ◯ No
What type(s) of tobacco does the patient use?	☐ Cigarettes ☐ Vape Products ☐ Chewing Tobacco ☐ Cigars ☐ Other (Select all that apply)
Describe other tobacco used	_____

What is the patient's pack years smoking history?	_____ (Packs per Day x Years of Smoking)
Does the patient consume alcohol?	◯ Yes ◯ No
How many average drinks per week does the patient consume?	_____ (1 drink = 12oz of beer, 5oz of wine or 1.5oz of hard liquor or spirits)
Does the patient use illicit drugs	◯ Yes ◯ No ◯ Prefers not to Answer
What drugs does the patient use?	☐ Cannabis ☐ Benzodiazepines ☐ Opiates ☐ Cocaine ☐ Methamphetamine ☐ Barbiturates ☐ Ecstasy or MDMA ☐ Hallucinogenic drugs (LSD, mushrooms, DMT) ☐ Dissociative drugs (PCP, Ketamine) ☐ Other (Select all that apply)
Other used drugs	_____
Is the participant a healthcare worker?	◯ Yes ◯ No
Is the participant a clinical laboratory worker?	◯ Yes ◯ No

PK Study

Record ID	_____
Was consent obtained for the patient to participate in the PK substudy?	◯ Yes ◯ No
Time of baseline (0 Hour) PK lab draw	_____
Time of 2 hour PK lab draw	_____
Time of 4 hour PK lab draw	_____
Time of 6 hour PK lab draw	_____

PROMIS Survey

Record ID	_____
Is the patient able to complete the PROMIS survey on this study day?	◯ Yes ◯ No (It is permissible to complete this survey +/- 1 day if the patient is unable to complete the survey on the indicated study day)
Why is the patient unable to complete the PROMIS survey?	☐ Patient intubated ☐ Patient with Altered Mental Status ☐ Patient in procedure or operating room ☐ Other
Explain other reason for the PROMIS Survey not being completed	_____
Time of Completion	_____

Please indicate the number that best reflects the amount of shortness of breath you experienced in the past day...

Shortness of breath in general	◯ 0 - No shortness of breath ◯ 1 ◯ 2 ◯ 3 ◯ 4 ◯ 5 ◯ 6 ◯ 7 ◯ 8 ◯ 9 ◯ 10 - Worst possible shortness of breath
Intensity of shortness of breath	◯ 0 - When I had shortness of breath, it felt very mild ◯ 1 ◯ 2 ◯ 3 ◯ 4 ◯ 5 ◯ 6 ◯ 7 ◯ 8 ◯ 9 ◯ 10 - When I had shortness of breath, it felt very severe

Frequency of shortness of breath	◯ 0 - I never had shortness of breath ◯ 1 ◯ 2 ◯ 3 ◯ 4 ◯ 5 ◯ 6 ◯ 7 ◯ 8 ◯ 9 ◯ 10 - I always had shortness of breath
Duration of shortness of breath	◯ 0 - When I had shortness of breath, it lasted only for a moment ◯ 1 ◯ 2 ◯ 3 ◯ 4 ◯ 5 ◯ 6 ◯ 7 ◯ 8 ◯ 9 ◯ 10 - When I had shortness of breath, it lasted for a very long time
I've been short of breath	◯ 0 - Not at all ◯ 1 - A little bit ◯ 2 - Somewhat ◯ 3 - Quite a bit ◯ 4 - Very much

Randomization

Record ID	_____
Was the participant randomized?	◯ Yes ◯ No
Please upload the randomization confirmation for this participant.	
Why was the participant not randomized?	☐ Did not meet inclusion criteria after consent ☐ Met an exclusion criteria after consent ☐ Unwilling to comply with study procedures ☐ Felt too sick ☐ Not interested ☐ Other
If other selected, please explain.	_____

Reconsent

Record ID	_____
Was study enrollment completed with a legally authorized representative (LAR)?	◯ Yes ◯ No
Reconsent needs to be obtained from the participant for the study when, or if, they become capable of consent	
During the hospitalization, did the patient become able to reconsent?	◯ Yes ◯ No
Did the patient provide their consent to continue in the study?	◯ Yes ◯ No
Please provide a brief description of why the patient required reconsent	_____
Date of reconsent	_____

Research Blood Sample

Record ID	_____
NOTE: Blood samples are completed once at either Baseline or Day 1. Only record this data once.	
Were the blood samples collected on this study day?	◯ Yes ◯ No
Why was the blood sample not collected on this study day?	☐ Sample collected on another day ☐ Bedside nurse unavailable ☐ Patient refused ☐ Courier or transporter unavailable ☐ Other
Explain other reason for the blood sample not being collected on this study day?	_____
Time of blood sample collection	_____

Research Swab Sample

Record ID	_____
NOTE: Swab samples are completed once at either Baseline or Day 1. Only record this data once.	
Was the swab collected on this study day?	◯ Yes ◯ No
Time of swab sample collection	_____
Why was the swab sample not collected?	☐ Bedside nurse unavailable ☐ Patient refused ☐ Courier or transporter unavailable ☐ Other ☐ No swabs available
Explain other reason why the swab was not collected on this study day	_____

SOFA Score

Record ID

_____

Use the WORST value from the study day

FiO2 Calculation

Were arterial blood gases drawn on this study day?

◯ Yes
◯ No

What is the PaO2 of the arterial blood gas?

_____
(mmHg)

What is the SpO2 today?

_____
(For patients with an Sp02 of 100%, please ask bedstaff to reduce oxygen dose until the participant is below 97% to get a more accurate view of oxygen requirement.)

Is the patient intubated or on CPAP/BiPAP?

◯ Yes
◯ No

What is the FiO2 on the ventilator at the time of the ABG?

(List as decimal between 0.21 - 1.0)

_____
(21% is 0.21)

Please the record the PEEP for Intubated, CPAP, or BiPAP participants

◯ PEEP 8 or less
◯ PEEP 8-12
◯ PEEP 12+
(cmH20)

What is the oxygen flow rate of the patient's supplemental O2?

_____
(Liters Per Minute. Record 0 if the patient is not on supplemental oxygen. For patients with an Sp02 of 100%, please ask bedstaff to reduce oxygen dose until the participant is below 97% and record that oxygen dose.)

FiO2

_____

PaO2 / FiO2 ratio

_____

PaO2 / FiO2 ratio

_____

SaO2 / FiO2 ratio

_____

SaO2 / FiO2 ratio _____

Pa02/Fi02 or Sa02/Fi02 Scoring Chart Want a calculator? Use this link here.

Respiratory SOFA Score	PaO2/FiO2	SaO2/FiO2				
	No Positive Pressure		Positive Pressure			
			PEEP<8	PEEP 8-12	PEEP>12	
0	>=400	>400	>=502	>=515	>=425	Ineligible values for IP enrollment
1	<400	<=400	<502	<515	<425	
2	<300	<=315	<370	<387	<332	
3	<200	<=235	<240	<259	<234	
4	<100	<=150	<115	<130	<129	

If utilizing a Sa02/Fi02 value via the calculator, please record the value here. _____

Organ System Scores

Respiratory?

◯ 0
◯ 1
◯ 2
◯ 3
◯ 4
(From Above Value)

Platelet Count (Coagulation)

◯ ≥ 150
◯ < 150
◯ < 100
◯ < 50
◯ < 20
(Platelets (x10^9L))

Bilirubin (Hepatic)

◯ < 1.2
◯ 1.2-1.9
◯ 2.0-5.9
◯ 6.0-11.9
◯ >12
(Bilirubin (mg/dL))

Creatinine (Renal)

◯ < 1.2
◯ 1.2-1.9
◯ 2.0-3.4
◯ 3.5-4.9
◯ >5.0
(creatinine (mg/dL))

Blood Pressure (Cardiovascular)	◯ No Hypotension ◯ MAP Less than 70 ◯ On vasopressors, dopamine Less than 5 mcg/kg/min or dobutamine (any dose) ◯ Dopamine Greater than 5 mcg/kg/min or Epi/Norepi Less than 0.1 mcg/kg/min ◯ Dopamine Greater than 15 mcg/kg/min or Epi/Norepi Greater than 0.1 mcg/kg/min (Any pressor need means that the score will be 3+)
Glasgow Coma Scale (CNS)	◯ 15 ◯ 13-14 ◯ 10-12 ◯ 6-9 ◯ < 6 (GCS)
Where any sections of the SOFA score not documented for this study day?	☐ Respiratory ☐ Platelet/Coagulation ☐ Bilirubin/Hepatic ☐ Creatinine/Renal ☐ Blood Pressure/CV ☐ GCS/Nervous ☐ All documented
Total SOFA Score	_____

Study Drug Administration

Record ID	_____
How Many TOTAL doses of study drug did the patient receive?	_____
Date & Time of 1st Study Drug Administration	_____
Date & Time of 2nd Study Drug Administration	_____

Missed Study Drug Doses

Were any scheduled study drug doses missed?	◯ Yes ◯ No
How many study drug doses were missed?	◯ 1 ◯ 2
Provide explanation of why these study drug doses were missed	◯ Bedside staff unavailable to administer ◯ Participant refusal ◯ Administration error ◯ Pharmacy/drug unavailable ◯ Other
Please describe the administration error	_____
If other selected, please describe.	_____

Vitals Data

Record ID

_____

Collect Vitals as Close to 7:00AM as Possible

Systolic Blood Pressure

_____

Diastolic Blood Pressure

_____

Mean Arterial Pressure

_____

Blood Pressure Method

◯ Cuff
◯ Arterial Line

Temperature

_____
(Celsius)

Heart Rate

_____

Respiratory Rate

_____

Oxygen Saturation

_____

Ventilatory Status

Is the Patient on Supplemental Oxygen or Intubated

◯ Yes
◯ No

What Type of Supplemental Oxygen is the Patient Receiving?

☐ Nasal Cannula
☐ High Flow Nasal Cannula (flow rate 30 liters per minute +)
☐ BiPAP
☐ CPAP
☐ Face Mask / Non-rebreather
☐ Endotracheal Intubation
☐ ECMO

What is the FiO2?

If not measured, estimate FiO2 as 0.21 + (0.03 x liters per minute oxygen)

_____

What is the Ventilator FiO2

_____

What is the Ventilator Tidal Volume?

_____

What is the Peak End Expiratory Pressure (PEEP)?

_____

Is the patient in the prone position?

◯ Yes
◯ No

12 Health Survey

Record ID _____

Is the patient able to complete the 12 Health Survey on this study day?
- ◯ Yes
- ◯ No

Date & Time of Completion _____

Why is the patient unable to complete the 12 Health Survey on this study day?
- ☐ Research personnel unable to contact patient
- ☐ Patient refused
- ☐ Patient with altered mental status
- ☐ Other

Explain other reason patient was unable to complete the 12 Health Survey on this study day _____

12 Health Survey

In general, would you say your health is:
- ◯ Excellent
- ◯ Very Good
- ◯ Good
- ◯ Fair
- ◯ Poor

The following questions are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

	YES - Limited a lot	YES - Limited a little	No - Not limited at all
Moderate activities such as moving a table, a vacuum cleaner, bowling, or playing golf	◯	◯	◯
Climbing several flights of stairs	◯	◯	◯

During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

	Yes	No
Accomplished less than you would like	◯	◯
Were limited in the kind of work or other activities	◯	◯

During the past 4 weeks, how much did pain interfere with your normal work (including work outside the home and housework)?
- ◯ Not at all
- ◯ A little bit
- ◯ Moderately
- ◯ Quite a bit
- ◯ Extremely

These questions are about how you have been feeling during the past 4 weeks.
For each question, please give the one answer that comes closest to the way you have been feeling.

How much of the time during the past 4 weeks...

	All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time
Have you felt calm & peaceful?	◯	◯	◯	◯	◯	◯
Did you have a lot of energy?	◯	◯	◯	◯	◯	◯
Have you felt down-hearted and blue?	◯	◯	◯	◯	◯	◯

During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting friends, relatives, etc.)?

◯ All of the time
◯ Most of the time
◯ Some of the time
◯ A little of the time
◯ None of the time

Admission Medications

Record ID _____

Please complete one CRF for every hospital admission through day 90.

If multiple admissions for this participant through day 90, enter the admission date for this case report form. _____

Was the patient receiving any of the below medications for this admission?

	No	Yes	Unknown
Oral / Orogastric fluids	○	○	○
Intravenous fluids	○	○	○
Antiviral medications	○	○	○
Corticosteroids	○	○	○
Antibiotics	○	○	○
Antifungal agents	○	○	○
Antimalarial agents	○	○	○
Experimental agents	○	○	○
Non-steroidal anti-inflammatory Drugs (NSAIDs)	○	○	○
Vasopressors	○	○	○
Inhaled beta agonists	○	○	○
500cc fluid bolus for hypotension	○	○	○
Remdesivir	○	○	○
Interleuken Inhibitors	○	○	○
Vitamin C	○	○	○
Convalesent Plasma	○	○	○
Heparin	○	○	○

What Vasopressor(s) is the Patient on this Study Day?

- ☐ Norepinephrine
- ☐ Epinephrine
- ☐ Phenylephrine
- ☐ Vasopressin
- ☐ Dobutamine
- ☐ Dopamine
- ☐ Isoproterenol
- ☐ Milrinone

(select all that apply)

Maximum Norepinephrine Infusion Rate on this Study Day? _____

Maximum Epinephrine Infusion Rate on this Study Day? _____

Maximum Phenylephrine Infusion Rate on this Study Day?	_____
Maximum Vasopressin Infusion Rate on this Study Day?	_____
Maximum Dobutamine Infusion Rate on this Study Day?	_____
Maximum Dopamine Infusion Rate on this Study Day?	_____
Maximum Isoproterenol Infusion Rate on this Study Day?	_____
Maximum Milrinone Infusion Rate on this Study Day?	_____
What antiviral medication(s) is the patient taking?	☐ Ribavirin ☐ Lopinavir/Ritonavir ☐ Neuraminidase inhibitor ☐ Interferon Alpha ☐ Interferon Beta ☐ Other (Select all that apply)
What other antiviral medication is the patient receiving?	_____
What type of corticosteroids is the patient receiving?	☐ Oral ☐ Intravenous ☐ Inhaled (Select all that apply)
List the corticosteroid(s) that the patient is receiving	_____
What is the daily maximum dose (w/ units) of the corticosteroid?	_____
List the antifungal medication(s) that the patient is taking	_____
List the antimalarial medication(s) that the patient is taking	_____
List the experimental agent(s) that the patient is receiving	_____
What type of heparin is the patient receiving?	◯ UFH ◯ LMWH ◯ Full Dose Heparin ◯ Prophylaxis

Adverse Event Prompting

Record ID	_____
What follow up visit is being completed?	◯ Day 2 ◯ Day 3 ◯ Day 4 ◯ Day 6 ◯ Day 8 ◯ Day 9 ◯ Day 10 ◯ Day 15 ◯ Day 28 ◯ Day 90
AE prompt date	_____
Are you using any medications other than study drug to help?	☐ Acetaminophen (Tylenol) ☐ Ibuprofen (Advil) ☐ Cetirizine (Zyrtec) ☐ Phenylephrine (Sudafed) ☐ Hydroxychloroquine ☐ Azithromycin ☐ Other ☐ None
If other is selected, please add name of medication	_____
Please prompt the participant by asking if they have experienced any of the following since last contact with study team.	☐ Worsening fatigue ☐ Syncope ☐ Angioedema (swelling of face, lips, tongue, throat) ☐ Shortness of breath ☐ Worsening cough ☐ Decreased urine output (as determined by participant) ☐ None of these (For expected AEs)
Please prompt the participant by asking if they have experienced any of the following since last contact with study team.	☐ Hospitalization ☐ Respiratory distress requiring any oxygen ☐ New cardiac arrythmias ☐ Any kidney injury requiring treatment ☐ New renal replacement therapy requirement ☐ None of these (For expected SAEs)
It appears an AE or SAE of special interest was reported by the participant. Please proceed to the "Event Reporting" CRF and complete.	
If the participant was hospitalized, how many days did it take to resume normal activities of daily living (ADLs)?	_____ (Days. Leave blank if still hospitalized)

From randomization to day 28, how many encounters with a healthcare provider has the participant completed?

_____

(Defined as a visit to urgent care, clinic, emergency department, or admission)

Day 90

Record ID	_____
Is the Patient Alive at Day 90?	◯ Yes ◯ No
Date of 90 Day Follow Up	_____
What was the Patient's Date of Death?	_____
Study complete?	◯ Yes ◯ No

Early Withdrawal

Record ID	_____
Did the participant withdraw early?	◯ Yes ◯ No
Date of early withdrawal notification	_____
Please describe why the participant withdrew.	☐ Due to adverse event ☐ Consent withdrawn ☐ Lost to follow up ☐ Removed by investigator ☐ Other (Select all that apply)
If other was selected, please explain.	_____
Does the participant consent to partial withdrawal?	◯ Yes ◯ No (Defined as stopping all contact with investigators but allow for continued access to EMR to capture outcomes.)
Does the study participant still consent to future research with collected bio-specimens?	◯ Yes ◯ No

Eligibility

Record ID _____

Inclusion Criteria

Presumptive positive laboratory test for COVID-19 based on local laboratory standard	◯ Yes ◯ No
Is the patient 18+ years old	◯ Yes ◯ No
Does the patient present with upper respiratory symptoms and/or fever?	◯ Yes ◯ No (Defined as cough, fatigue, runny nose, fever over 101.5 F, etc)

It Appears that the Participant DOES NOT Meet Inclusion CriteriaDo Not Proceed with Enrollment!

Exclusion Criteria

Will randomization be >72 hours since meeting inclusion criteria	◯ Yes ◯ No
Was the first reported symptom >7 days before randomization?	◯ Yes ◯ No
Is the patient currently taking an angiotensin converting enzyme inhibitor (ACEi) or Angiotensin receptor blocker (ARB)?	◯ Yes ◯ No
Does the patient have a history of prior reaction or intolerance to an ARB or ACEi?	◯ Yes ◯ No

It Appears that the Participant Meets Study Exclusion CriteriaDo Not Proceed with Enrollment!

Is the patient pregnant? A pregnancy test is required for females less than 60 years old.	◯ Yes ◯ No (If male or female 60 years or older, select no)
Is the patient breastfeeding?	◯ Yes ◯ No (If male, select no)
If the patient is of childbearing age and potential, are they unwilling to use contraception for the duration of the study? Study Approved Contraception Methods: Hormonal pill, IUD, implant, injection, condom use or commitment of abstinence.	◯ Yes ◯ No

Is there a patient reported or electronic health record history of kidney disease? Defined as any of the following: 1. Any history of dialysis 2. History of chronic kidney disease stage III or IV 3. Estimated Glomerular Filtration Rate (eGFR) of LESS THAN 30 mL/min/1.73m^2 within 30 days of randomization 4. Other kidney disease that in the opinion of the investigator would affect losartan clearance.	◯ Yes ◯ No
Does the patient have self reported dehydration within the past 72 hours?	◯ Yes ◯ No
Does the patient report significantly decreased urine output in the last 72 hours?	◯ Yes ◯ No
Is there a patient reported or electronic health record history of liver disease? Defined as any of the following: 1. Cirrhosis 2. History of hepatitis B or C 3. Documented AST or ALT >3 times the upper limit of normal within 3 months of randomization (if available in electronic health record) 4. Other liver disease that in the opinion of the investigator would affect losartan clearance.	◯ Yes ◯ No
Is there a recorded potassium level >5.0 mmol/L within 7 days of study enrollment?	◯ Yes ◯ No
Is the patient being concurrently treated with Aliskiren (Brand names Tekturna or Rasilez)?	◯ Yes ◯ No
Is there an inability to obtain informed consent?	◯ Yes ◯ No
Most recent documented mean arterial pressure (MAP) prior to enrollment below 65 mmHg?	◯ Yes ◯ No (Proceed to "Baseline Vitals" CRF for MAP calculator)

It Appears that the Participant Meets Study Exclusion CriteriaDo Not Proceed with Enrollment!

Randomization

Enrolling Site

◯ M Health
◯ Hennepin
◯ Mayo

What is the participant's age?

◯ 18-59 years old ◯ 60 years or older
(For randomization)

Calculate eligible/ineligible

_____
(eligible=18, any other amount not eligible)

Based on the submitted data, the participant appears eligible for randomization. Please proceed to the randomization system.

PI Attestation

As PI of this site, I attest that I have review the inclusion and exclusion criteria for this patient and confirm that they are an appropriate candidate for randomization.

_____
(Investigator to complete attestation retrospectively)

Site PI Name

_____

Enrollment Data

Record ID

_____

Date & Time of First Healthcare Provider Contact

_____
(Presentation to ED or drive-up testing. Leave blank if unknown)

What was the first date that the patient had upper respiratory symptoms of COVID-19 (cough, rhinorrhea) or a fever >101.5F?

If patient can not recall the exact date, use a estimated date.

_____

How many days did the patient have symptoms before seeking care?

_____
(Days. For those who are asymptomatic at enrollment, enter zero.)

What COVID-19 Signs & Symptoms did the participant experience

	No	Yes	Unknown
Fever	○	○	○
Cough (dry)	○	○	○
Cough (with sputum production)	○	○	○
Cough (with hemoptysis)	○	○	○
Sore Throat	○	○	○
Runny Nose (rhinorrhea)	○	○	○
Wheezing	○	○	○
Chest Pain	○	○	○
Muscle Aches (myalgias)	○	○	○
Joint Pain	○	○	○
Abdominal Pain	○	○	○
Fatigue / Malaise	○	○	○
Shortness of Breath	○	○	○
Inability to Walk	○	○	○
Headache	○	○	○
Altered mental status	○	○	○
Seizures	○	○	○
Vomiting/Nausea	○	○	○
Diarrhea	○	○	○
Conunctivitis	○	○	○

Skin Rash	◯	◯	◯
Skin ulcers	◯	◯	◯
Lymphadenopathy	◯	◯	◯
Bleeding (Hemorrhage)	◯	◯	◯
Loss of smell	◯	◯	◯
Loss of taste	◯	◯	◯
Other	◯	◯	◯

Medications at Time of Enrollment

Has the patient been taking any other prescribed COVID-19 outpatient medications prior to enrollment?

◯ Yes
◯ No

What COVID-19 medications was the patient taking as an outpatient?

☐ Hydroxychloroquine
☐ Acetaminophen (Tylenol)
☐ Ibuprofen
☐ Azithromycin
☐ Other(s)

If other, list the other medication(s) the patient was taking to treat COIVD-19 prior to enrollment?

_____

Has the patient taken any of the following medications within 14 days of enrollment?

☐ Angiotensin converting enzyme inhibitors (ACE inhibitors)
☐ Angiotensin II receptor blockers (ARBs)
☐ Non-steroidal anti-inflammatory (NSAID)
☐ Unknown
☐ None

COVID-19 Sample

Date & Time of First Positive COVID-19 Sample Collection

_____

Date & Time of COVID-19 Sample Result

_____

Time of COVID-19 Testing

_____
(min)

Event Reporting

Record ID

_____

Are there events to report for this study day?

◯ Yes
◯ No

What Type of Event is Being Reported?

☐ Note to File
☐ Adverse Event (AE)
☐ Protocol Deviation
(AEs Include (but are not limited to): New hypotension due to study drug, electrolyte abnormalities, acute kidney injury, difficulty breathing, significant changes to urination, myalgias)

Name of Person Filing

_____

Note to File

Date & Time of Note to File

_____

Note to File Details

_____

Adverse Event

Date and time of AE report

_____

Date & Time of AE

_____

Which organ system(s) is affected?

☐ Nervous
☐ Respiratory
☐ Renal
☐ Circulatory
☐ Digestive
☐ Excretory
☐ Reproductive
☐ Muscular
☐ Skeletal
☐ Integumentary
☐ Immune
☐ Endocrine
☐ Unsure - PI will be prompted for input
(select all that apply)

Expected Adverse Events include (but are not limited to) :
Worsening fatigue
Syncope
Angioedema
Worsening cough
Dyspnea
Decreased urine output

Expected Serious Adverse Events include (but are not limited to) :
Respiratory distress requiring supplemental, or increased supplemental, oxygen

New cardiac arrhythmia
Any kidney injury requiring treatment
New renal replacement therapy

AE of special interest?

◯ Yes
◯ No

SAE of special interest?

◯ Yes
◯ No

Is this a serious adverse event?

◯ Yes
◯ No

These include any event that results in any of the following:
1. Fatal
2. Life threatening
3. Requires or prolongs the hospital stay
4. Results in significant disability or incapacity
5. A congenital anomaly or birth defect
6. An important medical event

Did AE continue for >1 day?

◯ Yes
◯ No

Discontinue study drug for related Serious Adverse Event

Discontinue study drug for related Adverse Event lasting >1 day

---

Reduce study drug for related Adverse Event

Was study drug reduced or discontinued due to this AE?

◯ No
◯ Reduced
◯ Discontinued

Which of the following drug reduction/discontinuation procedures was followed?

◯ Decrease in study drug from twice a day to once a day if currently dosing twice daily
◯ Discontinuation of study drug if only taking once daily
◯ Discontinuation of study drug at the discretion of the investigator

---

When was the study drug reduced?

_____

When was the study drug discontinued?

_____

Adverse Event Details

_____
(Please include start time, disposition (if continuing or resolved), and any corrective actions (treatment, withdrawal, etc) that occurred as a result)

List ICD10 code associated with this adverse event

_____
(Keyword search)

PI Attestation - (For PI Completion ONLY)

According to the PI, which organ system(s) is affected?

- ☐ Nervous
- ☐ Respiratory
- ☐ Renal
- ☐ Circulatory
- ☐ Digestive
- ☐ Excretory
- ☐ Reproductive
- ☐ Muscular
- ☐ Skeletal
- ☐ Integumentary
- ☐ Immune
- ☐ Endocrine

(Select all that may apply)

Scales Used Attribute Adverse Events: The Principal Investigator will assess the relationship of all AEs to any drug or study procedure: Definitely Related: There is clear evidence to suggest a causal relationship, and other possible contributing factors can be ruled out. The clinical event, including an abnormal laboratory test result, occurs in a plausible time relationship to study agent/intervention administration and cannot be explained by concurrent disease or other drugs or chemicals. The response to withdrawal of the study agent/intervention (de-challenge) should be clinically plausible. The event must be pharmacologically or phenomenologically definitive, with use of a satisfactory re-challenge procedure if necessary. Probably Related: There is evidence to suggest a causal relationship, and the influence of other factors is unlikely. The clinical event, including an abnormal laboratory test result, occurs within a reasonable time sequence to administration of the study agent/intervention, is unlikely to be attributed to concurrent disease or other drugs or chemicals, and follows a clinically reasonable response on withdrawal (de-challenge). Re-challenge information is not required to fulfill this definition. Possibly Related: There is some evidence to suggest a causal relationship (e.g., the event occurred within a reasonable time after administration of the trial medication). However, the influence of other factors may have contributed to the event (e.g., the subject's clinical condition, other concomitant events). Although an adverse drug event may rate only as "possible" soon after discovery, it can be flagged as requiring more information and later be upgraded to probable or certain as appropriate. Unlikely: A clinical event, including an abnormal laboratory test result, whose temporal relationship to study agent/intervention administration makes a causal relationship improbable (e.g., the event did not occur within a reasonable time after administration of the trial medication) and in which other drugs or chemicals or underlying disease provides plausible explanations (e.g., the subject's clinical condition, other concomitant treatments). Not related: The AE is completely independent of study agent/intervention administration, and/or evidence exists that the event is definitely related to another etiology. There must be an alternative, definitive etiology documented by the clinician.

In the opinion of the PI, was the AE related to the study drug or procedures?

- ◯ Not related
- ◯ Unlikely related
- ◯ Possibly related
- ◯ Probably related
- ◯ Definitely related

Scales Used to Grade Severity of Adverse Events: All AEs will be graded in the following manner: Grade 1 (Mild): Events require minimal or no treatment and do not interfere with the participant's daily activities. Grade 2 (Moderate): Events result in a low level of inconvenience or concern. Moderate events may cause some interference with functioning. Grade 3 (Severe): Events interrupt a participant's usual daily activity and may require systemic drug therapy or other treatment. Severe events are usually incapacitating. Grade 4 (Life-threatening): Any adverse drug experience that places the participant, in the view of the Investigator, at immediate risk of death from the reaction as it occurred (i.e., it does not include a reaction that had it occurred in a more severe form, might have caused death). Grade 5 (Death)

What grade is this Adverse Event?

- ◯ Grade 1 - Mild
- ◯ Grade 2 - Moderate
- ◯ Grade 3 - Severe
- ◯ Grade 4 - Life-threatening
- ◯ Grade 5 - Death

Expected Adverse Events include (but are not limited to) :
Worsening fatigue
Syncope
Angioedema
Worsening cough
Dyspnea
Decreased urine output

Expected Serious Adverse Events include (but are not limited to) :
Respiratory distress requiring supplemental, or increased supplemental, oxygen
New cardiac arrhythmia
Any kidney injury requiring treatment
New renal replacement therapy

Was the adverse event unexpected?
◯ Yes
◯ No

PI Name
_____

PI Signature of Attestation
_____

Time of Attestation
_____

Protocol Deviation

Date of Protocol Deviation
_____

Please provide details of the protocol deviation
_____
(Include details of: what happened, when was it discovered, what was done after the protocol deviation was discovered, was the protocol deviation resolved (if so, what was done), was patient harm caused as a result of this, and did the protocol deviation cause data collection to stop or the patient to be withdrawn early from the study.)

Please provide a corrective action plan to prevent this protocol deviation from repeating in the future, if applicable
_____

Home Vitals

Record ID	_____
When was the last contact with participant?	◯ Yesterday (24 hr or less) ◯ Two days (48 hr or more)
Blood pressure collected on this study day?	◯ Yes ◯ No
Systolic BP	_____ (mmHg)
Diastolic BP	_____ (mmHg)
MAP 1	_____
Was a temperature Reported on this study day	☐ Yes - Celsius ☐ Yes - Fahrenheit ☐ No Temperature Taken (If multiple obtained, record the highest temperature.)
Temperature Fahrenheit	_____
Temperature Celsius	_____
Measurement date	_____
Please explain why a vital sign was not collected in the past 24 hours	_____
Blood pressure collected on the previous day?	◯ Yes ◯ No
Systolic BP	_____ (mmHg)
Diastolic BP	_____ (mmHg)
MAP 2	_____

Was a temperature Reported on previous study day	☐ Yes - Celsius ☐ Yes - Fahrenheit ☐ No Temperature Taken (If multiple obtained, record the highest temperature.)
Temperature Fahrenheit	_____
Temperature Celsius	_____
Measurement date	_____
Please explain why a vital sign was not collected	_____

Hospital Discharge

Record ID

Please complete one CRF for every hospital admission through day 90.

Length of Stay

Did the Patient Survive to Hospital Discharge?
◯ Yes
◯ No

Date & Time of Hospital Admission

Date & Time of Hospital Discharge

Total Hospital Length of Stay

What was the Date & Time of Death?

What was the Presumed Cause of Death?

Intensive Care Unit Admission

Was the Patient Admited to the ICU During the Hospitalization?
◯ Yes
◯ No
(at any time)

First ICU Admit Date & Time

First ICU discharge or transfer out time

First ICU total length of stay

Was the patient transferred out of the ICU and then readmitted to the ICU during their hospitalization?
◯ Yes
◯ No

Second ICU admit date & time

Second ICU discharge or transfer out date & time

Second ICU total length of stay

Total ICU days

_____

Invasive Mechanical Ventilation

Was the patient on invasive mechanical ventilation at any time during the hospitalization?
◯ Yes
◯ No

Intubation Date & Time

_____

Extubation Date & Time

_____

Total Length of Intubation

_____

Was the patient extubated and reintubated during their hospitalization?
◯ Yes
◯ No

Date & Time of Second Intubation

_____

Date & Time of Second Extubation

_____

Second Intubation Length

_____

Total Intubation Time (if multiple intubations)

_____

Ventilator Free Days

_____

Ventilator Free Days

_____

Other Supplemental Oxygen Therapy

Was the patient on regular nasal cannula oxygen between between admission and discharge or day 28 (whichever comes first)?
◯ Yes
◯ No

If yes, was the nasal cannula oxygen discontinued prior to death, discharge or day 28?
◯ Yes
◯ No

Was the patient on high flow nasal cannula between between admission and discharge or day 28 (whichever comes first)?
High flow nasal cannula flow rate ≥ 30 liters per minute
◯ Yes
◯ No

If yes, was the high flow nasal cannula oxygen discontinued prior to death, discharge or day 28?	◯ Yes ◯ No
Was the patient on BiPAP between between admission and discharge or day 28 (whichever comes first)?	◯ Yes ◯ No
If yes, was the BiPAP discontinued before death, discharge or day 28?	◯ Yes ◯ No
Start time of any oxygen use through day 28	_____
End time of any oxygen use through day 28	_____
Oxygen free days	_____

ECMO

Was the Patient on Extracorporeal Membrane Oxygenation (ECMO) During the Hospitalization?	◯ Yes ◯ No
Date & Time of ECMO Flow Start	_____
Date & Time of ECMO Flow End	_____
Total Time on ECMO Flow	_____

Microbiology

Did the patient test POSITIVE for the flu during the hospitalization ?	◯ No ◯ Yes ◯ Not Tested
Date & Time of Positive Influenza Sample Collection	_____
What influenza strain did the patient test positive for?	◯ Influenza A ◯ Influenza B ◯ Both
Did the patient have a POSITIVE respiratory virus panel during the hospitalization?	◯ No ◯ Yes ◯ Not Tested
Date & Time of positive viral respiratory panel sample collection	_____

List positive findings from viral respiratory panel

_____

Did the patient have a POSITIVE blood culture between admission and day 7 of hospitalization?

◯ No
◯ Yes
◯ Not Tested

Date & Time of positive blood culture sample collection

_____

List positive findings from blood culture

_____

Did the patient have a POSITIVE respiratory culture between admission and day 7 of hospitalization?

◯ No
◯ Yes
◯ Not Tested

Date & Time of positive respiratory culture sample collection

_____

List positive findings from respiratory culture

_____

Complications

Did the patient develop a secondary bacterial pneumonia?

◯ Yes
◯ No

Did the patient develop ARDS?

◯ Yes
◯ No

Imaging

During admission, was a chest x-ray obtained?

◯ Yes
◯ No

For each chest x-ray, submit the clinical impression and date/time

_____
(Do not list all findings, only the primary clinical impression)

During admission, was CT chest obtained?

◯ Yes
◯ No

For each chest CT, submit the clinical impression and date/time

_____
(Do not list all findings, only the primary clinical impression)

Hospitalization Labs

Record ID _____

Leave blank if not available OR participant was not admitted during study.

For participants hospitalized, submit:

1 form of the INITIAL admission laboratory results.

1 form of the WORST/most severe laboratory results across the entire hospital admission.

For a hospitalized participant, are you completing the initial/admit lab results or the worst/most severe results?

◯ Initial/admit labs
◯ Most severe labs through discharge

White Blood Cell Count (WBC) _____ (k/cmm)

White Blood Cell Count (WBC) date/time of result _____

Hemogobin _____ (g/dL)

Hemogobin date/time result _____

Platelets _____ (k/cmm)

Platelets date/time _____

Sodium _____ (mEq/L)

Sodium date/time _____

Potassium _____ (mEq/L)

Potassium date/time _____

Chloride

_____
(mEq/L)

Chloride date/time

_____

Glucose

_____
(mg/dL)

Glucose date/time

_____

Creatinine

_____
(mg/dL)

Creatinine date/time

_____

Lactate

_____
(mmol/L)

Lactate date/time

_____

Procalcitonin

_____
(ng/mL)

Procalcitonin date/time

_____

Albumin

_____
(g/dL)

Albumin date/time

_____

AST (SGOT)

_____
(IU/L)

AST (SGOT) date/time

_____

ALT (SGPT)

_____
(IU/L)

ALT (SGPT) date/time

_____

Bilirubin (total)

_____
(mg/dL)

Bilirubin (total) date/time

_____

Troponin

_____
(ng/mL)

BNP/NT-proBNP

_____

Blood Gases

Arterial Blood Gases Drawn

◯ Yes
◯ No

Arterial Blood Gases Drawn Date/time

_____

Arterial pH

_____

Arterial PCO2

_____
(mmHg)

Arterial PO2

_____
(mmHg)

Arterial Bicarbonate

_____
(mEq/L)

Venous Blood Gases Drawn

◯ Yes
◯ No

Venous Blood Gases Drawn Date/time

_____

Venous PCO2

_____
(mmHg)

Venous PO2

_____
(mmHg)

Venous pH

_____

Venous Bicarbonate	_____ (mEq/L)

Microbiology

Did the patient test POSITIVE for Influenza?	◯ Yes ◯ No (select no if not tested)
Date & Time of Positive Influenza Sample Collection	_____
What Influenza Strain did the Patient Test Positive For?	◯ Influenza A ◯ Influenza B
Did the patient have a POSITIVE Viral Respiratory Panel?	◯ Yes ◯ No (Select no if not tested.)
Date & Time of Positive Viral Respiratory Panel Sample Collection	_____
List Positive Findings from Viral Respiratory Panel	_____

Loss To Follow Up

Record ID

_____

Loss to Follow Up

This form is to document attempts to contact the participant for their day 15 safety and bio-specimen testing if there was failure to follow-up.

15 Day Follow Up Status Instructions:

1. Participants will be contacted for follow up status.
2. Research staff will document all attempts to contact participants below.

	No	Yes
1st Attempt: Were you able to contact the participant?	◯	◯
2nd Attempt: Were you able to contact the participant?	◯	◯
3rd Attempt: Were you able to contact the participant?	◯	◯

Date of 15 Day Follow Up: 1st Attempt

_____

Date of 15 Day Follow Up: 2nd Attempt

_____

Date of 15 Day Follow Up: 3rd Attempt

_____

Write down notes about the results of this follow up attempt (e.g., whether phone answered, message left):

_____

Write down notes about the results of this follow up attempt (e.g., whether phone answered, message left):

_____

Write down notes about the results of this follow up attempt (e.g., whether phone answered, message left):

_____

Medication Adherence

Record ID	_____
Has the patient missed any study drug doses since the last follow-up call?	◯ Yes ◯ No (Based on patient report. Study drug TWICE daily oral tablet, or once daily if selected for renal-protective dosing.)
How many doses were missed?	_____
Why was the study drug dose missed?	_____

Ordinal Scale

Record ID _____

7-Point Ordinal Scale of Treatment Severity.
Complete for all participants for day 15.
Complete other study days through day 28 for participants that become hospitalized.
Select the most severe value applicable per study day.
Day 0 = randomization/baseline.

	Death	Hospitalized, on invasive mechanical ventilation or ECMO	Hospitalized, on non-invasive mechanical ventilation or high flow devices	Hospitalized, on any oxygen therapy	Hospitalized, not requiring oxygen therapy	Not hospitalized, limitation of activities of daily living	Not hospitalized, no limitations of activities of daily living
Day 0 (Baseline)	◯	◯	◯	◯	◯	◯	◯
Day 7	◯	◯	◯	◯	◯	◯	◯
Day 15	◯	◯	◯	◯	◯	◯	◯
Day 28	◯	◯	◯	◯	◯	◯	◯

Patient Information

Record ID

_____

Which M Health Site?

◯ UMMC - East Bank ED
◯ UMMC - West Bank ED
◯ Fairview Ridges ED
◯ Southdale ED
◯ Brooklyn Park Drive Through Testing
◯ Woodwinds Drive Through Testing
◯ Maplewood Drive Through Testing
◯ Oxboro Drive Through Testing

Local Site MRN

_____

Participant First Name

_____

Participant Last Name

_____

Sex

◯ Male
◯ Female

Patient Date of Birth

_____

Is the patient between the ages of 18-89?

◯ Yes
◯ No

Patient age

_____

Is the patient >89 years old?

◯ Yes
◯ No

Patient Age

_____

Stated Patient Weight

_____
(lb)

Weight (kg)

_____

Stated Patient Height

_____
(inch. 5 foot = 60 inches.)

Patient Height

_____
(cm)

BMI

_____

Race

◯ Caucasian
◯ Black or African American
◯ Native American or Alaskan Native
◯ Asian
◯ Native Hawaiian or Pacific Islander
◯ Hispanic
◯ Other / Unknown

Ethnicity

◯ Non-Hispanic or Latino
◯ Hispanic or Latino
◯ Unknown

Does the Patient Have Medical Insurance?

◯ Yes
◯ No

What Type of Medical Insurance Does the Patient Have?

☐ Medicaid
☐ Medicare
☐ Private Insurance
(select all that apply)

Contraception - For Women of Child-Bearing Age

Date of Negative Pregnancy Test

_____

Patient's Method of Contraception

☐ Hormonal Pill
☐ Condom
☐ IUD
☐ Subcutaneous Implant (Nexplanon)
☐ Injection (Depo-provera)
☐ Commitment to Abstinence
☐ Prior History of Hysterectomy
(select all that apply)

Pregnancy within the past 1 year?

◯ Yes ◯ No

Past Medical History

Organ Transplant

◯ Yes ◯ No

What Organ Transplant(s) has the patient had?

☐ Kidney
☐ Liver
☐ Heart
☐ Lung
☐ Other

What Other Organ Transplant?

_____

History of prior cardiothoracic surgery?

◯ Yes ◯ No

What Prior Cardiothoracic Surgery?	☐ Coronary Artery Bypass Graft (CABG) ☐ Valve Replacement ☐ Pacemaker ☐ Heart Transplant ☐ Other (select all that apply)
Describe Other Cardiothoracic Surgery	_____
Coronary Artery Disease (CAD)	◯ Yes ◯ No
Hypertension	◯ Yes ◯ No
Is the Patient Taking Medication for Hypertension? (NOT including study drug)	◯ Yes ◯ No
Pacemaker or AICD in place	◯ Yes ◯ No
Congestive Heart Failure (CHF)	◯ Yes ◯ No
Is the Patient's Ejection Fraction	◯ Reduced ◯ Preserved ◯ Both ◯ Unknown
Atrial Fibrillation	◯ Yes ◯ No
Stable Angina	◯ Yes ◯ No
Myocardial Infarction (MI)	◯ Yes ◯ No
Pulmonary Hypertension	◯ Yes ◯ No
Asthma	◯ Yes ◯ No
Has the Patient Been Evaluated in the ED or Admitted to the Hospital for Asthma in the Past Year?	☐ ED Evaluation ☐ Hospital Admission ☐ None
Chronic Obstructive Pulmonary Disease (COPD)	◯ Yes ◯ No
Chronic Bronchitis	◯ Yes ◯ No
Tuberculosis	◯ Yes ◯ No
Obstructive Sleep Apnea (OSA)	◯ Yes ◯ No

What Does the Patient Use to Treat Their Obstructive Sleep Apnea?	☐ CPAP ☐ BiPAP ☐ Home O2 ☐ Nothing ☐ Unknown (Select all that apply)
Other Pulmonary Disease	◯ Yes ◯ No (Emphysema, lung cancer, cystic fibrosis, etc.)
Describe Other Pulmonary Disease(s)	_____
Diabetes Mellitus	◯ Yes ◯ No
What Type of Diabetes?	◯ Insulin Dependent (Type I) ◯ Non-Insulin Dependent (Type II)
Chronic neurologic disorder (e.g. ALS, Parkinson's, Alzheimer's, multiple sclerosis, Huntington's, epilepsy, etc.)	◯ Yes ◯ No
Human immunodeficiency virus infection and acquired immune deficiency syndrome (HIV/AIDS)	◯ Yes ◯ No
Current or previous diagnosis of cancer?	◯ Yes ◯ No (Any cancer requiring treatment)
If history of cancer is YES, please describe which organ(s) affected.	☐ Brain ☐ Ear/Nose/Throat ☐ Heart ☐ Lung ☐ Stomach ☐ Liver ☐ Kidney ☐ Bone ☐ Muscle ☐ Blood/lymphoma/leukemia ☐ Other
If other is selected, please explain.	_____

Medication History

Home Oxygen Use	◯ Yes ◯ No (Not for Sleep Apnea)
What is the Flow Rate of the Patient's Home Oxygen?	_____ (Liters Per Minute)

What medication classes is the participant prescribed to treat hypertension?	☐ Beta-adrenergic blockers (-olol name suffix) ☐ Calcium channel blockers (amlodipine, diltiazem, verapamil) ☐ Diuretics (furosemide, hydrochlorothiazide) ☐ Alpha-adrenergic blockers (doxazosin, prazosin, terazosin) ☐ Alpha-beta adrenergic blockers (Carvedilol, labetalol) ☐ Vasodilators (hydralazine, minoxidil) ☐ Aldosterone receptor blockers (eplerenone, spironolactone)
Chronic Corticosteroid Use, including inhaled or pills	◯ Yes ◯ No (Inhaled or Systemic within the past week)
Chronic NSAID use	◯ Yes ◯ No (Aspirin, Ibuprofen, Naproxen, etc)
What Type of Steroids?	☐ Inhaled ☐ Systemic (select all that apply)
If yes to HIV, is the patient on anti-retroviral therapy (ART)?	◯ Yes ◯ No ◯ Unknown
Baseline antiviral use?	◯ Yes ◯ No
Describe the participant antiviral use	◯ Chronic ◯ Acute (since current illness onset)
Immunosuppressant Medications	◯ Yes ◯ No

Social History

Does the Patient Use Tobacco or nicotine?	◯ Yes ◯ No
What type(s) of tobacco does the patient use?	☐ Cigarettes ☐ Vape Products ☐ Chewing Tobacco ☐ Cigars ☐ Other (Select all that apply)
Describe other tobacco used	_____
What is the Patient's Pack Year Smoking History?	_____ (Packs per Day x Years of Smoking)
Does the Patient Consume Alcohol?	◯ Yes ◯ No

How Many Drinks Per Week Does the Patient Consume?	_____ (Averaged per week. One drink defined as 5 oz glass of wine, 12 oz beer, 1.5 oz hard liquor)
Does the Patient Use Illicit Drugs	◯ Yes ◯ No ◯ Prefers not to Answer
What Drugs Does the Patient Use?	☐ Cannabis ☐ Benzodiazepines ☐ Opiates ☐ Cocaine ☐ Methamphetamine ☐ Barbiturates ☐ Ecstasy or MDMA ☐ Hallucinogenic drugs (LSD, mushrooms, DMT) ☐ Dissociative drugs (PCP, Ketamine) ☐ Other
What Additional Drugs Does the Patient Use?	_____
IS the participant a healthcare worker?	◯ Yes ◯ No
Is the participant a clinical laboratory worker?	◯ Yes ◯ No

PROMIS Survey

Record ID	_____
Is the patient able to complete the PROMIS Survey on this study day?	◯ Yes ◯ No
Time of Completion	_____
Why was the patient unable to complete the PROMIS Survey on this study day	☐ Research personnel unable to contact patient ☐ Patient refused ☐ Patient with altered mental status ☐ Other
Explain other reason patient was unable to complete the PROMIS Survey on this study day	_____

Please indicate the number that best reflects the amount of shortness of breath you experienced in the past day...

Shortness of breath in general	◯ 0 - No shortness of breath ◯ 1 ◯ 2 ◯ 3 ◯ 4 ◯ 5 ◯ 6 ◯ 7 ◯ 8 ◯ 9 ◯ 10 - Worst possible shortness of breath
Intensity of shortness of breath	◯ 0 - When I had shortness of breath, it felt very mild ◯ 1 ◯ 2 ◯ 3 ◯ 4 ◯ 5 ◯ 6 ◯ 7 ◯ 8 ◯ 9 ◯ 10 - When I had shortness of breath, it felt very severe

Frequency of shortness of breath	◯ 0 - I never had shortness of breath ◯ 1 ◯ 2 ◯ 3 ◯ 4 ◯ 5 ◯ 6 ◯ 7 ◯ 8 ◯ 9 ◯ 10 - I always had shortness of breath
Duration of shortness of breath	◯ 0 - When I had shortness of breath, it lasted only for a moment ◯ 1 ◯ 2 ◯ 3 ◯ 4 ◯ 5 ◯ 6 ◯ 7 ◯ 8 ◯ 9 ◯ 10 - When I had shortness of breath, it lasted for a very long time
I've been short of breath	◯ 0 - Not at all ◯ 1 - A little bit ◯ 2 - Somewhat ◯ 3 - Quite a bit ◯ 4 - Very much

Randomization

Record ID	_____
Was the participant randomized?	◯ Yes ◯ No
Please upload the randomization confirmation for this participant	
Why was the participant consented but not randomized?	☐ Did not meet all inclusion criteria ☐ Met an exclusion criteria ☐ Unwilling to comply with study procedures ☐ Other
If other selected, please explain	_____

Research Blood Sample

Record ID	_____
NOTE: Blood samples are completed once at either Baseline or Day 1. Only record this data once.	
Were the blood samples collected on this study day?	◯ Yes ◯ No
Why was the blood sample not collected on this study day?	☐ Sample collected on another day ☐ Bedside nurse unavailable ☐ Patient refused ☐ Courier or transporter unavailable ☐ Other
Explain other reason for the blood sample not being collected on this study day?	_____
Time of blood sample collection	_____

SOFA Score

Record ID

_____

Only complete this CRF if the participant becomes hospitalized during study. Submit 1 form for the intial/admission SOFA. Submit 1 form for the worst SOFA score during admission.

SOFA date

_____

FiO2 Calculation

Were arterial blood gases drawn on this study day?

◯ Yes
◯ No

What is the PaO2 of the arterial blood gas?

_____

What is the lowest SpO2 today?

_____

Is the patient intubated?

◯ Yes
◯ No

What is the FiO2 on the ventilator at the time of the ABG?

(List as decimal between 0.21 - 1.0)

_____
(So 21% is 0.21)

What is the oxygen flow rate of the patient's supplemental O2?

_____
(Liters Per Minute. Record 0 if the patient is not on supplemental oxygen.)

FiO2

_____

PaO2 / FiO2 ratio

_____

PaO2 / FiO2 ratio

_____

Estimated PaO2 / FiO2 ratio

_____

Estimated PaO2 / FiO2 ratio

_____

Organ System Scores

Respiratory (PaO2/FiO2 or SpO2/FiO2)?	◯ PaO2/FiO2 > 400 | SpO2/FiO2 > 302 ◯ PaO2/FiO2 < 400 | SpO2/FiO2 < 302 ◯ PaO2/FiO2 < 300 | SpO2/FiO2 < 221 ◯ PaO2/FiO2 < 200 | SpO2/FiO2 < 142 ◯ PaO2/FiO2 < 100 | SpO2/FiO2 < 67 (From Above Value)
Platelet Count (Coagulation)	◯ ≥ 150 ◯ < 150 ◯ < 100 ◯ < 50 ◯ < 20 (Platelets (x10^9L))
Bilirubin (Hepatic)	◯ < 1.2 ◯ 1.2-1.9 ◯ 2.0-5.9 ◯ 6.0-11.9 ◯ >12 (Bilirubin (mg/dL))
Creatinine (Renal)	◯ < 1.2 ◯ 1.2-1.9 ◯ 2.0-3.4 ◯ 3.5-4.9 ◯ >5.0 (creatinine (mg/dL))
Blood Pressure (Cardiovascular)	◯ No Hypotension ◯ MAP Less than 70 ◯ On vasopressors, dopamine Less than 5 mcg/kg/min or dobutamine (any dose) ◯ Dopamine Greater than 5 mcg/kg/min or Epi/Norepi Less than 0.1 mcg/kg/min ◯ Dopamine Greater than 15 mcg/kg/min or Epi/Norepi Greater than 0.1 mcg/kg/min (Any pressor need means that the score will be 3+)
Glasgow Coma Scale (CNS)	◯ 15 ◯ 13-14 ◯ 10-12 ◯ 6-9 ◯ < 6 (GCS)
Total SOFA Score	_____

Study Oropharyngeal Samples

Record ID	_____
Was the Oropharyngeal Swab Collected on this Study Day?	◯ Yes ◯ No
Courier Specimen Tracking Number	_____ (If available)
Collection date	_____
Why was the Oropharyngeal Sample not Collected?	☐ Patient forgot/refused ☐ Courier not available ☐ Other
Explain other reason why oropharyngeal study swab was not collected?	_____

Vitals and Labs

Record ID

_____

If Completed (Leave blank if not completed)

Systolic Blood Pressure

_____
(mmHg)

Diastolic Blood Pressure

_____
(mmHg)

Mean Arterial Pressure (MAP)

_____

Temperature

_____
(Fahrenheit (F))

Temperature conversion

_____
(Celsius (C))

Heart Rate

_____

Respiratory Rate

_____
(Breaths per minute)

Oxygen Saturation

_____
(%)

Labs

Creatinine result

_____
(mg/dL)

Potassium result

_____
(mmol/L)