Expanded Access Program Sample Data Entry Forms

This document contains historical data entry forms created and used for the purposes of the Mayo Clinic-led Expanded Access Program (EAP) for the treatment of COVID-19. The forms were developed to facilitate access to convalescent plasma to patients in need across the country.

The intent of this data collection form packet is solely to provide a reference for the primary data collection documents.

Program information
This program was initiated on April 3, 2020, and enrollment was closed on August 21, 2020.

This program was funded by BARDA, conducted under FDA oversight for IND 19832 and had the Mayo Clinic IRB serve as the IRB of record for all sites participating in the program.

Only the approved versions of the forms, which were posted on the website while the program was active, are included in this packet.

Key program identifiers
IND# 19832
NCT# 04338360
IRB# 20-003312

See the program Regulatory Documents for more information.

Local Physician/PI Information

Did you complete the physician/PI registration form? If not, complete the Physician/PI Registration Form and return to complete the Patient Enrollment Form

◯ Yes
◯ No

You have indicated above that you have NOT completed the Physician/PI Registration Form. Please complete this form before returning to complete the Patient Enrollment Form. Thank you.

Local Physician/PI Last Name

_____

Local Physician/PI First Name

_____

Local Physician/PI ID Number (select one)

◯ NPI number
◯ DEA number

Local Physician/PI NPI Number

_____

Local Physician/PI DEA Number

_____

Local Physician/PI Cell Phone Number

_____

Local Physician/PI Email

_____

Confirm Physician/PI email (type email address again)

_____

E-mail addresses do not match (please correct)

This alert will vanish when matching confirmation e-mail is entered.

Contact Information for Office Nurse/Research Coordinator/Other Support Person

Would you like to provide contact information for an office nurse/research coordinator/other support person?

◯ Yes
◯ No

Last name of office nurse/research coordinator/other support person

_____

First name of office nurse/research coordinator/other support person

_____

Telephone number of office nurse/research coordinator/other support person	_____
Email of office nurse/research coordinator/other support person	_____
Confirm office nurse/research coordinator/other support person email (type email address again)	_____

E-mail addresses do not match (please correct)

This alert will vanish when matching confirmation e-mail is entered.

Informed Consent

There are 3 options for obtaining informed consent and they should be applied in the following order.

Option 1 (most preferred)- Obtain written informed consent from the patient. Option 2- Use a LAR/Authorized Representative to sign the informed consent document if the patient is not able to provide consent because of an impairment or being unable to communicate (i.e., on a ventilator and sedated). Option 3- When Option 1 or Option 2 are NOT feasible, you may utilize an exception for informed consent in an emergency (21 CFR 50.23) which allows you to discuss the participation with a second physician who concurs with your recommendation of enrolling the patient in the Expanded Access Program (EAP). The second physician must put a note in the patient's medical record indicating their concurrence of the patient participating in the EAP. You are also responsible for informing the patient or the LAR, as time progresses, of the patient's enrollment in the study and answer their questions. Patients may elect to withdraw from the study but their data will remain in the databank and you are required to fill out the 4 hour infusion, 7 day and 30 day forms for safety evaluation.

Common Questions:

What if I cannot get into the room to consent the patient? We understand that it may be too difficult or challenging to obtain written informed consent in person, especially if the patient is critically ill and not able to provide consent. If the treating physician/PI is unable to be physically in the room with the patient at the time of written informed consent, they or their designee trained to get informed consent can speak with the patient via a telemedicine or telephone device, and ask the patient to sign the consent form. The patient or their family member or health care worker can photograph the consent form and email it with signature to the physician/PI. What if the LAR/Legal representative is not at the hospital? If the LAR/designee is unable to be physically in the room with the patient at the time of written informed consent, the physician/PI or their designee trained to get informed consent can speak with the LAR via a telemedicine or telephone device, and ask them to sign the consent form. They can photograph the consent form and email it with signature to the physician/PI. You can also email us at uscovidplasma@mayo.edu for additional discussion.

Informed consent (IC) has been obtained	◯ Yes ◯ No
If Yes, was it obtained by	◯ Patient signing IC- preferred choice and must be first option if possible ◯ LAR/Surrogate signing IC ◯ Use of emergency exception for written IC with a second physician agreeing with use of convalescent plasma and documenting agreement in chart
Date informed consent obtained	_____

Patient Information

Patient's Blood Type (ABO typing on patient must be performed before enrollment)	◯ A+ ◯ AB+ ◯ B+ ◯ O+ ◯ A- ◯ AB- ◯ B- ◯ O-
Patient's Last Name (must provide for safety of matching to blood product)	_____
Patient's First Name (must provide for safety of matching to blood product)	_____
Patient's Initials (First Middle Last) (If no middle name use "X" as the middle initial)	_____ (First Middle Last (ex. KAB))
Medical Record Number	_____
Gender of Patient	◯ Female ◯ Male ◯ Intersex ◯ Transgender ◯ Prefer not to disclose
Patient's Date of Birth	_____ (MM-DD-YYYY (ex. 05-18-1989))
Date of COVID-19 Diagnosis	_____ (MM-DD-YYYY (ex. 04-02-2020))
Age at COVID-19 Diagnosis	_____

Race (select all that apply)	☐ Asian ☐ American Indian or Alaska Native ☐ Black or African American ☐ White ☐ Native Hawaiian or Other Pacific Islander ☐ Other or Unknown
Ethnicity	◯ Hispanic/Latino ◯ Not Hispanic/Latino
Weight	◯ kg ◯ lbs
Weight (kg)	_____ (kg)
Weight (lbs)	_____ (lbs)
Height	◯ cm ◯ in
Height (cm)	_____ (cm)
Height (in)	_____ (in)

NOTE: Plasma may not be immediately available.

Inclusion Criteria (all must be present) Age at least 18 years Laboratory confirmed diagnosis of infection with SARS-CoV-2 Admitted to an acute care facility for the treatment of COVID-19 complications Severe or life threatening COVID-19, or judged by the treating provider to be at high risk of progression to severe or life-threatening disease Informed consent provided by the patient or healthcare proxy	☐ I confirm
Which applies to the patient (select one)	◯ Currently has severe/life-threatening COVID-19 ◯ At high risk of progression to severe/life-threatening disease (judged by provider)

Severe or life-threatening COVID-19 is defined by one or more of the following: (check all that apply)	☐ Dyspnea ☐ Respiratory frequency ≥ 30/min ☐ Blood oxygen saturation ≤ 93% ☐ Partial pressure of arterial oxygen to fraction of inspired oxygen ratio < 300 ☐ Lung infiltrates > 50% within 24 to 48 hours ☐ Respiratory failure ☐ Septic shock ☐ Multiple organ dysfunction or failure

Patient Status Updates

Are you willing to provide brief daily status updates on the patient's condition? This brief daily report of three multiple-choice questions can be provided by anyone with direct knowledge of the patient's condition (research coordinator, medical students, etc). If so, please select "Opt-In" and simply enter the email of the person that will be in charge of the daily reporting for this patient below.	☐ Opt In ☐ Opt out
Email address to send Patient Status Update Form	_____
Confirm email address for Patient Status Update Form	_____
E-mail address does not match (please correct)	
What was the initial status of the patient upon enrollment?	◯ Uninfected ◯ Infected but Asymptomatic ◯ Mild ◯ Moderate ◯ Severe ◯ Critical ◯ End Stage

Medical History

Patient Information

Patient Code: [record_id]

Patient's Last Name: [last_name]

Patient's First Name: [name_first]

Patient MRN: [mrn]

Patient's Date of Birth: [enroll_dateofbirth]

Date of First Plasma Transfusion: [date_infusion][first-instance]

Exposure to COVID+ Individuals

Exposure to individuals who are positive for COVID-19

- ☐ Unknown
- ☐ Household
- ☐ Occupational: Healthcare Worker
- ☐ Occupational: First Responders (Police/EMS/Firefighters)
- ☐ Occupational: Other
- ☐ Other known contacts

Other exposure to COVID positive patient

_____

Medications

Select Medications at Admission

- ☐ ARB
- ☐ Ace Inhibitors
- ☐ Neither
- ☐ Unknown

Medications during this hospital stay

- ☐ ARB
- ☐ Ace Inhibitor
- ☐ Azithromycin
- ☐ Remdesivir
- ☐ Steroids
- ☐ Chloroquine
- ☐ Hydroxychloroquine
- ☐ None of these medications used

Pre-Existing Conditions

History of smoking

- ◯ Current smoker
- ◯ Past smoker
- ◯ Never smoked
- ◯ Unknown

Pre-Existing Conditions (Select all that apply)	☐ History of lung disease (ex. COPD, lung cancer) ☐ Cancer other than above ☐ History of cardiovascular conditions ☐ Obesity ☐ HIV positive ☐ HCV positive (Hepatitis C) ☐ On immunosuppressive therapy ☐ Diabetes ☐ None
History of Lung Disease (Select all that apply)	☐ COPD (chronic bronchitis, emphysema) ☐ Lung cancer ☐ Asthma ☐ Interstitial lung disease ☐ Other lung-related conditions (please specify) ☐ None
Specify other Lung-related Condition	_____
History of Cardiovascular Disease (Select all that apply)	☐ Stroke ☐ Coronary Artery Disease (including prior myocardial infarct or MI) ☐ Valvular Heart Disease ☐ Peripheral Vascular Disease ☐ Hypertension ☐ Arrhythmias ☐ Heart Failure ☐ Myocarditis ☐ Cardiomyopathy ☐ Prior Coronary Artery Bypass Graft (CABG) ☐ Other (please specify) ☐ None
Specify Other Cardiovascular Disease	_____

Biomarkers Prior to Transfusion (fill in any available)

Troponin T	◯ ng/mL ◯ ng/L
Troponin T (ng/mL)	_____ (ng/mL)
Troponin T (ng/L)	_____ (ng/L)
Troponin I	◯ ng/mL ◯ ng/L
Troponin I (ng/mL)	_____ (ng/mL)

Troponin I (ng/L)

_____
(ng/L)

NT-proBNP (pg/mL)

_____
(pg/mL)

Creatinine (mg/dL)

_____
(mg/dL)

Blood Urea Nitrogen (BUN) (mg/dL)

_____
(mg/dL)

C Reactive Protein (CRP)

◯ mg/L
◯ mg/dL

C Reactive Protein (CRP) (mg/L)

_____
(mg/L)

C Reactive Protein (CRP) (mg/dL)

_____
(mg/dL)

Ferritin

◯ ng/ml
◯ mcg/L

Ferritin (ng/ml)

_____
(ng/ml)

Ferritin (mcg/L)

_____
(mcg/L)

IL-6 (pg/mL)

_____
(pg/mL)

COVID-19 Symptoms at Time of Enrollment

COVID-19 symptoms at time of enrollment (Optional)	☐ Shortness of breath ☐ Chills ☐ Fatigue ☐ Myalgia ☐ Fever ☐ Sore throat ☐ Dry cough ☐ Headache ☐ Dizziness/light-headedness ☐ Loss of smell/taste (anosmia/dysgeusia) ☐ Stomach/abdominal pain ☐ Nausea ☐ Vomiting (emesis) ☐ Diarrhea ☐ Decreased appetite (Anorexia) ☐ Palpitations ☐ Chest discomfort ☐ Chest discomfort/pain (Angina) ☐ Myocarditis ☐ Other ☐ Unknown ☐ None
Other COVID-19 Symptoms	_____

Patient Status Prior to Transfusion Note: If you are awaiting plasma or not ready to transfuse, you may leave this section blank and return to complete this section later

Was the patient in the ICU prior to transfusion?	◯ Yes ◯ No
What date was patient admitted to ICU prior to transfusion?	_____
Was the patient given supplemental oxygen prior to transfusion?	◯ Yes ◯ No
What date was the patient was given supplemental oxygen prior to transfusion?	_____
Was the patient mechanically ventilated prior to transfusion?	◯ Yes ◯ No
What date was patient placed on mechanical ventilation prior to transfusion?	_____
Number of days from symptom onset to plasma transfusion	_____
Number of days in hospital prior to plasma transfusion	_____
Number of days in ICU prior to plasma transfusion	_____
Number of days patient was on mechanical ventilation prior to plasma transfusion	_____

Highest level of hospital respiratory support prior to transfusion	◯ Oxygen supplementation ◯ Non-Invasive Positive-Pressure Ventilation NIPPV (e.g. CPAP, BiPAP, high-flow nasal cannulation) ◯ Mechanical ventilation/intubation ◯ Extra Corporeal Membrane Oxygenation (ECMO) ◯ None

Plasma from "Outside" Source

Was convalescent plasma administered from a source "Outside" of the EAP? Example: Patient received plasma under an eIND.	◯ Yes ◯ No
When was convalescent plasma administered from a source "Outside" of the EAP?	_____
How much convalescent plasma was administered from a source "Outside" of the EAP (mL)?	_____

If you would like to leave sections of this form incomplete for now to return later, please do the following:

1. Select "Submit" below and then select "Okay" on the incomplete alert pop-up. Your data WILL be saved despite the form not registering as complete.

2. Return to your survey queue via the following link: [survey-queue-link]

Patient Status Update

Thank you for participating in the Expanded Access Program.

The purpose of this form is to collect brief daily status updates on the patient referenced below. We will send you a daily email reminder with the link to your queue and a reminder to fill out an additional day unless you opt-out on the final page of this form.

Please verify the information below and select a date to provide your patient status update.

Patient Information

Physician Last Name: [pi_lastname]

Patient Code: [record_id]
Patient Medical Record Number: [mrn]
Patient First Name: [name_first]
Patient Last Name: [last_name]
Patient Date of Birth: [enroll_dateofbirth]

Patient Enrollment Date: [informed_date]

Patient Initial Status: [psu_initial_status]

Selection Date

Patient Status Selection Date

Please select the date for which you would like to update the patient status.	_____ (Select the "Today" button if you are providing today's status update. Otherwise, select a previous date to provide an update for a previous day.)
Has the patient received convalescent plasma in the past 24 hours?	◯ Yes ◯ No

Patient Initial Status as of [informed_date]: [psu_initial_status] Please provide patient status updates for [selection_date_psu] below.

Was the patient in the ICU on [selection_date_psu]?	◯ Yes ◯ No
Was the patient on a ventilator on [selection_date_psu]?	◯ Yes ◯ No
How did the condition of the patient change on [selection_date_psu]?	◯ Patient Died ◯ Patient Condition Worsened ◯ Patient Condition Remained the Same ◯ Patient Condition Improved ◯ Patient Discharged from Hospital ◯ Patient Condition Unknown

If you have not already done so, please fill out a Serious Adverse Event Report and complete the End of Study Form for this patient.

If you have not already done so, please complete the End of Study Form for this patient.

Daily Patient Status Update Email Reminders Preference

Would you like to opt-out of the daily reminder emails for the status updates on this patient?

Please select "Yes" if your patient has died, been discharged, or you no longer wish to receive the reminder for other reasons.

- ◯ No, I would like to continue to receive daily reminders to provide the status update
- ◯ Yes, I want to STOP receiving reminders to complete the status update

Plasma Transfusion Form

Thank you for participating in the 4 hour post-transfusion Initial Data Collection Form: US Expanded Access Program for Convalescent Plasma for the Treatment of Patients with COVID-19.

NOTE: Mayo Clinic will serve as the IRB of record. You are required by Federal Regulation to report Serious Adverse Events (SAEs) on SAE Report Form.

Please fill in the form with as much detail as possible.

This form is for Patient Code: [record_id]

The purpose of the study is to provide access to investigational convalescent plasma for patients in acute care facilities infected with SARS-CoV-2 who have severe or life-threatening COVID-19, or who are judged by a healthcare provider to be at high risk of progression to severe or life-threatening disease.

Information, protocol, consent forms, site registration, and enrollment forms are available at www.USCOVIDplasma.org.

If you have any questions or difficulties please email USCOVIDplasma@mayo.edu, which will be monitored from 7am-7pm CST.

Patient Information

Patient Code: [record_id]

Patient's Last Name: [last_name]

Patient's First Name: [name_first]

Patient MRN: [mrn]

Patient's Date of Birth: [enroll_dateofbirth]

Is the above patient information correct?

◯ Yes
◯ No

Please find the correct patient survey link in your email.
If you cannot find the correct link send an email to uscovidplasma@mayo.edu

Local Physician/PI and Other Support Person Information

Local Physician/PI Last Name: [pi_lastname]

Local Physician/PI Email: [physician_email]

Office Nurse/Research Coordinator/Other Support Person Last Name: [coordinator_last]

Office Nurse/Research Coordinator/Other Support Person First Name: [coord_first]

Office Nurse/Research Coordinator/Other Support Person Email: [coord_email]

Additional Contact Position: [contact_pos1]

Last Name: [contact_lastname1]

First Name: [contact_firstname1]

Email: [contact_email1]

Additional Contact Position: [contact_pos2]

Last Name: [contact_lastname2]

First Name: [contact_firstname2]

Email: [contact_email2]

Additional Contact Position: [contact_pos3]

Last Name: [contact_lastname3]

First Name: [contact_firstname3]

Email: [contact_email3]

Additional Contact Position: [contact_pos4]

Last Name: [contact_lastname4]

First Name: [contact_firstname4]

Email: [contact_email4]

Additional Contact Position: [contact_pos5]

Last Name: [contact_lastname5]

First Name: [contact_firstname5]

Email: [contact_email5]

Is your name/email listed in the above Physician/PI and Other Support Person Information?

◯ Yes
◯ No

If your name/email is not listed, please complete Additional Contact form for further email correspondence upon completion of this form.

Plasma Transfusion Information

Was plasma transfusion given to the patient?

◯ Yes
◯ No

Please return to this form when you have administered plasma to your patient.

If you no longer intend to administer plasma, please complete the "Death/Discharge/No Transfusion" form.

Date of plasma transfusion

_____
(MM-DD-YYYY (ex. 04-02-2020))

Start of transfusion Time (local time)

_____
(Please use 24-Hour Time (ex. 19:00))

Was transfusion started and then stopped prematurely?

You must complete the rest of the questions in this form even if the transfusion was stopped early.

- ◯ Yes
- ◯ No

Why was the transfusion stopped prematurely?

- ◯ Less than severe allergic transfusion reaction (NOT requiring medical intervention)
- ◯ Other reason

Please specify reason transfusion was stopped prematurely

_____

How many units of plasma were given to the patient being reported on this transfusion form?

Note: Two units within a 12 hour window can be reported on this transfusion form

- ◯ 1
- ◯ 2

How many hours between the two units of plasma?

_____

With more than 12 hours between units of plasma, this should be recorded as a separate transfusion.

Please select 1 unit above and fill out a separate transfusion form from your survey queue for the additional transfusion.

Total volume of plasma transfused (mL)

_____
(mL)

Notes on multiple transfusions (i.e. approved by FDA or possible deviation)

_____

What was the source of the plasma?

Note: Specific Center should be listed on plasma unit bag

- ◯ American Red Cross (ARC)
- ◯ Vitalant
- ◯ OneBlood
- ◯ America's Blood Centers (ABC)
- ◯ Medical Center/Hospital blood bank
- ◯ City/region-wide blood bank

Select City/Region-wide Blood Bank

◯ Other City/Region-wide Blood Bank
◯ Appelton Blood Bank
◯ Atlanta Blood Services
◯ Aurora/Versiti
◯ Banco de Sangre de Servicios Mutuos, Inc.
◯ Blood Assurance
◯ Blood Bank of Alaska
◯ Blood Bank of Delmarva
◯ Blood Bank of Hawaii
◯ Blood Connection
◯ Bloodworks
◯ Bloodworks Northwest
◯ Carter Blood Bank
◯ Carter BloodCare
◯ Cascade Regional Blood Services
◯ CBC-Dayton
◯ Central California Blood Center
◯ Central Pennsylvania Blood Bank
◯ Children's Hospital Colorado
◯ Coastal Bend Blood Center
◯ Community Blood Bank of NWPA and WNY
◯ Community Blood Center of Kansas City
◯ Community Blood Center of the Ozarks
◯ Community Blood Center, Appleton
◯ Delmarva/Blood Bank of Delmarva
◯ Gulf Coast Regional Blood Center
◯ Hoxworth Blood Center
◯ Innovative Blood Resources
◯ Inova Blood Donor Services
◯ Kentucky Blood Center
◯ LIFELINE Blood Services
◯ LifeServe Blood Center
◯ LifeShare Blood Center
◯ LifeSouth Community Blood Centers, Inc.
◯ LifeStream
◯ MEDIC Regional Blood Center
◯ Memorial Blood Centers
◯ Miller Keystone Blood Center
◯ Mississippi Blood Services
◯ Mississippi Valley Regional Blood Center
◯ New York Blood Center (NYBC)
◯ Oklahoma Blood Institute
◯ Rhode Island Blood Center
◯ Rock River Valley Blood Center
◯ Roswell Park Cancer Institute Blood Bank
◯ San Diego Blood Bank
◯ Shepeard Community Blood Center
◯ South Bend Medical Foundation
◯ South Texas Blood and Tissue Center
◯ St. Mary's Blood Center
◯ Stanford Blood Center
◯ Suncoast Blood Bank
◯ The Blood Connection
◯ The Blood Center (New Orleans)
◯ UNC Blood Donation Center
◯ Versiti
◯ We Are Blood
◯ Western KY Regional Blood Center

Name of City/Region-wide Blood Bank

_____

Standard Plasma Label for your reference to identify the correct plasma number

[Attachment: "plasma_label.JPG"]

Plasma Unit Identifying Number

_____
(Entry should be W followed by numbers (ex. W0368 20 173804))

Donor Plasma Unit ABO-type

◯ A+
◯ AB+
◯ B+
◯ O+
◯ A-
◯ AB-
◯ B-
◯ O-
◯ Low Anti-A Titer Group O

Second Plasma Unit Identified Number

_____
(Entry should be W followed by numbers (ex. W0368 20 173804))

Second Donor Plasma Unit ABO-type

◯ A+
◯ AB+
◯ B+
◯ O+
◯ A-
◯ AB-
◯ B-
◯ O-
◯ Low Anti-A Titer Group O

Serious Adverse Events

1=Death 2=Transfusion related acute lung injury (TRALI) 3=Transfusion related circulatory overload (TACO) 4=Transfusion related infection 5=Severe allergic transfusion reaction (requiring medical intervention other than antihistamines) 6=Severe hemolytic transfusion reaction (requiring medical intervention) 7=Severe anaphylactic reaction 8=VF ventricular arrhythmia requiring treatment 9=VT ventricular arrhythmia requiring treatment 10=Atrial arrhythmia requiring treatment 11=Atrial fibrillation requiring treatment 12=Cardiac arrest 13=Need for ECMO or ventricular assistance 14=Thromboembolic or thrombotic complication 15=Need for ICU transfer (since transfusion) 16=Need for increased oxygen support (since transfusion) 17=Need for mechanical ventilation (since transfusion) 18=Development of sustained low blood pressure (SBP < 80 or need for IV pressure support in estimation of treating physicians) 99=Other SAE not listed

Are there any of the above SAEs to report within 4 hours of transfusion?

◯ Yes
◯ No

If yes, please report all SAEs on the Serious Adverse Events form

Serious Adverse Event Report

Thank you for completing a Serious Adverse Event Report Form for the US Expanded Access Program for Convalescent Plasma for the Treatment of Patients with COVID-19.

NOTE: You are required by Federal Regulation to report Serious Adverse Events (SAEs) utilizing this form.

Please fill out one form for each SAE that occurs in as much detail as possible.

This form is unique to Patient Code: [record_id]

Information, protocol, consent forms, site registration, and enrollment forms are available at www.USCOVIDplasma.org.

If you have any questions or difficulties please email USCOVIDplasma@mayo.edu, which will be monitored from 7am-7pm CST.

Patient Information

Patient Code: [record_id]

Patient's Last Name: [last_name]

Patient's First Name: [name_first]

Gender of Patient: [enroll_gender_patient]

Patient's Date of Birth: [enroll_dateofbirth]

Date of First Plasma Transfusion: [date_infusion][first-instance]

Local Physician/PI and Other Support Person Information

Local Physician/PI Last Name: [pi_lastname]

Local Physician/PI Email: [physician_email]

Office Nurse/Research Coordinator/Other Support Person Last Name: [coordinator_last]

Office Nurse/Research Coordinator/Other Support Person First Name: [coord_first]

Office Nurse/Research Coordinator/Other Support Person Email: [coord_email]

Additional Contact Position: [contact_pos1]

Last Name: [contact_lastname1]

First Name: [contact_firstname1]

Email: [contact_email1]

Additional Contact Position: [contact_pos2]

Last Name: [contact_lastname2]

First Name: [contact_firstname2]

Email: [contact_email2]

Additional Contact Position: [contact_pos3]

Last Name: [contact_lastname3]

First Name: [contact_firstname3]

Email: [contact_email3]

Additional Contact Position: [contact_pos4]

Last Name: [contact_lastname4]

First Name: [contact_firstname4]

Email: [contact_email4]

Additional Contact Position: [contact_pos5]

Last Name: [contact_lastname5]

First Name: [contact_firstname5]

Email: [contact_email5]

Is your name/email listed in the above Physician/PI and Other Support Person Information?

◯ Yes
◯ No

If your name/email is not listed, please provide additional contact information below for further email correspondence.

Serious Adverse Events (SAEs) after transfusion (expect sponsor follow up):

1=Death 2=Transfusion related acute lung injury (TRALI) 3=Transfusion related circulatory overload (TACO) 4=Transfusion related infection 5=Severe allergic transfusion reaction (requiring medical intervention other than antihistamines) 6=Severe hemolytic transfusion reaction (requiring medical intervention) 7=Severe anaphylactic reaction 8=VF ventricular arrhythmia requiring treatment 9=VT ventricular arrhythmia requiring treatment 10=Atrial arrhythmia requiring treatment 11=Atrial fibrillation requiring treatment 12=Cardiac arrest 13=Need for ECMO or ventricular assistance 14=Thromboembolic or thrombotic complication 15=Need for ICU transfer (since transfusion) 16=Need for increased oxygen support (since transfusion) 17=Need for mechanical ventilation (since transfusion) 18=Development of sustained low blood pressure (SBP < 80 or need for IV pressure support in estimation of treating physicians) 99=Other SAE not listed

Select the Serious Adverse Event (SAE) that occurred	☐ Death ☐ TRALI ☐ TACO ☐ Transfusion related infection ☐ Severe allergic transfusion reaction ☐ Severe hemolytic transfusion reaction ☐ Severe anaphylactic reaction ☐ VF ventricular arrhythmia ☐ VT ventricular arrhythmia ☐ Atrial arrhythmia ☐ Atrial fibrillation ☐ Cardiac arrest ☐ Need for ECMO or ventricular assistance ☐ Thromboembolic or thrombotic complication ☐ Need for ICU transfer ☐ Need for increased oxygen support ☐ Need for mechanical ventilation ☐ Development of sustained low blood pressure (SBP < 80 or need for IV pressure support in estimation of treating physicians) ☐ Other SAE not listed
Briefly state what the other SAE not listed is (example: seizure)	_____
SAE Onset Date	_____ (MM-DD-YYYY (ex. 04-02-2020))
Time of SAE Onset (if known)	_____ (Please use 24-Hour Time (ex. 19:00))
Did the SAE occur within 4 hours of transfusion?	◯ Yes ◯ No
Category of the SAE	◯ Limiting self-care or other disabling event ◯ Hospitalization or prolongation of hospitalization indicated ◯ Life-threatening, urgent intervention required ◯ Other important medical event ◯ Significant disability
Relationship to Expanded Access Treatment (assessed by Treating Physician)	◯ Not related ◯ Possibly related ◯ Probably related ◯ Definitely related
Was the SAE unexpected?	◯ Yes ◯ No
What was the outcome of the SAE?	◯ Resolved with no sequelae ◯ Resolved with sequelae ◯ Ongoing ◯ Severity change ◯ Death

After completion of this report, please submit an "Death Report Form" to report the death of this patient.

Date local physician/PI was made aware?

_____
(MM-DD-YYYY (ex. 04-02-2020))

Is blood bank report on the transfusion reaction available?

◯ Yes
◯ No

Please email the blood bank report to USCOVIDplasma@mayo.edu

Brief description of the nature of the Serious Adverse Event (SAE)

_____

List or describe medications and/or actions

If none, state "None"

_____

List any relevant tests, laboratory data, history: (May include preexisting medical conditions)

If none, state "None"

_____

Full Name of Local Physician/PI (Electronic Signature)

_____

Date (Electronic Signature)

_____
(MM-DD-YYYY (ex. 04-05-2020))

Serious Adverse Event Resolution

Please complete the survey below.

Thank you!

SAE Data Provided

SAE type: [sae][current-instance]

SAE Start Date: [event_start_sae][current-instance]
SAE Start Time (if given): [onset_time_sae][current-instance]

SAE Resolution Data

Has the SAE been resolved?

◯ Yes
◯ No

SAE Resolution Date

_____
(MM-DD-YYYY (ex. 04-02-2020))

Time of SAE Resolution (if known)

_____
(Please use 24-Hour Time (ex. 19:00))

Please return by selecting "Edit Response" in your survey queue when this SAE is resolved. Thank you.

Discharge/No Transfusion Report Form

Thank you for participating in the Expanded Access Program.

If you have any questions or difficulties please email USCOVIDplasma@mayo.edu, which will be monitored from 7am-7pm CST.

Patient Information

Patient Code: [record_id]

Patient's Last Name: [last_name]

Patient's First Name: [name_first]

Gender of Patient: [enroll_gender_patient]

Patient's Date of Birth: [enroll_dateofbirth]

Date of First Plasma Transfusion: [date_infusion][first-instance]

Local Physician/PI and Other Support Person Information

Local Physician/PI Last Name: [pi_lastname]

Local Physician/PI Email: [physician_email]

Office Nurse/Research Coordinator/Other Support Person Last Name: [coordinator_last]

Office Nurse/Research Coordinator/Other Support Person First Name: [coord_first]

Office Nurse/Research Coordinator/Other Support Person Email: [coord_email]

Additional Contact Position: [contact_pos1]

Last Name: [contact_lastname1]

First Name: [contact_firstname1]

Email: [contact_email1]

Additional Contact Position: [contact_pos2]

Last Name: [contact_lastname2]

First Name: [contact_firstname2]

Email: [contact_email2]

Additional Contact Position: [contact_pos3]

Last Name: [contact_lastname3]

First Name: [contact_firstname3]

Email: [contact_email3]

Additional Contact Position: [contact_pos4]

Last Name: [contact_lastname4]

First Name: [contact_firstname4]

Email: [contact_email4]

Additional Contact Position: [contact_pos5]

Last Name: [contact_lastname5]

First Name: [contact_firstname5]

Email: [contact_email5]

Is your name/email listed in the above Physician/PI and Other Support Person Information?	◯ Yes ◯ No

If your name/email is not listed, please complete Additional Contact form for further email correspondence upon completion of this form.

End of Study

End of study date	_____
End of study reason	◯ Plasma not ordered ◯ Plasma not given ◯ Discharged from hospital
Explain the circumstances for why the plasma was not given. (Select all that apply)	◯ Medical team or blood bank advised not to transfused ◯ Patient improved and transfusion was clinically unwarranted ◯ Patient deteriorated ◯ Patient died ◯ Plasma not available ◯ Patient discharged or transferred ◯ Patient or LAR declined plasma transfusion ◯ Other
Other reason why plasma transfusion was not administered	_____
Discharge date	_____
Please provide any additional information regarding conditions of discharge or follow-up (optional).	_____

Patient Condition Prior to Transfusion

Prior to Transfusion the patient had the following conditions:

Admission into the ICU

Oxygen supplementation

Mechanical Ventilation

Please update the improvement of the patient's condition.

Was the patient discharged from ICU?
◯ Yes
◯ No

When was the patient discharged from ICU?
_____

Was the supplemental oxygen requirement reduced?
◯ Yes
◯ No

When was the supplemental oxygen requirement reduced?
_____

Was the patient removed from mechanical ventilation?
◯ Yes
◯ No

When was the patient removed from mechanical ventilation?
_____

Additional Improvement Outcomes

Additional Primary Improvement Outcomes

(Select all that apply)

☐ Resolution of Acute Respiratory Distress Syndrome (ARDS) as judged by physician (if applicable)
☐ COVID-19 symptom improvement
☐ SARS-CoV-2 PCR negative
☐ None

When did ARDS resolve?
_____

When did the patient's symptoms improve?
_____

When did the patient test negative for SARS-CoV-2 by PCR?
_____

Re-Hospitalization Form

Thank you for participating in the Expanded Access Program.

Please fill in the form with as much detail as possible.

The day of transfusion is considered day zero.

This form is unique to Patient Code: [record_id]

Information, protocol, consent forms, site registration, and enrollment forms are available at www.USCOVIDplasma.org.

If you have any questions or difficulties please email USCOVIDplasma@mayo.edu, which will be monitored from 7am-7pm CST.

Patient Information

Patient Code: [record_id]

Patient's Last Name: [last_name]

Patient's First Name: [name_first]

Gender of Patient: [enroll_gender_patient]

Patient's Date of Birth: [enroll_dateofbirth]

Date of First Plasma Transfusion: [date_infusion][first-instance]

Local Physician/PI and Other Support Person Information

Local Physician/PI Last Name: [pi_lastname]

Local Physician/PI Email: [physician_email]

Office Nurse/Research Coordinator/Other Support Person Last Name: [coordinator_last]

Office Nurse/Research Coordinator/Other Support Person First Name: [coord_first]

Office Nurse/Research Coordinator/Other Support Person Email: [coord_email]

Additional Contact Position: [contact_pos1]

Last Name: [contact_lastname1]

First Name: [contact_firstname1]

Email: [contact_email1]

Additional Contact Position: [contact_pos2]

Last Name: [contact_lastname2]

First Name: [contact_firstname2]

Email: [contact_email2]

Additional Contact Position: [contact_pos3]

Last Name: [contact_lastname3]

First Name: [contact_firstname3]

Email: [contact_email3]

Additional Contact Position: [contact_pos4]

Last Name: [contact_lastname4]

First Name: [contact_firstname4]

Email: [contact_email4]

Additional Contact Position: [contact_pos5]

Last Name: [contact_lastname5]

First Name: [contact_firstname5]

Email: [contact_email5]

Is your name/email listed in the above Physician/PI and Other Support Person Information?
◯ Yes
◯ No

If your name/email is not listed, please complete Additional Contact form for further email correspondence upon completion of this form.

Hospitalization Information

Was the patient re-hospitalized after the discharge that was reported on the End of Study Form
◯ Yes
◯ No

This form is only required if the patient is re-hospitalized. Please exit this form.

You may return to the survey queue at this link - [survey-queue-link]

When was the patient re-hospitalized?

_____

Why was the patient re-hospitalized?

_____

Since re-hospitalization, has the patient ever been in the ICU?
◯ Yes
◯ No

When was the patient admitted to the ICU?

_____

Since re-hospitalization, was the patient given supplemental oxygen?
◯ Yes
◯ No

When was the patient given supplemental oxygen?

_____

Since re-hospitalization, was the patient ever on mechanical ventilation?
◯ Yes
◯ No

When was the patient placed on mechanical ventilation?	_____
Highest level of hospital respiratory support since re-hospitalization?	◯ Oxygen Supplementation ◯ Non-Invasive Positive-Pressure Ventilation NIPPV (e.g. CPAP, BiPAP, high-flow nasal cannulation) ◯ Mechanical ventilation/intubation ◯ Extra Corporeal Membrane Oxygenation (ECMO) ◯ None
Since re-hospitalization, has the patient been administered additional plasma?	◯ No, NOT PLANNING to administer additional plasma ◯ No, but PLANNING to administer additional plasma ◯ Yes, additional plasma has been administered

Please submit this form and return to the queue to fill out an additional transfusion form for this patient when plasma is administered

Please submit this form and fill out an additional end of study form now available in your survey queue.

Death Report Form

Please complete the survey below.

Thank you!

Patient Information

Patient Code: [record_id]

Patient's Last Name: [last_name]

Patient's First Name: [name_first]

Patient MRN: [mrn]

Patient's Date of Birth: [enroll_dateofbirth]

Date of First Plasma Transfusion: [date_infusion][first-instance]

Local Physician/PI and Other Support Person Information

Local Physician/PI Last Name: [pi_lastname]

Local Physician/PI Email: [physician_email]

Office Nurse/Research Coordinator/Other Support Person Last Name: [coordinator_last]

Office Nurse/Research Coordinator/Other Support Person First Name: [coord_first]

Office Nurse/Research Coordinator/Other Support Person Email: [coord_email]

Additional Contact Position: [contact_pos1]

Last Name: [contact_lastname1]

First Name: [contact_firstname1]

Email: [contact_email1]

Additional Contact Position: [contact_pos2]

Last Name: [contact_lastname2]

First Name: [contact_firstname2]

Email: [contact_email2]

Additional Contact Position: [contact_pos3]

Last Name: [contact_lastname3]

First Name: [contact_firstname3]

Email: [contact_email3]

Additional Contact Position: [contact_pos4]

Last Name: [contact_lastname4]

First Name: [contact_firstname4]

Email: [contact_email4]

Additional Contact Position: [contact_pos5]

Last Name: [contact_lastname5]

First Name: [contact_firstname5]

Email: [contact_email5]

Is your name/email listed in the above Physician/PI and Other Support Person Information?

◯ Yes
◯ No

If your name/email is not listed, please complete Additional Contact form for further email correspondence upon completion of this form.

Patient Death Information

Did the patient pass away?

◯ Yes
◯ No

This form is only to intended to be filled out if the patient has died. If your patient has been discharged, please return to the survey queue below and select the Discharge/No Transfusion Form. Thank you.

Survey Queue Link: [survey-queue-url]

Date of Death

_____
(MM-DD-YYYY (ex. 04-03-2020))

Presumed or Known Cause of Death

_____

Additional Contacts (optional)

Thank you for your desire to participate in the US Expanded Access Program for Convalescent Plasma for the Treatment of Patients with COVID-19!

Information, protocol, consent forms, site registration, and enrollment forms are available at www.USCOVIDplasma.org.

If you have any questions or difficulties enrolling please email USCOVIDplasma@mayo.edu, which will be monitored from 7am-7pm CST.

Local Physician/PI Last Name: [pi_lastname]

Local Physician/PI Email: [physician_email]

Office Nurse/Research Coordinator/Other Support Person Last Name: [coordinator_last]

Office Nurse/Research Coordinator/Other Support Person First Name: [coord_first]

Office Nurse/Research Coordinator/Other Support Person Email: [coord_email]

Additional Contact

Do you need to add another contact at this time?	◯ Yes ◯ No
Additional Contact Position	◯ Physician ◯ Office Nurse/Research Coordinator/Other Support Person
Additional Contact Last Name	_____
Additional Contact First Name	_____
Additional Contact Phone Number	_____
Additional Contact Email	_____
Confirm Additional Contact Email (type email address again)	_____

E-mail addresses do not match (please correct)

Additional Contact

Do you need to add another contact at this time?	◯ Yes ◯ No
Additional Contact Position	◯ Physician ◯ Office Nurse/Research Coordinator/Other Support Person
Additional Contact Last Name	_____
Additional Contact First Name	_____
Additional Contact Phone Number	_____
Additional Contact Email	_____
Confirm Additional Contact Email (type email address again)	_____
E-mail addresses do not match (please correct)	

Additional Contact

Do you need to add another contact at this time?	◯ Yes ◯ No
Additional Contact Position	◯ Physician ◯ Office Nurse/Research Coordinator/Other Support Person
Additional Contact Last Name	_____
Additional Contact First Name	_____
Additional Contact Phone Number	_____
Additional Contact Email	_____
Confirm Additional Contact Email (type email address again)	_____
E-mail addresses do not match (please correct)	

Additional Contact

Do you need to add another contact at this time?	◯ Yes ◯ No
Additional Contact Position	◯ Physician ◯ Office Nurse/Research Coordinator/Other Support Person
Additional Contact Last Name	_____
Additional Contact First Name	_____
Additional Contact Phone Number	_____
Additional Contact Email	_____
Confirm Additional Contact Email (type email address again)	_____
E-mail addresses do not match (please correct)	

Additional Contact

Do you need to add another contact at this time?	◯ Yes ◯ No
Additional Contact Position	◯ Physician ◯ Office Nurse/Research Coordinator/Other Support Person
Additional Contact Last Name	_____
Additional Contact First Name	_____
Additional Contact Phone Number	_____
Additional Contact Email	_____
Confirm Additional Contact Email (type email address again)	_____
E-mail addresses do not match (please correct)	