Patient Follow-Up Questions

Please complete the following information about the patient.

You can use the [survey-queue-link:survey queue button] at the top right of the screen to navigate back to previous forms if needed.

The unique Subject ID for this patient is

[record-name]

Please record this Subject ID and maintain the link to your patient until notified by the coordinating center that the link can be destroyed. The coordinating center will use the Subject ID to reference your patient since no PHI maybe shared outside of your institution.

Day 0 is defined as the collection date of first positive COVID-19 diagnostic test.

Please answer the following questions for HCT Patients

What was the HCT donor's CMV serostatus?

- ◯ Negative
- ◯ Positive
- ◯ Equivocal or Indeterminate
- ◯ Unknown

What post-transplant primary disease prophylaxis or therapy other than systemic steroids (e.g., GvHD) did the patient receive? Select all that apply.

- ☐ Tyrosine kinase inhibitor (TKI)
- ☐ Azacitidine
- ☐ Sorafenib
- ☐ Decitabine
- ☐ Brentuximab
- ☐ CART cells
- ☐ Donor lymphocyte infusion
- ☐ Cytotoxic T cells
- ☐ Rituximab
- ☐ Other
- ☐ Not available or Unknown

Did the patient have acute or chronic GvHD at the time of COVID-19 diagnosis?

- ◯ Yes - Acute
- ◯ Yes - Chronic
- ◯ No
- ◯ Unknown

If Acute GvHD, please review the organ systems below and select the maximum acute GvHD grade or if the patient did not have GvHD involved for that organ system?

	Grade 1	Grade 2	Grade 3	Grade 4	None or not involved
Skin	◯	◯	◯	◯	◯
Liver	◯	◯	◯	◯	◯
GI Tract	◯	◯	◯	◯	◯
Other	◯	◯	◯	◯	◯

If Chronic GvHD, please review the organ systems below and select the maximum chronic GvHD grade or if the patient did not have GvHD involved for that organ system?

	Grade 1	Grade 2	Grade 3	Grade 4	None or not involved
Skin	◯	◯	◯	◯	◯
Nails	◯	◯	◯	◯	◯
Vulva or Vagina	◯	◯	◯	◯	◯
Eyes	◯	◯	◯	◯	◯
Hair	◯	◯	◯	◯	◯
Mouth	◯	◯	◯	◯	◯
Salivary Gland	◯	◯	◯	◯	◯
Respiratory tract	◯	◯	◯	◯	◯
Gastrointestinal	◯	◯	◯	◯	◯
Liver	◯	◯	◯	◯	◯
Musculoskeletal	◯	◯	◯	◯	◯
Immune system	◯	◯	◯	◯	◯
Serositis	◯	◯	◯	◯	◯
Hematopoietic system	◯	◯	◯	◯	◯
Other	◯	◯	◯	◯	◯

Please answer the following questions for Cellular Therapy patients

Did the patient receive commercial or investigational CARTx product?

◯ Commercial
◯ Investigational
◯ Unknown

CARTx drug name

◯ Yescarta
◯ Kymriah
◯ Other
◯ Unknown

If Other, specify

_____

Cellular therapy conditioning regimen

◯ Cyclophosphamide and Fludarabine
◯ Other
◯ Unknown

If Other, specify

_____

Other protocol-driven combination therapies to boost cellular therapy efficiency? E.g., PD1 inhibitors, ibrutinib, T-APCs (PLAT-03).	◯ Yes ◯ No ◯ Unknown
If Yes, please list	_____
Did the patient develop cytokine release syndrome (CRS)?	◯ Yes ◯ No ◯ Unknown
If Yes, what was the CRS severity (ASTCT criteria)?	◯ 1 ◯ 2 ◯ 3 ◯ 4 ◯ 5 ◯ Unknown
When did CRS occur?	◯ After COVID-19 diagnosis ◯ 0 to 2 weeks prior to COVID-19 diagnosis ◯ 3 to 4 weeks prior to COVID-19 presentation ◯ 5 to 12 weeks prior to COVID-19 presentation ◯ 13 weeks or more prior to COVID-19 presentation
CRS treatment (select all that apply)	☐ Steroids ☐ Tocilizumab ☐ Other ☐ Unknown
If Other, specify	_____
Did the patient develop neurotoxicity after cellular therapy?	◯ Yes ◯ No ◯ Unknown
If yes, neurotoxicity severity (immune effector cell-associated neurotoxicity syndrome - ASTCT criteria) - maximum	◯ 1 ◯ 2 ◯ 3 ◯ 4 ◯ 5 ◯ Unknown
When did neurotoxicity occur?	◯ After COVID-19 diagnosis ◯ 0 to 2 weeks prior to COVID-19 diagnosis ◯ 3 to 4 weeks prior to COVID-19 presentation ◯ 5 to 12 weeks prior to COVID-19 presentation ◯ 13 weeks or more prior to COVID-19 presentation
Did the patient ever have HCT prior to most recent CT?	◯ Yes ◯ No ◯ Unknown
Number of transplants prior to most recent CT?	◯ 1 ◯ 2 ◯ 3 ◯ 4 ◯ 5 ◯ Unknown

Thank you for continuing the survey. Please press submit to proceed

Please answer the following questions for Immunocompromised Patients

Was the patient's chemotherapy modified or delayed due to COVID-19? (Check all that apply)

- ☐ No change
- ☐ Modified
- ☐ Delayed
- ☐ Patient was not receiving chemotherapy at the time of COVID-19
- ☐ Unknown

Please answer the following questions for Solid Organ Transplant Patients

Transplant-related outcomes

- ☐ Acute cellular rejection
- ☐ Antibody-mediated rejection
- ☐ Graft dysfunction
- ☐ Graft failure
- ☐ Other
- ☐ None of these

If other, please describe.

_____

Were the patient's immunosuppression medications changed due to COVID-19?

- ◯ Yes
- ◯ No
- ◯ Unknown

What were the changes to the immunosuppression medications?

- ☐ Increased
- ☐ Decreased
- ☐ Discontinued
- ☐ Started
- ☐ Unknown

CMV Infection

Did the patient develop cytomegalovirus reactivation/viremia on or before Day 28?

◯ Yes ◯ No ◯ Unknown

Enter the peak viral load (copies/mL) resulted on or before Day 28.

_____
(copies/mL)

COVID-19 Case Followup Information

Please complete the following information about the patient's COVID-19 case.

This form asks for information up to 28 days after the date of first positive COVID-19 test, so please finalize only if patient has reached Day 28. If you wish complete this survey at a later time, submit this form and follow the link provided in the email to return to the survey.

You can use the [survey-queue-link:survey queue button] at the top right of the screen to navigate back to previous forms if needed.

Please contact Pidtrancoordinators@stjude.org with any questions.

The unique Subject ID for this patient is

[record-name]

Please record this Subject ID and maintain the link to your patient until notified by the coordinating center that the link can be destroyed. The coordinating center will use the Subject ID to reference your patient since no PHI maybe shared outside of your institution.

The following questions are about your patient's COVID-19 episode on or prior to Day 28.

In order for us to gather as much valuable information as possible, some questions may refer to the intial survey period (on or prior to Day 7), Day 8 through Day 28 or both.

Day 0 is defined as the collection date of first positive COVID-19 diagnostic test.

Patient Information

Was the patient ONLY seen at a COVID-19 testing center?	◯ Yes ◯ No
Was the patient diagnosed at another center and referred to your center for care?	◯ Yes ◯ No ◯ Unknown
What is the name of the other center? If you you do not know the name, please leave this field blank. We will use this information to check if this patient has been entered in the registry already.	_____

Does the patient have a history using any of the following? (Check all that apply)	☐ Vaping or E-cigarette ☐ Cigarettes ☐ Cigars ☐ Pipe ☐ Marijuana ☐ Other tobacco products ☐ Other recreational drugs ☐ Unknown ☐ None of the above

The following questions refer to ON OR BEFORE DAY 7

Was testing for COVID-19 performed in the 14 days prior to Day 0?	◯ Yes ◯ No ◯ Unknown (Day 0 is defined as the collection date of first positive Covid-19 diagnostic test.)
If yes, on what day prior to Day 0 was the test collected? For example, if a negative test was collected 5 days prior to Day 0, enter "-5".	_____ (If there are multiple test days, separate each day with a semi-colon.)
Was an oxygen saturation obtained 72 hours prior to Day 0 and up to Day 7?	◯ Yes ◯ No
If yes, what was the lowest oxygen saturation value obtained between - 72 hours through Day 7?	_____ (%)
Was the patient pregnant during their COVID-19 episode?	◯ No or Not Applicable ◯ Yes - 1st trimester ◯ Yes - 2nd trimester ◯ Yes - 3rd trimester

In addition to the symptoms reported in the initial survey, did the patient present any of the following symptoms from - 3 days to Day 7?

	Yes	No	Unknown
Joint Pain	◯	◯	◯

Did the patient present with any of the following between -3 Days through Day 7?
If the patient did present with one of the following, select the day first reported.

	No	Day -3	Day -2	Day -1	Day 0	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Stroke	○	◉	◉	◉	○	○	○	○	○	○	○	○
Encephalitis	○	○	○	○	○	○	○	○	○	○	○	○
Shock	○	○	○	○	○	○	○	○	○	○	○	○
Multi-System Inflammatory Syndrome in Children (MIS-C) | Pediatric Inflammatory Multisystem Syndrome (PIMS)	○	○	○	○	○	○	○	○	○	○	○	○
Kawasaki Syndrome	○	○	○	○	○	○	○	○	○	○	○	○
Sepsis	○	○	○	○	○	○	○	○	○	○	○	○
Disseminated intravenous coagulation (DIC)	○	○	○	○	○	○	○	○	○	○	○	○
ARDS	○	○	○	○	○	○	○	○	○	○	○	○
Pulmonary embolism	○	○	○	○	○	○	○	○	○	○	○	○
Respiratory failure	○	○	○	○	○	○	○	○	○	○	○	○
Thrombotic event (DVT, PE, other) or MIcrothrombotic event	○	○	○	○	○	○	○	○	○	○	○	○
Dermatological manifestations	○	○	○	○	○	○	○	○	○	○	○	○

Briefly describe the thrombotic complication.

_____

Please select the type of dermatological manifestations and the day first reported.

	No	Day -3	Day -2	Day -1	Day 0	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Maculopapular rash	○	◉	◉	◉	○	○	○	○	○	○	○	○
Urticaria	○	○	○	○	○	○	○	○	○	○	○	○
Livedo Reticularia (mottled, lace like discoloration of skin)	○	○	○	○	○	○	○	○	○	○	○	○
Vesicular eruption	○	○	○	○	○	○	○	○	○	○	○	○
COVID toes	○	○	○	○	○	○	○	○	○	○	○	○

Did the patient receive any of the following supportive therapies for COVID-19 from Day -3 to Day 7? If yes, please select the day started.

	No	Day -3	Day -2	Day -1	Day 0	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
ECMO Support	○	◉	◉	◉	○	○	○	○	○	○	○	○
Circulatory support or pressor support	○	○	○	○	○	○	○	○	○	○	○	○
Dialysis or hemodialysis	○	○	○	○	○	○	○	○	○	○	○	○

Are the patient's immunizations up to date for their age at the time of COVID-19 diagnosis?	◯ Yes ◯ No ◯ Unknown
Has the patient received any MMR vaccinations?	◯ 1 dose ◯ 2 doses ◯ 3 doses ◯ Yes, but number of doses unknown ◯ Patient has NOT received any MMR vaccinations ◯ Unknown
Has the patient received the 2020-2021 seasonal influenza vaccine?	◯ No ◯ Yes - 1 dose ◯ Yes - 2 doses ◯ Unknown
Is there any information available in the patient's medical record from Day 8 to Day 28?	◯ Yes ◯ No

The following questions refer to between DAY 8 to DAY 28

Signs and Symptoms

Were any COVID-19 related symptoms reported between Days 8 and 28?	◯ Yes ◯ No

If Yes, please review the following symptoms and check if any were present during any of the following days (up to Day 28). Check all that apply.

	Not Present	Days 8 to 14	Day 15 to 21	Days 22 to 28	Unknown
Fever >100.4 ? (38.0 C)	☐	☐	☐	☐	☐
Muscle aches (myalgia)	☐	☐	☐	☐	☐
Headache	☐	☐	☐	☐	☐
Eye redness (conjunctivitis)	☐	☐	☐	☐	☐
Runny nose (rhinorrhea)	☐	☐	☐	☐	☐
Sore throat	☐	☐	☐	☐	☐
Cough (new onset or worsening of chronic cough)	☐	☐	☐	☐	☐
Bloody sputum (hemoptysis)	☐	☐	☐	☐	☐
Shortness of breath (dyspnea)	☐	☐	☐	☐	☐
Wheezing	☐	☐	☐	☐	☐
Apnea	☐	☐	☐	☐	☐
Chest pain	☐	☐	☐	☐	☐
Abdominal pain	☐	☐	☐	☐	☐
Nausea	☐	☐	☐	☐	☐
Vomiting	☐	☐	☐	☐	☐
Diarrhea (>3 loose/looser than normal stools/24hr period)	☐	☐	☐	☐	☐
Seizures	☐	☐	☐	☐	☐
Loss of smell	☐	☐	☐	☐	☐
Loss of taste	☐	☐	☐	☐	☐
Decreased oral intake	☐	☐	☐	☐	☐
Lethargy	☐	☐	☐	☐	☐
Hypothermia	☐	☐	☐	☐	☐
Joint pain	☐	☐	☐	☐	☐
lymphadenopathy	☐	☐	☐	☐	☐
Altered mental status	☐	☐	☐	☐	☐

Other symptoms reported that were not listed above? ◯ Yes ◯ No

If Yes, please describe.

_____

Did the patient present with any of the following between Day 8 and 28? Check all that apply.	☐ Stroke ☐ Encephalitis ☐ Thrombotic event or microthrombotic event ☐ Shock ☐ MIS-C or PIMS ☐ Kawasaki Syndrome ☐ Maculopapular Rash ☐ Urticaria ☐ Livedo Reticularis (mottled, lace like discoloration of skin) ☐ Vesicular Eruption ☐ COVID Toes ☐ Sepsis ☐ DIC ☐ ARDS ☐ Pulmonary embolism ☐ Respiratory failure ☐ None of the above
Day patient presented with Stroke	_____
Day patient presented with Encephalitis.	_____
Day patient presented with thrombotic event or microthrombotic event	_____
Briefly describe the thrombotic event.	_____
Day patient presented with Shock.	_____
Day patient presented with PIMS/MIS-C	_____
Day patient presented with Kawasaki Syndrome.	_____
Day patient presented with Maculopapular Rash.	_____
Day patient presented with Urticaria.	_____
Day patient presented with Livedo Reticularis.	_____
Day patient presented with Vesicular Eruption.	_____
Day patient presented with COVID Toes.	_____

Day patient presented with Sepsis. _____

Day patient presented with DIC. _____

Day patient presented with ARDS. _____

Day patient presented with pulmonary embolism. _____

Day patient presented with respiratory failure. _____

Was the patient diagnosed with lower respiratory tract infection between Day 8 and Day 28? ◯ Yes ◯ No ◯ Unknown

What day was the patient first diagnosed with a lower respiratory tract infection? (e.g., Day 3, Day 20, etc.) _____

Diagnostic Imaging

Were there any new abnormal X-ray findings between Day 8 and Day 28? ◯ Yes ◯ No

Select which abnormal findings were reported from Day 8 to Day 28

	Yes	No	Unknown
Lobar consolidation	◯	◯	◯
Multifocal or patchy opacity	◯	◯	◯
Interstitial infiltrates	◯	◯	◯
Bronchial or peribronchial thickening/cuffing	◯	◯	◯

Were there any new abnormal CT findings between Day 8 and Day 28? ◯ Yes ◯ No

Select which abnormal findings were reported from Day 8 to Day 28.

	Yes	No	Unknown
Lobar consolidation	◯	◯	◯
Multifocal or patchy opacity or ground glass opacity	◯	◯	◯
Interstitial infiltrates	◯	◯	◯
Nodule(s)	◯	◯	◯

Bronchial or peribronchial thickening/cuffing	◯	◯	◯
Tree-in-bud opacities	◯	◯	◯

Did the patient receive any of the following between Day 8 and Day 28?

	Never	Unknown	Between Day 8 and 15	Between Day 16 and 23	Between Day 24 and 28
ECMO support	☐	☐	☐	☐	☐
Circulatory support or pressor use	☐	☐	☐	☐	☐
Dialysis or hemodialysis	☐	☐	☐	☐	☐

The following questions refer to ANY TIME ON OR BEFORE DAY 28

Did the patient have a SARS-CoV-2 Serology test performed?
◯ Yes ◯ No ◯ Unknown

What was the result of the serology antibody assay?
◯ Positive
◯ Negative
◯ Equivocal
◯ Unknown

Day of first positive serology test.
_____
(Day 0 is the date of initial positive COVID-19 test.)

Did the patient have any subsequent PCR testing that was positive from Day 1 through Day 28?
◯ No (no additional positive testing)
◯ 1 positive test
◯ 2 positive tests
◯ 3 positive tests
◯ 4 positive tests
◯ Unknown
(Such as test of cure or resolution of viral shedding)

Day 1st positive test was collected.
_____

Day 2nd positive test was collected.
_____

Day 3rd positive test was collected.
_____

Day 4th positive test was collected.
_____

Was a interleukin-6 (IL-6) level (pg/mL) collected between Day 0 and Day 28?
◯ Yes ◯ No ◯ Unknown

Enter the peak IL-6 level between Day 0 and Day 28.
_____
(Report as pg/mL)

Was the patient hospitalized for COVID-19 at any time on or before Day 28?	◯ Yes ◯ No ◯ Already hospitalized for reasons other than COVID-19
Was the hospitalization extended due to COVID-19?	◯ Yes ◯ No ◯ Unknown
If Yes, how many days was the patient hospitalized?	_____
Was the patient admitted to the ICU for COVID-19 on or before Day 28?	◯ Yes ◯ No
If Yes, how many days was the patient in the ICU?	_____

Supportive Care

Did the patient have any oxygen requirements on or before Day 28?	◯ Yes ◯ No ◯ Unknown (Supplemental oxygen use is defined as the delivery of oxygen by any modality, including nasal cannula, mask, noninvasive positive pressure ventilation, or mechanical ventilation, and was recorded if sustained for >4 hours for each day. If patients received oxygen support as baseline given their underlying diseases, only supplemental oxygen use beyond their baseline requirements will be counted.)
Nasal cannula	◯ Yes ◯ No
How many days received?	_____
High flow	◯ Yes ◯ No
How many days received?	_____
BIPAP/CPAP	◯ Yes ◯ No
How many days received?	_____
Mask	◯ Yes ◯ No
How many days received?	_____
Mechanical Ventilation	◯ Yes ◯ No
How many days received?	_____

Other	◯ Yes ◯ No
If Other, please describe and how many days received	_____
Was the patient treated with anti-coagulation?	◯ No ◯ Yes - Full dose anti-coagulation ◯ Yes - Prophylactic subcutaneous heparin or enoxaparin only ◯ Unknown
Select the anti-coagulant agent(s) used.	☐ Heparin ☐ Enoxaparin ☐ Warfarin ☐ Apixaban ☐ Rivaroxaban ☐ Argatroban ☐ Bivalrudin ☐ Other ☐ Unknown
Specify other anti-coagulant agent.	_____
Anticipated duration of anti-coagulation	_____ (days)

COVID-19 Directed Therapy

Did the patient receive any of the following COVID-19 directed therapy on or before Day 28?	☐ Lopinovir/Ritonovir ☐ Hydrocholorquine ☐ Interferon ☐ Ribavirin ☐ Remdesivir ☐ Azithromycin ☐ Tocilizumab ☐ Darunavir/Cobicistat ☐ Siltuximab ☐ Anakinra ☐ Convalescent Plasma ☐ IVIG ☐ Favirapir ☐ Losartan ☐ Other ☐ None of the above
What day was LPV/RTV treatment initiated?	_____
How many days of LPV/RTV did the patient receive?	_____
What day was Hydroxychloroquine treatment initiated?	_____
How many days of Hydroxychloroquine did the patient receive?	_____

What day was Interferon treatment initiated?	_____
How many days of Interferon did the patient receive?	_____
What day was Ribavirin treatment initiated?	_____
How many days of Ribavirin did the patient receive?	_____
What day was Remdesivir treatment initiated?	_____
How many days of Remdesivir did the patient receive?	_____
Select which way Remdesivir was provided to the patient?	◯ Clinical trial ◯ Emergency single patient request (Compassionate use) ◯ Expanded access program (EAP) ◯ Emergency use authorization (EUA) ◯ Unknown
What day was Azithromycin treatment initiated?	_____
How many days of Azithromycin did the patient receive?	_____
What day was Tocilizumab treatment initiated?	_____
How many days of Tocilizumab did the patient receive?	_____
What day was Darunavir/Cobicistat treatment initiated?	_____
How many days of Darunavir/Cobicistat did the patient receive?	_____
What day was Siltuximab treatment initiated?	_____
How many days of Siltuximab did the patient receive?	_____
What day was Anakinra treatment initiated?	_____
How many days of Anakinra did the patient receive?	_____

What day was IVIG treatment initiated?

_____

If yes, how many days IVIG did the patient receive?

_____

What day was COVID-19 convalescent plasma treatment initiated?

_____

How many days of COVID-19 Convalescent Plasma did the patient receive?

_____

What day was Favirapir treatment initiated?

_____

How many days of Favirapir did the patient receive?

_____

What day was Losartan treatment initiated?

_____

How many days of Losartan did the patient receive?

_____

Please list the other treatment given

_____

What day was the other treatment initiated?

_____

How many days of this other therapy did the patient receive?

_____

Co-pathogens

Did the patient have any new co-infections since Day 7 or any co-infections that were not reported on the initial survey?

◯ Yes
◯ No
◯ Unknown

Were any co-pathogens found in BLOOD? ◯ Yes ◯ No

If Yes, please list below. If the patient had multiple co-pathogens, use a semi-colon to separate names of pathogens

Were any co-pathogens identified in the UPPER RESPIRATORY TRACT (e.g., nose, throat, sputum)? ◯ Yes ◯ No ◯ Unknown

If Yes, please list below. If the patient had multiple co-pathogens, use a semi-colon to separate names of pathogens

Were any co-pathogens detected in TRACHEAL ASPIRATE? ◯ Yes ◯ No ◯ Unknown

If Yes, please list below. If the patient had multiple co-pathogens, use a semi-colon to separate names of pathogens

Were any co-pathogens identified in the LOWER RESPIRATORY TRACT (bronchoalveolar lavage or lung biopsy)? ◯ Yes ◯ No ◯ Unknown

If Yes, please list below. If the patient had multiple co-pathogens, use a semi-colon to separate names of pathogens

Survival Status

Did the patient die on or before Day 28?

◯ Yes
◯ No
◯ Unknown

If Yes, was death COVID-19 related? ◯ Yes ◯ No ◯ Unknown

If Yes, what was the cause of death?

◯ Respiratory failure
◯ Myocarditis
◯ Other
◯ Unknown

If Other, please specify _____

How many days after Day 0 did patient die? _____

(Day 0 is defined as the collection date of first positive COVID-19 diagnostic test.)

COVID-19 Status at Day 28

Has the patient's COVID-19 episode resolved?

Resolution of signs and symptoms AND/OR negative COVID-19 laboratory test resulted.

◯ Yes
◯ No
◯ Unknown

If yes, please select the following criteria (select all that apply).

☐ Negative COVID-19 test result obtained
☐ Signs and symptoms resolved
☐ Unknown test status
☐ Unknown signs and symptoms status

How many days after Day 0 was the first COVID-19 negative laboratory test collected? _____

If yes, how many days after Day 0 did the patient's signs and symptoms resolve?	_____
Is there any other relevant information you would like to share about this patient? If you have no additional information to share, please leave this field blank.	_____