Global COVID-19 in Pediatric Oncology

For laboratory-confirmed SARS-CoV-2/COVID-19

Hospital Record No: …… Case Form No: ……..

For hospital record-keeping only. Do not report to online registry.

Instructions for users: *This registry has 3 components: The diagnosis and presentation form, the 30 day follow up form, and the 60 day follow up form. Day 0 is defined as the onset of SARS-CoV-2/COVID-19 symptoms, or positive test, whichever is earlier. Any field that is not known should be left blank or marked as UNKNOWN if required. No identifying information for the patient is requested, and none should be provided. At the completion of the online form, respondents will see a unique code for each form that respondent should retain, in the event that they wish to return to add or change any information. The data entered for each case will be available to download (PDF) at the completion of the form and emailed to the email address provided. All initial case reports will receive the 30 Day Follow-up form by email. Cases which have not recovered at 30 days will receive the 60 Day Follow-up form by email. For questions about this project, contact COVID19ChildhoodCancer@STJUDE.ORG.*

Center (Institution) Reporting Case

Name and email address of reporter (required): ……..

Institution name: …….. City: …….. Country: ……..

Patient Information (Initial Presentation)

1. New **laboratory-confirmed** case: ☐ Yes ☐ No Previously recovered and experiencing **reinfection?** ☐ Yes ☐ No

2. Sex: ☐ M ☐ F ☐ Other Is the patient 2 years of age or older? ☐ Yes If yes, age in years: _____

☐ No If no, age in months: _____ *(use 0-23 months)*

3. Which of the following samples were obtained and returned a SARS-CoV-2/COVID-19 positive result? (select all that were positive)

☐ Nasal swab ☐ Nasopharyngeal swab ☐ Oropharyngeal swab

☐ Tracheal aspirate ☐ Bronchioalveolar lavage (BAL) ☐ Blind BAL

☐ Stool/anal swab ☐ Blood serology ☐ Saliva

☐ Other (specify):
……

4. Did the patient receive a SARS-COV2 vaccine prior to this infection? ☐ Yes ☐ No *(jump to 5)* ☐ Unknown *(jump to 5)*

4a. If yes, what vaccine?

☐ Anhui Zhifei Longcom ☐AstraZeneca/Oxford/Covishield ☐ Bharat/Covaxin

☐ CanSino/Convidecea (Ad5-nCoV) ☐ CureVac AG ☐ EpiVacCorona ☐ Finlay-FR2

☐ Janssen (Johnson&Johnson) ☐ Moderna ☐ Novavax ☐ Pfizer/BioNTech

☐ QazCovid-in ☐ Sanofi Pasteur / GSK ☐ Sinopharm / Beijing ☐ Sinopharm / Wuhan

☐ Sinovac / CoronaVac ☐ Sputnik V / Gamaleya ☐ Zydus Cadila ☐ Other (specify) _____

☐ Unknown

4b. How many doses of the vaccine has the recipient received? ☐ 1 ☐2 ☐3 ☐Unknown

4c. How long ago did the patient receive his/her last dose of SARS-CoV2 vaccine?

☐ 0-14 days ☐ 15 days – 1 month ☐ >1 month – 3 months ☐ >3 months – 6 months ☐ >6 months ☐ Unknown

5. What is the underlying malignancy of this patient?

☐ Acute lymphoblastic leukemia ☐ Hodgkin lymphoma ☐ Ewing sarcoma ☐ Retinoblastoma

☐ Acute myeloid leukemia ☐ Burkitt lymphoma ☐ Hepatoblastoma ☐ Rhabdomyosarcoma

☐ Acute lymphoblastic lymphoma ☐ Neuroblastoma ☐ Wilms tumor

☐ Central nervous system tumor (specify*) ☐ Other non-Hodgkin lymphoma (specify*) ☐ Osteosarcoma ☐ Non-CNS Germ cell tumors

☐ Other malignancy (specify*)

*Specify malignancy details: ……

6. What type of treatment (if any) is the patient receiving?

☐ Cancer-directed therapy ☐ Palliative therapy (including oral chemotherapy) *(jump to 7)* ☐ Follow-up (treatment completed) *(jump to 6a)*

☐ Disease monitoring ("watch and wait"; no active treatment) *(jump to 8)* ☐ Unknown *(jump to 7)*

If receiving cancer-directed OR palliative therapy, select all that apply: ☐ Chemotherapy ☐ Surgery ☐ Radiation Therapy

If chemotherapy, when was the last treatment? ☐ Within the last 30 days ☐ More than 30 days ago

☐ Unknown

If acute lymphoblastic leukemia or lymphoma, select the phase of treatment that applies: ☐ Induction ☐ Consolidation ☐ Reinduction ☐ Interim maintenance ☐ Maintenance or continuation ☐ Relapse/Refractory therapy ☐ Immunotherapy/cell therapy ☐ Unknown

If acute myeloid leukemia or other lymphomas, specify the regimen ☐ Initial therapy regimen ☐ Relapse/refractory therapy ☐ Unknown

If surgery, when was the last surgery? ☐ Within the last 30 days ☐ More than 30 days ago

If radiation therapy, when was the last treatment? ☐ Within the last 30 days ☐ More than 30 days ago

6a. If on follow-up, how long since the last chemotherapy? ☐ < 3 months ☐ 3 to < 12 months ☐ 1 to 5 years ☐ > 5 years

7. Has the patient received a stem cell transplant, or receiving preparative therapy for stem cell transplant? ☐ Yes, already received stem cell transplant ☐ Yes, receiving preparative therapy *(jump to 8)* ☐ No *(jump to 8)* ☐ Unknown *(jump to 8)*

If already received transplant, what type? ☐ Autologous stem cells ☐ Matched related stem cells ☐ Matched unrelated stem cells ☐ Haploidentical stem cells ☐ Cord blood ☐ Unknown

How many days post-transplant is the patient at the time of SARS-CoV-2/COVID-19 presentation? ☐ <30 days ☐ 31-99 days ☐ 100-300 days ☐ > 300 days ☐ Unknown

8. At time of SARS-CoV-2/COVID-19 presentation, what were the counts of the following? (leave blank if unknown)

Absolute Neutrophil Count: ……. cells/mm^3 Absolute Lymphocyte Count: ……. cells/mm^3

Risk Factors

9. Has the patient ever had radiation therapy? ☐ Yes ☐ No *(jump to 10)* ☐ Unknown *(jump to 10)*

If yes, what type(s) of radiation therapy did the patient receive? Select all that apply ☐ Total Body Irradiation ☐ Lung(s) ☐ Mediastinum ☐ Head/Neck ☐ Craniospinal irradiation ☐ Other

When did the radiation therapy occur? ☐ 0-12 weeks ago ☐ 13-36 weeks ago ☐ >36 weeks ago

10. Besides malignancy, does the patient have other comorbidities? *Select all that are known*

☐ Exposure to pulmonary toxins *(specify*)* ☐ History of high-dose steroids within the 14 days prior to day 0 ☐ GVHD

☐ Preexisting cardiac dysfunction/abnormality ☐ Preexisting pulmonary disease ☐ Trisomy 21 ☐ Obesity ☐ Other (specify)**

☐ None ☐ Unknown

Specify pulmonary toxin exposure: ……

If other comorbidities, specify: ……

SARS-CoV-2/COVID-19 Factors

11. Was the patient symptomatic when tested for SARS-CoV-2/COVID-19? ☐ Yes ☐ No *(jump to 12)* ☐ Unknown *(jump to 12)*

If symptomatic, what symptoms were present? *Select all that apply*

☐ Fever >100.4F/>38 C	☐ Cough	☐ Sore throat	☐ Headache	☐ Nausea	☐ Vomiting
☐ Body aches/myalgia	☐ Shortness of breath	☐ Tachypnea	☐ Diarrhea	☐ Lethargy	☐ Chills
☐ Rhinorrhea	☐ Stuffy nose	☐ Loss of sense of smell	☐ Loss of sense of taste		☐ Skin manifestation
☐ Chest pain	☐ Conjunctivitis	☐ Mucositis/Mucous membrane changes	☐ Swollen hands and/or feet		☐ Swollen lymph nodes
☐ Altered mental status	☐ Seizures	☐ Other symptoms *(specify):* ……			

11a. How many days were symptoms present when tested for SARS-CoV-2/COVID-19? ……. days *leave blank if unknown*

12. Is this a suspected case of Multisystem Inflammatory Syndrome in Children? ☐ Yes ☐ No *(jump to 13)*

If yes, does the child meet criteria for complete or incomplete Kawasaki disease? ☐ Yes ☐ No ☐ Unknown
If yes, did the patient have evidence of involvement of >/=2 organ systems? ☐ Yes ☐ No ☐ Unknown

If yes, which organ systems were involved? ☐ Cardiac ☐ Renal ☐ Respiratory ☐ Hematologic ☐ Gastrointestinal ☐ Dermatologic ☐ Neurological

If yes, did the patient present with signs or symptoms of shock? ☐ Yes ☐ No ☐ Unknown

If yes, have alternative causes for the patient´s symptoms/clinical presentation been eliminated as etiologies? ☐ Yes ☐ No ☐ Unknown

If yes, does the patient have laboratory evidence of inflammation? ☐ Yes ☐ No ☐ Unknown
If so, which evidence? ☐ Elevated CRP ☐ Elevated ESR ☐ Elevated fibrinogen ☐ Elevated D Dimer ☐ Elevated ferritin ☐ Elevated LDH ☐ Elevated IL-6 ☐ Elevated neutrophils ☐ Low lymphocytes ☐ Low albumin ☐ Other
If other (please specify): ……..

If yes, was there evidence of impaired myocardial function? ☐ Yes ☐ No ☐ Unknown
If so, what evidence? ☐ Myocardial dysfunction ☐ Pericarditis ☐ Valvulitis ☐ Coronary abnormalities ☐ Elevated troponin ☐ Elevated BNP ☐ Other ***If other (please specify)***: ……

13. Did the patient have radiographic imaging (chest radiograph, computer tomography) of the chest? ☐ Yes ☐ No *(jump to 14)* ☐ Unknown *(jump to 14)*

What were the findings? ☐ Normal *(jump to 14)* ☐ Abnormal but expected (due to underlying cancer) *(jump to 14)* ☐ Unknown *(jump to 14)* ☐ Abnormal (attributed to COVID-19)

Specify abnormal findings attributed to COVID-19: ……

14. Were there any co-pathogens identified while testing for COVID-19? ☐ Yes ☐ No *(jump to 15)* ☐ Unknown *(jump to 15)*

If yes, select the source (select all that apply): ☐ Blood ☐ Respiratory ☐ Other Source (specify source): ……

If blood sample, specify bloodborne pathogen(s): ……
If respiratory sample, specify pathogen(s): ……
If other source, specify other source of co-pathogens(s): ……
If other sample, specify pathogen(s): ……

15. What was the status of the patient's clinical respiratory infection at presentation? *Select the highest applicable severity of infection*
In this instance, we are defining a lower respiratory tract infection (LRTI) as: A positive test for COVID-19 in upper respiratory tract samples (e.g. nasal wash) in conjunction with a physician diagnosis of pneumonia and/or bronchiolitis, or a positive test for COVID-19 in lower respiratory tract samples (e.g. tracheal aspirate, bronchoalveolar lavage)

☐ Patient had no respiratory symptoms
☐ Upper respiratory tract infection
☐ Lower respiratory tract infection (e.g. pneumonia/bronchiolitis)
☐ Unknown

16. Did the patient require admission at the time of initial presentation?

☐ Yes, new admission
☐ No admission required
☐ Patient was already admitted at time of SARS-CoV-2/COVID-19 diagnosis
☐ Unknown

17. Follow up at 30 days post infection is requested. If this case is already more than 30 days old, the follow up form will be sent immediately. Would you like access to the 30-day follow up form? ☐ Yes ☐ No

If patient has already died, you should select Yes, and complete the 30 days follow up form now to record patient death.

END OF INITIAL REPORT FORM (FORM 1 OF 3)

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Follow-Up Form (30 days after symptoms onset)

1. Was the patient hospitalized during the course of the SARS-CoV-2/COVID-19 illness?

- ☐ Yes, at the time of presentation
- ☐ Yes, after convalescence at home and deterioration
- ☐ Yes, patient was already hospitalized for another reason (e.g. management of primary disease)
- ☐ No, managed at home *(jump to 2)*
- ☐ Unknown *(jump to 2)*

If yes, is the patient still hospitalized? ☐ Yes ☐ No

How many days was the patient hospitalized? (Including today, if still hospitalized) …….days

2. Based on the SARS-CoV-2/COVID-19 diagnosis, did the patient receive any SARS-CoV-2/COVID-19 specific therapy? ☐ Yes ☐ No *(jump to 3)* ☐ Unknown *(jump to 3)*

Specify SARS-CoV-2/COVID-19 therapy (select all that apply):

☐ Hydroxychloroquine	☐ Nitazoxanide	☐ Lopinavir/ritonavir	☐ Remdesivir
☐ Interferon	☐ Ribavarin	☐ Intravenous Immunoglobulins (IVIG)	☐ Azithromycin
☐ Steroids	☐ Convalescent plasma	☐ Ivermectin	☐ Tocilizumab
☐ Oseltamivir	☐ Favipiravir	☐ Anakinra	☐ Ruxolitinib
☐ Other	☐ Unknown		

☐ Other therapy *(specify):* ……

3. Was the patient admitted to a higher level of care due to his/her COVID-19 infection? ☐ Yes ☐ No *(jump to 4)* ☐ Unknown *(jump to 5)*

Identify the highest level of care that the patient received

- ☐ Intensive Care Unit (ICU)
- ☐ Intermediate Care Unit (IMCU)/High Dependency Unit (HDU)
- ☐ Emergency Room
- ☐ Unknown

Is the patient still receiving higher care? ☐ Yes ☐ No

How many days did the patient spend in the highest level of care? (Approximate number of days, including today, if still in higher care) …….days

4. What was the reason the patient did not receive a higher level of care?

- ☐ Patient status did not require higher level of care
- ☐ No space available in higher care
- ☐ Other (describe) ……

5. What was the most severe status of the patient's clinical respiratory infection during the course of the SARS-CoV-2/COVID-19 illness? *Select the highest applicable severity of infection*

In this instance, we are defining a lower respiratory tract infection (LRTI) as: A positive test for COVID-19 in upper respiratory tract samples (e.g. nasal wash) in conjunction with a physician diagnosis of pneumonia and/or bronchiolitis, or a positive test for COVID-19 in lower respiratory tract samples (e.g. tracheal aspirate, bronchoalveolar lavage)

- ☐ Patient had no respiratory symptoms
- ☐ Upper respiratory tract infection
- ☐ Lower respiratory tract infection (e.g. pneumonia/bronchiolitis)
- ☐ Unknown

6. What was the highest level of respiratory support required? (select one)

- ☐ Room air *(jump to 7)*
- ☐ Regular nasal cannula/facemask
- ☐ High-flow nasal cannula
- ☐ CPAP/BiPap
- ☐ Intubation
- ☐ Unknown *(jump to 7)*

How many days total of oxygen support did the patient require? (Approximate number of days, including today if patient is still on oxygen support) ……days

How many days total of intubation did the patient require? (Approximate number of days, including today if patient is still intubated) ……days

7. Did the patient experience organ dysfunction / organ impairment as a consequence of SARS-CoV-2 /COVID-19? Select all that apply:

- ☐ None
- ☐ Cardiac
- ☐ Renal
- ☐ Neurologic
- ☐ Multiorgan
- ☐ Unknown

8. At follow-up (30 days after symptom onset) what is the patient's status?

- ☐ SARS-CoV-2 / COVID-19 infection cleared (lab confirmed, clinically well)
- ☐ SARS-CoV-2 / COVID-19 infection clinically resolved (not lab confirmed)
- ☐ Tests for SARS-CoV-2 / COVID-19 continue positive but asymptomatic
- ☐ Tests for SARS-CoV-2 / COVID-19 continue positive and patient is sick from SARS-CoV-2 / COVID-19 and complications
- ☐ Expired, due to SARS-CoV-2 / COVID-19 infection or its complications
- ☐ Expired, due to non-SARS-CoV-2 / COVID-19 cause
- ☐ Unknown

If expired, how many days between date of positive SARS-CoV-2 /COVID 19 sample and date of patient death?
……days

9. During this reporting interval (0-30 days), was oncology treatment plan modified due to SARS-CoV-2/COVID-19? (select all that apply)

- ☐ Yes, chemotherapy dose(s) reduced
- ☐ Yes, chemotherapy dose(s) withheld
- ☐ Yes, radiation therapy was delayed
- ☐ Yes, surgery was delayed
- ☐ No, oncology treatment was delivered as planned
- ☐ Unknown

10. If this case is not resolved/expired, it qualifies for a 60-day follow-up form. If this case is already more than 60 days old, the follow-up form will be sent immediately. Would you like access to complete the 60-day follow-up form? ☐ Yes ☐ No

END OF 30-DAY FOLLOW-UP FORM (FORM 2 OF 3)

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Follow-Up Form (60 days after symptoms onset)

1. At this time what is the patient's SARS-CoV-2 /COVID-19 infection status?

- ☐ SARS-CoV-2 / COVID-19 infection cleared (lab confirmed, clinically well)
- ☐ SARS-CoV-2 / COVID-19 infection clinically resolved (not lab confirmed)
- ☐ Tests for SARS-CoV-2 / COVID-19 continue positive but asymptomatic
- ☐ Tests for SARS-CoV-2 / COVID-19 continue positive and patient is sick from SARS-CoV-2 / COVID-19 and complications
- ☐ Expired, due to SARS-CoV-2 / COVID-19 infection or its complications
- ☐ Expired, due to non-SARS-CoV-2 / COVID-19 cause
- ☐ Unknown

2. During this reporting interval (30-60 days), was oncology treatment plan modified due to SARS-CoV-2/COVID-19? (select all that apply)

- ☐ Yes, chemotherapy dose(s) reduced;
- ☐ Yes, chemotherapy dose(s) withheld;
- ☐ Yes, radiation therapy was delayed
- ☐ Yes, surgery was delayed
- ☐ No, oncology treatment was delivered as planned;
- ☐ Not applicable (patient not receiving cancer-directed treatment)
- ☐ Unknown

END OF 60-DAY FOLLOW-UP FORM (FORM 3 OF 3)