Biomedical Recommended Measures

Subject Number

COVID-19 Pediatric Biomedical Recommended Measures

The following document includes the Biomedical Pediatric Working Group's recommended instruments for collecting information on the Group's Tier 1 and Tier 2 data elements, organized by Domain.

Document Notes:

- Navigation: You may use the Navigation Pane to efficiently navigate the document. To do so, click "View" on the top of the Word doc and check the box labeled "Navigation Pane" under "Show."

- Endnotes: References are marked by endnotes; you may hover over or click on the endnote to display the reference, and modifications to the source if applicable.

- Tiers: Tier 1 elements are marked in Blue, Tier 2 elements are marked in Green

Common Data Elements (CDE) User Guidance:

- Unless specified, the units for specified age groups are in years.

Please click the link below to download the document.

[Attachment: "Data Harmonization to Accelerate COVID-19 Pediatric Research_vF.pdf"]



Baseline Child Health

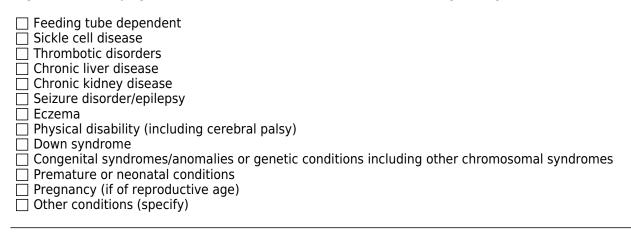
Date participant was enrolled in study (protocol specific)

Underlying Conditions

Significant underlying medical conditions at the time of COVID-19 testing or diagnosis:

 Diabetes type I 🗌 Diabetes type II Obesity 🗆 Asthma Bronchopulmonary dysplasia (BPD) Cystic fibrosis Obstructive sleep apnea Tracheomalacia Cancer HIV/AIDS 🗍 Hematopoietic cell recipient/bone marrow transplant recipient Solid organ transplant recipient Rheumatologic conditions (e.g. rheumatoid arthritis, systemic lupus erythematosus, vasculitis) □ Hypertension Congenital heart disease ☐ Heart failure □ Cardiomyopathy History of Kawasaki Disease (not a current diagnosis) History of MIS-C (not a current diagnosis) Inflammatory bowel disease

Significant underlying medical conditions at the time of COVID-19 testing or diagnosis:



Specify Other



Premature and Neonatal Co	onditions (Tier	2)
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Fetal malnutrition
Extreme immaturity
Cerebral hemorrhage at birth
Spinal cord injury at birth
Birth asphyxia
Respiratory diseases
Hypoxic-ischemic encephalopathy
] Other

Specify other

Family History Comorbidities (Tier 2)

Have any family members (parent/sibling) been diagnosed with any of the following medical conditions currently or in the past?

Obesity		⊖ Yes	⊖ No	🔿 Unknown	
Diabetes type l		⊖ Yes	⊖ No	🔿 Unknown	
Diabetes type II		⊖ Yes	⊖ No	🔿 Unknown	
Fibromyalgia (amplified pain syndro	ome)	⊖ Yes	⊖ No	🔿 Unknown	
Rheumatologic conditions (e.g. rhe systemic lupus erythematosus, vas		⊖ Yes	⊖ No	🔿 Unknown	
Thrombotic disorders		⊖ Yes	⊖ No	🔿 Unknown	
Other significant comorbidity (spec	fy)	⊖ Yes	⊖ No	🔿 Unknown	
Specify other significant comorbidit	у				
	Yes	No		Unknown	Prefer Not to Answer
If the participant is in first year of life, did the participant's mother test positive for COVID-19 while pregnant or nursing?	0	0		0	0
If participant is in first year of life, did the participant's father or other caregiver test positive for COVID-19?	0	0		0	0



Health Status (Height/Weight)				
Height				
		(cm)		
		⊖ Not av	ailable	
Weight				
		(g)		
		⊖ Not av	ailable	
Head Circumference (Only for children	less than two			
years of age) (Tier 2)		(cm)		
		🔿 Not av	ailable	
Breastfeeding (Tier 2)				
If the participant is in first year of life, is he or she being breastfed or fed pumped milk?	Yes	No	Unknown 〇	Prefer Not to Answer
COVID-19 Vaccination History				
Has the participant received a COVID-19 vaccine?	Yes	No	Unknown O	Prefer Not to Answer
Which vaccine brand/type did the part	cicipant receive?	 Pfizer Modern Johnsor AstraZe Unknov Other (n and Johnson eneca vn	
Specify Other				
Did the participant receive the second COVID-19 vaccine?	l dose of the	 ○ Yes ○ No ○ N/A ○ Unknov ○ Prefer N 	vn Not to Answer	
1st Date of vaccination				
2nd Date of vaccination				



Did the participant have any adverse read effects?	ctions or side	 ○ Yes ○ No ○ N/A ○ Unknown ○ Prefer Not 	to Answer	
PASC Symptom Resolution (Tier 2)			
If the participant had long COVID/post-act of COVID-19 (PASC) symptoms at the time vaccination, did those symptoms change?	e of	\bigcirc Yes, some \bigcirc Yes, worse	esolution of sympl improvement in ening of symptom nificant change	symptoms
Maternal COVID-19 Vaccination H	istory (Tier 2)			
	Yes	No	Unknown	Prefer Not to Answer
If participant is in first year of life, did the participant's mother receive vaccination for COVID-19 while pregnant or nursing?	0	0	0	0
Current Vaccination Status (Tier 2 Parent Report About Child	2)			
Turent Report About ennu	Yes	No	Unknown	Prefer Not to Answer
Are the patient's immunizations up to date for their age at the time of COVID-19 diagnosis/assessment?	0	0		O
If immunizations are not up to date, what	ic/aro the reacon(c)	for not boing up	to data? (Chack a	ll that apply)
 Clinic was closed because of COVID-19 Child had symptoms of COVID-19, so y You cancelled appointments to avoid to Other reasons related to COVID-19 Other reasons not related to COVID-19 Refused to answer) You cancelled appoir Deing around others/	ntment		an anac appry)
	Yes	No	Unknown	Prefer Not to Answer
Has the patient received any MMR vaccinations?	0	0	0	0
Has the patient received the current seasonal influenza vaccine?	0	0	0	0
Has the patient received palivizumab for prevention of respiratory syncytial virus (RSV)?	0	0	0	0



Has the patient received the BCG vaccination?	0	0	0	0
Date of most recent vaccination (ex for COVID-19)	cluding vaccination			_
Baseline Medications/Treatm	ent			
Current medication name inc medication)	luding birth con	trol medications a	nd injections (re	peat for each
Current Medication Name 1				
				<u> </u>
Current Medication Name 2				
Current Medication Name 3				
Respiratory support prior to onset o	f COVID-19?	⊖ Yes ⊖	No	
Specify, check all that apply (Tier 2))			

Non-invasive respiratory support (e.g., CPAP, BiPAP)
 Invasive respiratory support (e.g. mechanical ventilation via tracheostomy)
 Tracheostomy
 Supplemental oxygen
 Unknown/Uncertain



Manifestations: Clinical

Vital signs are routinely collected as part of the baseline visit to determine eligibility to participate in a trial, to serve as a reference point to select vital signs which may be trended during the trial, and to reveal potential indicators of severity and risk that may not otherwise be obvious. Thus, the Working Group recommends transmitting baseline vital signs as a common data point and encourages researchers to supplement this list with other vital signs as dictated by specific criteria in their individual trials.

The Working Group is not currently recommending frequency for documentation of vital signs. Study sites should provide any core vital sign data that are collected for routine monitoring of participants. For example, vital sign data for ICU patients are typically charted every hour, and these data should be available through the electronic health record.

For outpatient studies, core vital sign data elements should be taken with any in-person assessment. However, the reference time period for vital signs should be a 24-hour clock from midnight to midnight (00:00-23:59) to allow for consistency across studies.

Date and Time of Vital Signs	
Date	
	(MM/DD/YYYY)
Time	
	(ННММ)
Vital Sign Timepoints	
Baseline (e.g., at admission, at initial encounter if not admission)	 Admission Initial Encounter if not admission
Protocol specific timepoints (e.g., Day 1 AM, Day 1 PM, Day 2 AM, at discharge, etc.)	 Day 1 Day 2 Discharge
	⊖ Unknown
Vital Signs	
Body temperature	
	(Celsius)
	○ Unknown ○ N/A ○ Not Reported
Heart rate	
	(beats/min)
	○ Unknown ○ N/A ○ Not Reported
Systolic blood pressure	
	(mmHg)



	○ Unknown ○ N/A ○ Not Reported
Diastolic blood pressure	
	(mmHg)
	○ Unknown ○ N/A ○ Not Reported
Respiratory rate	
	(breaths/min)
	○ Unknown ○ N/A ○ Not Reported
Oxygen saturation	
	(%)
	○ Unknown ○ N/A ○ Not Reported
Supplemental oxygen	○ Yes ○ No
Symptoms/Dhysical Findings	

Symptoms/Physical Findings

Additional Guidance: Note that the two lists below are separated into an acute COVID-19/MIS-C symptom list and a Long COVID/PASC list (which includes the acute COVID-19/MIS-C list).

Which of the following were experienced during current illness and/or confirmed by physical exam?

For each symptom indicate Yes/No/Unknown

Acute COVID/MIS-C				
	Yes - Experienced	Yes - Experienced and Confirmed by Physical Exam	No	Unknown
Abdominal pain	0	0	\bigcirc	0
Bleeding	\bigcirc	\bigcirc	\bigcirc	\bigcirc
Chest pain	\bigcirc	\bigcirc	\bigcirc	\bigcirc
Cough	\bigcirc	\bigcirc	\bigcirc	\bigcirc
Cyanosis (bluish lips/face)	\bigcirc	\bigcirc	\bigcirc	\bigcirc
Diarrhea	\bigcirc	\bigcirc	\bigcirc	\bigcirc
Fatigue	\bigcirc	\bigcirc	\bigcirc	\bigcirc
Fever - documented	\bigcirc	\bigcirc	\bigcirc	\bigcirc

Duration in days



	Yes - Experienced	Yes - Experienced and Confirmed by Physical Exam	No	Unknown
Headache	\bigcirc	0	0	\bigcirc
Muscle or body aches	\bigcirc	\bigcirc	0	\bigcirc
Nasal congestion or runny nose	\bigcirc	\bigcirc	\bigcirc	\bigcirc
Nausea/vomiting	\bigcirc	\bigcirc	0	\bigcirc
Neck pain	\bigcirc	\bigcirc	\bigcirc	\bigcirc
New loss of taste or smell	\bigcirc	\bigcirc	0	\bigcirc
Palpitations	\bigcirc	\bigcirc	0	\bigcirc
Shortness of breath or difficulty breathing	0	0	0	0
Skin rash	0	0	\bigcirc	0
Sore throat	0	0	\bigcirc	0
Subjective fever/chills/rigors/night sweats	0	0	0	0
Swollen glands	0	0	\bigcirc	\bigcirc
-				
If confirmed by physical exam, ce		Yes - Experienced and Confirmed by Physical	No 🔿 Unknown	Unknown
If confirmed by physical exam, ce	n in diameter) ?	Yes - Experienced and	-	Unknown
If confirmed by physical exam, ce lymphadenopathy (at least 1.5 cn	n in diameter) ?	Yes - Experienced and Confirmed by Physical	-	Unknown
If confirmed by physical exam, ce lymphadenopathy (at least 1.5 cn Conjunctivitis (Red/pink eye(s)) Oral mucosal change	n in diameter) ?	Yes - Experienced and Confirmed by Physical	-	Unknown O O
If confirmed by physical exam, ce lymphadenopathy (at least 1.5 cm Conjunctivitis (Red/pink eye(s)) Oral mucosal change If confirmed by physical exam we cracked lips, strawberry tongue, a	n in diameter) ? Yes - Experienced	Yes - Experienced and Confirmed by Physical Exam O	-	0
If confirmed by physical exam, ce lymphadenopathy (at least 1.5 cm Conjunctivitis (Red/pink eye(s)) Oral mucosal change If confirmed by physical exam we cracked lips, strawberry tongue, a	n in diameter) ? Yes - Experienced	Yes - Experienced and Confirmed by Physical Exam O	No () ()	0
If confirmed by physical exam, ce lymphadenopathy (at least 1.5 cn Conjunctivitis (Red/pink eye(s))	n in diameter) ? Yes - Experienced	Yes - Experienced and Confirmed by Physical Exam O Yes O Yes O Yes - Experienced and Confirmed by Physical	No O No O Unknown	0



	Yes - Experienced	Yes - Experienced and Confirmed by Physical Exam	No	Unknown
Allodynia (pain out of proportion to the stimulus)	0	0	0	0
Altered level of consciousness/confusion	0	0	0	\bigcirc
Anorexia (decrease in appetite)	\bigcirc	\bigcirc	\bigcirc	0
Anxiety	\bigcirc	\bigcirc	\bigcirc	\bigcirc
Cannot move and/or feel one side of body or face	0	0	0	0
Depressed mood	\bigcirc	\bigcirc	0	0
Dizziness/lightheadedness/black outs	0	0	0	0
Exertional fatigue	\bigcirc	\bigcirc	\bigcirc	0
Forgetfulness	\bigcirc	\bigcirc	\bigcirc	\bigcirc
Irritability	\bigcirc	\bigcirc	\bigcirc	\bigcirc
Orthostasis (dizziness/lightheadedness/black outs on sitting up or standing)	0	0	0	0

If yes, confirmed by changes in heart rate/blood pressure? [Tier 2]	🔿 Yes 🔿 No 🔿 Unknown

	Yes - Experienced	Yes - Experienced and Confirmed by Physical Exam	No	Unknown
Joint pain	\bigcirc	0	0	0
Hallucinations (seeing or hearing things others do not see or hear) [should not be completed for children < 15 years old]	0	0	0	0
Hypersomnia	0	0	\bigcirc	0
Insomnia (difficulty sleeping)	\bigcirc	0	0	0
Malaise (including post-exertional malaise)	0	0	0	0
Muscle weakness	\bigcirc	0	0	0
Paresthesia (numbness or tingling somewhere in the body)	0	0	0	0
Persistent cough	0	0	0	0
If yes, productive?		⊖ Yes ⊖ N	o 🔿 Unknown	

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	Yes - Experienced	Yes - Experienced and Confirmed by Physical Exam	No	Unknown
Problems with balance	\bigcirc	\bigcirc	\bigcirc	\bigcirc
Problems with gait/falls	\bigcirc	\bigcirc	0	0
Toe rashes (red/purple sores or blisters on the feet, including the toes)	0	0	0	0
Trouble concentrating or difficulty thinking ("brain fog")	0	0	0	0
Weight loss	0	0	0	0
Failure of expected weight gain	\bigcirc	\bigcirc	\bigcirc	\bigcirc
Failure of expected linear growth	\bigcirc	\bigcirc	\bigcirc	\bigcirc
Other symptom(s)	0	0	0	0
Specify				-
Infant-Specific Symptoms/Ph	ysical Findings	(Tier 2)		
In addition to the above, which of t			luring illness?	
For each symptom indicate Yes/No,	/Unknown			
Dehydration		🔿 Yes 🔿 No) 🔿 Unknown	
Date Symptoms Presented				
		(MM/DD/YYYY)		-
Date Symptoms Resolved				
		(MM/DD/YYYY)		-
		Ongoing		
Full or bulging fontanelle		🔿 Yes 🔿 No) 🔿 Unknown	
Date Symptoms Presented				
		(MM/DD/YYYY)		-
Date Symptoms Resolved				
		(MM/DD/YYYY)		-
		○ Ongoing		
Fussiness		⊖ Yes ⊃ No) 🔿 Unknown	
Date Symptoms Presented				
		(MM/DD/YYYY)		-



Date Symptoms Resolved	
	(MM/DD/YYYY)
Increased work of breathing/shallow breathing	○ Yes ○ No ○ Unknown
Date Symptoms Presented	
	(MM/DD/YYYY)
Date Symptoms Resolved	
	(MM/DD/YYYY)
	○ Ongoing
Lethargy	○ Yes ○ No ○ Unknown
Date Symptoms Presented	
	(MM/DD/YYYY)
Date Symptoms Resolved	
	(MM/DD/YYYY)
Poor feeding	○ Yes ○ No ○ Unknown
Date Symptoms Presented	
	(MM/DD/YYYY)
Date Symptoms Resolved	
	(MM/DD/YYYY)
	○ Ongoing
Complications/Conditions	
Did the patient develop any of the following complications/condi organ system):	tions since the diagnosis of COVID (organized by
Fibromyalgia/amplified pain syndrome	○ Yes ○ No ○ Unknown
Date of Onset/Diagnosis (Tier 2)	
	(MM/DD/YYYY)



Date of Resolution (Tier 2)	
	(MM/DD/YYYY)
	○ Ongoing
Post viral fatigue syndrome	○ Yes ○ No ○ Unknown
Date of Onset/Diagnosis (Tier 2)	
	(MM/DD/YYYY)
Date of Resolution (Tier 2)	
	(MM/DD/YYYY)
	○ Ongoing
Seizure	○ Yes ○ No ○ Unknown
Date of Onset/Diagnosis (Tier 2)	
	(MM/DD/YYYY)
Date of Resolution (Tier 2)	
	(MM/DD/YYYY)
Stroke: intracerebral hemorrhage	○ Yes ○ No ○ Unknown
Date of Onset/Diagnosis (Tier 2)	
	(MM/DD/YYYY)
Date of Resolution (Tier 2)	
	(MM/DD/YYYY)
	○ Ongoing
Stroke: ischemic cerebrovascular accident	○ Yes ○ No ○ Unknown
Date of Onset/Diagnosis (Tier 2)	
	(MM/DD/YYYY)
Date of Resolution (Tier 2)	
	(MM/DD/YYYY)



Diabetic Ketoacidosis (DKA)	🔿 Yes 🔿 No 🔿 Unknown
Date of Onset/Diagnosis (Tier 2)	
	(MM/DD/YYYY)
Date of Resolution (Tier 2)	
	(MM/DD/YYYY)
New onset diabetes	○ Yes ○ No ○ Unknown
Date of Onset/Diagnosis (Tier 2)	
	(MM/DD/YYYY)
Date of Resolution (Tier 2)	
	(MM/DD/YYYY)
	Ongoing
Pancreatitis	○ Yes ○ No ○ Unknown
Date of Onset/Diagnosis (Tier 2)	
	(MM/DD/YYYY)
Date of Resolution (Tier 2)	
	(MM/DD/YYYY)
	○ Ongoing
Acute respiratory distress syndrome (ARDS)	○ Yes ○ No ○ Unknown
Date of Onset/Diagnosis (Tier 2)	
	(MM/DD/YYYY)
Date of Resolution (Tier 2)	
	(MM/DD/YYYY)
	Ongoing
Bronchiolitis	○ Yes ○ No ○ Unknown
Date of Onset/Diagnosis (Tier 2)	
	(MM/DD/YYYY)



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Date of Resolution (Tier 2)	
	(MM/DD/YYYY)
	○ Ongoing
Deterioration of prior chronic pulmonary diseases	○ Yes ○ No ○ Unknown
Date of Onset/Diagnosis (Tier 2)	
	(MM/DD/YYYY)
Date of Resolution (Tier 2)	
	(MM/DD/YYYY)
Lung fibrosis	○ Yes ○ No ○ Unknown
Date of Onset/Diagnosis (Tier 2)	
	(MM/DD/YYYY)
Date of Resolution (Tier 2)	
	(MM/DD/YYYY)
Pneumonia	○ Yes ○ No ○ Unknown
Date of Onset/Diagnosis (Tier 2)	
	(MM/DD/YYYY)
Date of Resolution (Tier 2)	
	(MM/DD/YYYY)
	○ Ongoing
Pulmonary embolism	○ Yes ○ No ○ Unknown
Date of Onset/Diagnosis (Tier 2)	
	(MM/DD/YYYY)
Date of Resolution (Tier 2)	
	(MM/DD/YYYY)



Cardiac arrhythmias	○ Yes ○ No ○ Unknown
Date of Onset/Diagnosis (Tier 2)	
	(MM/DD/YYYY)
Date of Resolution (Tier 2)	
	(MM/DD/YYYY)
	○ Ongoing
Cardiac failure	🔿 Yes 🔿 No 🔿 Unknown
Date of Onset/Diagnosis (Tier 2)	
	(MM/DD/YYYY)
Date of Resolution (Tier 2)	
	(MM/DD/YYYY)
	○ Ongoing
Cardiomyopathy	○ Yes ○ No ○ Unknown
Date of Onset/Diagnosis (Tier 2)	
	(MM/DD/YYYY)
Date of Resolution (Tier 2)	
	(MM/DD/YYYY)
	○ Ongoing
Coronary artery abnormalities	🔿 Yes 🔿 No 🔿 Unknown
Date of Onset/Diagnosis (Tier 2)	
	(MM/DD/YYYY)
Date of Resolution (Tier 2)	
	(MM/DD/YYYY)
	○ Ongoing
Myocarditis/pericarditis/ pericardial effusion	○ Yes ○ No ○ Unknown
Date of Onset/Diagnosis (Tier 2)	
	(MM/DD/YYYY)

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Date of Resolution (Tier 2)	
	(MM/DD/YYYY)
Myositis	🔿 Yes 🔿 No 🔿 Unknown
Date of Onset/Diagnosis (Tier 2)	
	(MM/DD/YYYY)
Date of Resolution (Tier 2)	
	(MM/DD/YYYY)
Shock	🔿 Yes 🔿 No 🔿 Unknown
Date of Onset/Diagnosis (Tier 2)	
	(MM/DD/YYYY)
Date of Resolution (Tier 2)	
	(MM/DD/YYYY)
Arthritis	🔿 Yes 🔿 No 🔿 Unknown
Date of Onset/Diagnosis (Tier 2)	
	(MM/DD/YYYY)
Date of Resolution (Tier 2)	
	(MM/DD/YYYY)
	Ongoing
Physical disability/muscular weakness	🔿 Yes 🔿 No 🔿 Unknown
Date of Onset/Diagnosis (Tier 2)	
	(MM/DD/YYYY)
Date of Resolution (Tier 2)	
	(MM/DD/YYYY)

REDCap

Acute kidney injury	○ Yes ○ No ○ Unknown
Date of Onset/Diagnosis (Tier 2)	
	(MM/DD/YYYY)
Date of Resolution (Tier 2)	
	(MM/DD/YYYY)
Acute liver dysfunction	○ Yes ○ No ○ Unknown
Date of Onset/Diagnosis (Tier 2)	
	(MM/DD/YYYY)
Date of Resolution (Tier 2)	
	(MM/DD/YYYY)
End stage renal disease (ESRD)	○ Yes ○ No ○ Unknown
Date of Onset/Diagnosis (Tier 2)	
	(MM/DD/YYYY)
Date of Resolution (Tier 2)	
	(MM/DD/YYYY)
Bleeding events	○ Yes ○ No ○ Unknown
Date of Onset/Diagnosis (Tier 2)	
	(MM/DD/YYYY)
Date of Resolution (Tier 2)	
	(MM/DD/YYYY)
	○ Ongoing
Deep vein thrombosis	○ Yes ○ No ○ Unknown
If there is a venous thrombosis, where is it located? (Tier 2)	 Intracranial Extracranial Both Unknown or not reported



Date of Onset/Diagnosis (Tier 2)	
	(MM/DD/YYYY)
Date of Resolution (Tier 2)	
	(MM/DD/YYYY)
Appendicitis	○ Yes ○ No ○ Unknown
Date of Onset/Diagnosis (Tier 2)	
	(MM/DD/YYYY)
Date of Resolution (Tier 2)	
	(MM/DD/YYYY)
Gastroesophageal reflux disease (GERD)	○ Yes ○ No ○ Unknown
Date of Onset/Diagnosis (Tier 2)	
	(MM/DD/YYYY)
Date of Resolution (Tier 2)	
	(MM/DD/YYYY)
Gastrointestinal hemorrhage	○ Yes ○ No ○ Unknown
Date of Onset/Diagnosis (Tier 2)	
	(MM/DD/YYYY)
Date of Resolution (Tier 2)	
	(MM/DD/YYYY)
Gastrointestinal perforation	○ Yes ○ No ○ Unknown
Date of Onset/Diagnosis (Tier 2)	
	(MM/DD/YYYY)
Date of Resolution (Tier 2)	
	(MM/DD/YYYY)

REDCap

Peritonitis	○ Yes ○ No ○ Unknown
Date of Onset/Diagnosis (Tier 2)	
	(MM/DD/YYYY)
Date of Resolution (Tier 2)	
	(MM/DD/YYYY)
Bacteremia	○ Yes ○ No ○ Unknown
Date of Onset/Diagnosis (Tier 2)	
	(MM/DD/YYYY)
Date of Resolution (Tier 2)	
	(MM/DD/YYYY)
Pulmonary aspergillosis	○ Yes ○ No ○ Unknown
Date of Onset/Diagnosis (Tier 2)	
	(MM/DD/YYYY)
Date of Resolution (Tier 2)	
	(MM/DD/YYYY)
Toxic shock syndrome (TSS)	○ Yes ○ No ○ Unknown
Date of Onset/Diagnosis (Tier 2)	
	(MM/DD/YYYY)
Date of Resolution (Tier 2)	
	(MM/DD/YYYY)
	○ Ongoing
Other (specify)	○ Yes ○ No ○ Unknown
Specify other	



Date of Onset/Diagnosis (Tier 2)

(MM/DD/YYYY)

Date of Resolution (Tier 2)

(MM/DD/YYYY)

 \bigcirc Ongoing



Manifestations: Laboratory

Labs at Diagnosis (work up of condition)

Additional Guidance: The Tier 1 lab values include, but are not limited to, those parameters necessary for the diagnosis of MIS-C (including markers of inflammation) and other conditions associated with acute and long COVID/PASC. Inclusion in Tier 1 does not suggest that all of these labs are recommended to be performed in all pediatric patients/studies, but rather that the test values or Not Done should be reported when performed.

Similar to vital signs, the Working Group is not currently recommending frequency for documentation of specific clinical labs. Study sites are encouraged to provide any lab data that are collected for routine monitoring of participants in addition to the value at diagnosis (i.e., work up of condition), which will vary between outpatient and inpatient settings. However, the reference time period for labs should be a 24-hour clock from midnight to midnight (00:00-23:59) to allow for consistency across studies.

○ Yes ○ No ○ Unknown
(MM/DD/YYYY)
(ННММ)
(MM/DD/YYYY)
(ННММ)
(MM/DD/YYYY)
(ННММ)
(MM/DD/YYYY)
(ННММ)



Date of Lab Sample Collection				
		(MM/DD/)	(YYY)	
Time of lab sample collection				
Time of lab sample conection				
		(HHMM)		
Date of Lab Sample Collection				
·		(MM/DD/Y	(YYY)	
			,	
Time of lab sample collection				
		(HHMM)		
For each of the below, report	test value at di	iagnosis (i.e., wo	ork up of conditio	n) or trial entry
with units or "Not Done"				
Any lab tests performed? (Tier	· 1)			
	Yes	No	Unknown	Not Performed
White blood cell count (WBC)	0	0	\bigcirc	\bigcirc
Result				
		([unit typ	e])	
	Yes	No	Unknown	Not Performed
Absolute lymphocyte count	\bigcirc			
(ALC)				
Result				
	~			
Absolute neutrophil count (ANC)	Yes 〇	No	Unknown	Not Performed
				-
Result				
Platelets	Yes	No	Unknown	Not Performed
	\smile	<u> </u>	\smile	\smile
Result				



· · · · · · · · · · · · · · · · · · ·	Yes	No	Unknown	Page Not Performed
C-reactive protein (CRP)	\bigcirc	\bigcirc		
Result				
Erythrocyte sedimentation rate	Yes	No O	Unknown	Not Performed
(ESR)				
Result				
Procalcitonin	Yes	No	Unknown	Not Performed
	<u> </u>	U	<u> </u>	
Result				
Ferritin	Yes	No O	Unknown	Not Performed
Result				
LDH	Yes	No O	Unknown	Not Performed
Result				
Albumin	Yes	No	Unknown	Not Performed
Result				
	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~		· · · · ·	
Glucose	Yes	No	Unknown 〇	Not Performed
Result				
Sodium	Yes	No O	Unknown	Not Performed
Result				



uential				Page 2
Creatinine	Yes	No	Unknown 〇	Not Performed
Result				
Blood urea nitrogen (BUN)	Yes	No	Unknown	Not Performed
Result				
Aspartate aminotransferase AST)	Yes	No	Unknown O	Not Performed
Result				
Alanine transaminase (ALT)	Yes	No O	Unknown	Not Performed
Result				
	Yes	No	Unknown	Not Performed
D-dimer	0	$\bigcirc$	$\bigcirc$	$\bigcirc$
Result				
Fibrinogen	Yes	No	Unknown	Not Performed
Result				
	Yes	No	Unknown	Not Performed
Froponin (TNI)	0	0	0	0
Result				
BNP/NT-Pro-BNP	Yes	No	Unknown	Not Performed
Result				
actate	Yes	No O	Unknown	Not Performed
Result				



Page 2	6
--------	---

Yes	No	Unknown	Not Dortormod
0	0	$\bigcirc$	Not Performed
Yes	No	Unknown	Not Performed
Yes	No O	Unknown	Not Performed
Yes	No O	Unknown	Not Performed
Yes	No	Unknown	Not Performed
Yes	No	Unknown	Not Performed
Yes	No	Unknown O	Not Performed
Yes	No	Unknown	Not Performed
	<pre> Yes Yes Yes Yes Yes Yes Yes Yes Yes Yes</pre>	○       ○         Yes       No         Yes       No	Yes       No       Unknown         O       O       O         Yes       No       Unknown         O       O       O         Yes       No       Unknown         Yes       No       Unknown



	Yes	No	Unknown	Page Not Performed
L-6	$\bigcirc$			
lesult				
			· · · · ·	
Complement	Yes	No	Unknown O	Not Performed
Result				
	Vez	N		Not Do aformo od
Hemoglobin A1C	Yes	No	Unknown O	Not Performed
Result				
	Yes	No	Unknown	Not Performed
Hq	0	0	0	0
Result				
	Yes	No	Unknown	Not Performed
pCO2	0	0	$\bigcirc$	0
Result				
	Yes	No	Unknown	Not Performed
baCO2	0	0	0	0
Result				
	Yes	No	Unknown	Not Performed
Calcium	0	0	0	0
Result				
	Yes	No	Unknown	Not Performed
Cerebrospinal fluid (CSF) WBC	0	0	$\bigcirc$	O
Result				
	Yes	No	Unknown	Not Performed
CSF red blood cell count (RBC)	0	0	$\bigcirc$	0
Result				



				Page 28
	Yes	No	Unknown	Not Performed
CSF Protein	$\bigcirc$	$\bigcirc$	$\bigcirc$	0
Result				
				_
	Yes	No	Unknown	Not Performed
CSF Glucose	0	0	$\bigcirc$	0
Result				
				_
	Yes	No	Unknown	Not Performed
Other, Specify	0	$\bigcirc$	0	0
Specify other				
				_
Result				
				_
Most Abnormal Labs (Tier 2)				
Any labs repeated during admission t abnormal than initial values?	that were more	⊖ Yes (	) No 🔿 Unknown	
	Yes	No	Unknown	Not Performed
White blood cell count (WBC)	$\bigcirc$	0	0	0
Result				
				_
	Yes	No	Unknown	Not Performed
Absolute lymphocyte count (ALC)	0	0	0	0
Result				
				_
	Yes	No	Unknown	Not Performed
Absolute neutrophil count (ANC)	0	0	0	0
Result				
	Yes	No	Unknown	– Not Performed
Platelets	$\bigcirc$	$\bigcirc$		
Result				



· · · · ·	Yes	No	Unknown	Page Not Performed
C-reactive protein (CRP)	0	$\bigcirc$	0	$\bigcirc$
Result				
	Yes	No	Unknown	Not Performed
Erythrocyte sedimentation rate ESR)	0	0	0	0
Result				
	Yes	No	Unknown	Not Performed
Procalcitonin	$\bigcirc$	$\bigcirc$		$\bigcirc$
Result				
	Yes	No	Unknown	Not Performed
Ferritin	0	0	0	0
Result				
	Yes	No	Unknown	Not Performed
_DH	0	0	0	0
Result				
	Yes	No	Unknown	Not Performed
Albumin	0	0	0	0
Result				
	Yes	No	Unknown	Not Performed
Glucose	0	0	0	0
Result				
	Yes	No	Unknown	Not Performed
Sodium	0	0	0	0
Result				



uential				Page 3
Creatinine	Yes	No	Unknown 〇	Not Performed
Result				
Blood urea nitrogen (BUN)	Yes	No O	Unknown	Not Performed
Result				
Aspartate aminotransferase AST)	Yes	No	Unknown 〇	Not Performed
Result				
Alanine transaminase (ALT)	Yes	No O	Unknown	Not Performed
Result				
	Yes	No	Unknown	Not Performed
D-dimer	0	$\bigcirc$	$\bigcirc$	$\bigcirc$
Result				
Fibrinogen	Yes	No	Unknown	Not Performed
Result				
	Yes	 No	Unknown	Not Performed
Froponin (TNI)	0	0	0	0
Result				
BNP/NT-Pro-BNP	Yes	No O	Unknown	Not Performed
Result				
actate	Yes	No ()	Unknown	Not Performed
Result				



Tier 2				
Absolute eosinophil count	Yes	No	Unknown	Not Performed
Result				
Absolute monocyte count	Yes	No O	Unknown	Not Performed
Result				
Absolute basophil count	Yes	No O	Unknown	Not Performed
Result				
Hemoglobin	Yes	No O	Unknown	Not Performed
Result				
Total bilirubin	Yes	No	Unknown	Not Performed
Result				
Prothrombin time (PT)	Yes	No O	Unknown	Not Performed
Result				
International normalized ratio (INR)	Yes	No	Unknown	Not Performed
Result				
Activated partial thromboplastin time (aPTT)	Yes	No	Unknown	Not Performed
Result				



	Yes	No	Unknown	Page Not Performed
L-6	$\bigcirc$	$\bigcirc$		
0	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$
lesult				
	Yes	No	Unknown	Not Performed
Complement	0	0	$\bigcirc$	0
Result				
	Yes	No	Unknown	Not Performed
Hemoglobin A1C	0	0	$\bigcirc$	0
Result				
	Yes	 No	Unknown	Not Performed
рН	$\bigcirc$			
Result				
	Yes	No	Unknown	Not Performed
pCO2	$\bigcirc$	0	0	0
Result				
	Yes	No	Unknown	Not Performed
paCO2	0	0	0	$\bigcirc$
Result				
	Vec	N		
Calcium	Yes 〇	No	Unknown 〇	Not Performed
Result				
	Yes	No	Unknown	Not Performed
Cerebrospinal fluid (CSF) WBC	0	0	0	0
Result				
	Yes	No	Unknown	Not Performed
CSF red blood cell count (RBC)	0	0	0	0
Result				



				Page 33
	Yes	No	Unknown	Not Performed
CSF Protein	0	0	0	0
Result				
	Yes	No	Unknown	Not Performed
CSF Glucose	0	0	0	0
Result				
	Yes	No	Unknown	Not Performed
Other, Specify	0	0	0	0
Specify other				
Result				
Other Viral/Bacterial/Fungal T	est Positive (Ti	er 2)		
Any other viral testing positive?			() No	
			0	
List other viral tests that were	e positive			
Specify other positive viral test				
Specify other positive viral test				
Specify other positive viral test				
Specify other positive viral test				
Specify other positive viral test				
Specify other positive viral test				



Blood Cultures	
Positive blood cultures?	⊖ Yes ⊖ No
Organism	
Date	
	(MM/DD/YYYY)
Organism	
Date	
	(MM/DD/YYYY)
Organism	
Date	
	(MM/DD/YYYY)
Organism	
Date	
	(MM/DD/YYYY)
Organism	
Date	
	(MM/DD/YYYY)
Organism	
Date	

(MM/DD/YYYY)



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## Manifestations: Cardiopulmonary Diagnostic Assessments

Additional Guidance: Similar to vital signs and clinical labs, the Working Group is not currently recommending frequency for documentation of specific cardiopulmonary assessments. Study sites are encouraged to provide any cardiopulmonary assessment data that are collected for monitoring of participants, in addition to the data reporting abnormality.

Cardiovascular Diagnos	tic Assessment Abnorn	nalities		
Did the patient have any car assessments performed (bey		() Yes	🔿 No 🛛 Unknown	
	Yes - abnormalities detected	Yes normal	No - not performed	Unknown
ECG (Tier 2)	0	0	0	0
Cardiovascular Diagnostic As	sessment Date			
Was there		<ul> <li>Abnori</li> <li>Perica</li> <li>Corona</li> </ul>		
	Yes - abnormalities detected	Yes normal	No - not performed	Unknown
ECHO (Tier 2)	0	0	0	0
Cardiovascular Diagnostic As	sessment Date			-
Was there		<ul> <li>Abnormal function</li> <li>Pericardial effusion</li> <li>Coronary artery abnormalities</li> </ul>		
	Yes - abnormalities detected	Yes normal	No - not performed	Unknown
Cardiac MRI (Tier 2)	0	0	0	0
Cardiovascular Diagnostic As	sessment Date			
Was there		<ul> <li>Abnormal function</li> <li>Pericardial effusion</li> <li>Coronary artery abnormalities</li> </ul>		



	Yes - abnormalities	Yes	normal	No - not performed	Page 3 Unknown
	detected	103	normai	No - not performed	UTIKITOWIT
Other test	0		0	0	0
Specify test					
Cardiovascular Diagnostic Assessr	nent Date				
Nas there		<ul> <li>Abnormal function</li> <li>Pericardial effusion</li> <li>Coronary artery abnormalities</li> </ul>			
Pulmonary Diagnostic Asses	ssment Abnormalit	ties			
Did the patient have any pulmonary diagnostic testing (beyond physical exam and radiographic imaging)			<ul><li>○ Yes</li><li>○ No</li><li>○ Unkno</li></ul>	wn	
Additional Guidance: Please note t Diagnostic Assessments, it is also Please refer to the footnote for 6-	used as a Cardiovascu	lar Diag	nostic Ass		th the Pulmonary
	Yes - abnormalities detected	Yes	normal	No - not performed	Unknown
6-Minute Walk Test (Tier 2) [only ages 6+]	0		0	0	0
Pulmonary Diagnostic Assessment	Date				
	(MM/DD/YYYY)				
	Yes - abnormalities detected	Yes	normal	No - not performed	Unknown
Pulmonary Function Test (Tier 2) [only ages 6+]	0		0	0	0
Pulmonary Diagnostic Assessment	Date				
	(MM/DD/YYYY)				
	Yes - abnormalities detected	Yes	normal	No - not performed	Unknown
Co-oximetry (Tier 2)	0		0	0	0
Pulmonary Diagnostic Assessment	Date				
	(MM/DD/YYYY)				



			Page 3
Yes - abnormalities detected	Yes normal	No - not performed	Unknown
0	0	0	$\bigcirc$
ment Date			
	(MM/DD/	YYYY)	
Yes - abnormalities detected	Yes normal	No - not performed	Unknown
0	0	0	0
	detected O sment Date Yes - abnormalities	detected O O O O O O O O O O O O O O O O O O O	detected O O O O O O O O O O O O O O O O O O O

(MM/DD/YYYY)



# **Manifestations: Imaging**

# **Radiographic Imaging Abnormalities**

Additional Guidance: Similar to vital signs and clinical labs, the Working Group is not currently recommending frequency for documentation of specific radiographic imaging. Study sites are encouraged to provide any radiographic imaging data that are collected for monitoring of participants, in addition to the data reporting abnormality.

	Yes - abnormalities detected	Yes normal	No - not performed	Unknown		
Did the patient have a chest x-ray performed?	0	0	0	0		
Date of Chest X-Ray						
		(MM/DD/	YYYY)			
Time of Chest X-Ray						
		(MM/DD/	YYYY)			
Tier 2						
Did the patient have any other r performed?	adiographic imaging	⊖ Yes	🔿 No 🔿 Unknown			
	Yes - abnormalities detected	Yes - normal	No - not performed	Unknown		
CT Brain	0	0	0	0		
Date of CT Brain						
	(MM/DD/YYYY)					
	Yes - abnormalities detected	Yes - normal	No - not performed	Unknown		
CT Chest	0	0	0	0		
Date of CT Chest						
		(MM/DD/	YYYY)			

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				Page	
	Yes - abnormalities detected	Yes - normal	No - not performed	Unknown	
CT Abdomen	0	0	0	0	
Date of CT Abdomen					
		(MM/DD/	YYYY)		
	Yes - abnormalities detected	Yes - normal	No - not performed	Unknown	
Lung Ultrasound	0	0	0	0	
Date of Lung Ultrasound					
		(MM/DD/	(YYY)		
	Yes - abnormalities detected	Yes - normal	No - not performed	Unknown	
Vascular Ultrasound	0	0	0	0	
Date of Vascular Ultrasound					
		(MM/DD/	(YYY)		
	Yes - abnormalities detected	Yes - normal	No - not performed	Unknown	
Abdominal Ultrasound	0	0	0	0	
Date of Abdominal Ultrasound					
		(MM/DD/	YYYY)		
	Yes - abnormalities detected	Yes - normal	No - not performed	Unknown	
Neonatal Ultrasound Brain	0	0	0	$\bigcirc$	
(Only performed on infants with open anterior fontanelle)					
Date of Neonatal Ultrasound (brai	n)				
	(MM/DD/YYYY)				
	Yes - abnormalities detected	Yes - normal	No - not performed	Unknown	
MRI Brain	0	0	0	0	
Date of MRI Brain					
		(MM/DD/	YYYY)		



				Page 40
	Yes - abnormalities detected	Yes - normal	No - not performed	Unknown
MRI Spine	$\bigcirc$	0	0	0
Date of MRI Spine				
		(MM/DD/	YYYY)	
	Yes - abnormalities detected	Yes - normal	No - not performed	Unknown
MRI Abdomen	0	0	0	0
Date of MRI Abdomen				
		(MM/DD/	YYYY)	
	Yes - abnormalities detected	Yes - normal	No - not performed	Unknown
Other radiographic imaging (specify test) performed	0	0	0	0
1. Specify test				
1. Date of Other Radiographic II	maging (Tier 2)			
		(MM/DD/	YYYY)	
2. Specify test 2				
2. Date of Other Radiographic II	maging (Tier 2)			
		(MM/DD/	YYYY)	
3. Specify test 3				
3. Date of Other Radiographic I	maging (Tier 2)			
		(MM/DD/	יייי)	

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# Diagnosis

SARS-CoV-2 Tested						
Has the participant been tested for S	SARS-CoV-2?		<ul> <li>Tested</li> <li>Not Tested</li> <li>Unknown</li> </ul>			
What was the result?			<ul> <li>Positive</li> <li>Negative</li> <li>Unknown</li> </ul>			
What tests were performed?						
Molecular amplification test (RT PCR SARS-CoV-2 RNA level Quantitative	, NAAT) -		⊖Yes ⊖	No 🔿 Unkn	own	
	Detected	Not Detected	Not detected in pooled specimen	Inconclusive	N/A or Not reported	Unknown
Result	0	0	0	0	0	0
Date of test						
Molecular amplification test (RT PCR SARS-CoV-2 RNA detection Qualitation			⊖ Yes ⊖	No 🔿 Unkn	own	
	Detected	Not Detected	Not detected in pooled specimen	Inconclusive	N/A or Not reported	Unknown
Result	0	$\bigcirc$	$\bigcirc$	$\bigcirc$	0	$\bigcirc$
Date of test						
SARS-CoV-2 Antigen - SARS-CoV-2 R	apid Antiger	ו	⊖ Yes ⊖	No 🔿 Unkn	own	
	Detected	Not Detected	Not detected in pooled specimen	Inconclusive	N/A or Not reported	Unknown

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						Page 42
Result	0	0	0	0	0	0
Date of test						
Serology - SARS CoV-2 IgM			⊖ Yes ⊂	No 🔿 Unkn	own	
	Detected	Not Detected	Not detected in pooled specimen	Inconclusive	N/A or Not reported	Unknown
Result	0	0	0	0	0	0
Date of test						
Serology - SARS CoV-2 IgG or Neu Antibody/Serologic	tralizing		⊖ Yes ⊂	) No 🔿 Unkno	own	
if yes, what is the antibody to?			○ Spike pro ○ Nucleoca	otein antibody apsid antibody		
	Detected	Not Detected	Not detected in pooled specimen	Inconclusive	N/A or Not reported	Unknown
Result	0	0	0	0	0	0
Date of test						
Other			⊖ Yes ⊂	No 🔿 Unkno	own	
Specify other test performed						
	Detected	Not Detected	Not detected in pooled specimen	Inconclusive	N/A or Not reported	Unknown
Result	0	$\bigcirc$	0	$\bigcirc$	0	0
Date of test						



Sample Type Collected (Tier 2)

Nasal
 Nasopharyngeal
 Saliva
 Endotracheal aspirate
 Bronchoalveolar lavage (BAL) fluid
 Blood
 Stool
 Cord Blood
 Unknown

- Unknown



# Treatment

Highest level of care received during	g the COVID-19 epis	sode?		
<ul> <li>Admitted to the intensive care un</li> <li>Admitted to the hospital</li> <li>Emergency Department assessm</li> <li>Outpatient (in-person and teleme</li> <li>Self-care alone/over-the-counter</li> <li>Unknown</li> </ul>	nent edicine)			
Date of current or any previous hos COVID-19	oital admission for			
Date of discharge				
Were any of the following conditions	s listed as a dischar	ge diagnosis for this	COVID-19 related ad	mission?
<ul> <li>Acute COVID</li> <li>MIS-C</li> <li>Kawasaki Disease</li> <li>Long COVID/Post-Acute Sequaela</li> <li>None of the above</li> </ul>	e of COVID (PASC)			
Date of current or any previous ICU	Admission			
Date of ICU Discharge				
Medications of Interest (Acute COVII	D/MIS-C/Long COVIE	D (PASC) Directed)		
What medications did the patient ta	ke or receive to trea	at Acute COVID-19/M	IIS-C/Long COVID (PA	SC)
	Yes	No	Unknown	Not Reported
Anti-coagulant - Heparin	0	0	$\bigcirc$	$\bigcirc$
Date Medication Started				
		(MM/DD/Y	YYY)	
Ongoing?		⊖ Yes (	⊖ No	
Date Medication Stopped				
		(MM/DD/Y	YYY)	
	Yes	No	Unknown	Not Reported
Anti-coagulant - Enoxaparin	$\bigcirc$	$\bigcirc$		
Date Medication Started				
		(MM/DD/Y	YYY)	



Ongoing?	○ Yes ○ No			
Date Medication Stopped				
		(MM/DD/Y	(YYY)	
Anti-coagulant - Warfarin	Yes	No O	Unknown	Not Reported
Date Medication Started				
		(MM/DD/Y	(YYY)	
Ongoing?	◯ Yes ◯ No			
Date Medication Stopped				
		(MM/DD/Y	(YYY)	
Anti-coagulant - Direct oral anticoagulant (DOAC)	Yes	No	Unknown	Not Reported
Date Medication Started				
		(MM/DD/Y	(YYY)	
Ongoing?		⊖ Yes	⊖ No	
Date Medication Stopped				
		(MM/DD/Y	(YYY)	
Anti-coagulant - Antiplatelets/Aspirin therapy	Yes	No O	Unknown O	Not Reported
Date Medication Started				
		(MM/DD/Y	(YYY)	
Ongoing?		⊖ Yes	⊖ No	
Date Medication Stopped				
		(MM/DD/Y	(YYY)	
Systemic antibiotic	Yes	No O	Unknown	Not Reported
Specify Antibiotic				



Date Medication Started				
		(MM/DD/YYYY)		
Ongoing?		⊖ Yes ⊖	No	
Date Medication Stopped				
		(MM/DD/YYY	Y)	
lmmune modulators/Immunosuppresants - Anakinra	Yes	No	Unknown O	Not Reported
Date Medication Started				
		(MM/DD/YYY	Y)	
Ongoing?		⊖ Yes ⊖	No	
Date Medication Stopped				
		(MM/DD/YYY	Y)	
lmmune modulators/Immunosuppresants - Tocilizumab	Yes	No	Unknown	Not Reported
Date Medication Started				
		(MM/DD/YYY	Y)	
Ongoing?		⊖ Yes ⊖	No	
Date Medication Stopped				
		(MM/DD/YYY	Y)	
lmmune modulators/Immunosuppresants - Convalescent plasma	Yes	No	Unknown	Not Reported
Date Medication Started				
		(MM/DD/YYY	Y)	
Ongoing?		⊖ Yes ⊖	No	
Date Medication Stopped				
		(MM/DD/YYY	Y)	

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				Page 47
Immune modulators/Immunosuppresants - SARS-CoV-2 monoclonal antibodies	Yes O	No O	Unknown O	Not Reported
Date Medication Started				
		(MM/DD/Y	YYY)	
Ongoing?		⊖ Yes (	) No	
Date Medication Stopped				
		(MM/DD/Y	YYY)	
lmmune modulators/Immunosuppresants - Intravenous immunoglobulins (IVIG)	Yes	No	Unknown O	Not Reported
Date Medication Started				
		(MM/DD/Y	YYY)	
Ongoing?		⊖ Yes (	⊖ No	
Date Medication Stopped				
		(MM/DD/Y	YYY)	
Immune modulators/Immunosuppresants - Interferon	Yes 〇	No O	Unknown O	Not Reported
Date Medication Started				
		(MM/DD/Y	YYY)	
Ongoing?		⊖ Yes (	) No	
Date Medication Stopped				
		(MM/DD/Y	YYY)	
	Yes	No	Unknown	Not Reported



Immune modulators/Immunosuppresants - Tumor necrosis factor (TNF) inhibitors (i.e. infliximab, etanercept, adalimumab)	0	0	0	0
Date Medication Started				
		(MM/DD/Y	YYY)	
Ongoing?		⊖ Yes (	) No	
Date Medication Stopped				
		(MM/DD/Y	YYY)	
	Yes	No	Unknown	Not Reported
lmmune modulators/Immunosuppresants - NSAID-Ibuprofen	0	0	O	0
Date Medication Started				
		(MM/DD/Y	YYY)	
Ongoing?		⊖ Yes (	) No	
Date Medication Stopped				
		(MM/DD/Y	YYY)	
Anti-viral/Anti-COVID - Remdesivir	Yes	No	Unknown O	Not Reported
Date Medication Started				
		(MM/DD/Y	YYY)	
Ongoing?		⊖ Yes (	) No	
Date Medication Stopped				
		(MM/DD/Y		
Anti-viral/Anti-COVID - Ribavirin	Yes	No	Unknown 〇	Not Reported
Date Medication Started				
		(MM/DD/Y	YYY)	
Ongoing?		⊖ Yes (	) No	



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Date Medication Stopped					
		(MM/DD/Y	_		
Diabetic Medications - Insulin	Yes 〇	No O	Unknown	Not Reported	
Date Medication Started					
		(MM/DD/Y	YYY)		
Ongoing?		⊖ Yes (	⊖ No		
Date Medication Stopped					
		(MM/DD/Y	YYY)		
Inhaled Medications - Inhaled steroids	Yes O	No O	Unknown O	Not Reported	
Date Medication Started					
		(MM/DD/Y	YYY)		
Ongoing?		⊖ Yes (			
Date Medication Stopped					
		(MM/DD/Y	YYY)		
Inhaled Medications - Albuterol	Yes	No O	Unknown O	Not Reported	
Date Medication Started					
		(MM/DD/Y	YYY)		
Ongoing?		⊖ Yes (	) No		
Date Medication Stopped					
		(MM/DD/YYYY)			
Inhaled Medications - Ipratropium	Yes	No	Unknown O	Not Reported	
Date Medication Started					
		(MM/DD/Y	YYY)		
Ongoing?		⊖ Yes (	⊃ No		



	(MM/DD/Y		
Yes	No	Unknown	Not Reported
	(MM/DD/Y	YYY)	
	⊖ Yes (	) No	
	(MM/DD/Y	YYY)	
Yes	No	Unknown 〇	Not Reported
	(MM/DD/Y	YYY)	
	⊖ Yes (	) No	
	(MM/DD/Y	YYY)	
Yes	No	Unknown O	Not Reported
	(MM/DD/Y	YYY)	
	⊖ Yes (	) No	
	(MM/DD/Y	YYY)	
Yes	No	Unknown	Not Reported
	Yes	Yes         No           (MM/DD/Y           (MM/DD/Y           Yes         No           (MM/DD/Y           Yes         No           (MM/DD/Y           Yes         No           Yes         No           (MM/DD/Y           Yes         No           (MM/DD/Y           Yes         No           (MM/DD/Y           Yes         No           Yes         No           Yes         No           Yes         No           Yes         No	O       O       O         (MM/DD/YYYY)       O       Yes         O       Yes       No         (MM/DD/YYYY)       O       O         Yes       No       Unknown         O       Yes       No         (MM/DD/YYYY)       O       Yes         Yes       No       Unknown         O       Yes       No         (MM/DD/YYYY)       O       Yes         Yes       No       Unknown         Yes       No       O         (MM/DD/YYYY)       O       Yes         Yes       No       Unknown         Yes       No       Unknown

(MM/DD/YYYY)



Ongoing?		⊖ Yes ⊖	No	
Date Medication Stopped				
		(MM/DD/YY)	(Y)	
Systemic Steriods - Fludrocortisone	Yes	No	Unknown O	Not Reported
Date Medication Started				
		(MM/DD/YY)	(Y)	
Ongoing?		⊖ Yes ⊖	No	
Date Medication Stopped				
		(MM/DD/YY)	(Y)	
Other medications	Yes	No	Unknown 〇	Not Reported
Specify other				
Date Medication Started				
		(MM/DD/YY)	(Y)	
Ongoing?		⊖ Yes ⊖	No	
Date Medication Stopped				
		(MM/DD/YY)	(Y)	
Timing of medications, particularl other relevant data elements, suc documenting the time as well as	ch as lab values. There the date when these s	fore, as appropriate, t	he Working Group I	for assessing recommends
Intensive Intervention (Tre	atment/Device) Yes	No	Unknown	Not Reported
nvasive mechanical ventilation (e.g., endotracheal intubation, mechanical ventilation via	Ö	0	0	$\bigcirc$
racheostomy)				
- 				
tracheostomy) Date Invasive Treatment Started		(MM/DD/YY)	(Y)	



Date Invasive Treatment Stopped				
		(MM/DD/Y	YYY)	
	Yes	No	Unknown	Not Reported
New tracheostomy	$\bigcirc$	0	0	$\bigcirc$
Date Invasive Treatment Started				
		(MM/DD/Y	YYY)	
Ongoing?		⊖ Yes (	) No	
Date Invasive Treatment Stopped				
		(MM/DD/Y	YYY)	
	Yes	No	Unknown	Not Reported
Noninvasive mechanical ventilation (e.g., CPAP, BiPAP, NIPPV)	0	0	0	0
Date Invasive Treatment Started				
		(MM/DD/Y	YYY)	
Ongoing?		⊖ Yes (	) No	
Date Invasive Treatment Stopped				
		(MM/DD/Y	YYY)	
	Yes	No	Unknown	Not Reported
Extracorporeal membrane oxygenation (ECMO)	0	0	0	0
Date Invasive Treatment Started				
		(MM/DD/Y	YYY)	
Ongoing?		⊖ Yes (	) No	
Date Invasive Treatment Stopped				
		(MM/DD/YYYY)		
	Yes	No	Unknown	Not Reported
Vasoactive medications	0	0	0	0
Date Invasive Treatment Started				
		(MM/DD/Y	YYY)	
Ongoing?		⊖ Yes (	⊃ No	



Date Invasive Treatment Stopped					
		(MM/DD/YYY			
Arterial catheter placement	Yes	No	Unknown 〇	Not Reported	
Date Invasive Treatment Started					
		(MM/DD/YYY	Y)	_	
Ongoing?		⊖ Yes ⊖ I	No		
Date Invasive Treatment Stopped					
		(MM/DD/YYY	Y)	_	
Cardiopulmonary resuscitation with/without return of spontaneous circulation	Yes	No	Unknown O	Not Reported	
Date Invasive Treatment Started					
		(MM/DD/YYY	Y)		
Ongoing?		⊖ Yes ⊖ I	No		
Date Invasive Treatment Stopped					
		(MM/DD/YYY	Y)		
Central venous catheter placement	Yes O	No	Unknown O	Not Reported	
Date Invasive Treatment Started					
		(MM/DD/YYY	Y)		
Ongoing?		⊖ Yes ⊖ I	No		
Date Invasive Treatment Stopped					
	(MM/DD/YYYY)				
Low flow oxygen therapy (e.g. nasal cannula, simple mask, face tent)	Yes O	No	Unknown O	Not Reported	
Date Invasive Treatment Started					

(MM/DD/YYYY)

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Ongoing?		⊖ Yes (	) No	
Date Invasive Treatment Stopped				
		(MM/DD/Y	YYY)	
High flow oxygen therapy	Yes	No	Unknown	Not Reported
Date Invasive Treatment Started				
		(MM/DD/Y	YYY)	
Ongoing?		⊖ Yes (	) No	
Date Invasive Treatment Stopped				
		(MM/DD/Y	YYY)	
Invasive management of thrombosis (e.g., surgical thrombectomy, endovascular thrombectomy, catheter-directed thrombolysis)	Yes	No	Unknown	Not Reported
Date Invasive Treatment Started				
		(MM/DD/Y	YYY)	
Ongoing?		⊖ Yes (	) No	
Date Invasive Treatment Stopped				
		(MM/DD/Y	YYY)	
Renal replacement therapy (RRT)	Yes	No	Unknown	Not Reported
Date Invasive Treatment Started				
		(MM/DD/Y	YYY)	
Ongoing?		⊖ Yes (	) No	
Date Invasive Treatment Stopped				
		(MM/DD/Y	YYY)	



				Page 55
Pacemaker placement	Yes	No O	Unknown O	Not Reported
Date Invasive Treatment Started				
		(MM/DD/Y	YYY)	_
Ongoing?		⊖ Yes (	) No	
Date Invasive Treatment Stopped				
		(MM/DD/Y	YYY)	_
Left ventricular assist device (LVAD)	Yes	No O	Unknown	Not Reported
Date Invasive Treatment Started				
		(MM/DD/Y	YYY)	_
Ongoing?		⊖ Yes (	) No	
Date Invasive Treatment Stopped				
		(MM/DD/Y	YYY)	_
Other intensive intervention	Yes O	No	Unknown O	Not Reported
Specify other				
				_
Date Invasive Treatment Started				
		(MM/DD/Y	YYY)	_
Ongoing?		⊖ Yes (	) No	
Date Invasive Treatment Stopped		(MM/DD/Y	YYY)	_
Do Not Resuscitate/Limitatio	n of Support			
Was there a "Do Not Resuscitate" o limitation of support?	rder or any other	⊖ Yes (	🔿 No i 🔿 Unknown	



# **Outcomes**

Patient Survival	
Did the patient die?	<ul> <li>○ Yes</li> <li>○ No</li> <li>○ Unknown</li> </ul>
Was the death COVID-19 related (including MIS-C)?	<ul> <li>Yes</li> <li>No</li> <li>Unknown</li> <li>N/A or not reported</li> </ul>
Date of Death	
If hospitalized for suspected or diagnosed COVID-19 and survived, to where was the participant discharged?	<ul> <li>Home</li> <li>Rehabilitation Facility/Nursing Facility</li> <li>Other</li> <li>Unknown</li> <li>N/A or not reported</li> </ul>
Specify other	
What was the COVID-19 severity at time of maximum severity of illness?	<ul> <li>Asymptomatic/presymptomatic infection</li> <li>Mild illness</li> <li>Moderate illness</li> <li>Severe illness</li> <li>Critical illness</li> <li>Unknown</li> <li>N/A or not reported</li> </ul>

#### NIH Severity Definitions:

- Asymptomatic or Presymptomatic Infection: Individuals who test positive for SARS-CoV-2 using a virologic test (i.e., a nucleic acid amplification test [NAAT] or an antigen test) but who have no symptoms that are consistent with COVID-19.

- Mild Illness: Individuals who have any of the various signs and symptoms of COVID-19 (e.g., fever, cough, sore throat, malaise, headache, muscle pain, nausea, vomiting, diarrhea, loss of taste and smell) but who do not have shortness of breath, dyspnea, or abnormal chest imaging.

- Moderate Illness: Individuals who show evidence of lower respiratory disease during clinical assessment or imaging and who have an oxygen saturation (SpO2) ?94% on room air at sea level.

- Severe Illness: Individuals who have SpO2 < 94% on room air at sea level, a ratio of arterial partial pressure of oxygen to fraction of inspired oxygen (PaO2/FiO2) < 300 mm Hg, or lung infiltrates >50%.

- Critical Illness: Individuals who have respiratory failure, septic shock, and/or multiple organ dysfunction.

- In pediatric patients, radiographic abnormalities are common and, for the most part, should not be the only criteria used to determine the severity of illness. The normal values for respiratory rate also vary with age in children; thus, hypoxia should be the primary criterion used to define severe COVID-19, especially in younger children.



# **Psychosocial Recommended Measures**

The following document includes the Psychosocial Pediatric Working Group's recommended instruments for collecting information on the Group's Tier 1 and Tier 2 recommended data elements, organized by Domain.

Document Notes:

- Navigation: You may use the Navigation Pane to efficiently navigate the document. To do so, click "View" on the top of the Word doc and check the box labeled "Navigation Pane" under "Show."

- Endnotes: References are marked by endnotes; you may hover over or click on the endnote to display the reference, and modifications to the source if applicable.

- Tiers: Tier 1 elements are marked in Blue, Tier 2 elements are marked in Green

Common Data Elements (CDE) User Guidance:

Unless specified as "Parent Self-Report", questions refer to the child study participant. Studies should choose between you/your child depending on if they are collecting information via child or parent/caregiver report. When information appears in brackets (such as [you/your child]), please choose the option relevant to the questionnaire.

"Parent Self-Report" - refers to parents answering about themselves.

"Parent Report About Child" - refers to parent answering about their child. Please note, sometimes the verbiage "this child" or "the child" is used rather than " your child" to maintain consistency with the language in the original measure.

"Child Self-Report" - refers to children answering about themselves.

Child Self-Report measures are recommended for specific age groups based on the following:

Validated: Recommendation is based on validation data, for example, PROMIS®, NIH Toolbox®, PhenX protocols validated in specified age ranges.

Used in COVID-19 Questionnaires: Recommendation is based on use of the items in pediatric cohort studies, for example, the Adolescent Brain Cognitive Development Study SM (ABCD Study®), Adolescent Behaviors and Experiences Survey (ABES), Environmental influences on Child Health Outcomes (ECHO) COVID-19 Questionnaires.

Modified*: For measures modified from adult questionnaires, this Working Group recommends implementing a 13+ age range. The Working Group has justified this approach using the Report of the ISPOR PRO good research practices for the assessment of children and adolescents task force; comparing the measures to existing measures asked of adolescents; and modifying questions to verify that the subject matter was appropriate for adolescents.

These "modified" age groups will have an asterisk next to them to mark that they are NOT yet validated or specifically used in pediatric populations, but the Working Group has found the recommendation reasonable.

Investigators may choose to consistently add " Prefer not to answer" or " Don't know" response choices to these questions. The Working Group has kept the question responses from the original source and has not added these answer choices uniformly. Participants have the right to refuse or skip any item.

The superscript "t" indicates that the element is " COVID-19 specific" (either a change from before the pandemic or language specific to the pandemic).

Unless specified, the units for specified age groups are in years.



Highest Education Level/Degree (Parent)	
Parent Self-Report	
What is the highest grade or level of school you have completed or the highest degree you have received?	<ul> <li>8th grade or less</li> <li>9th to 12th grade; no diploma</li> <li>High school graduate or GED completed</li> <li>Completed a vocational, trade, or business school program</li> <li>Some college credit, but no degree</li> <li>Associate Degree (AA, AS)</li> <li>Bachelor's Degree (BA, BS, AB)</li> <li>Master's Degree (MA, MS, MSW, MBA)</li> <li>Doctorate (PhD, EdD) or Professional Degree (MD, DDS, DVM, JD)</li> <li>Prefer not to answer</li> <li>Don't know</li> </ul>
Does this child have another parent or adult caregiver who lives in this household?	⊖ Yes ⊖ No
What is the highest grade or level of school this caregiver has completed?	<ul> <li>8th grade or less</li> <li>9th to 12th grade; no diploma</li> <li>High school graduate or GED completed</li> <li>Completed a vocational, trade, or business school program</li> <li>Some college credit, but no degree</li> <li>Associate Degree (AA, AS)</li> <li>Bachelor's Degree (BA, BS, AB)</li> <li>Master's Degree (MA, MS, MSW, MBA)</li> <li>Doctorate (PhD, EdD) or Professional Degree (MD, DDS, DVM, JD)</li> <li>Prefer not to answer</li> <li>Don't know</li> </ul>
English Proficiency (Parent) Parent Self-Report	
•	
Do you speak a language other than English at home?	○ Yes ○ No ○ Prefer not to answer
Since you speak a language other than English at home, we are English.	e interested in your own opinion of how well you speak

Would you say you speak English...

Very well
Well
Not well
Not at all



Number of Household Members	
Parent Self-Report or Child Self-Report (Ages 13+)	k
How many people live in your household now?	
	(Please enter a number)
Please indicate the number of adults living in your household	
	(Please enter a number)
Please indicate the number of children (< 18 years old) living in your household	
	(Please enter a number)
Employment Status (Parent)	
Parent Self-Report	
What is your current employment situation?	<ul> <li>Employed full-time</li> <li>Employed part-time</li> <li>Working without pay</li> <li>Not employed, but looking for work</li> <li>Not employed and not looking for work</li> <li>Retired</li> <li>Disabled, permanently or temporarily</li> <li>Student</li> <li>Other</li> <li>Don't know</li> </ul>
Specify other	
Does this child have another parent or adult caregiver who lives in this household?	⊖ Yes ⊖ No
Which of the following best describes this caregiver's current employment status?	<ul> <li>Employed full-time</li> <li>Employed part-time</li> <li>Working without pay</li> <li>Not employed, but looking for work</li> <li>Not employed and not looking for work</li> <li>Retired</li> <li>Disabled, permanently or temporarily</li> <li>Student</li> <li>Other</li> <li>Don't know</li> </ul>

Specify other



Employment Risk for COVID-19 "Frontline Status" (Family) (Tier 2)					
Parent Self-Report					
Are you or is anyone in your household employed in healthcare and have direct patient contact?	⊖ Yes	⊖ No	🔿 Unknown		
Are you or is anyone in your household a frontline or essential worker other than in healthcare (such as employed at a grocery store or factory)?	⊖ Yes	() No	O Unknown		
COVID 19 Effect on Work (Tier 2)					
Have you, or has anyone in your household, experienced a loss of employment income since the start of the COVID-19 pandemic (since March 2020)?	⊖ Yes	⊖ No			
Changes in Employment Situation					
Which of the following changes in employment have occurred	due to the	COVID-1	9 pandemic?		
Self Partner         (1) Move to remote work, telework         (2) Loss of hours         (3) Decreased pay         (4) Furloughed         (5) Loss of job         (6) Decreased job security         (7) Disruptions due to childcare challenges					

(8) Increased hours

(9) Another change (specify) _____

# Financial Strain (Family) (Tier 2) Parent Self-Report

# How difficult is/was it to meet each of the following needs for you and/or your family during the COVID-19 pandemic (since March 2020)?

-			
	Not Difficult	Somewhat Difficult	Very Difficult
Have enough money for food	$\bigcirc$	0	$\bigcirc$
Have enough money to pay for electricity or heating or water	0	0	0
Have enough money to pay for housing	0	Ο	0
Get help from community organizations that I trust	0	0	0
Get help from family members and friends	0	0	0



See a healthcare provider if you or your family needs it	0		0	0
Get routine / essential medications	0		0	0
Get transportation when I need it	$\bigcirc$		$\bigcirc$	$\bigcirc$
•	$\bigcirc$		0	$\bigcirc$
Use the internet for things like work, school, medical visits, socializing	U		U	0
Thinking about the future, over the r because of coronavirus, how challen make ends meet?		◯ A little ◯ No mo	nore challenging that more challenging theore challenging theore re challenging than usua hallenging than usua know	ian usual usual
Housing Instability (Family)				
Parent Self-Report				
Have any of the following occurred d	luring the COVID-19 pan	demic (since N	/arch 2020)?	
Relocation or moving from where yo pandemic (e.g., downsizing, moving etc.)		() Yes	○ No	
Faced possible eviction since March	2020	⊖ Yes	⊖ No	
Loss of your housing, or becoming he 2020	omeless since March	⊖ Yes	⊖ No	
Food Insecurity (Family)				
Parent Self-Report				
The following are several stat	ements that neonle	have made	about their foo	d situation Please
tell me whether the statemen				
members of your household in				-
includers of your nousehold in		ometimes true	Never true	Don't know
<ol> <li>The food that we bought just didn't last, and we didn't have money to get more.</li> </ol>	0	0	0	0

 $\bigcirc$ 

 $\bigcirc$ 

2. We couldn't afford to eat balanced meals.

 $\bigcirc$ 



 $\bigcirc$ 

3. In the last 12 months, since (date 12 months ago) did you or other adults in your household ever cut the size of your meals or skip meals because there wasn't enough money for food?	○ Yes ○ No ○ Don't know
Optional Screener: If any of the first 3 questions are answered a "sometimes true" or Q3 is "yes"), proceed to the next question.	
3a. How often did this happen - almost every month, some months but not every month, or in only 1 or 2 months?	<ul> <li>Almost every month</li> <li>Some months but not every month</li> <li>Only 1 or 2 months</li> <li>Don't know</li> </ul>
4. In the last 12 months, did you ever eat less than you felt you should because there wasn't enough money to buy food?	○ Yes ○ No ○ Don't know
5. In the last 12 months, were you ever hungry but didn't eat because you couldn't afford enough food?	○ Yes ○ No ○ Don't know
6.In the last 12 months, if you didn't have enough to eat or what Choose all that apply. (select all that apply)	you wanted to eat, why was that?
<ul> <li>Couldn't get out to buy food (for example, didn't have transp prevented you from getting out)</li> <li>Didn't want to go out to buy food</li> <li>Afraid to go out because of the chance of contracting COVID-</li> <li>Couldn't get groceries or meals delivered to me</li> <li>The stores didn't have the food I wanted</li> <li>Other(specify)</li> <li>I always had enough to eat and what I wanted to eat</li> </ul>	
Specify other	
Breakfast/Lunch from School (Tier 2) Parent Report About Child	
Did your child get breakfast and/or lunch from the school in the 2019-2020 school year before the COVID-19 pandemic?	○ Yes ○ No ○ Don't Know
If yes, did the school continue to provide breakfast and/or lunch during the COVID-19 pandemic (since March 2020)?	<ul> <li>No</li> <li>Yes, less frequently</li> <li>Yes, same frequency</li> <li>Yes, more frequently</li> </ul>



Household Income	
Parent Self-Report	
Thinking about members of your family living in this household, what is your combined annual income, meaning the total pre-tax income from all sources earned in the past year?	<ul> <li>\$0 to \$9,999</li> <li>\$10,000 to \$14,999</li> <li>\$15,000 to \$19,999</li> <li>\$20,000 to \$34,999</li> <li>\$35,000 to \$49,999</li> <li>\$50,000 to \$74,999</li> <li>\$75,000 to \$99,999</li> <li>\$100,000 to \$199,999</li> <li>\$200,000 or more</li> <li>Don't Know/Not sure</li> <li>Prefer not to answer</li> </ul>
Racial/Ethnic Discrimination	
Child Self-Report (Ages 13+)	
During your life, how often have you felt that you were treated badly or unfairly because of your race or ethnicity?	<ul> <li>Never</li> <li>Rarely</li> <li>Sometimes</li> <li>Most of the time</li> </ul>
Since the start of the pandemic (since March 2020), have you felt that you were treated badly or unfairly because of your race or ethnicity?	<ul> <li>Less</li> <li>Same amount</li> <li>More</li> <li>Not applicable (N/A)</li> </ul>
Coronavirus Racial/Ethnic Bias (Tier 2) Child Self-Report (Ages 15+)	

Please answer the following questions on your beliefs about how the coronavirus is affecting people of your race/ethnicity

I believe the country has become more dangerous for people in my racial/ethnic group because of fear of the coronavirus.	Strongly disagree	Somewhat disagree	Somewhat agree	Strongly agree
People of my race/ethnicity are more likely to lose their job because of the coronavirus.	Ο	Ο	0	0
l worry about people thinking l have the coronavirus simply because of my race/ethnicity.	0	0	0	0
Most social and mass media reports about the coronavirus create bias against people of my racial/ethnic group.	0	0	0	0



People of my race/ethnicity are more likely to get the	0	0	0	0
coronavirus. Due to the coronavirus, I have been cyberbullied because of my race/ethnicity.	0	0	0	0
Since the coronavirus, I have seen a lot more cyberbullying of people of my race/ethnicity.	0	0	0	0
Negative social media posts against people of my race/ethnicity have increased because of the coronavirus.	0	0	0	0



# **Educational Factors**

## Grade Level (School-age Child) Parent Report About Child

What is this child's current grade, grade equivalent, or year of school?

If this child is not assigned a specific grade or is homeschooled, mark the grade level of the curriculum the child receives. If between school years, mark the last grade level attended

○ Child has not yet started kindergarten

Full-day kindergarten
Partial-day kindergarten
1st grade
2nd grade
3rd grade
4th grade
5th grade
6th grade
7th grade
8th grade
9th grade
10th grade
11th grade
12th grade

#### Child Self-Report (Ages 12+)

Think about the school you [currently/last] [attend/attended]. What grade [are/were] you in?

4th grade
5th grade
6th grade
7th grade
8th grade
9th grade
10th grade
11th grade
12th grade

#### Current School Type Parent Report About Child

Is your child's current school a...

- A public school, including charter school or magnet school
- A private school, including private religious schools
- O Bureau of Indian Affairs (BIA) or tribal school
- O Early Childhood Center (school/center includes preschool and/or early elementary grades)
- Special Education school primarily serves children with disabilities
- O College, community college, or university
- Homeschool, including co-ops
- O Full-time cyber school



#### Child Self-Report (Ages 13+)*

Is your current school a...

- A public school, including charter school or magnet school
- A private school, including private religious schools
- O Bureau of Indian Affairs (BIA) or tribal school
- Early Childhood Center (school/center includes preschool and/or early elementary grades)
- O Special Education school primarily serves children with disabilities
- O College, community college, or university
- Homeschool, including co-ops
- Full-time cyber school

Note: for the remaining elements in this Domain, the questions are primarily for grades K-12:

Accommodations for Learning Difference Parent Report About Child			
Does your child have an Individualized Education Plan (IEP) or 504 plan?	⊖ Yes	⊖ No	⊖ Don't know
If yes, was your child receiving specialized services or resources on an Individualized Education Plan (IEP) or 504 plan in the 2019-2020 school year before the pandemic?	() Yes	⊖ No	⊖ Don't know
During the pandemic (since March 2020) were the child's services less, the same, or more frequent compared to before the pandemic?	<ul> <li>○ Less</li> <li>○ Same</li> <li>○ More</li> <li>○ N/A</li> </ul>		

#### **Changes to Schooling During Pandemic**

Additional Guidance:

This is a high level element to capture predominant forms of schooling during the different school years spanning the COVID-19 pandemic. For studies that want more detailed assessment of the length of time spent in the different forms of schooling during the COVID-19 pandemic, the Working Group proposes two strategies for investigators to consider:

1) using an event history calendar as a visual guide to obtain more specific month to month information on changes to schooling; from parents, and/or

2) obtaining the school district information on changes to schooling during the pandemic, noting this may only be applicable to students attending public schools (i.e., if the student answers Current School Type with 'A public school, including charter school or magnet school').

#### **Parent Report About Child**

From March 2020-June 2020, what was the predominant form of schooling for your child:

- O Attend school in person ONLY
- O Attend school remotely ONLY
- O Attend school via a hybrid model that included in person schooling and remote distance learning
- Not attend school because school was cancelled
- $\bigcirc$  Not attend school because child dropped out
- $\bigcirc$  Not attend school for other reason (please specify)
- $\bigcirc$  Not applicable (N/A)



From Sept 2020-June 2021, what was the predominant form of schooling for your child:

- O Attend school in person ONLY
- O Attend school remotely ONLY
- O Attend school via a hybrid model that included in person schooling and remote distance learning
- Not attend school because school was cancelled
- $\bigcirc$  Not attend school because child dropped out
- Not attend school for other reason (please specify)
- Not applicable (N/A)

From Sept 2021-present, what was the predominant form of schooling for your child:

- O Attend school in person ONLY
- Attend school remotely ONLY
- O Attend school via a hybrid model that included in person schooling and remote distance learning
- O Not attend school because school was cancelled
- O Not attend school because child dropped out
- Not attend school for other reason (please specify)
- $\bigcirc$  Not applicable (N/A)

## School Attendance/Absence (Tier 2) Parent Report About Child

Additional Guidance: Parent-reported absenteeism may be unreliable. Studies may alternatively seek to use school district records to calculate absences during each school year.

Since start of the current school year (or past school year if on summer break), about how many days did this child miss school (including missing remote learning)?

- No missed school days [skip next question]
- $\bigcirc$  1-3 days
- 4-6 days
- 7-10 days
- 11-15 days
- $\bigcirc$  15 or more days
- This child was not enrolled in school [skip next question]
- O Don't know [skip next question]

If more than 1 day was missed, about how many days did this child miss school (including missing remote learning) because of illness of you or a family member from COVID-19?

- No missed school days [skip next question]
- Ō 1-3 days
- $\bigcirc$  4-6 days
- 🔿 7-10 days
- 11-15 days
- 15 or more days
- This child was not enrolled in school
- Don't know



## Perception of Changes to Schooling (Tier 2) Parent Report About Child

Using a scale of 1-5, where 1 is not at all true, and 5 is completely true:

How true would you say each of the following statements is for your child's school/college, regarding how your experiences were/are during the COVID-19 pandemic (since March 2020)

	1, Not at all true	2	3	4	5, Completely true
Remote learning is as effective as live/traditional classroom lectures for my child.	0	0	0	0	0
My child can meet his/her educational goals with remote learning.	0	0	0	0	0
My child has sufficient social interaction with peers during remote learning.	0	0	0	0	0
It seems my child experiences a lack of interest during remote learning.	0	0	0	0	0
It seems my child experiences frustration during remote learning.	0	0	0	0	0

## School Risk and Protective Factors (Tier 2) Child Self-Report (Ages 12-18)

**Teacher Relationships** 

	Strongly Disagree	Disagree	Neither Agree or Disagree	Agree	Strongly Agree
1. Teachers understand my problems	0	0	0	$\bigcirc$	0
<ol><li>Teachers and staff seem to take a real interest in my future</li></ol>	0	0	0	0	0
<ol> <li>Teachers are available when I need to talk with them</li> </ol>	0	0	0	0	0
4. It is easy to talk with teachers	$\bigcirc$	0	$\bigcirc$	$\bigcirc$	0
5. Students get along well with teachers	0	0	0	0	0
6. At my school, there is a teacher or some other adult who notices when I'm not there	0	0	0	0	0



7. Teachers at my school help us children with our problems	0	0	0	0	0
8. My teachers care about me	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$
9. My teacher makes me feel good about myself	0	0	0	0	0

#### School Connectedness

	Strongly Disagree	Disagree	Neither Agree or Disagree	Agree	Strongly Agree
10. My schoolwork is exciting	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$
11. Students can make suggestions on courses that are offered	0	0	0	0	0
12. Students are publicly recognized for their outstanding performances in speech, drama, art, music, etc.	0	0	0	0	0
13. If this school had an extra period during the day, I would take an additional academic class	0	0	0	0	0
14. This school makes students enthusiastic about learning	0	0	0	0	0
15. Students are frequently rewarded or praised by faculty and staff for following school rules	0	0	0	0	0

## Academic Support

	Strongly Disagree	Disagree	Neither Agree or Disagree	Agree	Strongly Agree
16. I usually understand my homework assignments	0	0	0	$\bigcirc$	0
17. Teachers make it clear what work needs to be done to get the grade I want	0	0	0	0	0
18. I believe that teachers expect all students to learn	0	0	0	0	0
19. I feel that I can do well in this school	0	0	0	0	0
20. My teachers believe that I can do well in my school work	0	0	0	0	0
21. I try hard to succeed in my classes	0	0	0	0	0

Order and Discipline



					Page 70
	Strongly Disagree	Disagree	Neither Agree or Disagree	Agree	Strongly Agree
22. Classroom rules are applied equally	0	0	0	$\bigcirc$	0
23. Problems in this school are solved by students and staff	0	0	0	0	0
24. Students get in trouble if they do not follow school rules	0	0	0	0	0
25. The rules of the school are	$\bigcirc$	0	$\bigcirc$	$\bigcirc$	0
fair 26. School rules are enforced consistently and fairly	0	0	0	$\bigcirc$	0
27. My teachers make it clear to me when I have misbehaved in class	0	0	0	0	0
28. Discipline is fair	0	0	0	0	0

(Only answer if in-person schooling)

School Physical Environment

	Strongly Disagree	Disagree	Neither Agree or Disagree	Agree	Strongly Agree
29. The school grounds are kept clean	0	0	0	0	0
30. My school is neat and clean	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$	0
31. My school buildings are generally pleasant and well maintained	0	0	0	0	0
32. My school is usually clean and tidy	0	0	0	0	0

#### School Social Environment

	Strongly Disagree	Disagree	Neither Agree or Disagree	Agree	Strongly Agree
33. I am happy with the kinds of students who go to my school	0	0	0	$\bigcirc$	0
34. I am happy, in general, with the other students who go to my school	0	0 (		0	0
Perceived Exclusion/Privilege					
	Strongly Disagree	Disagree	Neither Agree or Disagree	Agree	Strongly Agree



	Strongly	Disagree	Neither Agree or	Agree	Strongly Agree
Academic Satisfaction					
37. The same kids always get to use things, like a computer, a ball or a piano, when we play	0	0	0	0	0
36. At my school, the same kids get chosen every time to take part in after-school or special activities	0	0	0	0	0
35. At my school, the same person always gets to help the teacher	0	0	0	0	0

	Disagree	-	Disagree	-	
38. I am happy about the number of tests I have	0	$\bigcirc$	0	0	0
39. I am happy about the amount of homework I have	0	0	0	0	0

Academic Performance/Achievement

Child Self-Report (Ages 10+)/Parent Report About Child

In the months before the pandemic (2019-February 2020) how would you describe your/your child's grades in school?

Below average (D's or F's)
Average (C's)
Good (B's)
Very good (A's and B's)
Excellent (A's)
I/my child was not graded
Refused
Don't know

During the current school year (or most recent school year if on summer break) how would you describe your/your child's grades in school?

Below average (D's or F's)
Average (C's)
Good (B's)
Very good (A's and B's)
Excellent (A's)
I/my child was not graded
Refused
Don't know



# Childcare (Tier 2)

#### Parent Self-Report

How has the COVID-19 outbreak affected your regular childcare/supervision of school aged children (K-12)? (Mark all that apply)

□ I had difficulty arranging for childcare/supervision

I had to pay more for childcare/supervision

☐ My co-parent or I no longer needed child care

My co-parent or I had to change our work schedule or quit our job to care for our children

My regular childcare/supervision was not affected by the COVID-19 outbreak

I do not have a school-age child who needed regular supervision

#### **Computer and Internet Access**

Parent Report About Child

How often is a computer/laptop or other digital device (e.g., tablet) available to your child for educational purposes to support remote distance learning?

Always available
 Usually available
 Sometimes available
 Rarely available
 Never available
 N/A

Is/are the computer(s) or other digital device(s) ...? (Select all that apply)

O Provided by the child's school or school district to use outside of school

 $\bigcirc$  Provided by someone in the household or family, or it is the child's

 $\bigcirc$  Provided by another source

 $\bigcirc$  N/A

How often is the Internet available to your child for educational purposes to support remote distance learning?

○ Always available

O Usually available

○ Sometimes available

O Rarely available

O Never available

○ N/A

Are Internet services ...? (Select all that apply)

Paid	for	by	the	child	ren's	schoo	l or	school	district

- Paid for by someone in the household or family
- Paid for by another source
- 🗌 N/A



# **Community, Family, and Peer Factors**

Social Connection/Support	
Child Self-Report (Age 13+)	
Compared to before the COVID-19 outbreak (before March 2020), do you feel	<ul> <li>Much less socially connected</li> <li>Less socially connected</li> <li>Slightly less socially connected</li> <li>Slightly more socially connected</li> <li>More socially connected</li> <li>Much more socially connected</li> </ul>
Parent Report About Child (Age 8+)	
Compared to before the COVID-19 outbreak (before March 2020), does your child seem	<ul> <li>Much less socially connected</li> <li>Less socially connected</li> <li>Slightly less socially connected</li> <li>Slightly more socially connected</li> <li>More socially connected</li> <li>Much more socially connected</li> </ul>

# Emotional Support/Social Support (Tier 2) NIH Toolbox Emotional Support FF Ages 8-17 v2.0

#### Child Self-Report (Ages 8-17)

## In the past month, please describe how often...

· · · · · · · · · · · · ·					
	Never	Rarely	Sometimes	Usually	Always
l have someone who understands my problems	0	0	0	0	0
I have someone who will listen to me when I need to talk	0	$\bigcirc$	0	$\bigcirc$	0
l have someone to talk with when l have a bad day	0	0	0	0	0
There is someone around to help me if l need it	0	0	0	0	0
l can get helpful advice from others when dealing with a problem	0	0	0	0	0
l get useful advice about important things in my life	0	0	0	0	0
l have someone to talk with about school problems	0	0	0	0	0



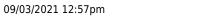
Compared to before the COVID	)-19 pandemic (bef	ore March 2020)	
l have someone who understands my problems	Less	The same	More O
l have someone who will listen to me when I need to talk	0	0	0
l have someone to talk with when l have a bad day	0	0	0
There is someone around to help me if I need it	0	0	0
l can get helpful advice from others when dealing with a problem	0	0	0
l get useful advice about important things in my life	0	0	0
l have someone to talk with about school problems	0	0	0

# Peer Relationships (Tier 2) Parent Report About Child (Ages 1-5)

## In the past 7 days...

·	Never	Almost never	Sometimes	Often	Almost always
My child shared with other kids	$\bigcirc$	$\bigcirc$	0	$\bigcirc$	$\bigcirc$
My child played well with other children	$\bigcirc$	0	$\bigcirc$	0	0
My child laughed and smiled with other children	$\bigcirc$	0	0	0	0
My child showed interest in other children	$\bigcirc$	$\bigcirc$	0	$\bigcirc$	$\bigcirc$

Compared to before the COVID-19 pandemic (before March 2020)					
	Less	The same	More		
My child shares with other kids	$\bigcirc$	$\bigcirc$	0		
My child plays well with other children	0	0	0		
My child laughs and smiles with other children	0	0	0		
My child shows interest in other children	0	0	0		





# Parent Report About Child (Ages 5-17)

### In the past 7 days...

	Never	Almost Never	Sometimes	Often	Almost Always
My child felt accepted by other kids his/her age	0	$\bigcirc$	0	0	0
My child was able to count on his/her friends	0	0	0	0	0
My child was good at making friends	0	0	0	0	0
My child and his/her friends helped each other out	0	$\bigcirc$	0	0	0
Other kids wanted to be my child's friend	0	0	0	0	0
Other kids wanted to be with my child	0	$\bigcirc$	0	0	0
Other kids wanted to talk to my child	0	$\bigcirc$	0	0	0

Compared to before the COVI	D-19 pandemic (bef	fore March 2020)	
	Less	The same	More
My child feels accepted by other kids his/her age	0	Ο	0
My child is able to count on his/her friends	0	0	0
My child is good at making	$\bigcirc$	0	$\bigcirc$
friends My child and his/her friends help each other out	0	0	0
Other kids want to be my child's friend	0	0	0
Other kids want to be with my child	0	0	0
Other kids want to talk to my child	0	0	0

# Child Self-Report (Ages 8-17)

# PROMIS Pediatric Item Bank v2.0 - Peer Relationships - Short Form 8a

### In the past 7 days...

	Never	Almost Never	Sometimes	Often	Almost Always
l felt accepted by other kids my age	$\bigcirc$	$\bigcirc$	$\bigcirc$	0	0



l was able to count on my friends l was able to talk about everything with my friends	0 0	0 0	0 0	0 0	0 0
I was good at making friends My friends and I helped each other out	0 0	0 0	0 0	0 0	0 0
Other kids wanted to be my friend Other kids wanted to be with me Other kids wanted to talk to me	0 0 0	0 0 0	0 0 0	0 0 0	0 0 0

Compared to before the COVID-19 pandemic (before March 2020)					
	Less	The same	More		
I felt accepted by other kids my age	0	0	0		
l am able to count on my friends	0	0	$\bigcirc$		
l am able to talk about everything with my friends	0	0	0		
I am good at making friends	0	0	$\bigcirc$		
My friends and I help each other out	0	0	0		
Other kids want to be my friend	0	0	$\bigcirc$		
Other kids want to be with me	0	0	$\bigcirc$		
Other kids want to talk to me	0	0	0		

# Family Impact/Household Interpersonal Conflict (Tier 2)

Parent Self-Report

How have/were you and your child(ren) (been) getting along during the COVID-19 outbreak (since March 2020)?

<ul> <li>Very well - no problems or tension</li> <li>Well - occasional tension, some tension, but manageable</li> <li>Okay - some tension and sometimes things get out of hand (a</li> <li>Not very well - tense, lots of arguing, unsettled feeling, definit</li> <li>Terribly</li> </ul>		
ls this a change from how you were getting along before the outbreak (before March 2020)?	⊖ Yes	⊖ No
Child Self-report (Ages 13+)		
How [have/were] YOU and your parent(s) (been) getting along du	uring the	COVID-19 outbreak (since March 2020)?
<ul> <li>Very well - no problems or tension</li> <li>Well - occasional tension, some tension, but manageable</li> <li>Okay - some tension and sometimes things get out of hand (a</li> <li>Not very well - tense, lots of arguing, unsettled feeling, definit</li> <li>Terribly</li> </ul>		

Is this a change from how you were getting ale	ong
before the outbreak (before March 2020)?	-

⊖Yes ⊖
--------

#### If study approval and privacy ensured;

### INTERVIEWER: IF CONDUCTING PHONE INTERVIEW, PLEASE SAY THE FOLLOWING:

# For the next 3 questions, I am going to ask you about some private matters, so please turn your speakerphone off.

During the COVID-19 outbreak (since March 2020), did things ever get to the point where an adult you were living with got physically violent with a child (for example, shoved, hit, kicked, or shook [her/him/them])?	() Yes	⊖ No
During the COVID-19 outbreak (since March 2020), was an adult in your household ever physically violent with you (for example, shoved, hit, kicked, or shook you)?	⊖ Yes	⊖ No
During the COVID-19 outbreak (since March 2020), did things ever get to the point where an adult you were living with got physically violent with someone else (for example, shoved, hit, kicked, or shook someone else)?	() Yes	⊖ No

Additional Guidance: Guidance for conducting child maltreatment research and reporting varies depending on the scope of the project, study participants, setting of the study (school, hospital, etc.) and state mandatory reporting laws. More information on state statutes can be found at the HHS Childwelfare.gov site:

https://www.childwelfare.gov/pubPDFs/manda.pdf (2019). Researchers should consult with their IRBs to minimize risks to study participants, appropriately consent and adhere to ethical practices and regulatory requirements for including vulnerable children in research: https://www.hhs.gov/ohrp/regulations-and-policy/guidance/special-protections-for-children/index.html. Additional NICHD resources for forensic or evidence-based interviewing of children include: http://nichdprotocol.com/ , https://youth.gov/content/nichdinvestigative-interview-protocol.

#### Community Support (Cohesion) (Tier 2)

Paren Self-Report

Now I'm going to read some statements about things that people in your neighborhood may or may not do.

For each of these statements, please tell me whether you strongly agree, agree, neither agree nor disagree, disagree or strongly disagree.

	5, 5				
	Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree
This is a close-knit neighborhood	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$
People around here are willing to help their neighbors	$\bigcirc$	0	0	0	0



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People in this neighborhood generally don't get along with each other	0	0	0	0	0
People in this neighborhood do not share the same values	0	0	0	0	0
People in this neighborhood can be trusted	0	0	0	0	0

For each of the following, please tell me if it is very likely, likely, neither likely nor unlikely, unlikely, or very unlikely that people in your neighborhood would act in the following manner

unlikely, or very unlikely that	Very likely	Likely	Neither likely nor unlikely	Unlikely	Very unlikely
If a group of neighborhood children were skipping school and hanging out on a street corner, how likely is it that your neighbors would do something about it?	0	0	O	0	0
If some children were spray-painting graffiti on a local building, how likely is it that your neighbors would do something about it?	0	0	0	0	0
If a child was showing disrespect to an adult, how likely is it that people in your neighborhood would scold that child?	0	0	0	0	0
If there was a fight in front of your house and someone was being beaten or threatened, how likely is it that your neighbors would break it up?	0	0	0	0	0
Suppose that because of budget cuts the fire station closest to your home was going to be closed down by the city. How likely is it that neighborhood residents would organize to try to do something to keep the fire station open?	0	0	0	0	0



# **Social Media/Screen Time**

#### Time Spent in Front of a Screen (Tier 2)

Child Self-Report (Ages 13+)*/Parent Report About Child

ON MOST WEEKDAYS, about how much time did [you/your child] spend in front of a TV, computer, cellphone or other electronic device watching programs, playing games, accessing the Internet or using social media? Do not include time spent doing schoolwork.

○ Less than 1 hour

🔿 1 hour

○ 2 hours

○ 3 hours

 $\bigcirc$  4 or more hours

Compared to before the COVID-19 outbreak (before March 2020), how much are [you/your child] now doing of the following:

Spending time watching TV/videos (such as YouTube), playing video/computer games, or using social media for educational purposes, including schoolwork

Less
 Same amount
 More

Spending time watching TV/videos (such as YouTube), playing video/computer games, or using social media for non-educational purposes

Less
 Same amount
 More

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# **Well-being Factors**

Well-Being

)				
Not at all	Rarely	Sometimes	Often	Very often
0	0	0	0	0
Not at all	Rarely	Sometimes	Often	Very often
0	0	0	0	0
	0	Not at all Rarely	Not at all Rarely Sometimes	Not at all Rarely Sometimes Often

# Well-being (Tier 2) NIH Toolbox Positive Affect Fixed Form v2.0

Child Self-Report (Ages 8-12)

In the past 7 days,					
	Not at all	A little bit	Somewhat	Quite a bit	Very much
I felt attentive	$\bigcirc$	0	$\circ$	$\bigcirc$	$\bigcirc$
I felt delighted	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$
l felt calm	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$
l felt at ease	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$
I felt enthusiastic	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$
I felt interested	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$
l felt confident	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$
I felt energetic	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$
I felt able to concentrate	0	0	0	0	0
Child Self-Report (Ages 1	3-17)				
In the past 7 days,					
	Not at all	A little bit	Somewhat	Quite a bit	Very much
l felt cheerful	0	$\bigcirc$	0	0	$\bigcirc$
I felt attentive	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$



#### Confidential

I felt delighted	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$
l felt joyful	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$
I felt at ease	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$
I felt enthusiastic	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$
I felt interested	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$
I felt peaceful	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$
I felt good-natured	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$
l felt content	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$

#### Parent Report About Child (Ages 3-12)

#### In the past 7 days,

	Not at all	A little bit	Somewhat	Quite a bit	Very much
My child was cheerful	$\bigcirc$	0	$\bigcirc$	$\bigcirc$	$\bigcirc$
My child was delighted	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$
My child was inspired	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$
My child was happy	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$
My child was alert	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$
My child was joyful	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$
My child was enthusiastic	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$
My child was interested	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$
My child was confident	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$

# Coping Strategies (Tier 2) Child Self-Report (Ages 13+)

What have you done to cope with your stress related to the COVID-19 outbreak? (Mark all that apply)

- □ Arts and crafts projects
- Cooking/baking
- Drinking alcohol
- Engaging in more family activities (e.g., games, sports)
- Exercising/walking
- □ Increasing time reading books, or doing activities like puzzles and crosswords
- Meditation and/or mindfulness practices
- Spiritual/religious practices
- Talking to my healthcare providers more frequently, including mental healthcare providers (e.g., therapists, psychologists, counselors)
- Texting, calling or video-calling family members or friends
- Using tobacco (e.g., smoking), using marijuana (e.g., smoking, edibles), vaping
- Volunteer work
- $\hfill\square$  I have not done any of these things to cope with the COVID-19 outbreak



#### Parent Report About Child (Ages 8+)

Which of the following strategies [have been/were] helpful to YOUR CHILD while staying at home because of the COVID-19 outbreak?

- Arts and crafts projects
- Cooking/baking
- Engaging in more family activities (e.g., games, sports)
- Exercising/walking
- Increasing time reading books, or doing activities like puzzles and crosswords
- Meditation and/or mindfulness practices
- Spiritual/religious practices
- Talking to healthcare providers more frequently, including mental healthcare providers (e.g., therapists, psychologists, counselors)
- Texting, calling or video-calling family members or friends
- Volunteer work
- ☐ My child has not done any of these things to cope with the COVID-19 outbreak

# Loneliness (Tier 2) Child Self-Report (Ages 13+)*

Is your life lonelier because of the COVID-19 pandemic?

⊖ Yes ⊃ No



# **Covid19 Attitudes Behaviors And Experiences**

### Household COVID-19 Exposure Parent Report About Child/Child Self-Report (Ages 13+)

During the COVID-19 outbreak (since March 2020), did [you/your child] ever live with someone that was sick with COVID-19?

○ Yes ○ No

Not sure, I think someone [I/my child] lived with might have had COVID-19

If yes or not sure, who was this? (select all that may apply)

[My/Child's] Parent
 [My/Child's] Sibling
 [My/Child's] Grandparent
 [My/Child's] Other family members (e.g., aunt, uncle, cousin)
 [My/Child's] Roommate
 Other

Specify Other

If yes, did any of them die because of COVID-19?

⊖ Yes ⊃ No

If yes, who died? (select all that may apply)

[My/Child's] Parent

[My/Child's] Sibling

[My/Child's] Grandparent

[My/Child's] Other family members (e.g., aunt, uncle, cousin)

[My/Child's] Roommate

Other

Specify Other

## Ability to Isolate (Tier 2) Parent Self-Report

If it were necessary, could a member of your household isolate themselves from the rest of your household due to suspected COVID-19 infection for as long as needed?

To effectively isolate during a COVID-19 infection, the infected family member would need to stay in a specific "sick room" away from other people or animals and, if possible, use a separate bathroom.

○ Yes○ No○ Unknown



# Belief That COVID is Serious Disease (Tier 2) Parent Self-Report/Child Self-Report (Ages 13+)*

I believe that COVID-19 is a serious disease.

○ Yes
 ○ No
 ○ Unsure (or don't know)

## Adherence to Social Distancing/Face Coverings (Tier 1) Parent Self-Report/Child Self-Report (Ages 13+)*

To the best of your knowledge, which of the following can protect you and your family from COVID-19? (Mark all that apply)

□ Standing 6 feet from another person

- Wearing a face mask
- Working from home
- Distance learning (or taking school classes over the computer or remotely)

□ Vaccination for COVID-19

#### Vaccine Attitudes (Tier 2)

#### Parent Self-Report

Which of the following applies to your plans about the COVID vaccine for your child(ren)?

O My child(ren) is/are already vaccinated

- O I plan on getting the COVID vaccine for my child(ren) as soon as it is available
- O I plan on getting the COVID vaccine for my child(ren) eventually
- I do not plan on getting the COVID vaccine for my child(ren)

○ I am unsure

If you do not plan on getting the COVID vaccine for your child(ren), why not (mark all that apply)?

🗌 Not available

- Doctor/healthcare provider did not recommend
- My friends and family did not recommend
- □ I have read information that suggests it is unsafe
- □ The vaccine was not well tested in ethnically diverse people
- The vaccine was not well tested among children
- □ I cannot afford the vaccine
- □ I do not have time to take my child to be vaccinated
- My child is at low risk and does not need it
- □ It is riskier to go and get it than to stay at home
- □ Worried about side effects
- □ The vaccine's technology hasn't been tested enough
- ☐ The vaccine was approved too fast
- □ No long-term safety data available
- Concerned about vaccine storage
- My child already had COVID-19
- Other (please specify):

Specify other reason



# **COVID-19 Stress and Worry**

# Worry/Anxiety About COVID-19 (Tier 2)

Child Self-Report (Ages 9+)

During the COVID-19 pandemic (since March 2020)						
	Not at all	Slightly	Moderately	Very	Extremely	
How worried have you been about coronavirus (COVID-19)?	0	0	0	0	0	
How worried have others around you been about coronavirus (COVID-19)?	0	0	0	0	0	
How worried have you been about changes to schooling in the 2020-2021 school year (e.g., missing school in-person)?	0	0	0	0	0	
How much do you think your life has changed due to coronavirus (COVID-19)?	0	0	0	0	0	
How hopeful have you been that the coronavirus/COVID-19 crisis in your area will end soon?	0	0	0	0	0	

In the past week:					
	Not at all	Slightly	Moderately	Very	Extremely
How worried have you been about coronavirus (COVID-19)?	0	0	0	0	0
How worried have others around you been about coronavirus (COVID-19)?	0	0	0	0	0
How worried have you been about changes to schooling in the 2020-2021 school year (e.g., missing school in-person)?	0	0	0	0	0
How much do you think your life has changed due to coronavirus (COVID-19)?	0	0	0	0	0
How hopeful have you been that the coronavirus/COVID-19 crisis in your area will end soon?	0	0	0	0	0



# Stress Related to COVID-19 (Tier 2)

Child Self-Report (Ages 13+)

During the COVID-19 pandemic (since March 2020), how often did you:						
	Not at all	Rarely	Sometimes	Often	Very often	
Have difficulty sleeping	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$	
Startle easily	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$	
Have angry outbursts	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$	
Feel a sense of time slowing	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$	
down Feel in a daze	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$	
Try to avoid thoughts and feelings about COVID-19	$\bigcirc$	$\bigcirc$	0	0	0	
Try to avoid reading or watching information about COVID-19	0	0	0	0	0	
Have distressing dreams about COVID-19	0	0	0	0	0	
Feel distressed when you saw something that reminded you of COVID-19	0	0	0	0	0	



# **Health Related Behaviors**

Physical Activity (Tier 2) Parent Report About Child (Ages 5+)	
During the past week, on how many days did this child exercise, play a sport, or participate in physical activity (including physical education classes) for at least 60 minutes?	<ul> <li>○ 0 days</li> <li>○ 1-3 days</li> <li>○ 4-6 days</li> <li>○ Every day</li> </ul>
How has this changed compared to before the COVID-19 outbreak (before March 2020)?	<ul> <li>Fewer days</li> <li>Same number of days</li> <li>More days</li> <li>Don't know</li> </ul>
Sleep Quality Child Self-Report (Ages 13+)*	

 How has your quality of sleep changed compared to before the COVID-19 outbreak (before March 2020)?
 It's gotten a lot worse

 It's gotten a little worse
 Stayed the same

 It's gotten a little better
 It's gotten a lot better

Additional Guidance: DSM-5 Cross-Cutting Symptom Measure (below) also covers sleep problems and refers to subsequent PROMIS measures for sleep impairment.

## Sleep Duration (Tier 2) Child Self-Report (Ages 13+)*/Parent Report About Child

Consider the question as pertaining to the last week in your/your child's life.

How many hours of sleep did you/your child get on most nights?	<ul> <li>More than 11 hours</li> <li>9-11 hours</li> <li>8-9 hours</li> <li>7-8 hours</li> <li>5-7 hours</li> <li>Less than 5 hours</li> <li>Don't know</li> </ul>
How has this changed compared to before the COVID-19 outbreak (before March 2020)?	<ul> <li>Less time</li> <li>Same time</li> <li>More time</li> <li>Don't know</li> </ul>

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# Baseline Child Health [also covered in Joint Group Discussion section] Parent Report About Child

# Has a doctor or other health care provider EVER told you that this child has...

Tourette Syndrome	⊖ Yes	⊖ No
if yes, does this child CURRENTLY have the condition?	⊖ Yes	⊖ No
Depression	⊖ Yes	○ No
if yes, does this child CURRENTLY have the condition?	⊖ Yes	⊖ No
Anxiety problems	⊖ Yes	⊖ No
if yes, does this child CURRENTLY have the condition?	⊖ Yes	⊖ No
Autism or Autism Spectrum Disorder (ASD), Asperger's Disorder, Pervasive Developmental Disorder (PDD)	⊖ Yes	⊖ No
if yes, does this child CURRENTLY have the condition?	⊖ Yes	⊖ No
Attention Deficit Disorder or Attention Deficit Hyperactive Disorder (ADD/ADHD)*	⊖ Yes	⊖ No
if yes, does this child CURRENTLY have the condition?	⊖ Yes	⊖ No
Chronic fatigue	⊖ Yes	⊖ No
if yes, does this child CURRENTLY have the condition?	⊖ Yes	⊖ No
Post-traumatic stress disorder (PTSD)	⊖ Yes	⊖ No
if yes, does this child CURRENTLY have the condition?	⊖ Yes	⊖ No
Suicidal thoughts or behaviors	⊖ Yes	⊖ No
if yes, does this child CURRENTLY have the condition?	⊖ Yes	⊖ No
Mania or bipolar disorder	⊖ Yes	⊖ No
if yes, does this child CURRENTLY have the condition?	⊖ Yes	⊖ No



Has a doctor, other health care provider, or e	ducator EVER	told you that this child has
Behavioral disorder or conduct problems	⊖ Yes	⊖ No
if yes, does this child CURRENTLY have the condition?	⊖ Yes	⊖ No
Developmental delay	⊖ Yes	⊖ No
if yes, does this child CURRENTLY have the condition?	⊖ Yes	⊖ No
Intellectual disability (formerly known as mental retardation)	⊖ Yes	⊖ No
if yes, does this child CURRENTLY have the condition?	⊖ Yes	⊖ No
Speech or other language disorder	⊖ Yes	⊖ No
if yes, does this child CURRENTLY have the condition?	⊖ Yes	⊖ No
Learning disability	⊖ Yes	⊖ No
if yes, does this child CURRENTLY have the condition?	⊖ Yes	⊖ No



# **Mental And Behavioral Health**

# **Overall Physical and Mental/Emotional Health**

# Note: Collect BOTH Parent-Self Report and either Child-Self Report or Parent Report About Child

Parent Self-Report					
	Excellent	Very good	Good	Fair	Poor
In general, how is your physical health?	0	0	0	0	0
In general, how is your mental or emotional health?	0	0	0	0	0
Parent Report About Child					
	Excellent	Very good	Good	Fair	Poor
In general, how is your childs physical health?	0	0	0	0	0
In general, how is your childs mental or emotional health?	0	0	0	0	0
Child Self-Report (Ages 8+)					
	Excellent	Very good	Good	Fair	Poor
In general, how would you rate your physical health?	0	0	0	0	0
In general, how would you rate your mental health, including your mood and your ability to think?	0	0	0	0	0

# **Current Mental Health Symptoms**

Tier 1: DSM-5 Cross-cutting Symptom Measure, PROMIS Depressive Symptoms, PROMIS Anxiety, PROMIS Fatigue

Tier 2: CRIES-8 Trauma, RCADS, PROMIS Pain Interference, Externalizing Symptoms

Additional Guidance: For younger children (Ages 1-5), the Working Group recommends using the PROMIS Early Childhood parent report measures for Anxiety, Anger/Irritability, Depressive Symptoms, Sleep Health, and Global Health found on HealthMeasures. PROMIS Early Childhood does not yet cover Fatigue or Pain Interference.

## Organized below by:

1) Parent Report About Child (all measures except Trauma)

2) Child Self-Report



Parent Report About Child: Current Mental Health Symptoms Tier 1: DSM-5 Cross-Cutting Symptom Measure (Ages 6-17)

The National Institute of Mental Health (NIMH) in consultation with the Wellcome Trust and other funders of mental health research has identified the DSM-5 Cross-Cutting Symptom Measure as part of a minimal list of data collection instruments that would be ideal for use by all mental health researchers conducting clinical research to facilitate and harmonize mental health data collection.

These measures have been selected using either the PhenX consensus process (https://www.phenxtoolkit.org/collections/view/1) or the International Consortium for Health Outcomes Measurement (ICHOM) (https://www.ichom.org/resource-library/category/condition-specific-resources/depression-anxiety/) with additional consideration for successful use of the measures in various countries.

During the past TWO (2) WEEKS, how much (or how often) has your child					
	0-None Not at all	1-Slight Rare less than a day or two	2-Mild Several days	3-Moderate More than half the days	4-Severe Nearly every day
<ol> <li>Complained of stomach aches, headaches, or other aches and pains?</li> </ol>	0	0	0	0	0
2. Said he/she was worried about his/her health or about getting sick?	0	0	0	0	0

I. Somatic Symptoms - Highest Domain Score (clinician)

н.					
	0-None Not at all	1-Slight Rare less than a day or two	2-Mild Several days	3-Moderate More than half the days	4-Severe Nearly every day
3. Had problems sleeping-that is, trouble falling asleep, staying asleep, or waking up too early?	0	0	0	0	0
II. Sleep Problems - Highest Doma	in Score (cliniciar	ı) —			
III.					
	0-None Not at all	1-Slight Rare less than a day or two	2-Mild Several days	3-Moderate More than half the days	4-Severe Nearly every day
4. Had problems paying attention when he/she was in class or doing his/her homework or reading a book or playing a game?	0	0	0	Ο	0
III. Inattention - Highest Domain S	core (clinician)				



IV.					
	0-None Not at all	1-Slight Rare less than a day or two	2-Mild Several days	3-Moderate More than half the days	4-Severe Nearly every day
5. Had less fun doing things than he/she used to?	0	0	0	0	0
6. Seemed sad or depressed for several hours?	0	0	0	0	0
IV. Depression - Highest Domain S	Score (clinician)	_			
V. & VI.					
	0-None Not at all	1-Slight Rare less than a day or two	2-Mild Several days	3-Moderate More than half the days	4-Severe Nearly every day
<ol><li>Seemed more irritated or easily annoyed than usual?</li></ol>	0	0	0	0	0
8. Seemed angry or lost his/her temper?	0	0	0	0	0
V. Anger & VI. Irritability - Highest (clinician)	Domain Score	_			
VII.					
	0-None Not at all	1-Slight Rare less than a day or two	2-Mild Several days	3-Moderate More than half the days	4-Severe Nearly every day
9. Started lots more projects than usual or did more risky things than usual?	0	0	0	0	0
10. Slept less than usual for him/her but still had lots of energy?	0	0	0	0	0
VII. Mania Highest - Domain Score	e (clinician)				
VIII.				2.11	
	0-None Not at all	1-Slight Rare less than a day or two	2-Mild Several days	3-Moderate More than half the days	4-Severe Nearly every day
11. Said he/she felt nervous,					



12. Not been able to stop worrying?	0	0	0	0	0
13. Said he/she couldnt do things he/she wanted to or should have done, because they made him/her feel nervous?	0	0	0	0	0

VIII. Anxiety Highest - Domain Score (clinician)

IX.					
	0-None Not at all	1-Slight Rare less than a day or two	2-Mild Several days	3-Moderate More than half the days	4-Severe Nearly every day
14. Said that he/she heard voices - when there was no one there - speaking about him/her or telling him/her what to do or saying bad things to him/her?	0	0	0	0	0
15. Said that he/she had a vision when he/she was completely awake - that is, saw something or someone that no one else could see?	0	0	0	0	0

IX. Psychosis - Highest Domain Score (clinician)

х.					
	0-None Not at all	1-Slight Rare less than a day or two	2-Mild Several days	3-Moderate More than half the days	4-Severe Nearly every day
16. Said that he/she had thoughts that kept coming into his/her mind that he/she would do something bad or that something bad would happen to him/her or to someone else?	0	0	0	0	0
17. Said he/she felt the need to check on certain things over and over again, like whether a door was locked or whether the stove was turned off?	0	0	0	0	0



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18. Seemed to worry a lot about things he/she touched being dirty or having germs or being poisoned?	0	0		0	0	(	0
19. Said that he/she had to do things in a certain way, like counting or saying special things out loud, in order to keep something bad from happening?	0	0		0	0	(	0
X. Repetitive Thoughts and Behaviors - Score (clinician)	Highest Domain					-	
XI. In the past TWO (2) WEEKS	has your child						
20. Had an alcoholic beverage (beer, w etc.)?	rine, liquor,		⊖ Yes	⊖ No	🔿 Don't know		
21. Smoked a cigarette, a cigar, or pipe snuff or chewing tobacco?	e, or used		⊖ Yes	⊖ No	🔿 Don't know		
22. Used drugs like marijuana, cocaine drugs (like ecstasy), hallucinogens (like heroin, inhalants or solvents (like glue) methamphetamine (like speed)?	e LSD),		() Yes	⊖ No	○ Don't know		
23. Used any medicine without a docto (e.g., painkillers [like Vicodin], stimular Ritalin or Adderall], sedatives or tranqu sleeping pills or Valium], or steroids)?	nts [like		⊖ Yes	⊖ No	○ Don't know		
XI. Substance Use - Highest Domain Sc	ore (clinician)					-	
XII.							
24. In the past TWO (2) WEEKS has he/ wanting to kill himself/herself or about commit suicide?			⊖ Yes	⊖ No	🔿 Don't know		
25. Has he/she EVER tried to kill himse	lf/herself?		⊖ Yes	⊖ No	🔿 Don't know		
XII. Suicidal Ideation/ Suicide Attempts Domain Score (clinician)	- Highest					-	



# **Tier 2: After meeting thresholds**

Domain	Domain Name	Threshold to guide further inquiry	DSM-5 Level 2 Cross-Cutting Symptom Measure available online
Ι.	Somatic Symptoms	Mild or greater	LEVEL 2—Somatic Symptom—Parent/Guardian of Child Age 6–17 (Patient Health Questionnaire 15 Somatic Symptom Severity (PHQ-15)
II.	Sleep Problems	Mild or greater	LEVEL 2—Sleep Disturbance—Parent/ Guardian of Child Age 6–17 (PROMIS— Sleep Disturbance—Short Form) ¹
III.	Inattention	Slight or greater	LEVEL 2—Inattention—Parent/Guardian of Child Age 6–17 (SNAP-IV)
IV.	Depression	Mild or greater	LEVEL 2—Depression—Parent/Guardian of Child Age 6–17 (PROMIS Emotional Distress—Depression—Parent Item Bank)
V.	Anger	Mild or greater	LEVEL 2—Anger—Parent/Guardian of Child Age 6–17 (PROMIS Emotional Distress—Calibrated Anger Measure—Parent)
VI.	Irritability	Mild or greater	LEVEL 2—Irritability—Parent/Guardian of Child Age 6–17 (Affective Reactivity Index)
VII.	Mania	Mild or greater	LEVEL 2—Mania—Parent/Guardian of Child Age 6–17 (adapted from the Altman Self-Rating Mania Scale)
VIII.	Anxiety	Mild or greater	LEVEL 2—Anxiety—Parent/Guardian of Child Age 6–17 (adapted from PROMIS Emotional Distress—Anxiety—Parent Item Bank)
IX.	Psychosis	Slight or greater	None
Х.	Repetitive Thoughts and Behaviors	Mild or greater	None
XI.	Substance Use	Yes/ Don't Know	LEVEL 2—Substance Use—Parent/Guardian of Child Age 6–17 (adapted from the NIDA-modified ASSIST)/LEVEL 2—Substance Use—Child Age 11–17 (adapted from the NIDA-modified ASSIST)
XII.	Suicidal Ideation/ Suicide Attempts	Yes/ Don't Know	None

## I. Somatic Symptoms

# LEVEL 2 Somatic Symptom Parent/Guardian of Child Age 6-17 (Patient Health Questionnaire 15 Somatic Symptom Severity (PHQ-15)

During the past 7 days how much has your child been bothered by any of the following problems?

	Not bothered at all	Bothered a little	Bothered a lot
Stomach pain	0	$\bigcirc$	$\bigcirc$
Back pain	0	0	$\bigcirc$
Pain in his or her arms, legs, or joints (knees, hips, etc.)	0	0	0
Headaches	0	0	0
Chest pain	0	0	$\bigcirc$
Dizziness	0	0	$\bigcirc$
Fainting spells	0	$\bigcirc$	$\bigcirc$
Feeling his or her heart pound or race	0	0	0
Shortness of breath	0	0	0



Constipation, loose bowels, or diarrhea	0	0	0
Nausea, gas, or indigestion	0	0	$\bigcirc$
Feeling tired or having low	0	0	0
energy Trouble sleeping	0	$\bigcirc$	0

Total/Partial Raw Score:

Prorated Score: (if 10 or more items answered)

#### **II. Sleep Problems**

## LEVEL 2-Sleep Disturbance-Parent/ Guardian of Child Age 6-17 (PROMIS-

#### Sleep Disturbance-Short Form)

Instructions to parent/guardian:

On the DSM-5 Level 1 cross-cutting questionnaire that you just completed you indicated that during the past 2 weeks your child receiving care has been bothered by problems sleeping-that is trouble falling asleep staying asleep or waking up too early at a mild or greater level of severity.

The questions below ask about these feelings in more detail and especially how often your child receiving care has been bothered by a list of symptoms during the past 7 days.

In the past 7 days					
	Not at all	A little bit	Somewhat	Quite a bit	Very much
His/her sleep was restless.	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$	0
	Not at all	A little bit	Somewhat	Quite a bit	Very much
He/She was satisfied with his/her sleep.	0	0	0	0	0
His/her sleep was refreshing.	0	$\bigcirc$	0	0	$\bigcirc$
	Not at all	A little bit	Somewhat	Quite a bit	Very much
He/she had difficulty falling asleep.	0	0	0	0	0
In the past 7 days					
	Never	Rarely	Sometimes	Often	Always
He/she had trouble staying asleep.	$\bigcirc$	0	0	0	0
He/she had trouble sleeping	0	$\bigcirc$	0	0	0
	Never	Rarely	Sometimes	Often	Always
He/she got enough sleep.	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$



In the past 7 days					
	Very poor	Poor	Fair	Good	Very good
His/her sleep quality was	0	0	0	0	0
Total/Partial Raw Score					
Prorated Total Raw Score					
		_			
III. Inattention					

#### LEVEL 2 Inattention Parent/Guardian of Child Age 6-17 (SNAP-IV)

Instructions to parent/guardian:

On the DSM-5 Level 1 cross-cutting questionnaire that you just completed you indicated that during the past 2 weeks your child receiving care has been bothered by problems paying attention when he/she was in class or doing his/her homework or reading a book or playing a game at a slight or greater level of severity.

The questions below ask about these feelings in more detail and especially how often your child receiving care has been bothered by a list of symptoms during the past 7 days.

In the past 7 days my child							
	Not at All	Just a Little	Quite a Bit	Very Much			
<ol> <li>Often fails to give close attention to details or makes careless mistakes in schoolwork, work, or other activities.</li> </ol>	0	0	0	0			
<ol> <li>Often has difficulty sustaining attention in tasks or play activities.</li> </ol>	0	0	0	0			
3. Often does not seem to listen when spoken to directly.	0	0	0	0			
4. Often does not follow through on instructions and fails to finish schoolwork, chores, or duties.	0	0	0	0			
5. Often has difficulty organizing tasks and activities.	0	0	0	0			
6. Often avoids, dislikes, or is reluctant to engage in tasks that require sustained mental effort (e.g. schoolwork or homework).	0	0	0	0			



7. Often loses things necessary for tasks or activities (e.g. toys, school assignments, pencils, books, or tools.)	0	0	0	0	
8. Often is distracted by extraneous stimuli.	0	0	0	0	
Total/Partial Raw Score:				_	
Prorated Total Raw Score: (if 1-2 items left unanswered)					
Average Total Score				_	
IV. Depression					

# LEVEL 2 Depression Parent/Guardian of Child Age 6-17 (PROMIS Emotional Distress Depression Parent Item Bank)

Instructions to parent/guardian:

On the DSM-5 Level 1 cross-cutting questionnaire that you just completed, you indicated that during the past 2 weeks your child receiving care has been bothered by not finding interest or pleasure in doing things and/or seeming down, depressed, or hopeless at a mild or greater level of severity.

The questions below ask about these feelings in more detail and especially how often your child receiving care has been bothered by a list of symptoms during the past 7 days.

In the past 7 days, my child					
	Never	Almost Never	Sometimes	Often	Almost Always
1. Could not stop feeling sad.	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$
2. Felt alone.	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$
<ol> <li>Felt like he/she couldnt do anything right.</li> </ol>	0	$\bigcirc$	0	0	$\bigcirc$
4. Felt lonely.	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$
5. Felt sad.	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$
6. Felt unhappy.	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$
7. Thought that his/her life was bad.	0	$\bigcirc$	0	0	0
8. Didnt care about anything.	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$	0
9. Felt stressed.	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$
10. Felt too sad to eat.	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$
11.Wanted to be by himself/herself.	0	0	0	0	0

Total/Partial Raw Score:



#### V. Anger

#### Instructions to parent/guardian:

On the DSM-5 Level 1 cross-cutting questionnaire that you just completed you indicated that during the past 2 weeks your child receiving care has been bothered by seeming irritated or easily annoyed and/or seeming angry or lost his/her temper at a mild or greater level of severity.

The questions below ask about these feelings in more detail and especially how often your child receiving care has been bothered by a list of symptoms during the past 7 days.

In the past SEVEN (7) DAYS					
	Never	Almost Never	Sometimes	Often	Almost Always
1. My child felt mad.	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$
2. My child was so angry he/she felt like yelling at somebody.	0	0	0	0	0
<ol><li>My child was so angry he/she felt like throwing something.</li></ol>	$\bigcirc$	0	0	0	0
4. My child felt upset.	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$	0
5. When my child got mad, he/she stayed mad.	0	0	0	0	0
Total/Partial Raw Score:					
Prorated Total Raw Score:					

T-Score:

## VI. Irritability LEVEL 2 Irritability Parent/Guardian of Child Age 6-17 (Affective Reactivity Index)

Instructions to parent/guardian:

On the DSM-5 Level 1 cross-cutting questionnaire that you just completed you indicated that during the past 2 weeks your child receiving care has been bothered by seeming irritated or easily annoyed and/or seeming angry or lost his/her temper at a mild or greater level of severity.

The questions below ask about these feelings in more detail and especially how often your child receiving care has been bothered by a list of symptoms during the past 7 days.

# In the last SEVEN (7) DAYS and compared to others of the same age how well does each of the following statements describe the behavior/feelings of your child?

#### Please try to answer all questions.

Not True

Somewhat True

Certainly True

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1. Is easily annoyed by others.	0	0	$\bigcirc$
2. Often loses his/her temper.	0	0	$\bigcirc$
3. Stays angry for a long time.	0	$\bigcirc$	$\bigcirc$
4. Is angry most of the time.	0	$\bigcirc$	$\bigcirc$
5. Gets angry frequently.	0	0	$\bigcirc$
6. Loses temper easily.	0	0	$\bigcirc$
7. Overall irritability causes him/her problems	0	0	0

Total/Partial Raw Score:

Prorated Total Raw Score: (if 1 item is left unanswered)

#### VII. Mania

# LEVEL 2 Mania Parent/Guardian of Child Age 6-17 (adapted from the Altman Self-Rating Mania Scale)

Instructions to parent/guardian:

On the DSM-5 Level 1 cross-cutting questionnaire you just completed you indicated that during the past 2 weeks your child receiving care has been bothered by sleeping less than usual but still have a lot of energy and/or only sleeping for a short time at night at a mild or greater level of severity.

The five statement groups or questions below ask about these feelings in more detail.

1. Please read each group of statements/question carefully.

2. Choose the one statement in each group that best describes the way your child has been feeling for the past week.

3. Check the box next to the number/statement selected.

4. Please note: The word occasionally when used here means once or twice; often means several times or more and frequently means most of the time.

#### Question 1

○ He/she does not feel happier or more cheerful than usual.

- $\bigcirc$  He/she occasionally feels happier or more cheerful than usual.
- $\bigcirc$  He/she often feels happier or more cheerful than usual.
- $\bigcirc$  He/she feels happier or more cheerful than usual most of the time.
- $\bigcirc$  He/she feels happier or more cheerful than usual all of the time.

#### Question 2

- $\bigcirc$  He/she does not feel more self-confident than usual.
- $\bigcirc$  He/she occasionally feels more self-confident than usual.
- $\bigcirc$  He/she often feels more self-confident than usual.
- $\bigcirc$  He/she frequently feels more self-confident than usual.
- $\bigcirc$  He/she feels extremely self-confident all of the time.



#### Question 3

 $\bigcirc$  He/she does not need less sleep than usual.

 $\bigcirc$  He/she occasionally needs less sleep than usual.

- He/she often needs less sleep than usual.
- $\bigcirc$  He/she frequently needs less sleep than usual.
- O He/she can go all day and all night without any sleep and still not feel tired.

#### Question 4

- $\bigcirc$  He/she does not talk more than usual.
- $\bigcirc$  He/she occasionally talks more than usual.
- $\bigcirc$  He/she often talks more than usual.
- O He/she frequently talks more than usual.
- $\bigcirc$  He/she talks constantly and cannot be interrupted.

#### Question 5

- O He/she has not been more active (either socially sexually at work home or school) than usual.
- O He/she has occasionally been more active than usual.
- O He/she has often been more active than usual.
- He/she has frequently been more active than usual.
- O He/she is constantly more active or on the go all the time.

Total/Partial Raw Score:

Prorated Total Raw Score: (if 1 item is left unanswered)

#### **VIII.** Anxiety

# LEVEL 2 - Anxiety - Parent/Guardian of Child Age 6-17 (adapted from PROMIS Emotional Distress-Anxiety-Parent Item Bank)

Instructions to parent/guardian:

On the DSM-5 Level 1 cross-cutting questionnaire that you just completed, you indicated that during the past 2 weeks your child receiving care has been bothered by feeling nervous, anxious, or scared, not being able to stop worrying, and/or couldn't do things he/she wanted to or should have done because they made him/her feel nervous at a mild or greater level of severity.

The questions below ask about these feelings in more detail and especially how often your child receiving care has been bothered by a list of symptoms during the past 7 days.

	Never	Almost Never	Sometimes	Often	Almost Always
Felt nervous.	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$
Felt scared.	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$
Felt worried.	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$



In the SEVEN (7) DAYS, my of Felt like something awful might happen.	hild said tha	t he/she 〇	0	0	0
Worried when he/she was at home.	$\bigcirc$	0	0	0	0
Got scared really easy. Worried when he/she was away from home.	0 0	0 0	0 0	0 0	0 0
Worried about what could happen to him/her.	$\bigcirc$	0	0	0	0
Worried when he/she went to bed at night.	$\bigcirc$	0	0	0	0
Was afraid of going to school.	$\bigcirc$	0	0	0	0
Total/Partial Raw Score					
Prorated Total Raw Score					
T-Score		_			
XI. Substance Use					

Instructions to parent/guardian:

On the DSM-5 Level 1 cross-cutting questionnaire that you just completed, you indicated that during the past 2 weeks your child receiving care has been bothered by having an alcoholic beverage; smoking a cigarette, a cigar, or pipe or used snuff or chewing tobacco; using drugs like marijuana, cocaine or crack, club drugs, hallucinogens, heroin, inhalants or solvents, or methamphetamine and/or using any medicine without a doctor's prescription.

The questions below ask about these feelings in more detail and especially how often your child receiving care has been bothered by a list of symptoms during the past two (2) weeks.

During the past TWO (2) WEEKS, about how often did your child									
	Not at All	Less Than a Day or Two	Several Days	More Than Half the Days	Nearly Every Day				
a. Have an acloholic beverage (beer, wine, liquor, etc.) ?	$\bigcirc$	0	0	0	0				
b. Have 4 or more drinks in a single day?	0	0	0	0	0				
c. Smoke a cigarette, a cigar, or pipe or used snuff or chewing tobacco?	0	0	0	0	0				



	Not at All	Less Than a Day or Two	Several Days	More Than Half the Days	Nearly Every Day
d. Painkillers (like Vicodin)	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$
e. Stimulants (like Ritalin, Adderall)	0	0	0	0	0
f. Sedatives or tranquilizers (like sleeping pills or Valium)	0	0	$\bigcirc$	0	$\bigcirc$

h. Other medicinesOOOOi. MarijuanaOOOOOj. Cocaine or crackOOOOOk. Club drugs (like ecstasy)OOOOOI. Hallucinogens (like LSD)OOOOOm. HeroinOOOOOOn. Inhalants or solvents (likeOOOOOo. Methamphetamine (likeOOOOO		Not at All	Less Than a Day or Two	Several Days	More Than Half the Days	Nearly Every Day
h. Other medicinesImage: Orgon and Constraints or solvents (like end or solvents (lik	g. Steroids	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$
j. Cocaine or crack O O O O O O k. Club drugs (like ecstasy) O O O O O O I. Hallucinogens (like LSD) O O O O O O m. Heroin O O O O O O n. Inhalants or solvents (like O O O O O O O glue) O. Methamphetamine (like O O O O O O O	h. Other medicines	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$
k. Club drugs (like ecstasy)       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O <td< td=""><td>i. Marijuana</td><td>$\bigcirc$</td><td>$\bigcirc$</td><td>$\bigcirc$</td><td>$\bigcirc$</td><td>$\bigcirc$</td></td<>	i. Marijuana	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$
I. Hallucinogens (like LSD)       O       O       O       O         m. Heroin       O       O       O       O       O       O         n. Inhalants or solvents (like       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O	j. Cocaine or crack	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$
m. HeroinOOOOn. Inhalants or solvents (likeOOOOglue)OOOOOo. Methamphetamine (likeOOOO	k. Club drugs (like ecstasy)	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$
n. Inhalants or solvents (like O O O O O O O O O O O O O O O O O O O	I. Hallucinogens (like LSD)	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$
glue) o. Methamphetamine (like O O O O	m. Heroin	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$
glue) 9. Methamphetamine (like O O O O O		$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$
speed)	glue) o. Methamphetamine (like speed)	0	0	0	0	0

# Prorated Total Raw Score: (If 1 item is left unanswered)

Additional Guidance: These CDEs include questions that can potentially identify respondents who are at risk of suicide. Investigators implementing this protocol should consult with their IRBs to develop a risk management plan specific to their study to ensure the safety of participants. Investigators should also ensure their studies are compliant with federal, state, and institutional regulations and policies and inform participants of limits of confidentiality when a participant endorses imminent risk of harm to self or others.

The following link provides additional information and guidelines for suicide-related research: https://www.nimh.nih.gov/funding/clinical-research/conducting-research-with-participants-at-elevated-risk-for-suicide-considerations-for-researchers.

#### Tier 1: Anxiety, Depression, Fatigue PROMIS scales (Parent Proxy Versions)

Due to early research demonstrating the presence of COVID-19/pandemic related mental health symptoms, anxiety, depressive symptoms and fatigue PROMIS measures were designated Tier 1 in addition to the DSM-5 screener.

Parent About Child:



# **PROMIS Anxiety**

# Age 1-5 (available not shown) Age 5-17 (shown)

In the past 7 days

	Never	Almost Never	Sometimes	Often	Almost Always
My child felt nervous.	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$
My child felt scared.	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$
My child felt worried.	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$
My child felt like something awful might happen.	0	0	0	0	0
My child worried when he/she was at home.	0	0	0	0	0
My child got scared really easy.	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$
My child worried about what could happen to him/her.	0	0	0	0	0
My child worried when he/she went to bed at night.	0	0	0	0	0

# **PROMIS Depressive Symptoms**

# Age 1-5 (available not shown) Age 5-17 (shown)

In the past 7 days

My child could not stop feeling	Never	Almost Never	Sometimes	Often	Almost Always
sad.	<u> </u>	C	C	C	0
My child felt everything in his/her life went wrong.	$\bigcirc$	0	0	$\bigcirc$	0
My child felt like he/she couldn't do anything right.	$\bigcirc$	0	0	$\bigcirc$	0
My child felt lonely.	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$
My child felt sad.	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$
It was hard for my child to have fun.	$\bigcirc$	0	0	0	0



### **PROMIS Fatigue**

#### Age 5-17

Age J-17					
	Never	Almost Never	Sometimes	Often	Almost Always
Being tired made it hard for my child to play or go out with friends as much as he/she would like.	0	0	0	0	0
My child felt weak.	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$
My child got tired easily.	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$
Being tired made it hard for my child to keep up with	$\bigcirc$	$\bigcirc$	0	0	0
schoolwork. My child had trouble finishing things because he/she was too tired.	0	0	0	0	0
My child had trouble starting things because he/she was too tired.	0	0	0	0	0
My child was so tired it was hard for him/her to pay attention.	$\bigcirc$	0	0	0	0
My child was too tired to do sports or exercise.	$\bigcirc$	0	0	0	0
My child was too tired to do things outside.	0	0	0	0	0
My child was too tired to enjoy the things he/she likes to do.	$\bigcirc$	0	0	0	0

#### Tier 2: RCADS Anxiety and Depression Scale (Parent Report About Child)

Due to early research demonstrating the presence of COVID-19/pandemic related mental health symptoms, anxiety, and depression RCADS measures were designated Tier 2 in addition to the DSM-5 screener and Tier 1 PROMIS measures.

# Please select the word that shows how often each of these things happens to your child. There are no right or wrong answers.

5 5				
	Never	Sometimes	Often	Always
1. My child worries about things	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$
2. My child feels sad or empty	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$
3. When my child has a problem, he/she gets a funny feeling in his/her stomach	0	0	0	0
4. My child worries when he/she thinks he/she has done poorly at something	0	0	0	0



5. My child feels afraid of being alone at home	0	0	0	0
6. Nothing is much fun for my child anymore	0	0	0	0
7. My child feels scared when taking a test	0	0	0	0
8. My child worries when he/she thinks someone is angry with him/her	0	0	0	0
9. My child worries about being away from me	0	0	0	0
10. My child is bothered by bad or silly thoughts or pictures in his/her mind	0	0	0	0
11. My child has trouble sleeping	$\bigcirc$	$\bigcirc$	0	$\bigcirc$
12. My child worries about doing badly at schoolwork	0	0	0	0
13. My child worries that something awful will happen to someone in the family	0	0	0	0
14. My child suddenly feels as if he/she can't breathe when there is no reason for this	0	0	0	0
15. My child has problems with his/her appetite	0	0	0	0
16. My child has to keep checking that he/she has done things right (like the switch is off, or the door is locked)	0	0	0	0
17. My child feels scared to sleep on his/her own	0	0	0	0
18. My child has trouble going to school in the mornings because of feeling nervous or afraid	0	0	0	0
19. My child has no energy for things	0	0	0	0
20. My child worries about looking foolish	0	0	0	0
21. My child is tired a lot	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$
22. My child worries that bad things will happen to him/her	0	0	0	0



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23. My child can't seem to get	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$
bad or silly thoughts out of				
his/her head				

# **Tier 2: Pain, Cognitive Function**

Pain Interference Parent Proxy

Age 8-17

In the past 7 days					
	Never	Almost Never	Sometimes	Often	Almost Always
My child had trouble sleeping when he/she had pain.	$\bigcirc$	0	0	0	0
My child felt angry when he/she had pain.	$\bigcirc$	0	0	$\bigcirc$	0
My child had trouble doing schoolwork when he/she had	$\bigcirc$	0	0	$\bigcirc$	0
pain. It was hard for my child to pay attention when he/she had pain.	$\bigcirc$	0	0	$\bigcirc$	0
It was hard for my child to run when he/she had pain.	$\bigcirc$	0	0	$\bigcirc$	0
It was hard for my child to walk one block when he/she had pain.	$\bigcirc$	0	0	0	0
It was hard for my child to have fun when he/she had pain.	0	0	0	0	0
It was hard for my child to stay standing when he/she had pain.	0	0	0	0	0

# **Cognitive Function Parent Proxy**

### Age 8-17

#### In the past 4 weeks

	None of the time	A little of the time	Some of the time	Most of the time	All of the time
Your child has to use written lists more often than other people his/her age so he/she will not forget things	0	0	0	0	0
It is hard for your child to pay attention to one thing for more than 5-10 minutes	0	0	0	$\bigcirc$	0



0	0	0	0	0
0	$\bigcirc$	$\bigcirc$	0	0
$\bigcirc$	$\bigcirc$	$\bigcirc$	0	0
0	0	0	0	0
0	0	0	0	0

#### **Tier 2: Externalizing Symptoms**

While prioritized as a Tier 2 measure, this Working Group does not recommend specific measures since the most commonly used measures (Child Behavior Checklist and Strengths and Difficulties Questionnaire) require licensing. The Multidimensional Assessment Profile of Disruptive Behavior (MAP-DB), is available for use as well and does not require a license.

#### **Child Self-Report: Current Mental Health Symptoms**

Tier 1: DSM-5 Cross-Cutting Symptom Measure (Ages 11-17)

The National Institute of Mental Health (NIMH), in consultation with the Wellcome Trust and other funders of mental health research, has identified the DSM-5 Cross-Cutting Symptom Measure as part of a minimal list of data collection instruments that would be ideal for use by all mental health researchers conducting clinical research to facilitate and harmonize mental health data collection. These measures have been selected using either the PhenX consensus process (https://www.phenxtoolkit.org/collections/view/1) or the International Consortium for Health Outcomes Measurement (ICHOM)

(https://www.ichom.org/resource-library/category/condition-specific-resources/depression-anxiety/) with additional consideration for successful use of the measures in various countries.

	0 - None (Not at all)	1 - Slight (Rare less than a day or two)	2 - Mild (Several days)	3 - Moderate (More than half the days)	4 - Severe (Nearly every day)
<ol> <li>Been bothered by stomach aches, headaches, or other aches and pains?</li> </ol>	0	0	0	0	0
2. Worried about your health or about getting sick?	0	0	0	0	0
I Highest Domain Score (clinicia	an)				



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Confidential
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	0 - None (Not at	1 - Slight (Rare	2 - Mild (Several	3 - Moderate	4 - Severe
	all)	less than a day or two)	days)	(More than half the days)	(Nearly every day)
3. Been bothered by not being able to fall asleep or stay asleep, or by waking up too early?	0	0	0	0	0
ll Highest Domain Score (clinicia	an)				
	0 - None (Not at all)	1 - Slight (Rare less than a day or two)	2 - Mild (Several days)	3 - Moderate (More than half the days)	4 - Severe (Nearly every day)
4. Been bothered by not being able to pay attention when you were in class or doing homework or reading a book or playing a game?	0	0	0	0	0
III Highest Domain Score (clinici	an)				
N/					
IV.	0 - None (Not at	1 - Slight (Bare	2 - Mild (Several	3 - Moderate	A - Severe
IV.	0 - None (Not at all)	1 - Slight (Rare less than a day or two)	2 - Mild (Several days)	3 - Moderate (More than half the days)	4 - Severe (Nearly every day)
IV. 5. Had less fun doing things than you used to?		less than a day		(More than half	(Nearly every



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V. & VI.					
	0 - None (Not at all)	1 - Slight (Rare less than a day or two)	2 - Mild (Several days)	3 - Moderate (More than half the days)	4 - Severe (Nearly every day)
7. Felt more irritated or easily annoyed than usual?	0	0	0	0	0
8. Felt angry or lost your temper?	0	0	0	0	0

& VI. - Highest Domain Score (clinician)

	0 - None (Not at all)	1 - Slight (Rare less than a day or two)	2 - Mild (Several days)	3 - Moderate (More than half the days)	4 - Severe (Nearly every day)
9. Started lots more projects than usual or done more risky things than usual?	0	0	0	0	0
10. Slept less than usual but still had a lot of energy?	0	0	0	0	0

VIII.					
	0 - None (Not at all)	1 - Slight (Rare less than a day or two)	2 - Mild (Several days)	3 - Moderate (More than half the days)	4 - Severe (Nearly every day)
11. Felt nervous, anxious, or scared?	0	0	0	0	0
12. Not been able to stop worrying?	0	0	0	0	0
13. Not been able to do things you wanted to or should have done, because they made you feel nervous?	0	0	0	0	0

VIII. - Highest Domain Score (clinician)



IX.					
	0 - None (Not at all)	1 - Slight (Rare less than a day or two)	2 - Mild (Several days)	3 - Moderate (More than half the days)	4 - Severe (Nearly every day)
14. Heard voiceswhen there was no one there - speaking about you or telling you what to do or saying bad things to you?	0	0	0	0	0
15. Had visions when you were completely awake - that is, seen something or someone that no one else could see?	0	0	0	0	0

#### IX. - Highest Domain Score (clinician)

X.	0 - None (Not at	1 - Slight (Rare	2 - Mild (Several	3 - Moderate	4 - Severe
	all)	less than a day or two)	days)	(More than half the days)	(Nearly every day)
16. Had thoughts that kept coming into your mind that you would do something bad or that something bad would happen to you or to someone else?	0	0	0	0	0
17. Felt the need to check on certain things over and over again, like whether a door was locked or whether the stove was turned off?	0	0	0	0	0
18. Worried a lot about things you touched being dirty or having germs or being poisoned?	0	0	0	0	0
19. Felt you had to do things in a certain way, like counting or saying special things, to keep something bad from happening?	0	0	0	0	0

X. - Highest Domain Score (clinician)



#### In the past TWO (2) WEEKS, have you

XI.		
20. Had an alcoholic beverage (beer, wine, liquor, etc.)?	⊖ Yes	⊖ No
21. Smoked a cigarette, a cigar, or pipe, or used snuff or chewing tobacco?	⊖ Yes	⊖ No
22. Used drugs like marijuana, cocaine or crack, club drugs (like Ecstasy), hallucinogens (like LSD), heroin, inhalants or solvents (like glue), or methamphetamine (like speed)?	⊖ Yes	⊖ No
23. Used any medicine without a doctors prescription to get high or change the way you feel (e.g., painkillers [like Vicodin], stimulants [like Ritalin or Adderall], sedatives or tranquilizers [like sleeping pills or Valium], or steroids)?	⊖ Yes	⊖ No
XII.		
24. In the last 2 weeks, have you thought about killing yourself or committing suicide?	⊖ Yes	⊖ No
25. Have you EVER tried to kill yourself?	⊖ Yes	⊖ No

#### **Tier 2: After meeting thresholds**

Domain	Domain Name	Threshold to guide further inquiry	DSM-5 Level 2 Cross-Cutting Symptom Measure available online
I.	Somatic Symptoms	Mild or greater	LEVEL 2—Somatic Symptom—Child Age 11–17 (Patient Health Questionnaire Somatic Symptom Severity [PHQ-15])
II.	Sleep Problems	Mild or greater	LEVEL 2—Sleep Disturbance—Child Age 11-17 (PROMIS—Sleep Disturbance— Short Form) ¹
III.	Inattention	Slight or greater	None
IV.	Depression	Mild or greater	LEVEL 2—Depression—Child Age 11–17 (PROMIS Emotional Distress— Depression—Pediatric Item Bank)
V.	Anger	Mild or greater	LEVEL 2—Anger—Child Age 11–17 (PROMIS Emotional Distress—Calibrated Anger Measure—Pediatric)
VI.	Irritability	Mild or greater	LEVEL 2—Irritability—Child Age 11–17 (Affective Reactivity Index [ARI])
VII.	Mania	Mild or greater	LEVEL 2—Mania—Child Age 11–17 (Altman Self-Rating Mania Scale [ASRM])
VIII.	Anxiety	Mild or greater	LEVEL 2—Anxiety—Child Age 11–17 (PROMIS Emotional Distress—Anxiety— Pediatric Item Bank)
IX.	Psychosis	Slight or greater	None
Х.	Repetitive Thoughts & Behaviors	Mild or greater	LEVEL 2—Repetitive Thoughts and Behaviors—Child 11–17 (adapted from the Children's Florida Obsessive-Compulsive Inventory [C-FOCI] Severity Scale)
XI.	Substance Use	Yes/ Don't Know	LEVEL 2—Substance Use—Child Age 11–17 (adapted from the NIDA-modified ASSIST)
XII.	Suicidal Ideation/ Suicide Attempts	Yes/ Don't Know	None



#### I. Somatic Symptoms

# LEVEL 2-Somatic Symptom-Child Age 11-17 (Patient Health QuestionnaireSomatic Symptom Severity [PHQ-15])

During the past 4 weeks, how much have you been bothered by any of the following problems?

	Not bothered at all	Bothered a little	Bothered a lot
a. Stomach pain	0	$\bigcirc$	$\bigcirc$
b. Back pain	$\bigcirc$	$\bigcirc$	0
c. Pain in your arms, legs, or joints (knees, hips, etc.)	0	0	0
d. Menstrual cramps or other problems with your periods (women only)	0	0	0
e. Headaches	0	0	$\bigcirc$
f. Chest pain	0	$\bigcirc$	0
g. Dizziness	0	0	0
h. Fainting spells	0	$\bigcirc$	0
i. Feeling your heart pound or race	0	0	0
j. Shortness of breath	0	0	0
k. Pain or problems during sexual intercourse	Ο	0	0
l. Constipation, loose bowels, or diarrhea	0	0	0
m. Nausea, gas, or indigestion	0	0	$\bigcirc$
n. Feeling tired or having low energy	0	0	0
o. Trouble sleeping	$\bigcirc$	$\bigcirc$	$\cap$

#### **II. Sleep Problems**

#### LEVEL 2-Sleep Disturbance Child Age 11-17 (PROMIS-Sleep Disturbance-Short Form)

Instructions to the child: On the DSM-5 Level 1 cross-cutting questionnaire that you just completed, you indicated that during the past 2 weeks you have been bothered by not being able to fall asleep or stay asleep or by waking up too early at a mild or greater level of severity.



In the past 7 days					
	Not at all	A little bit	Somewhat	Quite a bit	Very much
My sleep was restless.	0	0	0	0	0
	Not at all	A little bit	Somewhat	Quite a bit	Very much
I was satisfied with my sleep.	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$
My sleep was refreshing.	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$
	Not at all	A little bit	Somewhat	Quite a bit	Very much
I had difficulty falling asleep.	0	0	0	0	0
In the past 7 days					
	Never	Rarely	Sometimes	Often	Always
I had trouble staying asleep.	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$	0
I had trouble sleeping.	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$
	Never	Rarely	Sometimes	Often	Always
l got enough sleep.	0	$\bigcirc$	0	0	0
In the past 7 days					
	Very poor	Poor	Fair	Good	Very good
My sleep quality was	0	0	0	0	0
Total/Partial Raw Score					
Prorated Total Raw Score					
T-score					

#### **IV. Depression**

# LEVEL 2-Depression-Child Age 11-17 (PROMIS Emotional Distress-Depression-Pediatric Item Bank)

Instructions to the child: On the DSM-5 Level 1 cross-cutting questionnaire that you just completed, you indicated that

during the past 2 weeks you have been bothered by having little interest or pleasure in doing things and/or feeling down, depressed, or hopeless at a mild or greater level of severity.



In the past 7 days					
	Never	Almost Never	Sometimes	Often	Almost Always
I could not stop feeling sad.	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$
I felt alone.	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$
l felt everything in my life went wrong.	0	$\bigcirc$	0	0	$\bigcirc$
I felt like I couldn't do anything right.	$\bigcirc$	0	0	0	0
l felt lonely.	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$
l felt sad.	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$
l felt unhappy.	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$
I thought that my life was bad.	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$
Being sad made it hard for me to do things with my friends.	$\bigcirc$	0	0	0	0
l didn't care about anything.	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$
l felt stressed.	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$
l felt too sad to eat.	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$
l wanted to be by myself.	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$
It was hard for me to have fun.	$\bigcirc$	$\bigcirc$	$\bigcirc$	0	0

#### V. Anger

# LEVEL 2-Anger-Child Age 11-17 (PROMIS Emotional Distress-Calibrated Anger Measure-Pediatric)

Instructions to the child:

On the DSM-5 Level 1 cross-cutting questionnaire that you just completed, you indicated that during the past 2 weeks you have been bothered by feeling irritated or easily annoyed and/or feeling angry or lost your temper at a mild or greater level of severity.

In the past 7 days.					
	Never	Almost Never	Sometimes	Often	Almost Always
l felt mad.	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$
I was so angry I felt like throwing something.	0	0	0	0	0
l was so angry I felt like yelling at somebody.	$\bigcirc$	0	0	$\bigcirc$	0
When I got mad, I stayed mad.	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$
l felt fed up.	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$
l felt upset.	$\bigcirc$	0	0	$\bigcirc$	0



#### **VI. Irritability**

#### LEVEL 2 Irritability-Child Age 11-17 (Affective Reactivity Index)

#### Instructions to the child:

On the DSM-5 Level 1 cross-cutting questionnaire that you just completed, you indicated that during the past 2 weeks you have been bothered by feeling irritated or easily annoyed and/or feeling angry or lost your temper at a mild or greater level of severity.

The questions below ask about these feelings in more detail and especially how often you have been bothered by a list of symptoms during the past 7 days.

## In the last SEVEN (7) DAYS and compared to others of the same age, how well does each of the following statements describe your behavior or feelings?

Am easily annoyed by others.

Not True
 Somewhat True
 Certainly True

#### VII. Mania

#### LEVEL 2-Mania-Child Age 11-17 (Altman Self-Rating Mania Scale [ASRM])

Instructions to the child:

On the DSM-5 Level 1 cross-cutting questionnaire you just completed, you indicated that during the past 2 weeks you have been bothered by feeling so active that you couldn't settle down and/or finding that you didn't sleep a lot at night at a mild or greater level of severity. The five statement groups or questions below ask about these feelings in more detail.

1. Please read each group of statements/question carefully.

- 2. Choose the one statement in each group that best describes the way you have been feeling for the past week.
- 3. Check the box next to the number/statement selected.

4. Please note: The word occasionally, when used here means once or twice; often means several times or more and frequently means most of the time.

#### Question 1

- O I do not feel happier or more cheerful than usual
- O I occasionally feel happier or more cheerful than usual
- $\bigcirc$  I often feel happier or more cheerful than usual
- $\bigcirc$  I feel happier or more cheerful than usual most of the time

 $\bigcirc$  I feel happier of more cheerful than usual all of the time

#### Question 2

- $\bigcirc$  I do not feel more self-confident than usual
- O I occasionally feel more self-confident than usual
- I often feel more self-confident than usual
- $\bigcirc$  I frequently feel more self-confident than usual
- $\bigcirc$  I feel extremely self-confident all of the time



#### Question 3

 $\bigcirc$  I do not need less sleep than usual

- $\bigcirc$  I occasionally need less sleep than usual
- O l often need less sleep than usual
- O I frequently need less sleep than usual
- O I can go all day and all night without any sleep and still not feel tired

#### Question 4

 $\bigcirc$  I do not talk more than usual.

- O I occasionally talk more than usual
- O I often talk more than usual
- O I frequently talk more than usual
- $\bigcirc$  I talk constantly and cannot be interrupted

#### Question 5

- I have not been more active (either socially, sexually, at work, home, or school) than usual
- $\bigcirc$  I have occasionally been more active than usual
- I have often been more active than usual
- O I have frequently been more active than usual
- O I am constantly more active or on the go all the time

Total/Partial Raw Score:

Prorated Total Raw Score: (if 1 item left unanswered)

#### VIII. Anxiety

#### LEVEL 2-Anxiety-Child Age 11-17 (PROMIS Emotional Distress-Anxiety-Pediatric Item Bank)

Instructions to the child:

On the DSM-5 Level 1 cross-cutting questionnaire that you just completed, you indicated that during the past 2 weeks you have been bothered by feeling nervous, anxious, or scared, not being able to stop worrying and/or not being able to do things you wanted to or should have done because they made you feel nervous at a mild or greater level of severity.

In the past 7 days					
	Never	Almost Never	Sometimes	Often	Almost Always
l felt like something awful might happen.	0	$\bigcirc$	0	0	0
l felt nervous.	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$
l felt scared.	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$
l felt worried.	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$



l worried about what could happen to me.	0	0	0	0	0
I worried when I went to bed at night.	0	0	0	0	0
l got scared really easy.	$\bigcirc$	0	0	0	0
I was afraid of going to school.	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$	0
I was worried I might die.	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$
I woke up at night scared.	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$
l worried when l was at home.	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$
l worried when l was away from home.	$\bigcirc$	0	0	0	0
It was hard for me to relax.	$\bigcirc$	0	0	0	0

#### X. Repetitive Thoughts & Behaviors

#### LEVEL 2-Repetitive Thoughts and Behaviors-Child 11-17 (adapted from the Children's Florida Obsessive-Compulsive Inventory [C-FOCI] Severity Scale)

Instructions to the child:

On the DSM-5 Level 1 cross-cutting questionnaire that you just completed, you indicated that during the past 2 weeks you have been bothered by "thoughts that kept coming into your mind that you would do something bad or that something bad would happen to you or to someone else", "feeling the need to check on certain things over and over again, like whether a door was locked or whether the stove was turned off", "worrying a lot about things you touched being dirty or having germs or being poisoned", and/or "feeling you had to do things in a certain way, like counting or saying special things, to keep something bad from happening" at a mild or greater level of severity.

During the past SEVEN (7) DAYS	
1. On average, how much time is occupied by these thoughts or behaviors each day?	<ul> <li>O-None</li> <li>1-Mild (less than an hour a day)</li> <li>2-Moderate (1 to 3 hours a day)</li> <li>3-Severe (3 to 8 hours a day)</li> <li>4-Extreme (more than 8 hours a day)</li> </ul>
1. Clinician use - Item score	
2. How much do they bother you?	<ul> <li>O-None</li> <li>1-Mild (slightly upsetting)</li> <li>2-Moderate (upsetting but still manageable)</li> <li>3-Severe (very upsetting)</li> <li>4-Extreme (overwhelming distress)</li> </ul>
2. Clinician use - Item score	



3. How hard is it for you to control them?	$\bigcirc$ 0-None $\bigcirc$ 1-Mild (usually able to control thoughts or				
	behaviors)				
	<ul> <li>2-Moderate (sometimes able to control thoughts or behaviors)</li> </ul>				
	$\bigcirc$ 3-Severe (not usually able to control thoughts or				
	behaviors) $\bigcirc$ 4-Extreme (unable to control thoughts or behaviors				
3. Clinician use - Item score					
4. How much do they cause you to avoid doing things, going places or being with people?	<ul> <li>0-None</li> <li>1-Mild (occasionally avoids things)</li> <li>2-Moderate (regularly avoids doing these things)</li> <li>3-Severe (frequently avoids these things)</li> <li>4-Extreme (nearly complete avoidance; can't leat the house)</li> </ul>				
4. Clinician use - Item score					
5. How much do they interfere with school, your social or family life, or your job?	<ul> <li>O-None</li> <li>1-Mild (slight interference)</li> <li>2-Moderate (definite interference with functioning, but can still manage)</li> <li>3-Severe (substantial interference)</li> <li>4-Extreme (near-total interference)</li> </ul>				
5. Clinician use - Item score					
Total/Partial Raw Score					
Prorated Total Raw Score (if 1 item is left unanswered)					
Average Total Score					
XI. Substance Use					

#### LEVEL 2 - Substance Use - Child Age 11-17 (adapted from the NIDA-modified ASSIST)

Instructions to the child:

On the DSM-5 Level 1 cross-cutting questionnaire that you just completed, you indicated that during the past 2 weeks you have been bothered by "having an alcoholic beverage"; "smoking a cigarette, a cigar, or pipe or used snuff or chewing tobacco"; "using drugs like marijuana, cocaine or crack, club drugs (like ecstasy), hallucinogens (like LSD), heroin, inhalants or solvents (like glue), or methamphetamine (like speed)"; and/or "using any medicine ON YOUR OWN, that is, without a doctor's prescription, to get high or change the way you feel."



During the past TWO (2) weeks, about how often did you									
	Not at All	Less Than a Day or Two	Several Days	More Than Half the Days	Nearly Every Day	Don't know			
a. Have an alcoholic beverage (beer, wine, liquor, etc.)?	0	$\bigcirc$	$\bigcirc$	0	0	$\bigcirc$			
b. Have 4 or more drinks in a single day?	0	$\bigcirc$	0	0	0	0			
c. Smoke a cigarette, a cigar, or pipe or use snuff or chewing tobacco?	0	0	0	0	0	0			

# During the past TWO (2) weeks, about how often did you use any of the following medicines ON YOUR OWN, that is, without a doctor's prescription or in greater amounts or longer than prescribed?

prescribed?						
	Not at All	Less Than a Day or Two	Several Days	More Than Half the Days	Nearly Every Day	Don't know
d. Painkillers (like Vicodin)	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$	0	$\bigcirc$
e. Stimulants (like Ritalin, Adderall)	0	0	0	0	0	0
f. Sedatives or tranquilizers (like sleeping pills or Valium)	$\bigcirc$	$\bigcirc$	0	$\bigcirc$	$\bigcirc$	0

Or drugs like:	Not at All	Less Than a Day or Two	Several Days	More Than Half the Days	Nearly Every Day	Don't know
g. Steroids	$\bigcirc$	$\bigcirc$	0	$\bigcirc$	$\bigcirc$	$\bigcirc$
h. Other medicines	$\bigcirc$	$\bigcirc$	0	$\bigcirc$	$\bigcirc$	$\bigcirc$
i. Marijuana	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$
j. Cocaine or crack	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$
k. Club drugs (like ecstasy)	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$
l. Hallucinogens (like LSD)	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$
m. Heroin	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$
n. Inhalants or solvents (like	$\bigcirc$	$\bigcirc$	0	$\bigcirc$	$\bigcirc$	$\bigcirc$
glue) o. Methamphetamine (like speed)	0	$\bigcirc$	0	0	$\bigcirc$	$\bigcirc$

Total/Partial Raw Score:

Total/Partial Raw Score:

Additional Guidance:

These CDEs include questions that can potentially identify respondents who are at risk of suicide. Investigators implementing this protocol should consult with their IRBs to develop a risk management plan specific to their study to ensure the safety of participants. Investigators should also ensure their studies are compliant with federal, state, and institutional regulations and policies and inform participants of limits of confidentiality when a participant endorses imminent risk of harm to self or others.

The following link provides additional information and guidelines for suicide-related research: https://www.nimh.nih.gov/funding/clinical-research/conducting-research-with-participants-at-elevated-risk-for-suicide-considerations-for-researchers.



projectredcap.org

#### Tier 1: Anxiety, Depression, Fatigue PROMIS scales Pediatric measures

Due to early research demonstrating the presence of COVID-19/pandemic related mental health symptoms, anxiety, depressive symptoms, and fatigue PROMIS measures were designated Tier 1 in addition to the DSM-5 screener.

l felt like something awful might happen.	Never	Almost Never	Sometimes	Often 〇	Almost Always
l felt nervous.	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$
l felt scared.	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$
l felt worried.	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$
I worried when I was at home.	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$
l got scared really easy.	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$
l worried about what could happen to me.	$\bigcirc$	$\bigcirc$	0	0	0
l worried when l went to bed at night.	$\bigcirc$	0	0	$\bigcirc$	0

In the	past	7	days	
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· · · · · · · · · · · · · · · · · · ·	Never	Almost Never	Sometimes	Often	Almost Always
I could not stop feeling sad.	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$
l felt alone.	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$
l felt everything in my life went wrong.	0	0	0	0	0
l felt like l couldn't do anything right.	$\bigcirc$	0	0	$\bigcirc$	0
l felt lonely.	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$
I felt sad.	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$
l felt unhappy.	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$
It was hard for me to have fun.	$\bigcirc$	0	$\bigcirc$	$\bigcirc$	0

In the past 7 days					
	Never	Almost Never	Sometimes	Often	Almost Always
Being tired made it hard for me to keep up with my schoolwork.	0	$\bigcirc$	0	0	0
Being tired made it hard for me to play or go out with my friends as much as I'd like.	0	0	0	0	0
l felt weak.	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$	0
l got tired easily.	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$
l had trouble finishing things because I was too tired.	0	$\bigcirc$	0	$\bigcirc$	0
l had trouble starting things because I was too tired.	0	$\bigcirc$	0	0	0



I was so tired it was hard for me to pay attention.	0	0	0	0	0
I was too tired to do sports or exercise.	0	0	0	0	0
I was too tired to do things outside.	0	0	0	0	$\bigcirc$
l was too tired to enjoy the things l like to do.	$\bigcirc$	0	0	0	$\bigcirc$

#### Tier 2: RCADS Anxiety and Depression Scale (Ages 8-18)

Due to early research demonstrating the presence of COVID-19/pandemic related mental health symptoms, anxiety, and depression RCADS measures were designated Tier 2 in addition to the DSM-5 screener and PROMIS Tier 1 measures.

Please select the word that sh	ows how ofte	en each of these thi	ngs happens to	you. There are
no right or wrong answers.				
	Never	Sometimes	Often	Always
1. I worry about things	0	$\bigcirc$	$\bigcirc$	$\bigcirc$
2. I feel sad or empty	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$
3. When I have a problem, I get a funny feeling in my stomach	0	0	0	0
4. I worry when I think I have done poorly at something	0	0	0	0
5. I would feel afraid of being on my own at home	0	0	0	0
6. Nothing is much fun anymore	0	$\bigcirc$	0	$\bigcirc$
<ol> <li>I feel scared when I have to take a test</li> </ol>	0	0	0	0
8. I feel worried when I think someone is angry with me	0	0	0	0
9. I worry about being away from my parents	0	0	0	0
10. I get bothered by bad or silly thoughts or pictures in my mind	0	0	0	0
11. I have trouble sleeping	0	0	0	0
12. I worry that I will do badly at my schoolwork	0	0	0	0
13. I worry that something awful will happen to someone in my	0	0	0	0

family

#### Confidential

				Page 123
14. I suddenly feel as if I can't breathe when there is no reason for this	Never	Sometimes 〇	Often	Always
15. I have problems with my appetite	0	0	0	0
16. I have to keep checking that I have done things right (like the switch is off, or the door is	0	0	0	0
locked) 17. I feel scared if I have to sleep on my own	0	0	0	0
18. I have trouble going to school in the mornings because I feel nervous or afraid	0	0	0	0
19. I have no energy for things	$\bigcirc$	0	0	0
20. I worry I might look foolish	$\bigcirc$	$\bigcirc$	$\bigcirc$	0
21. I am tired a lot	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$
22. I worry that bad things will happen to me	0	0	0	0
23. I can't seem to get bad or silly thoughts out of my head	0	0	0	0
24. When I have a problem, my heart beats really fast	0	0	0	0
	Never	Sometimes	Often	Always
25. I cannot think clearly	0	0	0	0
26. I suddenly start to tremble or shake when there is no reason for this	0	0	0	0
27. I worry that something bad will happen to me	0	0	0	0
28. When I have a problem, I feel shaky	0	0	0	0
29. I feel worthless	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$
30. I worry about making mistakes	0	0	0	0
31. I have to think of special thoughts (like numbers or words) to stop bad things from happening	0	0	0	0
32. I worry what other people think of me	0	0	0	0
33. I am afraid of being in crowded places (like shopping centers, the movies, buses, busy playgrounds)	0	0	0	0



34. All of a sudden, I feel really scared for no reason at all	0	0	0	0
35. I worry about what is going to happen	0	0	0	0
36. I suddenly become dizzy or faint when there is no reason for this	0	0	0	0
37. I think about death	0	$\bigcirc$	0	0
	Never	Sometimes	Often	Always
38. I feel afraid if I have to talk in front of my class	0	0	0	0
39. My heart suddenly starts to beat too quickly for no reason	0	0	0	0
40. I feel like I dont want to	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$
Move 41.1 worry that I will suddenly get a scared feeling when there is nothing to be afraid of	0	0	0	0
42. I have to do some things over and over again (like washing my hands, cleaning or putting things in a certain order)	0	0	0	0
43. I feel afraid that I will make a fool of myself in front of people	0	0	0	0
44. I have to do some things in just the right way to stop bad things from happening	0	0	0	0
45. I worry when I go to bed at night	0	0	0	0
46. I would feel scared if I had to stay away from home overnight	0	0	0	0
47. I feel restless	0	0	0	0

#### Tier 2

TRAUMA Age 8-17

CRIES-8

Below is a list of comments made by people after stressful life events. Please tick each item showing how frequently these comments were true for you during the past seven days. If they did not occur during that time, please tick the 'not at all' box.



Sometimes

<ol> <li>Do you think about it even when you don't mean to?</li> </ol>	0	0	0	0
2. Do you try to remove it from your memory?	0	0	0	0
<ol><li>Do you have waves of strong feelings about it?</li></ol>	0	0	0	0
4. Do you stay away from reminders of it (e.g. places or situations)?	0	0	0	0
5. Do you try to talk about it?	0	$\bigcirc$	0	0
6. Do pictures about it pop into your mind?	0	0	0	0
7. Do other things keep making you think about it?	0	0	0	0
8. Do you try not to think about it?	0	0	0	0

#### **PROMIS Pain Interference**

Age 8-17

In the past 7 days					
	Never	Almost Never	Sometimes	Often	Almost Always
I felt angry when I had pain.	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$
l had trouble doing schoolwork when I had pain.	$\bigcirc$	$\bigcirc$	0	0	$\bigcirc$
l had trouble sleeping when l had pain.	$\bigcirc$	0	0	$\bigcirc$	0
It was hard for me to pay attention when I had pain.	$\bigcirc$	0	0	0	$\bigcirc$
It was hard for me to run when I had pain.	0	0	0	0	0
lt was hard for me to walk one block when I had pain.	0	0	0	0	0
It was hard to have fun when I had pain.	0	0	0	0	0
It was hard to stay standing when I had pain.	0	0	0	0	0



#### PROMIS Cognitive Function Age 8-17

#### In the past 4 weeks

	None of the time	A little of the time	Some of the time	Most of the time	All of the time
I have to use written lists more often than other people my age so I will not forget things.	0	0	0	0	0
It is hard for me to pay attention to one thing for more than 5-10 minutes.	0	0	0	0	0
I have trouble keeping track of what I am doing if I get interrupted.	0	0	0	0	0
I have to read things several times to understand them.	0	0	0	0	0
I forget things easily.	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$
I have to work really hard to pay attention or I make mistakes	0	0	0	0	0
I have trouble remembering to do things like school projects or chores	0	0	0	0	0

#### **Tier 2: Externalizing Symptoms**

While prioritized as a Tier 2 measure, this Working Group does not recommend specific measures since the most commonly used measures (Child Behavior Checklist and Strengths and Difficulties Questionnaire) require licensing. The Multidimensional Assessment Profile of Disruptive Behavior (MAP-DB), is available for use as well and does not require a license.



### **Health Care**

#### **Health Insurance Status**

Parent Report About Child

What is the primary kind of health insurance or health care plan that your child has now?

○ Child does NOT have health insurance

• Private (purchased directly or through employment)

- 🔆 Public (Medicare, Medicaid, Tricare)
- Don't know

○ Prefer not to answer

COVID-19	Changes	to Health	Insurance
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#### **Parent Report About Child**

During this pandemic (since March 2020) has this child had a change in their health insurance coverage?

If yes, what changes occurred?

 $\bigcirc$  Loss of this child's health insurance

• Fewer benefits / less coverage from insurance

○ Gaining of insurance, for example as part of emergency coverage of Medicaid expansion

#### COVID-19 Changes to Health Care Access Parent Report About Child

#### 

○ Yes

 $\bigcirc$  No

Other (Specify)

☐ Vision Care ☐ Hearing Care ☐ Mental Health Services

Specify other

Please rate how much the coronavirus pandemic has changed your family's life in each of the following ways

Medical health care access

 $\bigcirc$  No change

- Appointments moved to telehealth
- Delays or cancellations in appointments and/or delays in getting prescriptions or regular vaccinations (e.g., MMR); changes have minimal impact on health
- O Unable to access needed care resulting in severe risk and/or significant impact



Please rate how much the coronavirus pandemic has changed your family's life in each of the following ways

Mental health treatment access

- $\bigcirc$  No change
- $\bigcirc$  Appointments moved to telehealth
- O Delays or cancellations in appointments and/or delays in getting prescriptions or regular vaccinations (e.g.,
- MMR); changes have minimal impact on health
- $\bigcirc$  Unable to access needed care resulting in severe risk and/or significant impact

#### **Receiving Behavioral Health/Mental Health Treatment (Tier 2)**

#### **Parent Report About Child**

During the COVID-19 pandemic (since March 2020), has this child received any treatment or counseling from a mental health professional? Mental health professionals include psychiatrists, psychologists, psychiatric nurses, and clinical social workers

<ul> <li>Yes</li> <li>No, but this child needed to see a mental health professional</li> <li>No, this child did not need to see a mental health professional</li> </ul>	
During the COVID-19 pandemic (since March 2020), has this child taken any medication because of difficulties with their emotions, concentration, or behavior?	○ Yes ○ No
Services for Developmental Needs (Tier 2)	
Has this child EVER received special services to meet their developmental needs such as speech, occupational, or behavioral therapy?	○ Yes ○ No
ls/was this child receiving these special services during the pandemic (since March 2020)?	⊖ Yes ⊖ No
Was this child receiving these special services before the pandemic (before March 2020)?	⊖ Yes ⊖ No



## Demographics

#### **COVID-19 Pediatric Joint Group Discussion Recommended Measures**

Sex	
What was the participant's sex assigned at birth?	<ul> <li>Female</li> <li>Male</li> <li>Intersex</li> <li>None of these describe the participant</li> <li>Prefer not to answer</li> </ul>
Age	
[ > 2 years] What is the participant's current age in years?	(years)
[ < 2 years ] What is the participant's current age in months?	(months)
Gestational age at birth (Tier 2) (Ages 0-2 years)	
If < 2 years of age, what was the participant's gestational age at birth (in weeks)?	(weeks)
	<ul><li>○ Unknown</li><li>○ Refused</li></ul>
Ethnicity	
Is the participant of Hispanic, Latino, or Spanish origin?	<ul> <li>No, not of Hispanic, Latino, or Spanish origin</li> <li>Yes, of Hispanic, Latino, or Spanish origin</li> <li>Prefer not to say</li> </ul>
Race	
What is the participant's race? Mark one or more boxes	<ul> <li>American Indian or Alaska Native</li> <li>Asian</li> <li>Black or African American</li> <li>Native Hawaiian or Other Pacific Islander</li> <li>White</li> <li>Some other race</li> <li>Prefer not to answer</li> </ul>
Zip Code	
What is the participant's 5-digit zip code?	



Additional Guidance: Participant's zip code and birth date are protected health information, please refer to the guidance document for more information.

#### Gender Identity (Tier 2)

Additional Guidance: The Working Group consulted the NIH Sexual & Gender Minority Research Office (SGMRO) to ascertain whether there is an established measure of Gender Identity validated in children as the PhenX P11801 Measure is for participants 18+ years.

As of now, there is not a preferred pediatric-specific validated measure, and this remains an important gap in the SGM data collection repertoire. There are many ongoing efforts to address this gap, including the work of the Measuring Sexual Orientation and Gender Identity (SOGI) Research Group's Youth Subgroup, and an in-progress NIH-commissioned consensus report from the National Academies of Sciences, Engineering, and Medicine on collecting sex, gender identity, and sexual orientation data. One measure used in ages 9-10 in the ABCD Study® is presented below, and this data element will be amended if future guidance on the topic is updated:

Are you transgender?

Parent Re	port about	Child (	Ages 9+)
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Is your child transgender?

$\sim$	Yes Maybe/dont know	

○ Did not understand

○ Yes○ Maybe

 $\bigcirc$  No

○ No
○ Decline to answer



## **Disability Functional Status**

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Disability Status (Tier 2)		
Child Self-Report (Ages 15+)		
<ol> <li>Are you deaf, or do you have serious difficulty hearing?</li> </ol>	⊖ Yes	⊖ No
2. Are you blind, or do you have serious difficulty seeing, even when wearing glasses?	⊖ Yes	⊖ No
3. Because of a physical, mental, or emotional condition, do you have serious difficulty concentrating, remembering, or making decisions? (5 years old or older)	() Yes	⊖ No
4. Do you have serious difficulty walking or climbing stairs? (5 years old or older)	() Yes	⊖ No
5. Do you have difficulty dressing or bathing? (5 years old or older)	⊖ Yes	⊖ No
6. Because of a physical, mental, or emotional condition, do you have difficulty doing errands alone such as visiting a doctor's office or shopping? (15 years old or older)	() Yes	⊖ No
Parent Report About Child (As used in National Sur	vey of Cl	hildren's Health)
Parent Report About Child (As used in National Sur           Ages 0-5 Does this child have any of the following?	vey of Cl	hildren's Health)
	vey of Cl	hildren's Health)
Ages 0-5 Does this child have any of the following?	-	
Ages 0-5 Does this child have any of the following? Deafness or problems with hearing? Blindness or problems with seeing even when wearing	) Yes	○ No
Ages 0-5 Does this child have any of the following? Deafness or problems with hearing? Blindness or problems with seeing even when wearing glasses?	) Yes	○ No
Ages 0-5 Does this child have any of the following?         Deafness or problems with hearing?         Blindness or problems with seeing even when wearing glasses?         Ages 6-11 Does this child have any of the following?         Serious difficulty concentrating, remembering, or making decisions because of a physical, mental, or	) Yes	○ No
Ages 0-5 Does this child have any of the following?         Deafness or problems with hearing?         Blindness or problems with seeing even when wearing glasses?         Ages 6-11 Does this child have any of the following?         Serious difficulty concentrating, remembering, or making decisions because of a physical, mental, or emotional condition?	) Yes ) Yes ) Yes	○ No ○ No
Ages 0-5 Does this child have any of the following?         Deafness or problems with hearing?         Blindness or problems with seeing even when wearing glasses?         Ages 6-11 Does this child have any of the following?         Serious difficulty concentrating, remembering, or making decisions because of a physical, mental, or emotional condition?         Serious difficulty walking or climbing stairs?	<ul> <li>Yes</li> <li>Yes</li> <li>Yes</li> <li>Yes</li> </ul>	<ul> <li>○ No</li> <li>○ No</li> <li>○ No</li> <li>○ No</li> </ul>
Ages 0-5 Does this child have any of the following?         Deafness or problems with hearing?         Blindness or problems with seeing even when wearing glasses?         Ages 6-11 Does this child have any of the following?         Serious difficulty concentrating, remembering, or making decisions because of a physical, mental, or emotional condition?         Serious difficulty walking or climbing stairs?         Difficulty dressing or bathing?	<ul> <li>Yes</li> <li>Yes</li> <li>Yes</li> <li>Yes</li> <li>Yes</li> <li>Yes</li> </ul>	<ul> <li>○ No</li> <li>○ No</li> <li>○ No</li> <li>○ No</li> <li>○ No</li> </ul>

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Serious difficulty concentrating, remembering, or making decisions because of a physical, mental, or emotional condition?	⊖ Yes	⊖ No		
Serious difficulty walking or climbing stairs?	⊖ Yes	⊖ No		
Difficulty dressing or bathing?	⊖ Yes	○ No		
Difficulty doing errands alone, such as visiting a doctor's office or shopping, because of a physical mental, or emotional condition?	() Yes	⊖ No		
Deafness or problems with hearing?	⊖ Yes	○ No		
Blindness or problems with seeing even when wearing glasses?	⊖ Yes	⊖ No		
Additional Guidance: For studies wanting to collect more than this short 6-item set, it is recommended to use the Washington Group / UNICEF Child Functioning Module, which serves as an international standard for assessing disability in children 2-4, and 5-17: https://www.washingtongroupdisability. com/question-sets/wgunicef-child-functioning-module-cfm/				
Special Health Care Needs (Tier 2)				
Parent Report About Child				
CSHCN: https://www.cahmi.org/projects/children-with-special-health-care-needs-screener/ • Special Health Care Needs 5 Item Screener https://depts.washington.edu/dbpeds/Screening%20Tools/CSHCN-CAMHIScreener.pdf				
1. Does your child currently need or use medicine prescribed by a doctor (other than vitamins)?	⊖ Yes	⊖ No		
1a. Is this because of ANY medical, behavioral or other health condition?	⊖ Yes	⊖ No		
1b. Is this a condition that has lasted or is expected to last for at least 12 months?	⊖ Yes	⊖ No		
2. Does your child need or use more medical care, mental health or educational services than is usual for most children of the same age?	() Yes	○ No		
2a. Is this because of ANY medical, behavioral or other health condition?	⊖ Yes	○ No		
2b. Is this a condition that has lasted or is expected to last for at least 12 months?	⊖ Yes	⊖ No		
3. Is your child limited or prevented in any way in his or her ability to do the things most children of the same age can do?	⊖ Yes	⊖ No		
3a. Is this because of ANY medical, behavioral or other health condition?	⊖ Yes	⊖ No		



3b. Is this a condition that has lasted or is expected to last for at least 12 months?	○ Yes ○ No
4. Does your child need or get special therapy, such as physical, occupational or speech therapy?	○ Yes ○ No
4a. Is this because of ANY medical, behavioral or other health condition?	○ Yes ○ No
4b. Is this a condition that has lasted or is expected to last for at least 12 months?	○ Yes ○ No
5. Does your child have any kind of emotional, developmental or behavioral problem for which he or she needs or gets treatment or counseling?	○ Yes ○ No
5a. Has this problem lasted or is it expected to last for at least 12 months?	○ Yes ○ No

Guidance: If respondents answer that children have any of these special needs or limitations and that the problem has lasted or is expected to last 12 months or more, children are classified as special needs and are asked more questions than children without special needs. The survey includes information on how often during the past 12 months medical, behavioral, or other health conditions affected the ability of the children identified as having special needs to do things other children of the same age do; how much these conditions affect the children's ability; and how often children's health care needs change.

#### **Normative Physical Functional Status**

#### Child Self Report (Ages 8-17)

When people are sick or not feeling well, it is sometimes difficult for them to do their regular activities.

In the past two weeks, would you have had any physical trouble or difficulty doing these						
activities?						
	No trouble	A little trouble	Some trouble	A lot of trouble	Impossible	
1. Walking to the bathroom	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$	
2. Walking up stairs	$\bigcirc$	$\bigcirc$	$\bigcirc$	0	$\bigcirc$	
3. Doing something with a friend. (For example, playing a game.)	0	0	0	0	0	
4. Doing chores at home	$\bigcirc$	0	$\bigcirc$	0	0	
5. Eating regular meals	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$	
6. Being up all day without a nap or rest	0	0	0	0	$\bigcirc$	
7. Riding the school bus or traveling in the car	0	0	0	0	0	



Remember, you are being asked about difficulty due to physical health					
	No trouble	A little trouble	Some trouble	A lot of trouble	Impossible
8. Being at school all day	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$
9. Doing the activities in gym class (or playing sports)	0	0	0	$\bigcirc$	$\bigcirc$
10. Reading or doing homework	0	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$
11. Watching TV	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$
12. Walking the length of a football field	0	0	0	0	$\bigcirc$
13. Running the length of a football field	0	0	0	0	$\bigcirc$
14. Going shopping	$\bigcirc$	$\bigcirc$	0	$\bigcirc$	$\bigcirc$
15. Getting to sleep at night and staying asleep	0	0	0	0	0

#### **Developmental Milestones (Tier 2)**

Parent Report About Child (Ages 0-5) by age bands:
SWYC: https://www.tuftschildrenshospital.org/The-Survey-of-Wellbeing-of-Young- Children/Age-Specific-Forms

Developmental Delay Screening/Surveillance (Tier 1)				
Parent Report about Child (Ages 9 months-5 years)				
DURING THE PAST 12 MONTHS, did this child see a doctor, nurse, or other health care professional for sick-child care, well-child check-ups, physical exams, hospitalizations, or any other kind of medical care?	⊖ Yes	⊖ No		
DURING THE PAST 12 MONTHS, did you, another family member or a friend have concerns about this child's learning, development, or behavior?	() Yes	⊖ No		
DURING THE PAST 12 MONTHS, did this child's doctors or other health care providers ask if you have concerns about this child's learning, development, or behavior?	() Yes	⊖ No		
DURING THE PAST 12 MONTHS, did you, another family member or a friend have concerns about this child's learning, development, or behavior that wasn't asked about by your provider?	() Yes	○ No		
DURING THE PAST 12 MONTHS, did a doctor or other health care provider have you or another caregiver fill out a questionnaire about observations or concerns you may have about this child's development, communication, or social behaviors? Sometimes a child's doctor or other health care provider will ask a parent to do this at home or during a child's visit.	() Yes	○ No		

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If yes, did the questionnaire ask about your concerns or observations about:

Mark ALL that apply.

How this child talks or makes speech sounds?How this child interacts with you and others?

If yes, and this child is 2-5 years of age:

Did the questionnaire ask about your concerns or observations about:

Mark ALL that apply.

□ Words and phrases this child uses and understands?

How this child behaves and gets along with you and others?



## **Baseline Child Health 2**

#### **Underlying Conditions (from Biomedical WG)**

Significant underlying medical conditions at the time of COVID-19 testing or diagnosis:

🗌 Diabetes type I	
Diabetes type II	
Obesity	
🗌 Asthma	
🗌 Bronchopulmonary dysplasia (BPD)	
Cystic fibrosis	
Obstructive sleep apnea	
Tracheomalacia	
Cancer	
Hematopoietic cell recipient/bone marrow transplant recipient	
Solid organ transplant recipient	
Rheumatologic conditions (e.g. rheumatoid arthritis, systemic lupus erythe	matosus, vasculitis)
Hypertension	
Congenital heart disease	
Heart failure	
Cardiomyopathy	
History of Kawasaki Disease (not a current diagnosis)	
History of MIS-C (not a current diagnosis)	
Inflammatory bowel disease	
Feeding tube dependent	
Sickle cell disease	
Thrombotic disorders	
Chronic liver disease	
Chronic kidney disease	
Seizure disorder/epilepsy	
Eczema	
Physical disability (including cerebral palsy)	
Down syndrome	
Congenital syndromes/anomalies or genetic conditions including other chro	omosomal syndromes
Premature or neonatal conditions	
Pregnancy (if of reproductive age)	
Other conditions (specify)	

Specify other

Premature and Neonatal Conditions (Tier 2)

- Fetal malnutrition
- Extreme immaturity
- Cerebral hemorrhage at birth
- Spinal cord injury at birth
- Birth asphyxia
   Respiratory diseases
- Hypoxic-ischemic encephalopathy
- Other

Specify other



Significant underlying conditions at the time of COVID-19 testing or diagnosis:

- Tourette Syndrome
- Depression
- Anxiety problems
- Autism, Asperger's Disorder, pervasive developmental disorder or other autism spectrum disorder
- Attention Deficit Disorder or Attention Deficit Hyperactivity Disorder (ADD/ADHD)
- Chronic fatigue
- Post-traumatic stress disorder (PTSD)
- Suicidal thoughts or behaviors
- Mania or bipolar disorder
- Behavioral disorder or conduct problems
- Developmental delay
- Intellectual disability (formerly known as mental retardation)
- Speech or other language disorder
- Learning disability

