

General Tips:

Patients ≥ 18 years old must be enrolled to Step 1 within 14 days of their positive SARS-CoV-2 test. If a patient is enrolled to Step 0 while awaiting a test result, the Step 1 registration in OPEN should be completed as soon as the positive test result is received to avoid missing the eligibility window; additional forms in RAVE (e.g. social and environmental factors, treatment summary) can be completed at a later date if this information is not immediately available or if the patient is hospitalized at the time of enrollment.

Patients <18 years old may be enrolled at any time as long as they had a positive SARS-CoV-2 test after January 31, 2020. Data for the follow-up timepoints should only be completed prospectively. For example, if a patient enrolls 3 months after the date the test is collected, the first follow-up timepoint for which data are collected will be the 3-month timepoint.

Timepoints without an in-person patient visit: Data collection is required at all timepoints, including those where patients do not have an in-person visit scheduled. For these timepoints, data collection should be remote.

Windows of Collection: A window of +/- 1 week is allowed for non-inpatient data and specimen collections at 2 weeks, 1 month, 2 months, and 3 months. A window of +/- 1 month is allowed for data and specimen collections at 6 months, 9 months, 12 months, and 2 years.

Date and Time formats: If a full date is not known, use the code “un”. For example, if a patient was diagnosed in December 2013 (day of month not known), enter “un DEC 2013”. If neither day nor month is known, enter “un UNK 2013.” Times must be entered using a 24-hour clock—i.e., 2:00 PM is recorded as “14:00”, midnight is recorded as “00:00.” If a time is not known, leave the field blank.

Comment Form: The “comment” form can be used at any timepoint to make comments on any form.

Reference Forms: Printable versions of all CRFs are available on the CTSU protocol website under Documents → Case Report Forms.

If you have additional questions about the data requirements or conduct of the study, please email the study mailbox at NCCaPS@mail.nih.gov for a prompt response.

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When is the form submitted?	Form Name	RAVE Folder	Tips/Form Information What questions are required?
Step 0 Enrollment Forms – complete <u>within 7 days</u> of Step 0 Enrollment			
Step 0 Enrollment	Histology and Disease	Enrollment	<p>This form contains details about the patient’s cancer, such as initial diagnosis date, staging, and any sites of metastases. Do not enter information about the patient’s COVID-19 illness in this form.</p> <p>Required fields: Primary disease site/histologic type, SnoMed Disease Term/Code, Initial Diagnosis Date, and Overall Disease Stage. This form must be completed to correctly populate Specimen and Shipping forms.</p> <p>Tips: The SnoMed drop-down list may include multiple relevant terms/codes. Please choose <u>the most detailed</u> appropriate code for the patient’s cancer diagnosis. For example, choose “lung adenocarcinoma” or “cervical adenocarcinoma in situ” rather than “adenocarcinoma.”</p>
Step 0 Enrollment	COVID-19 Symptoms	Baseline	<p>Required fields: In the past 7 days, has the patient experienced any symptoms due to COVID-19? Yes/No (required). If yes, check all that apply.</p> <p>Tips: Indicate if the patient has any of the listed COVID-19 symptoms and report any symptoms not on the list in the “Other, specify” box within the appropriate general category. (Be sure to view all lines if your default view splits the symptoms list into two pages.)</p> <p>*This form is also completed at Step 1, at each follow-up timepoint, and at inpatient admission.</p>
Automatically populated from OPEN at Step 0/1	Enrollment	Enrollment	<p>This form is automatically populated with demographic information from OPEN at Step 0.</p> <p>No additional data entry is required.</p>
Automatically populated from OPEN at Step 0/1	Administrative Enrollment	Enrollment	<p>This form is automatically populated with investigator and credit enrollment details from OPEN at Step 0.</p> <p>No additional data entry is required.</p>
Automatically populated from OPEN at Step 0/1	Patient Eligibility	Enrollment	<p>This form is automatically populated with patient eligibility data from OPEN at Step 0.</p> <p>No additional data entry is required.</p>
Step 0 Enrollment	Prior Treatment Summary	Baseline	<p>Basic cancer treatment history; additional details should be entered at Step 1 enrollment.</p> <p>Required Fields: For each cancer therapy type listed (systemic therapies, radiation therapy, and surgery) you must enter "Yes" if the patient has received this type of treatment or "No" the patient has not. If yes, you must either check that the therapy is ongoing or give a date of last dose (approximate dates are sufficient: for example, “un,” “UNK,” year).</p> <p>Tips: Information about past treatment from a physician note is sufficient to complete this form. "Yes" answers will trigger supplemental form(s) for additional therapy details. The supplemental form(s) should be completed if the patient enrolls to Step 1.</p>
Step 0 Enrollment	COVID-19 History (Step 0)	Baseline	<p>Brief questions about patient's SARS-CoV-2 test and test reason.</p> <p>All questions are required.</p> <p>*This form must be completed at both the Step 0 and Step 1.</p>

When is the form submitted?	Form Name	RAVE Folder	Tips/Form Information What questions are required?
Step 0 Enrollment	Cancer Status	Baseline	<p>Brief questions about patient's current cancer and treatment status.</p> <p>Required fields: All questions except study ID for other clinical trials are required.</p> <p>Tips: If patient is enrolled in other studies, provide the NCT number (identifier on ClinicalTrials.gov) if available or another study identifier. This is extremely important for tracking potential overlap in study participants.</p> <p>*This form is also completed at each follow-up timepoint.</p>
Step 0 Enrollment	Vital Signs	Vital Signs	<p>Performance status and basic vital signs. Choose either ECOG or Karnofsky/Lansky for Performance Status.</p> <p>Required fields: If the patient is not seen in person for the visit, only date of visit and performance status should be completed.</p> <p>*This form is also completed at Step 1 enrollment and at each follow-up timepoint.</p>
If patient goes off study because SARS-CoV-2 test is negative	Off Study	Off Study	<p>If a patient was enrolled while awaiting the result of a SARS-CoV-2 test and tests negative, this form must be completed to take the patient off-study. The Site will also need to enter the negative test result in OPEN under Step 1 to screen fail the patient.</p> <p>Required fields: Off study date and reason.</p>
<p>Step 1 Enrollment Forms – complete within 7 days of Step 1 Enrollment unless otherwise specified</p>			
Step 1 Enrollment	COVID-19 Symptoms	Baseline	<p>Required: In the past 7 days, has the patient experienced any symptoms due to COVID-19? Yes/No (required). If yes, check all that apply.</p> <p>Tips: Indicate if the patient has any of the listed COVID-19 symptoms and report any symptoms not on the list in the “Other, specify” box within the appropriate general category. (Be sure to view all lines if your default view splits the symptoms list into two pages.)</p> <p>*This form is also completed at Step 0, at each follow-up timepoint, and at inpatient admission.</p>
Step 1 Enrollment	Baseline Medical History	Baseline	<p>A list of yes/no questions and checkboxes to gather information about key relevant baseline medical conditions, including pulmonary, cardiac, renal, hepatic, or neurologic baseline medical conditions; current pregnancy; prior malignancy; anticoagulant treatment; etc.</p> <p>Required fields: Yes/no questions for disease categories and key conditions are required.</p> <p>Tips: Within the broader disease categories, check the boxes for all conditions a patient has within the category.</p>

When is the form submitted?	Form Name	RAVE Folder	Tips/Form Information What questions are required?
Step 1 Enrollment	COVID-19 History (Step 1)	Baseline	<p>More detailed questions about the SARS-CoV-2 testing and diagnosis, initial treatment (if any), and any suspected co-infections. The de-identified report for the SARS-CoV-2 test results should be uploaded.</p> <p>All questions are required.</p> <p>*This form must be completed at both the Step 0 and Step 1.</p>
Step 1 Enrollment	Prior: Therapy Supplement	Baseline	<p>For systemic therapy types selected on the Prior Treatment Summary form, provide dosing details. If multiple agents or therapies have been completed within a therapy type, add a new log line for each.</p> <p>Required fields: Date of first dose and name of therapy.</p> <p>Details of prior therapy must be completed within 30 days of Step 1 enrollment</p>
Step 1 Enrollment	Prior: Radiation Supplement	Baseline	<p>For radiation therapy types selected on the Prior Treatment Summary form, provide therapy details. Add a new log line for each additional prior treatment.</p> <p>Required fields: Start date and procedure name.</p> <p>Details of prior therapy must be completed within 30 days of Step 1 enrollment</p>
Step 1 Enrollment	Prior: Surgery Supplement	Baseline	<p>For surgery therapy types selected on the Prior Treatment Summary form, provide details. Add a new log line for each additional prior surgery.</p> <p>Required fields: Surgical approach (biopsy, resection, or other), date, anatomical location, and whether procedure was done with therapeutic intent.</p> <p>Details of prior therapy must be completed within 30 days of Step 1 enrollment</p>
Step 1 Enrollment	Social and Environmental Factors	Baseline	<p>Brief questions about tobacco, marijuana, and alcohol use, other exposures, and basic demographic information.</p> <p>Required fields: None required; enter all applicable information.</p> <p>Social and environmental history should be completed within 7 days of Step 1 enrollment for outpatients, or within 7 days of hospital discharge for inpatients.</p>
Step 1 Enrollment	New/Emerging Medical Issues	Baseline	<p>A list of yes/no questions and checkboxes to gather information about key new and emerging medical conditions that may be caused by COVID-19, including coagulation, pulmonary, cardiovascular, thromboembolic, gastrointestinal, infectious, neurologic, or other key conditions.</p> <p>Required fields: Yes/no questions for disease categories and key conditions are required.</p> <p>Tips: Within broader disease categories, check the boxes for all conditions a patient has developed within that category. For respiratory failure, check all treatment approaches that have been used. For Acute Respiratory Distress Syndrome (ARDS), indicate the Berlin criteria, if known (a rubric for the Berlin criteria is available on the CTSU protocol page).</p> <p>*This form is also completed at each follow-up timepoint and at hospital discharge.</p>

When is the form submitted?	Form Name	RAVE Folder	Tips/Form Information What questions are required?
Step 1 Enrollment	Additional Cancer History	Baseline	Brief questions to be completed if the patient has more than one cancer. Required fields: None required; enter all applicable information.
Step 1 Enrollment	Current COVID-19 Directed Medication	Current Therapies	Log requesting basic information about past and current COVID-19 treatments. Required fields: None required; enter all applicable information. *This log should be updated at each follow-up timepoint and after any COVID-19 hospitalization.
Step 1 Enrollment	Concomitant and Prior Medications	Current Therapies	Log requesting start and end date, therapy, dose, and indication for all current non-cancer medications and all current and prior COVID-19 medications. Required fields: Start date and therapy (free text) Tips: List <u>all current non-cancer medications</u> (including COVID-19 treatments), blood products/transfusions, vaccines and growth factor given. Please include the most recent influenza vaccine. Also list <u>any prior COVID-19-directed</u> medications. Prior medications other than those used to treat COVID-19 do not need to be entered. *This log should be updated at each follow-up timepoint and after any COVID-19 hospitalization.
Step 1 Enrollment	Current Cancer Therapy	Current Therapies	Log requesting therapy category, start and end date, therapy name, and dose information for all cancer therapies that the patient receives while on study. Include systemic therapy, surgery and radiation therapy. Required fields: None required; enter all applicable information. Tips: This form should be updated at each follow-up timepoint. Add end dates for any therapy that has been discontinued. If there is a change to a therapy dose, frequency, or regimen, enter a new log line at the new dose and update the existing log line with the end date. Do not change the dose on the original log line. *This log should be updated at each follow-up timepoint and after any COVID-19 hospitalization.
Step 1 Enrollment	Vital Signs	Vital Signs	Performance status and basic vital signs. Choose either ECOG or Karnofsky/Lansky scale for Performance Status. Required fields: If the patient is not seen in person for the visit, only date of visit and performance status should be completed. *This log should be completed at Step 0 enrollment, Step 1 enrollment and at each follow-up timepoint.

When is the form submitted?	Form Name	RAVE Folder	Tips/Form Information What questions are required?
<p>Step 1 Enrollment with information about the most recent labs done for the patient.</p>	Hematology	Lab: Hematology	<p>Required fields: A lab must be selected and the date, timepoint, and question “Have you selected a laboratory in the drop down above?” are required. Key labs expected to be most relevant for this study are highlighted in yellow. Enter data for all available labs.</p> <p>Tips for all lab forms:</p> <ol style="list-style-type: none"> 1. You must select a laboratory from the drop-down menu to populate the units and normal ranges. 2. Sites in the U.S. must choose “CTMS generic lab”. The pre-populated ranges may not be the ranges used at your institution; this is not a problem for this trial. 3. Select “Yes” to the question “Have you selected a laboratory in the drop down above?” <p>If the pre-populated units do not match the units used by your lab, please use the “comments” form (a separate form) to note the correct units.</p> <p>The lab tests that are highlighted are the most crucial for this study. Lab values that are not highlighted may also be entered.</p> <p>NOTE: After the log form has been submitted with lab results at one timepoint, you must return to the last entry when you want to submit a new set of lab results for the next timepoint. Please see the short training document on the CTSU with screenshots and instructions for how this is done.</p> <p>*These logs should be updated at each timepoint with lab results.</p>
	Blood Chemistry - Hepatic	Lab: Blood Chem - Hepatic	
	Blood Chemistry - Renal	Lab: Blood Chem - Renal	
	Pancreatic Thyroid and Cardiac	Lab: Chemistry - Pancreatic Thyroid and Cardiac	
	Blood Gases	Lab: Blood Gases	
	COVID-related Laboratory	Lab: COVID Specific	
<p>Step 1 Enrollment with information about the most recent imaging studies done and submitted via TRIAD for the patient.</p>	Imaging Studies Log	Lab: Imaging Studies	<p>Required fields: Collection date and time, imaging study type under the dropdown for “Lab Test Name,” Anatomical Region.</p> <p>Tips: Enter the imaging study information for all images submitted via TRIAD. Enter collection date and time, imaging study type under the dropdown for “Lab Test Name,” Anatomical Region, and Result. Indicated whether there are any COVID-19 related findings.</p> <p>For patients with any COVID-19 related findings on imaging in the first 6 months, any additional CT, MRI, or FDG-PET/CT performed for evaluation of COVID-19 during study participation should be collected. This determination should be made based on a review of available imaging at 6 months.</p> <p>*This log should be updated at each timepoint with imaging submissions.</p>
<p>Pediatric Patient Form (Step 1 Enrollment) – complete <u>within 7 days of Step 1 Enrollment</u> and update as needed</p>			
<p>Step 1 Enrollment (only for Patients < 18)</p>	Pediatric Exposure History and Ongoing Exposure	Pediatric	<p>Tips: This form is for pediatric patients only. Complete the form at baseline. Please include the most recent influenza vaccine on the concomitant and prior medications form. Add a log line to the table of household exposures for each household member diagnosed with COVID-19 (after January 31, 2020). If additional household members are diagnosed with COVID-19 while the patient is on-study, please add additional log lines.</p>

When is the form submitted?	Form Name	RAVE Folder	Tips/Form Information What questions are required?
Specimen Collection Forms – complete on the day of specimen collection			
With each research specimen submission	Specimen Submission Log	All Specimens	Tips: Use this form to record whether specimens were collected at each Study timepoint. If specimens were not collected, record the reason.
With each research specimen submission	Specimen Tracking Enrollment	All Specimens	Log form for use when submitting specimens using the Specimen Tracking System. Required fields: Assessment Timepoint and number of labels are required. Specimen category and specimen type have been pre-filled with “Blood”. <i>*This log should be completed with each research specimen submission.</i>
Pre-filled in RAVE	Tracking Contacts	All Specimens	No data entry required. This form is pre-filled automatically in RAVE.
With each research specimen submission	Specimen Transmittal	Specimen (N)	Required: Date of Specimen Collection, Collection Tube Type, Number of Specimens Collected, and Original Number of specimens available for submission. Tips: Pre-filled information is populated from the “Print Labels” form. Specimen source will be pre-filled as “Blood (General Blood Draw).” Most fields on this standard NCI form are not needed for this study.
	Copy Shipping	Specimen (N)	This form is not required. Use if same shipment is being used for multiple patients to make data entry easier. Tips: Use this form to copy shipping information already entered for another patient/specimen if the same shipment is being used for multiple patients.
With each research specimen submission	Shipping Status	Specimen (N)	Required fields: Courier name, shipping tracking number, shipping source, sender’s name, sender’s email, number of samples sent, shipping conditions, shipped date, and destination. Tips: Send email alert should not be checked until all specimens in the shipment have been entered.
	Receiving Status	Specimen (N)	No data entry required. This form is completed by the biorepository receiving specimens.
	Biopsy Path. Verification	Specimen (N)	No data entry required. No items currently required for this study.

When is the form submitted?	Form Name	RAVE Folder	Tips/Form Information What questions are required?
Adverse Event Forms – complete if there is an adverse event related to the research blood collection			
If there is an adverse event .	Blood Collection Adverse Event Presence	All Specimens	Required fields: “Are there any adverse events related to the collection of blood samples?” If Yes, the Blood Collection Adverse Events form will appear and must be completed.
If there is an adverse event .	Blood Collection Adverse Events	All Specimens	Required fields: Associated Specimen ID, timepoint, AE term, and start date. Tips: This will appear if the “Blood Collection Adverse Event Presence” form is completed to indicate there was an adverse event.
Health-Related Quality of Life Forms (Patients ≥ 18 years old) – enter data within 14 days of patient completion Window for patient completion of HRQOL Form is +/- 1 week for 1- and 3-month timepoint and +/- 1 month for 6-, 12- and 24-month timepoint Data must be entered into RAVE within 14 days of patient completion of HRQOL questionnaire			
1 ,3, 6, 12, and 24 months	HRQOL Collection Log	Quality of Life	Tips: The first question asks whether the patient consented to participate in the optional HRQOL collections: this question should be completed at the 1-month HRQOL collection timepoint. At each timepoint, add a new log line to record whether HRQOL items were completed.
1 ,3, 6, 12, and 24 months	PROMIS-29 Profile v2.0	Quality of Life	Required Fields: date, assessment timepoint.
1 ,3, 6, 12, and 24 months	PROMIS – Dyspnea Severity Short Form 5b	Quality of Life	Required Fields: date, assessment timepoint.
1 ,3, 6, 12, and 24 months	PROMIS – Social Isolation Short Form 4a	Quality of Life	Required Fields: date, assessment timepoint.
1 ,3, 6, 12, and 24 months	PROMIS – Cognitive Function Short Form 8a	Quality of Life	Required Fields: date, assessment timepoint.

When is the form submitted?	Form Name	RAVE Folder	Tips/Form Information What questions are required?
<p>Inpatient Forms – complete if patient is hospitalized for COVID-19 Admission and COVID-19 Symptom forms should be completed within 7 days of admission. All forms must be completed within 30 days of hospital discharge. <i>In order to see the inpatient folder, you must ADD EVENT on the patient home page and select INPATIENT from the drop-down menu. The inpatient folder will appear in the folders list below SARS-CoV-2 test and above the Labs folders.</i></p>			
At admission or based on information from hospital admission	Admission	Inpatient	<p>Required fields: Admission date.</p> <p>Tips: Information to complete this form should be available in the admission note or emergency room intake. Rubrics for the Level of Consciousness (APVU) and Emergency Severity Index Score are available on the CTSU protocol page.</p>
At admission or based on symptoms present at hospital admission	COVID-19 Symptoms	Inpatient	<p>Required: In the past 7 days, has the patient experienced any symptoms due to COVID-19? Yes/No (required). If yes, check all that apply.</p> <p>Tips: Indicate if the patient has any of the listed COVID-19 symptoms and report any symptoms not on the list in the “Other, specify” box within the appropriate general category. (Be sure to view all lines if your default view splits the symptoms list into two pages.)</p> <p><i>*This form is also completed at Step 0, at Step 1, and at each follow-up timepoint</i></p>
After patient discharge from the hospital (Add log items with the key daily values for each day of hospitalization.)	Vital Signs - Inpatient	Inpatient	<p>Required fields: Date of admission and clinical ordinal status on admission are required.</p> <p>Tips: Record COVID-19 clinical status ordinal scale, basic vital signs such as temperature, pulse, blood pressure, and oxygen at presentation and with minimums and maximums for 24-hour periods during hospitalization.</p> <p>If the patient was hospitalized outside of your institution, daily vital signs do not need to be recorded, but date of admission and clinical ordinal status on admission should be completed.</p> <p>If the patient was hospitalized for COVID-19 at enrollment or immediately prior to enrollment, please record daily key values for each day of hospitalization, including days prior to study enrollment.</p> <p>Note: This is different from the outpatient vital signs log. This form collects more specific information about vital signs during a hospital stay.</p>
After patient discharge from the hospital	New/Emerging Medical Issues	Inpatient	<p>A list of yes/no questions and checkboxes about key medical conditions that may be caused by COVID-19, including coagulation, pulmonary, cardiovascular, GI, infectious, neurologic, or other key conditions.</p> <p>Required fields: Yes/no questions for disease categories and key conditions are required.</p> <p>Tips: Within broader disease categories, check the boxes for all conditions a patient has developed within that category. For respiratory failure, check all treatment approaches that have been used. For Acute Respiratory Distress Syndrome (ARDS), indicate the Berlin criteria, if known (rubric available on the CTSU protocol page). Information to complete this form should be available in the patient’s discharge summary.</p> <p><i>*This form is also completed at Step 1 and at each follow-up timepoint.</i></p>

When is the form submitted?	Form Name	RAVE Folder	Tips/Form Information What questions are required?
After patient discharge from the hospital	Discharge	Inpatient	Questions about key elements of COVID-19 management, treatment, and test results during the course of the hospital stay. All applicable questions should be answered. Information to complete this form should be available in the patient’s discharge summary.
Lab Forms – complete at all timepoints with information about the patient’s most recent labs			
At any timepoint with information about the most recent labs done for the patient.	Hematology	Lab: Hematology	<p>Required fields: A lab must be selected and the date, timepoint, and question “Have you selected a laboratory in the drop down above?” are required. Key labs expected to be most relevant for this study are highlighted in yellow. Enter data for all available labs.</p> <p>Tips for all lab forms:</p> <ol style="list-style-type: none"> 1. You must select a laboratory from the drop-down menu to populate the units and normal ranges. 2. Sites in the U.S. must choose “CTMS generic lab”. The pre-populated ranges may not be the ranges used at your institution; this is not a problem for this trial. 3. Select “Yes” to the question “Have you selected a laboratory in the drop down above?” 4. If the pre-populated units do not match the units used by your lab, please use the “comments” form (a separate form) to note the correct units. <p>The lab tests that are highlighted are the most crucial for this study. Lab values that are not highlighted may also be entered.</p> <p>NOTE: After the log form has been submitted with lab results at one timepoint, you must return to the last entry when you want to submit a new set of lab results for the next timepoint. Please see the short training document on the CTSU with screenshots and instructions for how this is done.</p> <p>*These logs should be updated at each timepoint with lab results.</p>
	Blood Chemistry - Hepatic	Lab: Blood Chem - Hepatic	
	Blood Chemistry - Renal	Lab: Blood Chem - Renal	
	Pancreatic Thyroid and Cardiac	Lab: Chemistry - Pancreatic Thyroid and Cardiac	
	Blood Gases	Lab: Blood Gases	
	COVID-related Laboratory	Lab: COVID Specific	
At any timepoint with information about the most recent imaging studies done and submitted via TRIAD for the patient.	Imaging Studies Log	Lab: Imaging Studies	<p>Required fields: Collection date and time, imaging study type under the dropdown for “Lab Test Name,” Anatomical Region.</p> <p>Tips: Enter the imaging study information for all images submitted via TRIAD. Enter collection date and time, imaging study type under the dropdown for “Lab Test Name,” Anatomical Region, and Result. Indicated whether there are any COVID-19 related findings.</p> <p>For patients with any COVID-19 related findings on imaging in the first 6 months, any additional CT, MRI, or FDG-PET/CT performed for evaluation of COVID-19 during study participation should be collected. This determination should be made based on a review of available imaging at 6 months.</p> <p>*This log should be updated at each timepoint with imaging submissions.</p>

When is the form submitted?	Form Name	RAVE Folder	Tips/Form Information What questions are required?
At any timepoint with information about SARS- CoV-2 viral or antibody tests done for the patient.	SARS-CoV-2 Tests	SARS-CoV-2 Tests	<p>All questions are required.</p> <p>Tips: Include any antibody testing in addition to viral detection/diagnostic testing. This form does not need to be completed for the original test leading to study eligibility (prior to Step 0/1 enrollment).</p> <p><i>*This log should be updated at each timepoint with SARS-CoV-2 testing results.</i></p>
<p>Follow-up Forms – complete at each follow-up timepoint and enter data <u>within 14 days</u> of assessment Window for data collection is +/- 1 week for 2 week, 1, 2, and 3 month timepoint and +/- 1 month for 6, 9, 12, and 24 month timepoint. <i>For Pediatric patients, the follow-up timepoints correspond to date of positive SARS-CoV-2 test, not date of enrollment.</i></p>			
Each follow-up timepoint	Cancer Status	Follow Up	<p>Brief questions about patient's current cancer and treatment status.</p> <p>After saving this form (with a minimum of the timepoint entered), the additional forms will populate in the Follow Up folder.</p> <p>Required fields: All questions except study ID are required.</p> <p>Tips: If patient is enrolled in other studies, provide the NCT number (identifier on ClinicalTrials.gov) if available or another study identifier. This is extremely important for tracking potential overlap in study participants.</p> <p><i>*This form is also completed at Step 0 enrollment.</i></p>
Each follow-up timepoint	COVID-19 Symptoms	Follow Up	<p>Required: In the past 7 days, has the patient experienced any symptoms due to COVID-19? Yes/No (required). If yes, check all that apply.</p> <p>Tips: Indicate if the patient has any of the listed COVID-19 symptoms and report any symptoms not on the list in the “Other, specify” box within the appropriate general category. (Be sure to view all lines if your default view splits the symptoms list into two pages.)</p> <p><i>*This form is also completed at Step 0, at Step1, and at inpatient admission</i></p>
Each follow-up timepoint	Follow up COVID-19 Status	Follow Up	<p>Form with questions about COVID-19 status and management.</p> <p>Required: Enter all applicable information. COVID-19 Clinical status (ordinal scale) is required.</p>

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Each follow-up timepoint	Treatment or Assessment Disruption	Follow Up	<p>A log form asking for the type of treatment or assessment that has been disrupted (dropdown list including clinic visit, imaging, surgery, radiation, supportive care, or any type of cancer therapy), a free text field for description of the therapy, dropdown list of type of disruption, a free text field with additional details of the disruption, whether the disruption was related to COVID-19, and a dropdown list of the primary reason for disruption.</p> <p>Required fields: Please provide as much information as possible as this will help inform the key study outcomes of how COVID-19 interferes with cancer treatments and may impact patient outcomes.</p> <p>Tips: Missed or delayed blood transfusions, PJP prophylaxis, and growth factor administrations should be listed as supportive care.</p>
Each follow-up timepoint	New/Emerging Medical Issues	Follow Up	<p>A list of yes/no questions and checkboxes to gather information about key new and emerging medical conditions that may be caused by COVID-19, including coagulation, pulmonary, cardiovascular, thromboembolic, gastrointestinal, infectious, neurologic, or other key conditions.</p> <p>Required fields: Yes/no questions for disease categories and key conditions are required.</p> <p>Tips: Within broader disease categories, check the boxes for all conditions a patient has developed within that category. For respiratory failure, check all treatment approaches that have been used. For Acute Respiratory Distress Syndrome (ARDS), indicate the Berlin criteria, if known (a rubric for the Berlin criteria is available on the CTSU protocol page).</p> <p>*This form is also completed at Step 1 and at hospital discharge.</p>
Each follow-up timepoint	Follow Up Continuation	Follow Up	<p>Single question asking if patient will continue into the next follow up period; if yes, the next set of forms will appear for entry at the appropriate time.</p> <p>Entering data in this form is required to create a new follow-up folder for the next visit.</p> <p>*This form is completed at each follow-up timepoint.</p>
Each follow-up timepoint	Vital Signs	Vital Signs	<p>Performance status and basic vital signs. Choose either ECOG or Karnofsky/Lansky scale for Performance Status.</p> <p>Required fields: If the patient is not seen in person for the visit, only date of visit and performance status should be completed.</p> <p>*This log should be completed at Step 0 enrollment, Step 1 enrollment and at each follow-up timepoint.</p>
Each follow-up timepoint	Current COVID-19 Directed Medication	Current Therapies	<p>Log requesting basic information about past and current COVID-19 treatments.</p> <p>Required fields: None required; enter all applicable information.</p> <p>*This log should be updated at each follow-up timepoint</p>

When is the form submitted?	Form Name	RAVE Folder	Tips/Form Information What questions are required?
Each follow-up timepoint	Concomitant and Prior Medications	Current Therapies	<p>Log requesting start and end date, therapy, dose, and indication for all current non-cancer medications.</p> <p>Required fields: Start date and therapy (free text)</p> <p>Tips: List <u>all current non-cancer medications</u> (including COVID-19 treatments), blood products/transfusions, vaccines and growth factor given. Please include the most recent influenza vaccine. Also list <u>any prior COVID-19-directed</u> medications. Prior medications other than those used to treat COVID-19 do not need to be entered.</p> <p><i>*This log should be updated at each follow-up timepoint</i></p>
Each follow-up timepoint	Current Cancer Therapy	Current Therapies	<p>Log requesting therapy category, start and end date, therapy name, and dose information for all cancer therapies that the patient receives while on study. Include systemic therapy, surgery and radiation therapy.</p> <p>Required fields: None required; enter all applicable information.</p> <p>Tips: Add end dates for any therapy that has been discontinued. If there is a change to a therapy dose, frequency, or regimen, enter a new log line at the new dose and update the existing log line with the end date. Do not change the dose on the original log line.</p> <p><i>*This log should be updated at each follow-up timepoint.</i></p>
At any timepoint with information about the most recent labs done for the patient.	Hematology	Lab: Hematology	<p>Required fields: A lab must be selected and the date, timepoint, and question “Have you selected a laboratory in the drop down above?” are required. Key labs expected to be most relevant for this study are highlighted in yellow. Enter data for all available labs.</p> <p>Tips for all lab forms:</p> <ol style="list-style-type: none"> 1. You must select a laboratory from the drop-down menu to populate the units and normal ranges. 2. Sites in the U.S. must choose “CTMS generic lab”. The pre-populated ranges may not be the ranges used at your institution; this is not a problem for this trial. 3. Select “Yes” to the question “Have you selected a laboratory in the drop down above?” 4. If the pre-populated units do not match the units used by your lab, please use the “comments” form (a separate form) to note the correct units. <p>The lab tests that are highlighted are the most crucial for this study. Lab values that are not highlighted may also be entered.</p> <p>NOTE: After the log form has been submitted with lab results at one timepoint, you must return to the last entry when you want to submit a new set of lab results for the next timepoint. Please see the short training document on the CTSU with screenshots and instructions for how this is done.</p> <p><i>*These logs should be updated at each timepoint with lab results.</i></p>
	Blood Chemistry - Hepatic	Lab: Blood Chem - Hepatic	
	Blood Chemistry - Renal	Lab: Blood Chem - Renal	
	Pancreatic Thyroid and Cardiac	Lab: Chemistry - Pancreatic Thyroid and Cardiac	
	Blood Gases	Lab: Blood Gases	
	COVID-related Laboratory	Lab: COVID Specific	

When is the form submitted?	Form Name	RAVE Folder	Tips/Form Information What questions are required?
At any timepoint with information about the most recent imaging studies done and submitted via TRIAD for the patient.	Imaging Studies Log	Lab: Imaging Studies	<p>Required fields: Collection date and time, imaging study type under the dropdown for “Lab Test Name,” Anatomical Region.</p> <p>Tips: Enter the imaging study information for all images submitted via TRIAD. Enter collection date and time, imaging study type under the dropdown for “Lab Test Name,” Anatomical Region, and Result. Indicated whether there are any COVID-19 related findings.</p> <p>For patients with any COVID-19 related findings on imaging in the first 6 months, any additional CT, MRI, or FDG-PET/CT performed for evaluation of COVID-19 during study participation should be collected. This determination should be made based on a review of available imaging at 6 months.</p> <p>*This log should be updated at each timepoint with imaging submissions.</p>
At any timepoint with information about SARS-CoV-2 viral or antibody tests done for the patient.	SARS-CoV-2 Tests	SARS-CoV-2 Tests	<p>All questions are required.</p> <p>Tips: Include any antibody testing in addition to viral detection/diagnostic testing. This form does not need to be completed for the original test leading to study eligibility (prior to Step 0/1 enrollment).</p> <p>*This log should be updated at each timepoint with SARS-CoV-2 testing results.</p>
Off Study, Death Summary, and Comment Forms – complete as needed			
If patient goes off study	Off Study	Off Study	<p>Brief form with off study date, reason, and consent status, including whether patient withdraws consent for future use of banked specimens and data.</p> <p>Required fields: Off study date and reason.</p> <p>Tips: Patients who no longer consent to specimen collections should be taken off study with this form, since the specimen collections are mandatory for this study if the patient is having a clinical collection done.</p>
If patient dies while on study	Death Summary	Off Study	<p>Brief questions about patient's death.</p> <p>Required fields: Date of death, cause of death, and if autopsy results are available.</p>
As needed	Comment	Comment	<p>A free-text comment field to be used as needed to record comments related to other forms.</p> <p>Required fields: Date, form to which the comment applies (drop-down list)</p>