

VIT
VICTORY

Data Collection (REDCap)

Study Days and Data Collection

Study days are defined as follows and data must be collected according to study days:

- + **Study Day 1 = ACU admit date/time** (not randomization) until 23:59 the same day.
- + **Study Day 2** = the subsequent day starting at 00:00 to 23:59 that day.

Example: A patient is admitted to the ACU on July 8th, 2020 at 4:00 PM (16:00). The study days would be:

- + Study Day 1 = 2020-07-08 from 16:00 to 2020-07-08 at 23:59
- + Study Day 2 = 2020-07-09 from 00:00 to 2020-07-09 at 23:59
- + Data **MUST** be collected according to calendar day as described above
- + Do **NOT** collect data according to your flow sheet unless it runs from 00:00-23:59

REDCap™

Access REDCap™ at the following web address:

<https://ceru.hpcvl.queensu.ca/EDC2/redcap/>

REDCap is the electronic data capture system for the study.

Login with your Username and Password.

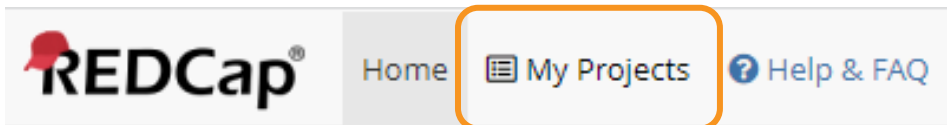


Log In

Please log in with your user name and password. If you are having trouble logging in, please contact [Support](#).

Username:	<input type="text"/>
Password:	<input type="password"/>
<input type="button" value="Log In"/>	Forgot your password?

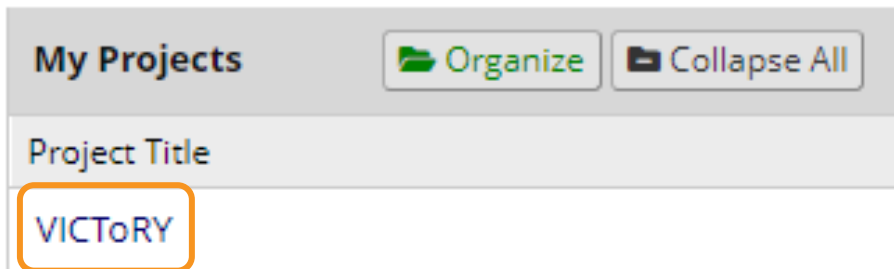
My Projects



- + Select **My Projects**
- + Then select **VICToRY**

Welcome to REDCap!

REDCap is a secure web platform for building and managing surveys. REDCap's streamlined process for rapidly creating offers a vast array of tools that can be tailored to virtual



Laboratory Units

After randomization of the first patient, you will need to enter the lab units for your site.

- + Select 'Arm 2: Laboratory Units'
- + Select your site number

Total records: 23 / In group: 6

Choose an existing Patient ID

Arm 1: Patient ▼

Arm 1: Patient

Arm 2: Laboratory Units

-- select record -- ▼

Laboratory Units

- + If the lab units used at your site are not listed please notify the PL.
- + If you lab changes the lab units used in their reports during the study please notify the PL.

Patient ID	1001
T-bilirubin	<input type="radio"/> mg/dL <input type="radio"/> μ mol/L reset
Serum Creatinine	<input type="radio"/> mg/dL <input type="radio"/> μ mol/L reset
Glucose	<input type="radio"/> mg/dL <input type="radio"/> mmol/L reset
Which is collected at your site?	<input type="radio"/> Urea <input type="radio"/> BUN reset
Urea	<input type="radio"/> mg/dL <input type="radio"/> mmol/L reset
Lactate Dehydrogenase (LDH)	<input type="radio"/> U/L <input type="radio"/> μ kat/L reset
Hemoglobin	<input type="radio"/> g/dL <input type="radio"/> mmol/L <input type="radio"/> g/L reset
Haptoglobin	<input type="radio"/> mg/dL <input type="radio"/> g/L reset
Serum HCO ₃	<input type="radio"/> mEq/L <input type="radio"/> mmol/L reset
Albumin	<input type="radio"/> g/dL <input type="radio"/> g/L reset

Patients Automatically Populated

Patients will automatically be added to REDCap **AFTER** they have been randomized in the CRS.

- + Click on **View / Edit Records**
- + **Arm 1: Patient** is the default
- + Select a patient from the dropdown list to open the data entry grid

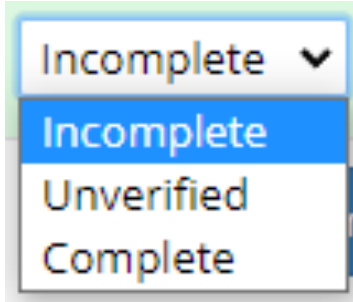
The screenshot displays a portion of the REDCap interface. At the top, a yellow banner indicates 'Total records: 23 / In group: 6'. Below this, a grey bar contains the text 'Choose an existing Patient ID' and a dropdown menu currently set to 'Arm 1: Patient'. A second dropdown menu is open, showing a list of patient IDs: '-- select record --', '-- select record --', 1001V001, 1001V002, 1001V003, 1001V004, and 1001V005. Below the patient selection area, another yellow banner reads 'Data Search'. At the bottom, a grey bar contains the text 'Choose a field to search' and a dropdown menu set to 'All fields'.

Event Grid

Data Collection Instrument	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Day 8	Adhock	Outcomes	6 Month Follow-Up
Baseline	<input type="radio"/>										
Trauma	<input type="radio"/>										
SOFA	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>			
Microbiology									<input type="radio"/>		
Ventilation/RRT										<input type="radio"/>	
Vasopressors And Inotropes	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>		<input type="radio"/>	
Vitamin C Dosing	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>				
Laboratory	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>			
Fluid Balance	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>			
Study Blood Work	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>			
Burn Related Procedures									<input type="radio"/>		
Protocol Violation	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>			
Events Of Interest										<input type="radio"/>	
Hospital Overview										<input type="radio"/>	
Deferred Consent										<input type="radio"/>	
COVID-19										<input type="radio"/>	
Survival Assessment											<input type="radio"/>
SF-36											<input type="radio"/>
ADL											<input type="radio"/>
IADL											<input type="radio"/>
Serious Adverse Event Report									<input type="radio"/>		
Site Investigator Confirmation											<input type="radio"/>






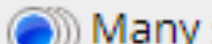
+ Click on a dot to open the corresponding form.

Form Status



- + When saving a form use the Form Status to control the colour of the dots.
- + The status does not influence queries.
- + Can be used as a visual reference of the status of the data entry for that form.

Legend for status icons:

- | | |
|--|--|
|  Incomplete |  Incomplete (no data saved) ? |
|  Unverified |  Many statuses (all same) |
|  Complete |  Many statuses (mixed) |

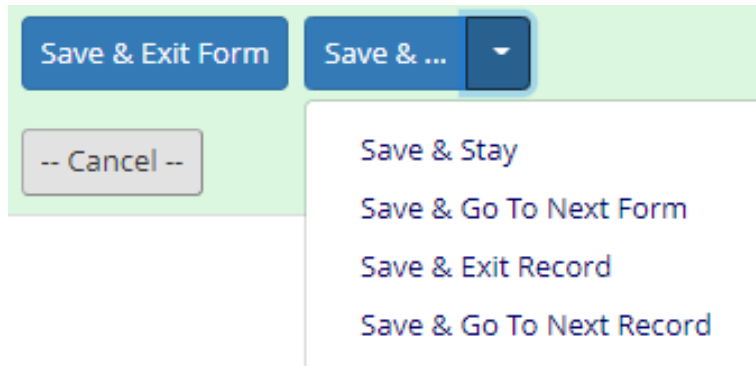
Repeating Forms

- + The following forms are repeating forms and are located on the Adhock Event.
 - + Microbiology
 - + Burn Related Procedures
 - + Serious Adverse Events
- + This function allows you to add as many instances of the form as you may need.

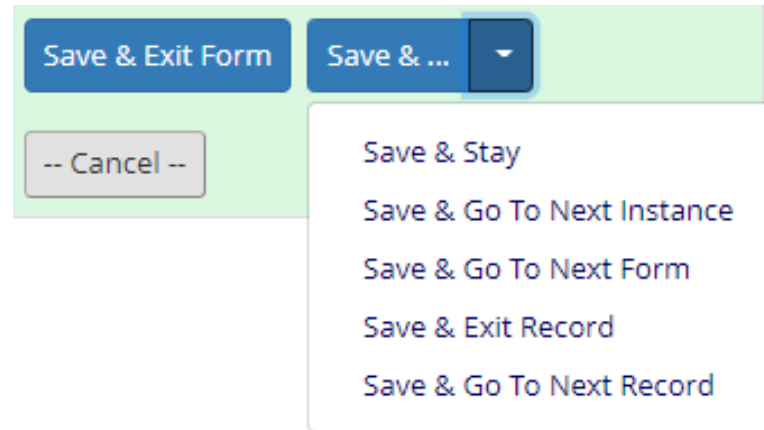


Saving Forms

- + Before leaving any form you must **Save** the data you have entered, or it will be lost.
- + Options when saving a regular form.



- + Options when saving a repeating form.



Worksheets and REDCap™

eCRF worksheets are provided to assist you in collecting required data. They are optional and can be edited to better suit your requirements.

The **Medical Chart** is the source document.

Exception: 6 Month Follow-up Questionnaires worksheets are the source documents – **need to keep**

Instructions for the eCRF worksheets must be reviewed.

Data Entry is done in REDCAP™ and forms may look different than the worksheets provided.

Data Collection Forms

- + For a complete overview of the data collection required please refer to the SPM and eCRF worksheets.

Baseline

- + Complete the Baseline data.
 - + Patient demographics
 - + Apache II Score
 - + Comorbidities
 - + Admission dates/times
 - + Co-enrollment
 - + Burn Injury information
 - + Clinical Frailty Scale

Demographics	
Age	<input type="text"/> years
Sex	<input type="radio"/> Female <input type="radio"/> Male reset
Ethnicity	<input type="radio"/> Hispanic or Latino <input type="radio"/> Not Hispanic or Latino reset
Race	<input type="radio"/> First Nations (i.e. Native American/Canadian, Inuit, etc.) <input type="radio"/> Asian <input type="radio"/> Black or African American <input type="radio"/> Pacific Islander or Native Hawaiian <input type="radio"/> White or Caucasian <input type="radio"/> Other (specify) reset
Apache II Score	<input type="text"/> Range: 5 to 60
Is the Apache II Score based on complete or partial data?	<input type="radio"/> Complete <input type="radio"/> Partial reset
Comorbidities	
Comorbidities?	<input type="radio"/> Yes <input type="radio"/> No reset
Tobacco use	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Not Available reset

Clinical Frailty Scale

- + Assessed by research staff based on interaction with family, treating teams, and review of the medical chart. Consider the time frame of the 2 weeks preceding the current acute episode.

	1. VERY FIT: People who are robust, active, energetic and motivated. These people commonly exercise regularly. They are among the fittest for their age.
	2. WELL: People who have no active disease symptoms but are less fit than category 1. Often, they exercise or are very active occasionally , e.g. seasonally.
	3. MANAGING WELL: People whose medical problems are well controlled , but are not regularly active beyond routine walking.
	4. VULNERABLE: While not dependent on others for daily help, often symptoms limit activities . A common complaint is being "slowed up", and/or being tired during the day.
	5. MILDLY FRAIL: These people often have more evident slowing , and need help in high order IADLs (finances, transportation, heavy housework, medications). Typically, mild frailty progressively impairs shopping and walking outside alone, meal preparation and housework.
	6. MODERATELY FRAIL: People who need help with all outside activities and with keeping house . Inside, they often have problems with stairs and need help with bathing and might need minimal assistance (cuing, standby) with dressing.
	7. SEVERELY FRAIL: Completely dependent for personal care , from whatever cause (physical or cognitive). Even so, they seem stable and not at high risk of dying (within ~ 6 months).
	8. VERY SEVERELY FRAIL: Completely dependent, approaching the end of life. Typically, they could not recover even from a minor illness.

Project Bookmarks

- + Resources such as the APACHE II Calculator can be found under **Project Bookmarks** in the left-hand menu.

The screenshot shows a software interface with a left-hand menu. The menu is organized into sections: 'Data Collection' (with a minus icon), 'Applications' (with a minus icon), and 'Help & Information' (with a minus icon). Under 'Data Collection', there are links for 'Record Status Dashboard' and 'View / Edit Records'. Below this is a section for 'Patient ID 1008V007' with a link to 'Select other record'. Under 'Applications', there is a link for 'Field Comment Log'. Under 'Project Bookmarks' (which is highlighted with an orange box), there are three links: 'APACHE II Calculator', 'MAP Calculator', and 'PaO2/FiO2 Calculator'. Under 'Help & Information', there is a link for 'Help & FAQ'.

Trauma

- + Indicate if the patient had a Traumatic Brain Injury.
- + If yes, select the mechanism of injury and enter the Glasgow Coma Score.

Traumatic Brain Injury	
Does the patient have a Traumatic Brain Injury?	<input checked="" type="radio"/> Yes <input type="radio"/> No <small>reset</small>
Mechanism of Traumatic Brain Injury (TBI) (check ALL that apply):	<input type="checkbox"/> Acceleration/Deceleration <input type="checkbox"/> Direct impact: blow to the head <input type="checkbox"/> Direct impact: head against object <input type="checkbox"/> Ground level fall <input type="checkbox"/> Fall from height > 1 meter <input type="checkbox"/> Crush <input type="checkbox"/> Blast <input type="checkbox"/> Other (specify)
Glasgow Come Scale (GCS)	
Eye Opening	<input type="radio"/> 1 - None <input type="radio"/> 2 - To Pain <input type="radio"/> 3 - To Speech <input type="radio"/> 4 - Spontaneous <small>reset</small>
Verbal Response	<input type="radio"/> 1 - None <input type="radio"/> 2 - Incomprehensible Words <input type="radio"/> 3 - Inappropriate Words <input type="radio"/> 4 - Confused <input type="radio"/> 5 - Oriented <small>reset</small>
Best Motor Response	<input type="radio"/> 1 - None <input type="radio"/> 2 - Extension <input type="radio"/> 3 - Abnormal flexion <input type="radio"/> 4 - Withdraws from pain <input type="radio"/> 5 - Localizes to pain <input type="radio"/> 6 - Obeys commands <small>reset</small>

Trauma

- + Indicate if the patient sustained trauma other than the burn injury.
- + If yes, select the site of injury and required treatments.

Other Trauma	
Did the patient sustain trauma other than the burn injury?	<input checked="" type="radio"/> Yes <input type="radio"/> No <small>reset</small>
Site of other injuries (check ALL that apply):	<input type="checkbox"/> Spine (associated neurological deficit) <input type="checkbox"/> Spine (not associated neurological deficit) <input type="checkbox"/> Extremities (bones, vessels, nerves, important soft tissue) <input type="checkbox"/> Chest <input type="checkbox"/> Abdomen <input type="checkbox"/> Pelvis (pelvic bones, rectum, vagina, bladder, urethra) <input type="checkbox"/> Face and skull
Was interventional radiology or an endovascular procedure used to treat or prevent bleeding (e.g. spleen, liver, endovascular repair of aorta)?	<input type="radio"/> Yes <input type="radio"/> No <small>reset</small>
Were any of the following Trauma Operative Interventions/Treatments performed?	<input type="checkbox"/> Thoracotomy <input type="checkbox"/> Craniotomy/craniectomy <input type="checkbox"/> Laparotomy <input type="checkbox"/> External or internal fixation of pelvic, femoral, tibial, or spinal fracture <input type="checkbox"/> None of the above

SOFA

- + The SOFA score will be collected daily.
- + Elements of the SOFA score not collected elsewhere will be collected here.

Lowest PaO₂/FiO₂ (PF ratio)	<input type="radio"/> ≥ 400 mmHg or N/A <input type="radio"/> 300 - 399 mmHg <input type="radio"/> 200 - 299 mmHg <input type="radio"/> 100 - 199 mmHg with respiratory support <input type="radio"/> < 100 mmHg with respiratory support	reset
Lowest Platelets	<input type="radio"/> ≥ 150 x10 ⁹ /L (10 ³ /μL) or N/A <input type="radio"/> 100 - 149 x10 ⁹ /L (10 ³ /μL) <input type="radio"/> 50 - 99 x10 ⁹ /L (10 ³ /μL) <input type="radio"/> 20 - 49 x10 ⁹ /L (10 ³ /μL) <input type="radio"/> < 20 x10 ⁹ /L (10 ³ /μL)	reset
Mean Arterial Pressure (MAP)	<input type="radio"/> < 70 mmHg <input type="radio"/> ≥ 70 mmHg	reset

Microbiology

- + The Microbiology form is located on the Adhock event.
- + Record Gram negative bacteremia that occurred >72 hours after ACU admission until hospital discharge, death, or 3 months after ACU admission, whichever comes first.
- + ONLY report cultures that meet **ALL** of the following criteria:
 1. Venous or arterial blood culture
 2. Positive for Gram negative bacteria
 3. >72 hours from Admission
 4. New infection (do not record subsequent positive cultures of an organism that has already been reported)

Ventilation

- + Indicate if the patient ever received invasive mechanical ventilation.
- + Up to 5 ventilation events can be recorded.

Ventilation Event 1	
Start Date	<input type="text"/> <small>31</small> Today Y-M-D YYYY-MM-DD
Start Time	<input type="text"/> Now H:M HH:MM 24hr
Start Time not available	<input type="checkbox"/> Not available
Stop Date & Time:	<input type="radio"/> Same as death date & time <input type="radio"/> Still vented 3 months post ACU admission <small>reset</small>
Stop Date	<input type="text"/> <small>31</small> Today Y-M-D YYYY-MM-DD
Stop Time	<input type="text"/> Now H:M HH:MM 24hr
Was mechanical ventilation re-instituted \geq 48 hours from the last mechanical ventilation stop date/time?	<input type="radio"/> Yes <input type="radio"/> No <small>reset</small>

Note: Do **not** record episodes of temporary ventilation (defined as < 48 hrs) unless it's the first episode.

Renal Replacement Therapy

- + Indicate if the patient received renal replacement therapy (dialysis) during their hospital stay. Answer whether RRT was started due to acute renal failure. If yes, enter the start and stop dates.

Renal Replacement Therapy (Dialysis)	
Did the patient receive renal replacement therapy (dialysis) during this ACU stay?	<input checked="" type="radio"/> Yes <input type="radio"/> No reset
The first time renal replacement therapy (dialysis) was started, was it due to acute renal failure?	<input checked="" type="radio"/> Yes <input type="radio"/> No reset
Start Date	<input type="text"/> YYYY-MM-DD <input type="button" value="Today"/> Y-M-D
Stop Date	<input type="radio"/> Same as death date & time <input type="radio"/> At 3 months, still on renal replacement therapy (dialysis) in hospital <input type="radio"/> Continued past hospital discharge <input type="radio"/> Actual stop date reset

Vasopressors and Inotropes

- + Daily indicate if a continuous infusion of vasopressors and/or inotropes were given.
- + Record the rate in $\mu\text{g}/\text{kg}/\text{min}$ (units/min for vasopressin)

Did the patient receive a continuous infusion of vasopressors or inotropes today?	<input checked="" type="radio"/> Yes <input type="radio"/> No	reset
Vasopressors		
Vasopressor or Inotrope Type	<input type="checkbox"/> Dopamine $>5\mu\text{g}/\text{kg}/\text{min}$ <input type="checkbox"/> Dobutamine <input checked="" type="checkbox"/> Norepinephrine <input type="checkbox"/> Epinephrine <input type="checkbox"/> Phenylephrine $>50\mu\text{g}/\text{min}$ <input type="checkbox"/> Vasopressin <input type="checkbox"/> Milrinone <input type="checkbox"/> Levosimendan	
Highest hourly rate of norepinephrine	<input type="text"/>	$\mu\text{g}/\text{kg}/\text{min}$

Vasopressors and Inotropes

- + On Outcomes record the start and stop date/time for all vasopressors and/or inotropes that were given until hospital discharge, death, or 3 months after ACU admission, whichever comes first.
- + Up to 5 events can be recorded for each vasopressor.
- + Considered a new event if stopped for ≥ 24 hours.





Did the patient receive a continuous infusion of vasopressors or inotropes during this ICU stay?	<input checked="" type="radio"/> Yes <input type="radio"/> No	reset
Vasopressors		
Vasopressor or inotrope Type	<input type="checkbox"/> Dopamine >5 μ g/kg/min <input type="checkbox"/> Dobutamine <input checked="" type="checkbox"/> Norepinephrine <input type="checkbox"/> Epinephrine <input type="checkbox"/> Phenylephrine >50 μ g/min <input type="checkbox"/> Vasopressin <input type="checkbox"/> Milrinone <input type="checkbox"/> Levosimendan	
Norepinephrine Event 1		
Start Date of norepinephrine	<input type="text"/> Today Y-M-D YYYY-MM-DD	
Start Time of norepinephrine	<input type="text"/> Now H:M HH:MM 24hr	
Stop date of norepinephrine	<input type="radio"/> Same as death date & time <input type="radio"/> Still on vasopressor/inotrope 3 months post ACU admission	reset
Actual Stop Date	<input type="text"/> Today Y-M-D YYYY-MM-DD	
Actual Stop Time	<input type="text"/> Now H:M HH:MM 24hr	
Was norepinephrine re-started ≥ 24 hours from the last norepinephrine stop date/time?	<input type="radio"/> Yes <input type="radio"/> No	reset

Continuous Infusion vs Bolus

- + We want you to record continuous infusions only, do not record bolus doses.
- + If it runs for more than 1 hr then continuous.
- + If < 1 hr then look at the intention of the order.
 - + If it's an order for x mL and then done it's likely a bolus.
 - + If it's an order to titrate dose to achieve a target MAP and another order is required to stop it, then likely continuous.

Vitamin C Dosing

- + Indicate how many times study intervention was given. Choices are 0-6.
- + If no intervention was given, select 0 and explain why. Reasons can include:
 - + “study intervention not started yet”
 - + “16 doses completed”

How many times was the study intervention given today?	  0 ▾
Please explain why study intervention was not given today.	  <input type="text"/>

Vitamin C Dosing

- + For each dose given, indicate if the dose was interrupted. There is space to record up to 3 interruptions.
- + Enter the start and stop times.

How many times was the study intervention given today?	<input type="text" value="4"/>	<input type="button" value="reset"/>
Dose 1		
Was the dose interrupted?	<input checked="" type="radio"/> Yes <input type="radio"/> No	<input type="button" value="reset"/>
How many times was the dose interrupted?	<input type="text" value="1"/>	
Initial Start Time	<input type="text"/> HH:MM 24hr	<input type="button" value="Now"/> H:M
First Stop Time	<input type="text"/> HH:MM 24hr	<input type="button" value="Now"/> H:M
Second Start Time	<input type="text"/> HH:MM 24hr	<input type="button" value="Now"/> H:M
Final Stop Time	<input type="text"/> HH:MM 24hr	<input type="button" value="Now"/> H:M
Was the full volume infused?	<input checked="" type="radio"/> Yes <input type="radio"/> No	<input type="button" value="reset"/>
Dose 2		

Vitamin C Dosing

- + If the full volume wasn't infused enter the total volume provided and the partial volume infused, along with the reason the full volume wasn't given. This is your PV.

Dose 1	
Was the dose interrupted?	<input type="radio"/> Yes <input checked="" type="radio"/> No reset
Initial Start Time	<input type="text"/> <input type="button" value="Now"/> H:M HH:MM 24hr
Final Stop Time	<input type="text"/> <input type="button" value="Now"/> H:M HH:MM 24hr
Was the full volume infused?	<input type="radio"/> Yes <input checked="" type="radio"/> No reset
Total volume provided	<input type="text"/> mL
Partial volume infused	<input type="text"/> mL
Please explain why the full dose of investigational product was not received:	<input type="text"/> Expand

Note: this is the record of the protocol violation, no need to complete the PV form as well.

Laboratory

Highest Serum Creatinine	<input type="text"/> <small>μmol/L OR mg/dL</small>
Serum Creatinine N/A	<input type="checkbox"/> Not Available
Highest T-bilirubin	<input type="text"/> <small>μmol/L OR mg/dL</small>
T-bilirubin N/A	<input type="checkbox"/> Not Available
Highest Urea	<input type="text"/> <small>mmol/L OR mg/dL</small>
Urea N/A	<input type="checkbox"/> Not Available
Glucose closest to 08:00 am	<input type="text"/> <small>mmol/L OR mg/dL</small>
Glucose N/A	<input type="checkbox"/> Not Available
Did the patient have a hypoglycemic event? (< 3.8 mmol/L or < 68.4 mg/dL)	<input type="radio"/> Yes <input type="radio"/> No
Highest Lactate Dehydrogenase (LDH)	<input type="text"/> <small>μkat/L OR U/L</small>
Lactate Dehydrogenase N/A	<input type="checkbox"/> Not Available
Lowest Arterial pH	<input type="text"/>
Arterial pH N/A	<input type="checkbox"/> Not Available
Lowest Serum HCO₃	<input type="text"/> <small>mmol/L OR mEq/L</small>
Serum HCO ₃ N/A	<input type="checkbox"/> Not Available

Highest Lactate Dehydrogenase (LDH)	<input type="text"/> <small>μkat/L OR U/L</small>
Lactate Dehydrogenase N/A	<input type="checkbox"/> Not Available
Lowest Arterial pH	<input type="text"/>
Arterial pH N/A	<input type="checkbox"/> Not Available
Lowest Serum HCO₃	<input type="text"/> <small>mmol/L OR mEq/L</small>
Serum HCO ₃ N/A	<input type="checkbox"/> Not Available
Lowest Albumin	<input type="text"/> <small>g/L OR g/dL</small>
Albumin N/A	<input type="checkbox"/> Not Available
Clinical suspicion of hemolysis?	<input type="radio"/> Yes <input type="radio"/> No reset
Lowest Hemoglobin	<input type="text"/> <small>mmol/L OR g/dL OR g/L</small>
Hemoglobin N/A	<input type="checkbox"/> Not Available
Highest Haptoglobin	<input type="text"/> <small>g/L OR mg/L</small>
Haptoglobin N/A	<input type="checkbox"/> Not Available
Highest Reticulocyte count	<input type="text"/> <small>%</small>
Reticulocyte count N/A	<input type="checkbox"/> Not Available



Fluid Balance

- + If blood products (pRBCs and plasma) or albumin are given, please record the volume.
- + Total volume IN will include any blood products and/or albumin received, and Total volume OUT will include urine output.

Were blood products given?	<input type="radio"/> Yes <input type="radio"/> No	reset
Albumin	<input type="radio"/> Yes <input type="radio"/> No	reset
Urine output	<input type="text"/> mL	
Fluid Balance		
Total volume of fluids IN	<input type="text"/> mL	
Total volume of fluids OUT	<input type="text"/> mL	
Fluid Balance	<input type="text"/> View equation	

Study Blood Work

- + If study blood work is done, please record if any non-study vitamin C was given.
- + Total daily dose is the amount given from 00:00-23:59.

Was study blood drawn?	<input checked="" type="radio"/> Yes <input type="radio"/> No, required <input type="radio"/> No, not required	reset
Time study blood was drawn	<input type="text"/> <input type="button" value="Now"/> H:M HH:MM 24hr	
EDTA Tube	<input type="radio"/> Yes <input type="radio"/> No	reset
Serum Tube	<input type="radio"/> Yes <input type="radio"/> No	reset
Non-Study Vitamin C		
Did the patient receive non-study Vitamin C today?	<input checked="" type="radio"/> Yes <input type="radio"/> No	reset
Total Daily Dose	<input type="text"/> mg/day	
Route	<input type="radio"/> IV <input type="radio"/> PO	reset

Burn Related Procedures

- + Record all burn related procedures from Hospital admission until Hospital discharge or death.

Date	<input type="text"/> <small>Today</small> Y-M-D
Was the procedure planned or unplanned?	<input type="radio"/> Planned <input type="radio"/> Unplanned <small>reset</small>
Where was the procedure done?	<input type="radio"/> OR <input type="radio"/> Burn unit/ICU <small>reset</small>
Type of procedure (check all that apply)	<input type="checkbox"/> Excision/Debridement (tangential, fascial, dermabrasion, hydrosurgical, enzymatic) <input type="checkbox"/> Temporary covering (xenograft, allograft, and artificial skin, dermal matrices) <input type="checkbox"/> Autograft <input type="checkbox"/> Autograft - Other (Autologous Regenerative Epidermal Suspension (i.e. RECELL®) and Cultured epithelial autograft (CEA)) <input type="checkbox"/> Excision and primary closure/composite tissue transfer <input type="checkbox"/> Escharotomy <input type="checkbox"/> Fasciotomy <input type="checkbox"/> Amputation <input type="checkbox"/> Other specify

Protocol Violations

- + Protocol violations/deviations for Vitamin C Dosing and Study Blood Work will be recorded on their respective forms.
- + Other protocol violations will be recorded on the Protocol Violation form such as:
 - + Dispensing/dosing error
 - + Accidental unblinding
 - + Open label IV Vitamin C given (> 200 mg/day)
 - + Oral Vitamin C given (> 1500 mg/day)
 - + Missed IP dose(s)
 - + Other (specify)

Events of Interest



- + For a new diagnosis of oxalate kidney stones, severe hemolysis, severe acid-base/electrolyte imbalances or refractory hypoglycemia record the date of diagnosis, if IP was stopped, and the SI/Sub-I rational for continuing or stopping IP.

Are there any Events of Interest to report?	<input checked="" type="radio"/> Yes <input type="radio"/> No	reset
New diagnosis of oxalate kidney stones?	<input checked="" type="radio"/> Yes <input type="radio"/> No	reset
Date of new diagnosis of oxalate kidney stones	<input type="text" value=""/> YYYY-MM-DD Today Y-M-D	
Was IP stopped?	<input type="radio"/> Yes <input type="radio"/> No	reset
Physicians rational as to why IP continued or stopped:	<input type="text"/>	Expand
Severe hemolysis?	<input type="radio"/> Yes <input type="radio"/> No	reset
Severe acid-base/ electrolyte imbalances?	<input type="radio"/> Yes <input type="radio"/> No	reset
Refractory hypoglycemia?	<input type="radio"/> Yes <input type="radio"/> No	reset

Hospital Overview

The following data are recorded on the Hospital Overview form:

- + ACU discharge information
- + Hospital discharge information, including the location discharged to
- + If deceased – death date, time, & cause of death

Did the patient die during this ACU stay?	<input type="radio"/> Yes
	<input checked="" type="radio"/> No, patient discharged
	<input type="radio"/> No, patient still in ACU at 3 months
	reset
ACU Discharge Date	<input type="text"/>  Today Y-M-D YYYY-MM-DD
ACU Discharge Time	<input type="text"/>  Now H:M HH:MM 24hr

Hospital Overview

ACU Stay #1	
Did the patient die during this ACU stay?	<input type="radio"/> Yes <input checked="" type="radio"/> No, patient discharged <input type="radio"/> No, patient still in ACU at 3 months
ACU Discharge Date	<input type="text" value="2022-05-09"/> <input type="button" value="Today"/> Y-M-D YYYY-MM-DD
ACU Discharge Time	<input type="text" value="09:40"/> <input type="button" value="Now"/> H:M HH:MM 24hr
Was the patient re-admitted to the ACU?	<input type="radio"/> Yes <input checked="" type="radio"/> No
Hospital Stay	
Did the patient die in hospital?	<input type="radio"/> Yes <input checked="" type="radio"/> No, Patient Discharged <input type="radio"/> No, Patient Still In Hospital At 3 months
Hospital Discharge Date	<input type="text" value="2022-05-25"/> <input type="button" value="Today"/> Y-M-D YYYY-MM-DD
Hospital Discharge Time	<input type="text" value="12:11"/> <input type="button" value="Now"/> H:M HH:MM 24hr
Discharged to	<input type="text" value="Long term care facility"/> ▼

- + Record outcome of ACU Stay #1 (death, discharge, consent withdrawal)
- + If applicable, record additional ACU Stays, Hospital Discharge, or death.

COVID-19

- + During the patient's hospital stay, record their COVID-19 status.

COVID-19 Status	<input checked="" type="checkbox"/>
Form Status	
Complete?	<input type="checkbox"/>
Lock this record for this form?	

Negative
 Positive
 Presumed Positive
 Not Tested/Unknown

- + If the patient tests positive, or negative, or is presumed positive record the date.

COVID-19 Status	<input type="checkbox"/>	Presumed Positive	▼
Date of positive/negative test or date patient presumed positive for COVID-19	<input type="checkbox"/>	<input type="text"/>	<input type="button" value="Today"/> Y-M-D

YYYY-MM-DD

- + If the patient initially tests negative, but then tests positive, record the positive test.

6 Month Assessments

MARK YOUR CALENDARS:

6 months after ACU admission +/- 2 weeks, survival status and follow-up assessments need to be completed.

We have programmed REDCap to send you two emails:

- + 5.5 months after ACU admission
- + 7 months after ACU admission

Please obtain survival status even if it is outside of the data collection window

Event Grid – After Outcomes

Data Collection Instrument	Day 1	Day 8	Adhock	Outcomes	6 Month Follow-Up
Baseline	<input type="radio"/>				
Trauma	<input type="radio"/>				
SOFA	<input type="radio"/>	<input type="radio"/>			
Microbiology			<input type="radio"/>		
Ventilation/RRT				<input type="radio"/>	
Vasopressors And Inotropes	<input type="radio"/>	<input type="radio"/>		<input type="radio"/>	
Vitamin C Dosing	<input type="radio"/>				
Laboratory	<input type="radio"/>	<input type="radio"/>			
Fluid Balance	<input type="radio"/>	<input type="radio"/>			
Study Blood Work	<input type="radio"/>	<input type="radio"/>			
Burn Related Procedures			<input type="radio"/>		
Protocol Violation	<input type="radio"/>	<input type="radio"/>			
Events Of Interest				<input type="radio"/>	
Hospital Overview				<input type="radio"/>	
Deferred Consent				<input type="radio"/>	
COVID-19				<input type="radio"/>	
Survival Assessment					<input type="radio"/>
SF-36					<input type="radio"/>
ADL					<input type="radio"/>
IADL					<input type="radio"/>
Serious Adverse Event Report			<input type="radio"/>		
Site Investigator Confirmation					<input type="radio"/>

- + The 6 Month Follow-up forms, including Survival Assessment are the last column on the VICToRY grid.

6 Month Survival

+ 6 Month Mortality is a Secondary Outcome of this Study

Was the survival status obtained? Yes No reset

Date survival status obtained 31 Today Y-M-D
YYYY-MM-DD

Source of Information Patient Alternative contact person(s) (Specify relationship) Family Physician Medical Records Obituaries Internet Other (specify) reset

Specify the alternative contact's relationship with the patient

Survival Status Alive Deceased reset

+ If the Alternative contact person is used remember to enter their relationship to the patient. **Do not enter proper names as they could identify the patient.**

6 Month Survival (continued)

- + It is vital that **EVERY** resource possible is used to obtain the 6 Month Survival Status of each patient.
- + If survival status is not obtained, please complete the form to confirm all attempts were made to obtain the information.

Was the survival status obtained? Yes No reset

Confirm which of the following were completed

- 3 attempts to contact the patient were made (mandatory)
- 3 attempts to contact the alternative contact person(s) were made (mandatory if applicable)
- Family doctor contacted (mandatory if available)
- No medical records on the patient available at month 6 (mandatory)
- Internet searches for the patient name did not reveal survival status (mandatory)

Last date known to be alive 31 Today Y-M-D
YYYY-MM-DD

6 Month Follow-up Assessments

The following questionnaires are completed 6 months after ACU admission +/- 2 weeks:

- + SF-36
- + ADL (Activities of Daily Living)
- + IADL (Instrumental Activities of Daily Living)
- + Questionnaires may be administered via a telephone call or in person.
- + Keep the completed questionnaires with your study documents.
- + Questionnaires may be completed over several calls or visits if necessary.
- + Of the three questionnaires the SF-36 is the most important.

NOTE: Late data is better than missing data.

Please make every attempt to complete the questionnaires, even if outside of the time parameters.

Guide to 6 month Follow-up forms

The following table provides a variety of patient outcome scenarios and a guide to which 6 month follow-up forms need to be completed in REDCap.

Scenario	Survival Status	SF-36	ADL	IADL
Patient died in ACU/Hospital (death date/time recorded on Hospital Overview form.	X	X	X	X
Discovered patient died AFTER hospital discharge, but BEFORE trying to contact the patient/alternate.	✓	X	X	X
Learned that the patient died from the alternate.	✓	X	X	X
Tried but never reached either the patient or alternate	✓	X	X	X
Reached the patient/alternate and only completed one questionnaire	✓	✓	✓	✓
Reached the patient/alternate and completed ALL questionnaires	✓	✓	✓	✓

SAEs

- + Worksheets are provided to assist with data collection if you wish to use them.
- + **SAEs must be entered in REDCap.**

Serious Adverse Event

Patient ID: _____

Name of Responsible Investigator:	
Institution:	
Report completed by:	
Date of Report:	Type of Report: <input type="checkbox"/> Initial <input type="checkbox"/> Follow-up # _____ <input type="checkbox"/> Final

Patient Information



Patient RZ #:	Age:	Sex: <input type="checkbox"/> Male <input type="checkbox"/> Female	Date patient started study intervention:
---------------	------	--	--

Event Information

Event Onset Date/time:	Name of Event:
Date Became Aware of Event:	
Description of Event:	

SAEs

- + A summary of the SAEs entered is located at the bottom of the grid.
- + Information displayed: Event Onset Date, Name of Event, Report type.
- + Each event should be entered as a single SAE and the form updated as new information becomes available.

Serious Adverse Event Report		
Adhock (Arm 1: Patient)		
(2)		
1		2022-04-27, Stroke, Final
2		2022-05-01, GI bleed, Follow-up
+ Add new		

Questions

