

VIT  
**VICTORY**

# Randomizing a Patient

# Central Randomization System (CRS)

<https://ceru.hpcvl.queensu.ca/EDC2/CRS/index.php>



## Central Randomization System

User name:

Password:

[Forgot Password?](#)

# CRS Access

- + Complete the Excel spreadsheet with the name, email address, and study role of each team member who needs CRS and/or REDCap access.
- + Each study team member needs their own CRS login. **Do not share.**
- + Send the Excel sheet to the Project Lead at CERU (via email preferred): [maureen.dansereau@queensu.ca](mailto:maureen.dansereau@queensu.ca)

SITE (INSTITUTION) NAME:			SITE NUMBER:		
FIRST NAME	LAST NAME	EMAIL ADDRESS	ROLE - Qualified Investigator, sub-Investigator, Research Coordinator, Dietitian, Data Entry, other	CRS ACCESS	REDCap ACCESS
<i>Example below:</i>					
Taylor	Beauchamp	<a href="mailto:taylor.beauchamp@institution.gov">taylor.beauchamp@institution.gov</a>	Research Coordinator	X	X

# CRS Login

- + If you already have access to the CRS for VICToRY your username and password will remain the same.
- + If you do not have access, you will receive an email with your username and temporary password. Change your password the first time you login.
- + There is now Multi-Factor Authentication (MFA) required every 30 days and the code will be sent to your email.
- + Access the CRS (Central Randomization System) at:  
<https://ceru.hpcvl.queensu.ca/EDC2/CRS/index.php>
- + Login to enter screening data and randomize patients.

# Multi-Factor Authentication (MFA)

- + Multi-Factor Authentication (MFA) has been added to the CRS.
- + The code will expire every 30 days.

**Your Multi-Factor Authentication Code (MFA) has expired. A new MFA code has been sent to your email address on file. Please enter the new code provided below.**

MFA Code:

Submit

# MFA (continued)

- + A code will be sent to your email.
- + For new accounts you will need to create your password and will then login and be asked for your MFA. During this process you will receive 2 MFA code emails. Please use the second one.

Your Multi-Factor Authentication Code (MFA) is: KQcq2Xmh

If you have any other questions please contact [IT support](#).

**DO NOT** reply to this email address.

# MFA (continued)

- + Once you have entered your new MFA code you will receive the following message and be redirected to the login screen.

**You have successfully updated your Multi  
Factor Authentication (MFA) code!**

You will now be redirected to the login screen...

# CRS Screening: who to enter

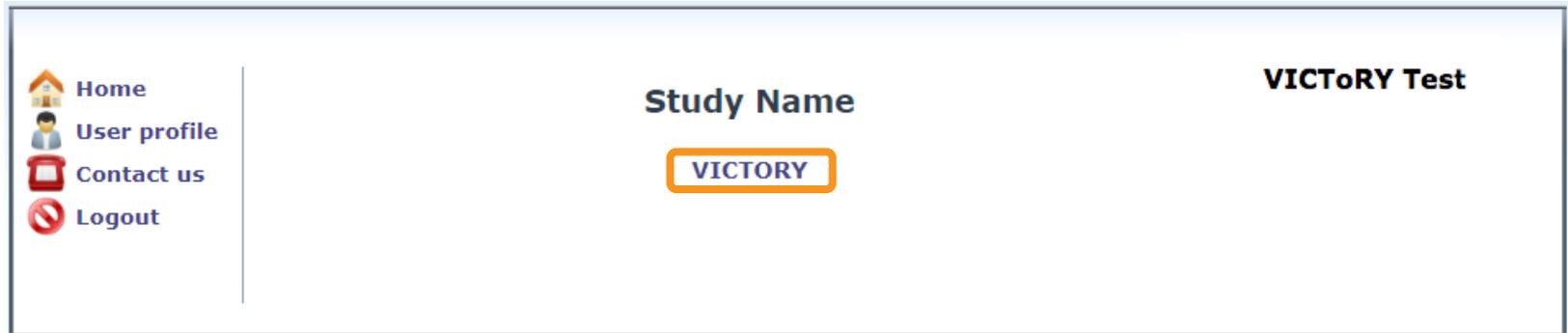
Enter all screened patients, who meet the inclusion criteria into the CRS:

- + Even if they meet an exclusion criteria
- + Even if you did not get consent

Inclusion Criteria Present	Exclusion Criteria Present	Informed Consent Obtained	Enter into CRS	Comments
✓	X	✓	✓	Randomized
✓	X	X	✓	Eligible but Not Randomized
✓	✓	Exclusion criteria met – Do not approach for consent	✓	Not Eligible
X	X	Inclusion criteria not met – Do not approach for consent	X	<b>Do NOT enter into CRS</b>

# CRS Home Screen

- + After you Login, you will see a list of studies you are participating in with CERU using the CRS.
- + Click on **VICToRY**



# CRS: Adding a Patient

+ To enter data for a new patient, select **Add Patient**

The screenshot displays the 'Site Status Page' for the VICToRY Test. On the left is a navigation menu with options: Home, User profile, Contact us, Logout, and Add patient (highlighted with an orange border). The main content area features a search bar labeled 'Find #' with a 'Find' button and the instruction '(enter Patient #)'. Below the search bar is a table with three columns: Screening #, Enrollment #, and Status. The table lists several patient records, with the second row (1002T011, 1002V011, Randomized) highlighted in red. On the right side, the test details are shown: VICToRY Test, Study: VICTORY, Site #: 1002, and Role: User.

Screening #	Enrollment #	Status
1002T013	1002V012	Randomized (REEN No)
1002T011	1002V011	Randomized
1002T010	1002V010	Randomized (REEN Yes)
1002T009	1002V009	Randomized (REEN No)
1002T008	1002V008	Randomized (REEN No)

# CRS: Inclusion Criteria

- + When you click **'Add Patient'** you will be taken to the Inclusion Criteria form.
- + Complete all fields and click **'Save'**, you will then be taken to the next form.

<b>Screening Date:</b>	<input type="text"/> (YYYY-MM-DD)
<b>A subject will be eligible for inclusion in this study only if all of the following criteria apply:</b>	
<b>1. Adult (<math>\geq</math> 18 years of age) at the time of consent</b>	<input type="radio"/> Yes <input type="radio"/> No
<b>2. Deep 2nd and/or 3rd degree burns requiring skin grafting with a minimum of Total Body Surface Area (TBSA) burn <math>\geq</math> 20%</b>	<input type="radio"/> Yes <input type="radio"/> No

Save

# CRS: Exclusion Criteria

+ Complete the exclusion criteria form.

<b>A subject will not be eligible for this study if any of the following criteria apply:</b>	
<b>1. &gt; 24 hours from admission to ICU or burn unit to assessment.</b>	<input type="radio"/> Yes <input type="radio"/> No
<b>2. Patients admitted to burn unit &gt; 24 hours from injury or accident.</b>	<input type="radio"/> Yes <input type="radio"/> No
<b>3. Patients who are moribund (not expected to survive the next 72 hours).</b>	<input type="radio"/> Yes <input type="radio"/> No
<b>4. Pregnancy (pregnancy will be ruled out as part of standard of care) or lactating.</b>	<input type="radio"/> Yes <input type="radio"/> No
<b>5. Enrolment in another industry sponsored ICU intervention study (co-enrollment in the RE-ENERGIZE trial is allowed)</b>	<input type="radio"/> Yes <input type="radio"/> No
<b>6. Receiving high-dose IV vitamin C already (enteral or oral vitamin C is allowed).</b>	<input type="radio"/> Yes <input type="radio"/> No
<b>7. Known glucose-6-phosphate dehydrogenase (G6PD) deficiency.</b>	<input type="radio"/> Yes <input type="radio"/> No
<b>8. Recent history of kidney stones (within the last year).</b>	<input type="radio"/> Yes <input type="radio"/> No

# CRS: Pre-Randomization

- + When the patient is eligible, complete the Pre-Randomization form.
- + Indicate whether you used Standard, Deferred, or Professional consent (you should only use consent types approved by your ethics).

<b>Did you confirm eligibility of the subject with the site investigator, or sub-investigator?</b>	<input checked="" type="radio"/> Yes <input type="radio"/> No
<b>Please indicate the name of the physician who confirmed subject eligibility</b>	<input type="text" value="Smith"/>
<b>Type of consent:</b>	<div style="border: 1px solid #ccc; padding: 5px;"><input checked="" type="checkbox"/> Standard (patient, family, SDM, LAR) <input type="checkbox"/> Deferred <input type="checkbox"/> Professional (impartial third party)</div>

# CRS: Pre-Randomization

- + When using **Standard** consent if the patient/SDM was not approached for consent, select the **primary** reason you did not approach for consent.

<b>Type of consent:</b>	Standard (patient, family, SDM, LAR) ▾
<b>Was SDM/subject approached for consent?</b>	<input type="radio"/> Yes <input checked="" type="radio"/> No
<b>Please indicate why SDM/subject was not approached for consent</b>	<div style="border: 1px solid #ccc; padding: 5px;"><p>✓</p><p>Next of kin or SDM not available</p><p>Missed subject</p><p>Language barriers</p><p>Family dynamics</p><p>Recommendation of clinical team</p><p>CRS unavailable</p><p>Pharmacy unavailable</p><p>Other, please specify</p></div>

# CRS: Pre-Randomization

- + If you approached for **Standard** consent and consent is NOT obtained, indicate the **primary** reason consent was not obtained.

Type of consent:	Standard (patient, family, SDM, LAR) ▾
Was SDM/subject approached for consent?	<input checked="" type="radio"/> Yes <input type="radio"/> No
Was consent obtained from the SDM/subject?	<input type="radio"/> Yes <input checked="" type="radio"/> No
Choose the most important reason why consent was not obtained	

- ✓
  - Too overwhelmed
  - Not interested
  - Did not respond (timed out)
  - Other, please specify

# CRS: Pre-Randomization

- + When using **Deferred or Professional** consent and consent is NOT obtained, indicate the **primary** reason consent was not obtained.

<b>Type of consent:</b>	Deferred <span>▼</span>
<b>Was Deferred/Professional consent obtained?</b>	<input type="radio"/> Yes <input checked="" type="radio"/> No
<b>Choose the most important reason why consent was not obtained</b>	<div style="border: 1px solid #ccc; padding: 5px;"><input checked="" type="checkbox"/> Professional refused <input type="checkbox"/> Recommendation of clinical team <input type="checkbox"/> Timed out <input type="checkbox"/> CRS unavailable <input type="checkbox"/> Pharmacy unavailable <input type="checkbox"/> Other, please specify</div>

# CRS: Pre-Randomization

- + Enter dates in YYYY-MM-DD format or click in the date box to open the calendar.
- + Enter Times per 24-hour clock. If time is before 10:00, you must enter a leading zero.

Consent Date	<input type="text" value="2020-06-08"/> (YYYY-MM-DD)
Consent Time	<input type="text" value="09:15"/> (HH:MM 24hr)
Height	<input type="text" value="172"/> <input checked="" type="radio"/> cm <input type="radio"/> inches
How was height obtained?	<input type="text" value="Measured"/> ▾
Weight	<input type="text" value="70"/> <input checked="" type="radio"/> kg <input type="radio"/> lbs
How was weight obtained?	<input type="text" value="Measured"/> ▾

- ✓ Measured
- Estimated
- Unknown

- + Indicate if height and weight were ‘measured’ or ‘estimated’, if you don’t know how they were obtained select ‘unknown’.

# CRS: Randomization

- + After clicking 'Save' on the bottom of the Pre-Randomization form, you will receive a **Randomization Confirmation**.
- + Print the page.
- + File it with your study records.
- + **Contact your pharmacy.**

You have **successfully RANDOMIZED** this subject to the VICTORY trial

<b>Randomization #:</b>	1002V011
<b>Randomization Date:</b>	2020-06-08 11:26 EST
<b>Height:</b>	172.00 cm
<b>Weight:</b>	70.00 kg
<b>BMI:</b>	23.7

Print page for your records

**Contact your pharmacy to alert them of this new randomization!**

**Note:** Remember to make an entry in the subject's medical chart to indicate they have been randomized to study treatment.

# Randomization and Screening Numbers

- + Every patient entered into the CRS will have a **Screening Number**.
- + Each patient randomized will **also** have a **Randomization Number**.

## Number format:

- + First 4 digits = your site number
- + 5th alpha character indicates Screened “T” or Randomized “V”
- + Last 3 digits = ascend sequentially starting with 001
  - + Screening and randomization numbers advance independently

## Example:

Screening #: 1002T006

Randomization #: 1002V003

This is the 6th patient screened and 3rd randomized

# Site Status Page

## Site Status Page

- + This page lists **all** patients screened and randomized **at your site**.
- + To view any patient in the list, click on the corresponding Screening # or Status.

Find #:  Find  
(enter Patient # )

Screening # <input type="radio"/>	Enrollment # <input checked="" type="radio"/>	Status
1094T015	1094V006	Randomized
1094T014	1094V005	Randomized
1094T013	1094V004	Randomized (REEN No)
1094T012	1094V003	Randomized (REEN Yes)
1094T006	1094V002	Randomized (REEN Yes)
1094T003	1094V001	Randomized (REEN No)
1094T011		Not Eligible
1094T010		Eligible but Not Randomized
1094T009		Eligible but Not Randomized
1094T008		Eligible but Not Randomized
1094T007		Not Eligible
1094T005		Eligible
1094T004		Not Eligible
1094T002		Not Eligible
1094T001		Not Eligible

# Patient Status Page

- + Indicates the status of each data entry form for the patient.
- + You may still open locked forms, but if any changes are required you will need to contact the PL.

## Patient Status Page

-  Inclusion Form
-  Exclusion Form
-  Pre-Randomization Form
-  Randomization Confirmation Form

Status	Symbol	Description
Completed		All data has been completed and saved.
Not Completed		Data has not yet been entered on the form.
Locked		The patient has been randomized and the data is locked (no longer able to be edited by the site user).

# Questions

