



The *REDOXS*[®] Study
REducing Deaths due to OXidative Stress

The *REDOXS*[®] Study

REducing Deaths from OXidative Stress

Sponsor

Dr. Daren Heyland, MD, FRCPC

Project Leaders

Rupinder Dhaliwal, RD and Janet Overvelde



Study Coordinator

REDOXS[©] Teamwork



Regulatory paperwork: pre-trial

- Ethics approval
- Consent form approved by Ethics

Essential elements according to GCP 4.8.10 must be included

- Regulatory approval
- Lab ranges and accreditation
- Qualified Investigator: CVs, licenses
- Research Coordinator: CVs
- Delegation of Authority Logs
- Web access logs

Delegation of Authority Log



The REDOX[®] Study
Evaluating Dantrolene due to Oxidative Stress

Delegation of Authority Log

This log is used by the Qualified Investigator (i.e. Site Investigator) to indicate the Site Staff that have a material effect on the conduct of the Study and to whom the Investigator has delegated significant Study related duties/tasks. The signatures and details on this log will also facilitate tracking of edits/changes of the Site records. This log is to be kept by the Qualified Investigator and the Sponsor.

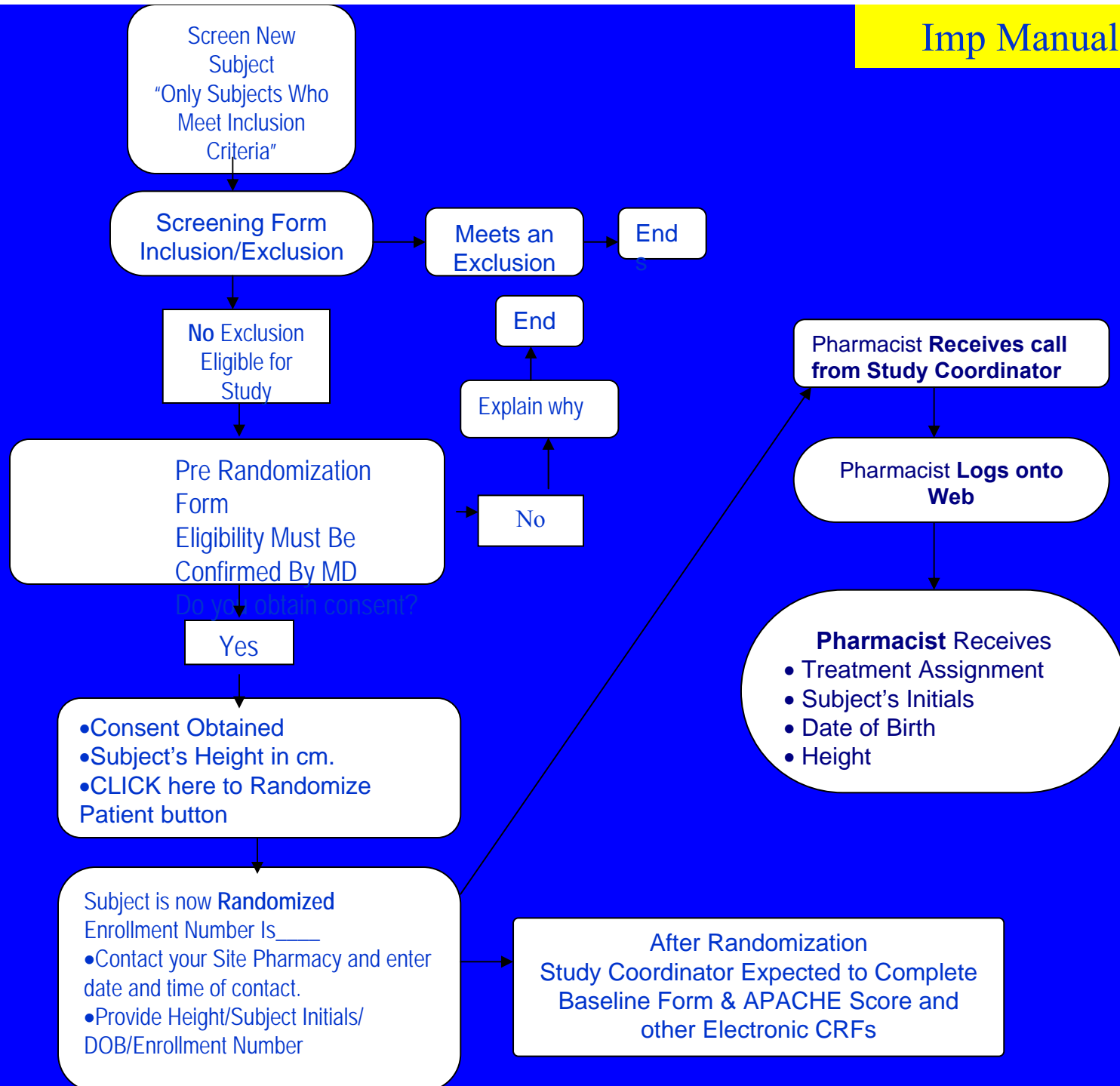
Name of Qualified Investigator: _____ Signature of Qualified Investigator: _____

Print Name	Signature	Initials	Study Role (Qualified Investigator*, sub- QI*, Research Coordinator (RC), Pharmacist, Technician, Dietitian)	Key Delegated Tasks (see next page)	Dates	
					Start	End

Sample of Delegated Tasks provided

Randomization
To be done by Research
Coordinator

Appendix 1
Randomization on Web

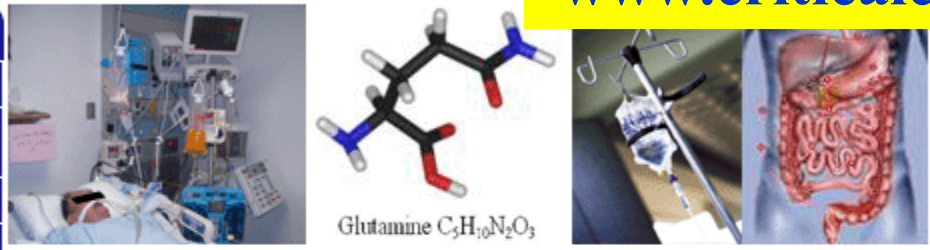




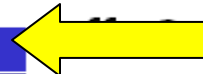
Critical Care Nutrition

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the improvement in nutrition therapies in intensive care units across the world.

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Important Announcements:

September 2008 update: The International Nutrition Survey data entry website will close at 5pm Eastern Standard Time (EST) on Tuesday 30th September. Limited data queries will be sent out shortly thereafter.

July 2008: See Resources Section of International Survey 2008 for the *new* [July 2008 Newsletter](#).

June 2008: See [resources](#) for [June 2008 International Survey](#)

NEWSROOM

Be the Best of the Best!

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Web Login Page

Home
Edit User Profile
Change Password
Contact Us
Logout

The REDOX[®] Study
REducing DEaths due to OXidative Stress

Login page

Maintenance: Please note that the Electronic data capture will be closed between 08:00 and 09:00 Eastern Standard time every Friday for regular maintenance.

Login Existing User
If you are an existing user, please enter your username and password below:

User Name
Password [Forgot your password?](#)

Login

Getting an error message, 'Invalid Session/ Session expired'? Make sure that your browser is properly configured to accept queensu.ca cookies. Click [here](#) for details.

Check if you need to configure web browser BEFORE your enrol !

Password assigned once regulatory approvals received

Inclusion/exclusion criteria

Refer to inclusion/exclusion criteria
cards

Inclusion Criteria

Imp Manual p 13-15

Inclusion Criteria

1. Mechanically ventilated adult patients (≥ 18 years old) admitted to your ICU.

2. And **with 2 or more** of the following organ failures related to their **acute** illness :
RECORD ALL ORGAN FAILURES
Reminder:
- **Organ Failures may have started before ICU admission but have to be present in ICU.**
- **Organ failures may have resolved at time of screening**

i. A PaO₂/FiO₂ ratio of ≤ 300
Date of onset of respiratory failure
Time (24 hrs)

ii. Clinical evidence of hypoperfusion defined as the need for vasopressor agents (norepinephrine, epinephrine, vasopressin, or ≥ 5 ug/kg/min of dopamine, or ≥ 50 ug/min phenylephrine) **for ≥ 2 hrs**
Date of onset of hypoperfusion failure
Time (24 hrs)

iii. In patients without known renal disease, renal dysfunction defined as a serum creatinine of ≥ 1.5 umol/L or a urine output of, ≤ 500 ml/last 24 hrs (or 80 ml/last 4 hours) (or observation not available). In patients with acute on chronic renal failure, an increase of ≥ 80 umol/L from baseline or pre-admission will be required. 500ml/last 24 hours (or 80ml/last 4 hours) will be required
Date of onset of renal dysfunction
Time (24 hrs)

iv. A platelet count of ≤ 50 mm³.
Date of onset of low platelet count
Time (24 hrs)

Save Clear Form

Times of organ failures:
record the onset of the
organ failure.

PF ratio ≤ 300 : record the
first one after ventilation

Exclusion Criteria

Imp Manual p 16-18

REDOXS Study Screening - Internet Explorer provided by Sympatico

https://ceru.hpcvl.queensu.ca/REDOXS/loadScreening2.do?id=187

File Edit View Favorites Tools Help

REDOXS Study Screening

The *REDOXS*® Study
REducing DEaths due to OXidative Stress

Screening #:55 **Screening (2 of 2)** Site name:TEST
KGH

Exclusion Criteria [Choose only 1 (most pertinent)]

- > 24 hours from admission to ICU
- Patients who are moribund (not expected to be in ICU for more than 48 hours due to imminent death).
- Patients with primary admission diagnosis of burns (>=30%BSA)
- Weight less than 50 kgs or greater than 200kgs
- Pregnant patients or lactating with the intent to breastfeed
- Cancer-metastatic cancer or Stage IV Lymphoma with an expected life expectancy of less than 6 months.
- None of the above

Home
Patient Status
Site Status
C
L

Done Internet 100%

should be >24 hours from ICU admission to time of consent

If transferred from another ICU, includes time in that ICU too!

Sign by SI and keep as source

Pre-Randomization


Consent

Critical Care Nutrition Survey Pre-Randomization - Microsoft Internet Explorer

File Edit View Favorites Tools Help

Address <https://ceru.hpcvl.queensu.ca/REDOXS/loadPreRand.do?id=53> Go Links

Google G Go 2 blocked Check AutoLink AutoFill Send to Settings

 The *REDOXS*® Study
REducing Deaths due to OXidative Stress

Screening #:19 **Pre - Randomization** Site name:KGH

Home
Patient Status
Site Status
Contact Us
Logout

Patient eligibility has been confirmed with MD
Name of Physician
Did you obtain consent YES NO
Patient's height in cm

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Done Internet

If Randomized

Imp Manual p 21

Critical Care Nutrition Survey Randomization - Microsoft Internet Explorer

Address: https://ceru.hpcvl.queensu.ca/REDOXS/loadRand.do?id=53

The REDOXs[®] Study
REducing Deaths due to OXidative Stress

You have successfully randomized this patient!
Randomization #6.
Please print off this page for your records.

Screening #: 19
Enrolment #: 6
Patients height in cm: 167.0
Randomization date/time: 12:20
Date, time: 15 Mar 2007 12:20

Clear Form

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Start | 3 Microsoft Of... | 2 Microsoft Of... | CRFs | Critical Care ... | EN | 1:16 PM

Print the page and notify the study pharmacist of:

- Patient randomization number
- Height in cms
- Patient initials and DOB

☒ Consent

Critical Care Nutrition Survey Pre-Randomization - Microsoft Internet Explorer

Address: <https://ceru.hpcvl.queensu.ca/REDOXS/loadPreRand.do?id=53>

The *REDOXS* Study
REducing Deaths due to OXidative Stress

Screening #: 19 **Pre - Randomization** Site name: KGH

Patient eligibility has been confirmed with MD

Name of Physician:

Did you obtain consent: YES NO

If answer NO then choose the most important reason the patient wasn't randomized

No family present
 Refused consent
 Missed patient
 Other

Save Clear Form

Home
Patient Status
Site Status
Contact Us
Logout

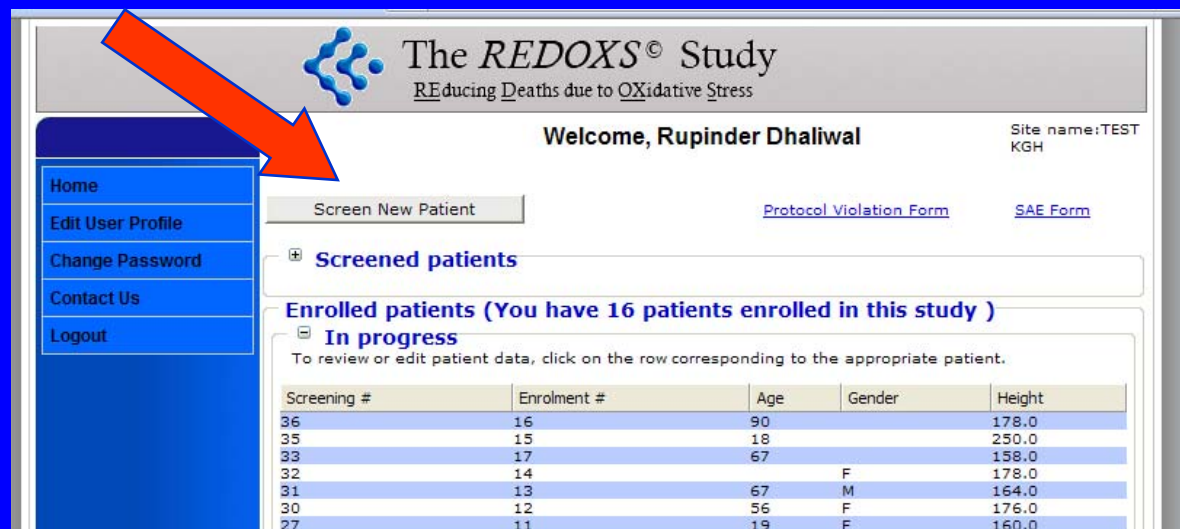
Start | 3 Microsoft... | Changes to ... | ver 3.0 IMM... | CRFs | Critical Ca... | EN | 1:09 PM

For patients that you do not enrol because they are going to be extubated soon (no exclusion criteria), choose NO to consent, and provide an explanation under OTHER reason.

Screening Logs (online)

Enter Screening Data for ALL patients meeting inclusion criteria, including those meeting an exclusion criteria and those that refuse consent

Do NOT need to submit other screening logs



The screenshot shows the user interface for 'The REDOXS[®] Study' with the subtitle 'REducing DEaths due to OXidative Stress'. The user is logged in as 'Rupinder Dhaliwal' at site 'TEST KGH'. A navigation menu on the left includes 'Home', 'Edit User Profile', 'Change Password', 'Contact Us', and 'Logout'. The main content area features a 'Screen New Patient' button, which is highlighted by a red arrow. Below this are sections for 'Screened patients' and 'Enrolled patients (You have 16 patients enrolled in this study)'. The 'In progress' section contains a table of patient data.

Screening #	Enrolment #	Age	Gender	Height
36	16	90		178.0
35	15	18		250.0
33	17	67		158.0
32	14		F	178.0
31	13	67	M	164.0
30	12	56	F	176.0
27	11	19	F	160.0

FAQs

I have made a mistake in the organ failure timing.

Can I change the screening data after I have randomized a patient?

Case study #1: eligible or not?

75 yr old male admitted to ICU with diagnosis of sepsis following complications post bowel surgery

Screening time Sept 21st 9:00 hours

ICU admission Sept 20th at 18:00 hrs

PF ratio < 300 Sep 20th 18:45 hrs

Renal failure Sept 20th 13:23 hrs

Hx of diabetes, CAD, seizure d/o on anticonvulsants

Case study # 2: Timing of Organ Failures

16: 10 hrs Patient admitted to ER, SOB, ABGs PF ratio ~~240~~

16:40 hrs in ER intubated on mechanical ventilation

16:50 in ER dopamine started ~~6~~ $6 \mu/\text{kg}/\text{min}$ until 18:00 hrs

17:00 in ER ABGs PF ratio 210

19:00 transferred to ICU

20:00 started on dopamine at $8 \mu/\text{kg}/\text{min}$ until 24:00 hrs

21:00 in ICU ABGs PF ratio 212

24: 00 in ICU dopamine d/c

You screen next morning at 09:00 hrs.

Is this patient eligible?

What is the timing of organ failures?

Obtaining Informed Consent

Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans

“Free and informed consent refers to the dialogue, information sharing and general process through which prospective subjects choose to participate in research involving themselves”

Timing : When?

Consent must be obtained within 24 hrs of admission to ICU

Who obtains consent?

- Site Investigator or delegate i.e. sub investigator or research nurse
- must be specified on the Delegation of Authority Log

Whom to get consent from?

- Patients are usually incapable given acuity of illness
- Substitute decision maker (SDM) or patient's legally acceptable representative

Pre-Consent

Check to see if patient has refused participation in research in general.

Ensure patient meets the inclusion & no exclusion criteria

Familiarize yourself with the patient's history

Discuss the eligibility criteria and appropriateness of enrolment with Site Investigator.

Involve nursing staff

Approach bedside nursing staff/medical staff for and update on the family's involvement and their degree of knowledge of the patient's condition.

Inform the appropriate nurse you are considering this patient for the REDOXS[©] Study.

Ask RN when family member is expected.

At the time of Consent

- Arrange for a quiet, private location for discussion with family member(s) with the Site Investigator/delegate.
- The Site Investigator will provide an overview of the study to the family members and inform them that their family member is appropriate for participation in the REDOXS[©] study. The Site investigator will then introduce the Research coordinator to the family.
- State that you are seeking permission for the patient to participate in a research study
- Highlight that your hospital promotes improving patient care through research

Language

- Use simple and clear language
- Avoid medical jargon
- Do NOT coerce family member
- Personalize the discussions i.e. “Patients like your family member, may benefit from participating in this study...”

Explain Study Procedures

- Feeding via EN or PN is standard of care
- Supplementation via Enteral and IV routes
- No blood will be taken
- Follow up at 3 and 6 months and interview with patient/family member.
 - Alternate family member contact for interview

Antioxidants and Glutamine

- Antioxidants are like vitamins/minerals that are naturally occurring substances that the human body needs to overcome serious illness.
- Glutamine is an a building block for protein, and plays many important functions in the body.
- In critical illness, these nutrients are found to be in low levels.
- Purpose of the study is to see if giving these supplements will improve the survival and reduce infections of sick patients in the ICU, like your family member.

Risks and benefits

- We won't know what your family member is receiving (blinded).
- Risks: No known risks but there maybe others that we do not know about. If the MD in charge of your family member feels that your family member is deteriorating because of the supplements, he can stop the study supplements.
- Your family member will be monitored daily
- Benefits: your family member may have a better chance of survival but we do not know for sure.

Other elements of ICF

- Voluntary participation
 - If refuse participation, will still receive the same medical care.
 - Consent may be withdrawn at any time
- No compensation, no cost
- Contact person for their rights and questions
- Data will be accessed but kept confidential

Provide ICF to SDM

- Provide a copy of the REB approved ICF to family for their review
- Give them sufficient time to ask questions and encourage them to speak to the Site Investigator.
- Ensure that they have understood that they are signing on behalf of their family member
- Provide contact numbers for questions or concerns

After consent obtained

- When the SDM has given consent, ensure that they have dated and signed the ICF. Provide them with one copy.
- Place a copy of the signed ICF in the medical chart and copies in your site files
- Write a note in the chart stating
 - Name of SDM who provided consent, relation to patient
 - Date and time that consent was received
 - Time that patient was randomized
 - Brief summary of REDOXS procedures

Follow up with SDM

- Thank the SDM for the opportunity to include the patient in REDOXS
- Provide the SDM with informal updates when you see them during future ICU visits, whether things are uneventful or not
- Ongoing contact with the SDM will help to make their exposure to medical research a positive experience

No Family around?

- Obtain consent by telephone
- Document in the medical chart that consent was obtained via telephone before the patient was randomized
- Follow up with the SDM to see that the ICF is signed as soon as possible.

Duration of Data Collection

For daily data

from **Study Day 1 until Day 30 unless ICU discharge (actual) or death occurs before day 30**

EXCEPT the following:

- Study Supplement Compliance: maximum of 28 days.
- Microbiology: -7 days ICU admission to ICU discharge (or maximum day 30).
- Antibiotics: -7 days ICU admission and stop dates may extend beyond ICU discharge. **Only those started before day 30**
- Patients with ICU stay < 5 days and transferred to ward: collect all daily data from Study Day 1 and continue for 5 days in total (=120 hrs).

Study Day 1 is from ICU admission to end of flowsheet.

Study Day 2 and subsequent days are according to your 24 hr flowsheet

Welcome Home Page (Site Status Page)

Imp Manual p11

The screenshot shows the REDOX Study ICU View website in a Windows Internet Explorer browser. The browser's address bar displays the URL: <https://ceru.hpcvl.queensu.ca/REDOXS/login.do?jsessionid=B709A1843DB337240FE53D27BD1503EA>. The website header features the REDOX logo and the text "The REDOX[®] Study" with the tagline "Reducing Deaths due to Oxidative Stress". A red arrow points to the logo. Below the header, a welcome message reads "Welcome, Rupinder Dhaliwal" and "Site name: TEST KGH". A navigation menu on the left includes links for Home, Edit User Profile, Change Password, Contact Us, and Logout. The main content area contains a "Screen New Patient" button, links for "Protocol Violation Form" and "SAE Form", and sections for "Screened patients", "Enrolled patients (You have 16 patients enrolled in this study)", and "Finalized patients". The "Enrolled patients" section includes a table with columns for Screening #, Enrollment #, Age, Gender, and Height. The "Finalized patients" section is currently empty.

Home
Edit User Profile
Change Password
Contact Us
Logout

Screen New Patient [Protocol Violation Form](#) [SAE Form](#)

Screened patients

Enrolled patients (You have 16 patients enrolled in this study)

In progress
To review or edit patient data, click on the row corresponding to the appropriate patient.

Screening #	Enrollment #	Age	Gender	Height
36	16	90		178.0
35	15	18		250.0
33	17	67		158.0
32	14		F	178.0
31	13	67	M	164.0
30	12	56	F	176.0
27	11	19	F	160.0
26	10		M	159.0
25	9	45		187.0
24	8	43	F	165.0
23	7	56	M	165.0
22	6	55	M	150.0
21	5			123.0
18	3	78	M	145.0

Finalized patients

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Patient Status Page

Patient Status Page Site name: KGH

Screening #: 24 Enrolment #: 8 Age: 43 Sex: F Height: 165.0

Screening/Baseline forms

[Screening \(1 of 2\)](#) ✓ [Screening \(2 of 2\)](#) ✓ [Pre-Randomization](#) ✓
[Randomization](#) ✓ [Patient Baseline](#) ✓ [APACHE II Worksheet](#) ✓
[Study Supplement Timelines](#) ✓ [Baseline Nutrition](#) ✓

Daily data

Day #	Date	Daily data	Study Supplement Compliance	Daily Nutrition Data	Vasopressor	Concomitant Medications
1	03/Apr/2007	!	!	Add	!	!
2	04/Apr/2007	!	Add		!	Add
3	05/Apr/2007	!			!	
4	06/Apr/2007	!			!	
5	07/Apr/2007	Add			!	
6	08/Apr/2007				!	
7	09/Apr/2007				Add	

Microbiology

Accession #	Date
121212	05/Apr/2007

[Add Microbiology](#)

Baseline

The **REDOXS** Study
REducing Deaths due to OXidative Stress

Screening #:20
Enrolment #:5

Patient Baseline Site name:KGH

Home
Patient Status
Site Status
Contact Us
Logout

Weight kgs
Sex Male Female
Ethnic Group
Diabetic YES NO
Type of Admission Medical Surgical: Elective Surgical: Emergency
Primary ICU diagnosis (Choose only one)
Primary ICU diagnosis is: NONE
Comorbidities (Choose all that apply)
Comorbidities is:
 NONE
 Pulmonary
 Neurological
 Endocrine
 Renal
 Gastrointestinal
 Cancer/immune
 Psychological
 Musculoskeletal
 Miscellaneous
Etiology of shock
Hospital Admission/Emergency Presentation Date Time (24 hrs)
ICU Admission Date Time (24 hrs)
Mechanical Ventilation Start Date Time (24 hrs)
Save Clear Form

- Hypotension
- Respiratory Failure

Logic Checks: time of organ failure and ICU admission

OK to wait

Must be completed
Logical sequence

APACHE II

May use existing APACHE score if available

Lowest and highest values

Score automatically generated

The **REDOXS** Study
REducing Deaths due to OXidative Stress

Screening #:20
Enrolment #:15

Apache II Worksheet Site name: KGH

Help

Does this patient have an APACHE II score available (from first 24 hrs admission to ICU)? YES NO

Chart Information

Enter the highest and lowest values for all variables within the first 24 hours from admission to ICU. The worksheet will calculate and display the severity score based on these values.

Metric	Low	High	Severity
Age		87	5
Temperature (°C)	37.7		
Router:	Core	Core	0
Systolic BP (mm Hg)	88		
Diastolic BP (mm Hg)	48		
Mean Arterial BP (mm Hg)	52.068		2
Heart Rate	189		3
Respiratory Rate	10		1
Oxygenation	No ABGs <input checked="" type="checkbox"/>		0
Serum HCO3		26.0	
Arterial pH			0
Serum Sodium (mmol/L)	141.0		0
Serum Potassium (mmol/L)	3.9		0
Serum Creatinine (umol/L)	132.6		2
<input type="checkbox"/> Acute renal failure			
Hematocrit (%)	40		0
White Blood Count (total/mm3) (in 1000s)	3.0		0
Glasgow Coma Scale			
Eye Opening	None		1
Verbal Response	None		1
Best Motor Response	None		1
Glasgow Coma Score			12
Chronic Health Points			
Elective postoperative patient			2
Total Apache II Score			27

Study Supplement Timelines

Duration of supplements:

- Minimum 5 days (120 hrs)
- Maximum 28 days

Start and stop dates
and times

The screenshot shows the 'Study Supplement Timelines' page for 'The REDOXs Study'. The page header includes the study logo and name, and the site name 'Kingston General'. The page is divided into sections for 'Enteral' and 'Parenteral' supplements. Each section has fields for 'Date enteral study supplements started' and 'Date enteral study supplements stopped', with corresponding time fields. The 'Enteral' section shows a start date of 10 Dec 2008 at 18:00 and a stop date of 11 Dec 2008 at 03:45. The 'Parenteral' section shows a start date of 10 Dec 2008 at 18:00 and a stop date of 11 Dec 2008 at 03:05. A 'Comments' field is also present at the bottom of the form.

Screening #:143
Enrolment #:45

Study Supplement Timelines

Site name: Kingston General

Enteral

Date enteral study supplements started: 10 Dec 2008 Time (24 hrs) 18:00

Date enteral study supplements stopped: 11 Dec 2008 Time (24 hrs) 03:45

Parenteral

Date parenteral study supplements started: 10 Dec 2008 Time (24 hrs) 18:00

Date parenteral study supplements stopped: 11 Dec 2008 Time (24 hrs) 03:05

Comments:

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Baseline Nutrition

Dietitian to collect:

- Prescribed kcal and protein (baseline)
- Type of nutrition support
- Start and stop date and times
- Refer to Dietitian Manual

Critical Care Nutrition Survey Nutrition (summary data) - Microsoft Internet Explorer

Address: <https://ceru.hpcvl.queensu.ca/REDOXS/loadDailyNutSumm.do?id=53>

The REDOX Study
REDucing Deaths due to OXidative Stress

Screening #:19
Enrolment #:6
Site name:KGH

Baseline Nutrition

Prescribed energy intake:

Prescribed protein intake:

Enteral nutrition

Enteral nutrition initiated prior to ICU admission & continued in ICU: YES NO Never received in ICU

Date & time enteral nutrition started: Time (24 hrs)

Date and time enteral nutrition stopped in ICU: Time (24 hrs)

Parenteral nutrition

Parenteral nutrition initiated prior to ICU admission: YES NO Never received in ICU

Date & time parenteral nutrition started: Time (24 hrs)

Date and time parenteral nutrition stopped in ICU: Time (24 hrs)

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Daily Data

Study Day 1 is from ICU admission to end of your 24 hr flowsheet.

Study Day 2 and subsequent days are according to your 24 hr flowsheet.

Dietitian to help by collecting the location of feeding tube

The REDOXs[®] Study
REDucing DEaths due to OXidative Stress

Daily Data

Day #	Date	HR highest	Temp C	U/O 24hrs	RR highest	PF ratio worst	Dialysis
1	28/Aug/2008	85	38.4	>= 500 mls	17.0		NO
2	29/Aug/2008	88	38.4	>= 500 mls	19.0	91.0	NO
3	30/Aug/2008	92	38.2	>= 500 mls	24.0	247.0	NO
4	31/Aug/2008	78	38.5	>= 500 mls	28.0	66.0	NO
5	01/Sep/2008	56	37.5	>= 500 mls	24.0	186.0	NO
6	02/Sep/2008	88	37.5	>= 500 mls	25.0	170.0	NO
7	03/Sep/2008	92	37.8	>= 500 mls	33.0	193.0	NO
8	04/Sep/2008	91	37.5	>= 500 mls	29.0		NO
9	05/Sep/2008	98	36.6	>= 500 mls	28.0		NO

Day #: 1 DATE: 28/Aug/2008

HR highest: 85 N/A BP lowest: systolic: 74 N/A
diastolic: 50 N/A

Temp C: 38.4 N/A U/O 24hrs: >= 500 mls N/A

Dialysis today: YES NO Mechanically Ventilated: YES NO

RR highest: 17.0 N/A PF ratio worst: N/A [See table](#)

WBC High: 14.4 N/A WBC Low: 8.5 N/A

Platelets lowest: 176.0 N/A BS am: 6.2 N/A

Cr highest: 120.0 N/A Urea highest: 5.2 N/A

Albumin highest: 37.0 N/A Bill highest: 20.0 N/A

Total gastric residual volumes: 0.0 N/A Total volume of gastric residuals discarded: 0.0 N/A

Location of feeding tube: Gastric presumed


Diarrhea >750ml or >5/day: YES NO

Daily Nutrition

- Dietitian to collect the data and give to SC
- Close to real time to ensure that patient is being fed adequately.
- Use checklist (online)

**Propofol \geq 6 hrs:
reminder to ask dietitians
to include this in calories
received**

Imp Manual: p 37

 The REDOXSM Study
REducing Deaths due to OXidative Stress

Screening #:19 Enrolment #:6 **Daily Nutrition** Site name:KGH

Home
Patient Status
Site Status
Contact Us
Logout

Day #: 1 DATE: 10/Mar/2007

Enteral Nutrition

Did patient receive Enteral nutrition today? YES
 NO

Total energy intake
Total protein intake

Formula (may up to 3)
(hold 'Ctrl' for multiple selections)

- MEAD JOHNSON: Portagen
- NESTLE: Peptamen with Prebio 1
- NESTLE: Peptamen
- NESTLE: Peptamen 1.5
- NESTLE: Peptamen VHP

EN interrupted due to intolerance?
(either high gastric residual volumes or emesis or aspiration of formula) YES NO

EN interrupted due to high urea or fluid concerns? YES NO

Parenteral Nutrition

Did patient receive Parenteral Nutrition today? YES
 NO

Total energy intake
Total protein intake
Type of Lipids

PN interrupted due to high urea or fluid concerns? YES NO

Save Reset Form New Day

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Study Supplement Compliance

- **Volumes must be monitored DAILY**
- **Daily Monitoring Log**
- If volumes \neq prescribed, report to CERU
protocol violation
protocol deviation



Collection in real time essential !

https://ceru.hpcvl.queensu.ca/REDOXS/loadSSD.do?id=12

The REDOXSC Study
REducing Deaths due to OXidative Stress

Screening #:19
Enrolment #:16

Study Supplement Compliance (daily data) Site name:KGH

Day #	Date	Enteral volume received	Parenteral volume received
1	10/Mar/2007	400.0	500.0

Day #: 1 DATE: 10/Mar/2007

Enteral Study Supplements
Volume Received (mls)
This is a Protocol deviation enter reason

Parenteral Study Supplements
Volume Received (mls)
This is a Protocol deviation enter reason
Route Any signs of phlebitis: YES NO

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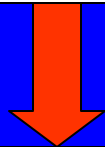
3 Microsoft Of... 4 Windows

Imp Manual: p 34

Protocol Violation

Volume of study supplement **actually received** is less than the prescribed volume in 24hrs

Enteral < 80% prescribed
Parenteral < 90% prescribed

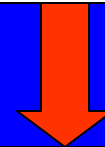


Complete Violation Form
within 24 hours of
discovery
&
Fax to CERU
Attention: Project Leader
(613) 548-2428

Protocol Deviation

Volume of study supplement **actually received** is less than the prescribed volume in 24hrs

Enteral \geq 80% < 100% prescribed
Parenteral \geq 90% < 100%
prescribed



Provide explanation on the
worksheet/web based data
entry (Study Supplement
Compliance)



The REDOXS[®] Study

REducing DEaths due to OXidative Stress

Welcome, Rupinder Dhaliwal

Site name: Kingston
General
[Edit](#)

Home

Edit User Profile

Change Password

Contact Us

Logout

Screen New Patient

[Protocol Violation Form](#) [SAE Form - Initial](#) [SAE Form - Follow-up](#)

Screened patients

Enrolled patients (You have 60 patients enrolled in this study)

In progress

To review or edit patient data, click on the row corresponding to the appropriate patient.

Screening #	Enrolment #	Status	Age	Gender	Height
163	60	in progress	78	F	145.0
162	59	in progress	57	M	165.0
161	58	in progress	34	F	152.0
160	57	in progress	74	M	182.0
159	56	in progress	72	M	177.0
158	55	in progress	67	M	170.0
157	54	in progress	85	M	170.0
156	53	in progress	81	F	165.0
155	52	locked	47	M	193.0
154	51	locked	52	M	165.0
153	50	in progress	79	M	175.0
152	49	in progress	61	M	185.0
151	48	in progress	70	M	162.6
150	47	in progress	59	M	192.0
149	46	in progress	77	M	173.0
119	41	in progress	52	M	175.0
109	35	locked	63	F	152.4
104	31	locked	40	F	142.0

Finalized patients

**Fax to CERU
within 24 hrs**

Protocol Violation Form

Not needed on :

• day of admit

• day of d/c



The **REDOXS**® Study
REducing Deaths due to OXidative Stress

Site _____
Patient Enrollment # _____

Protocol Violation Form

Study Coordinator Reporting: _____ Site Investigator _____

Date and time violation occurred:

dd	mmm	yyyy		

24 hr clock

Date and time violation discovered:

dd	mmm	yyyy		

24 hr clock

Type of violation: Enteral supplement < 80% Parenteral supplement < 90%
(check one or both)

Is the local Site Investigator aware of the violation?

Yes or No

If No, explain why? _____

Reasons for Violation (check all that apply):

<input type="checkbox"/> High gastric residuals	<input type="checkbox"/> No IV access
<input type="checkbox"/> No GI access	<input type="checkbox"/> Elevated urea
<input type="checkbox"/> Bowel Perforation or obstruction	<input type="checkbox"/> Fluid concerns
<input type="checkbox"/> Held for procedures or for OR	
<input type="checkbox"/> Other (provide explanation) _____	

Action Taken by Study Coordinator:

Enteral Feeding Protocol reviewed (attached) Yes or No

Motility agents recommended Yes or No

Small Bowel feeding recommended Yes or No

Rate of supplements doubled Yes or No

Comments:

Daily Monitoring Log



Pt Name: _____ ID#: _____
 Enrolment#: _____

Daily Monitoring Log

This data must be collected daily in real time. Please initial data entry at bottom of page.

Study Day		Day 1	Day 2	Day 3	Day 4	Day 5	Day 6
DD/MMM/YYYY							
ENTERAL	Study Supplement Volume (mL)	_____	_____	_____	_____	_____	_____
	Protocol Violation = 0-383 mL (fax violation to form to CERU within 24 hrs)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Protocol Deviation = 384-479 mL (reason for deviation)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
PARENTERAL	Study Supplement Volume (mL)	_____	_____	_____	_____	_____	_____
	Protocol Violation = 0-215 mL (fax violation to form to CERU within 24 hrs)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Protocol Deviation = 216-239 mL or > 240 mL (reason for deviation)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Route: (C)entral or (P)eripheral						
	If Peripheral, Phlebitis/extravasations	Y/N	Y/N	Y/N	Y/N	Y/N	Y/N
	Is there an SAE today that is SERIOUS and UNEXPECTED?	Y/N	Y/N	Y/N	Y/N	Y/N	Y/N

Vasopressors/Inotropes

Highest hourly dose received

https://ceru.hpcvl.queensu.ca/REDOXS/newVAS.do?id=53

The REDOXS[©] Study
REducing Deaths due to OXidative Stress

Screening #: 19
Enrolment #: 6

Vasopressors/Inotropes Site name: KGH

Vasopressor

Day #	Date	Dopamine	Norepinephrine	Epinephrine
Day #: 1	DATE: 10/Mar/2007			

Did patient receive any pressors/inotropes today? YES NO

Record highest hourly dose

Dopamine: (mcg/kg/min) Norepinephrine:

Epinephrine: Dobutamine: (mcg/kg/min)

Phenylephrine: Vasopressin: (units/minute)

Save Clear Form New Day

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Imp Manual: p 40

Concomitant Medications

Critical Care Nutrition Survey Concomitant Medications - Microsoft Internet Explorer

Address: https://ceru.hpcvl.queensu.ca/REDOXS/newCONC.do?id=53

The REDOXS[®] Study
REducing Deaths due to OXidative Stress

Screening #: 19
Enrolment #: 16
Concomitant Medications
Site name: KGH

Home
Patient Status
Site Status
Contact Us
Logout

Day #	Date	Hydrocortisone	Activated Protein C	Insulin units/day
Day #: 1	DATE: 10/Mar/2007			

Did patient receive any of these concomitant medications today? YES NO

Hydrocortisone YES NO

Activated Protein C YES NO

Motility agents (hold 'Ctrl' for multiple selections):
NONE
Motilium
Erythromycin
Metoclopramide

Insulin units/day (TOTAL)

Save Clear Form New Day

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Start | Inbox - Mic... | contacts | Critical Ca... | Changes to ... | ver 3.0 IMM... | EN

What about
decadron or
solumedrol or
Solu-cortef?

Imp Manual: p 41

ICU Infection Adjudication

ONLY if suspicion of infection as determined by either of the following:

New antibiotics OR
positive cultures after 72 hrs ICU admission

Must collaborate with the Site Investigator

Will not show up on patients status page if no antibiotics or positive cultures after 72 hrs

Microbiology

Collect all positive cultures within the period 7 days prior to ICU admission.

If culture date > 72 hrs ICU admission, 2 questions will be asked to help determine suspicion of ICU acquired infection.

The screenshot shows a web browser window titled "Critical Care Nutrition Survey Microbiology - Microsoft Internet Explorer". The address bar shows the URL: <https://ceru.hpcvl.queensu.ca/REDOXS/newMicro.do?id=53>. The page header includes the logo for "The REDOX Study" and the tagline "REducing Deaths due to OXidative Stress".

The main content area is titled "Microbiology" and includes a navigation menu on the left with options: Home, Patient Status, Site Status, Contact Us, and Logout. The page also displays "Screening #: 19", "Enrolment #: 16", and "Site name: KGH".

The "Sample" section contains the following fields:

- Accession Number:
- Date Culture Sent: Time (24 hrs):
- Sample Type:

The "Organisms" section features a list of organisms on the left and a list of susceptibilities on the right. The organisms list includes: Adenovirus, Aerogenes, Aeruginosa, Agalactiae (Group B Strep), Albicans, and Anginosus. The susceptibilities list includes: Acyclovir, Amikacin, Aminosalicylic acid, Amoxicillin/clavulanic, Amphotericin B, Ampicillin, Ampicillin/sulbactam, and Anti-HIV therapy-plec. The susceptibilities are categorized as Sensitive, Intermediate, or Resistant, with a "DELETE" button.

Below the organisms list, there are two questions:

- Quantitative Results:
- Is this culture a manifestation of a previously diagnosed infection? Yes No
- Is this culture from a routine surveillance? Yes No

At the bottom of the form, there are "Save Microbiology" and "Reset Form" buttons.

Suspicion of ICU Infection

- Is this culture a manifestation of a previously diagnosed infection?
- Is this a routine surveillance swab?

NEED TO ASK SITE INVESTIGATOR

- If NO to both.....flag for adjudication (to be done after ICU outcomes).



The REDOXs[®] Study

REducing DEaths due to OXidative Stress

Screening #:5
Enrolment #:4

Microbiology

[Help](#)

- Home
- Patient Status
- Site Status
- Contact Us
- Logout

Accession #	Date
GN-07-13369	28/Jun/2007
GN-07-13370	28/Jun/2007
07-195-0971	07/Jul/2007
07-196-0941	15/Jul/2007
07-169-0941	15/Jul/2007
07-196-0941	15/Jul/2007
07-199-2596	18/Jul/2007
07-199-2708	18/Jul/2007
07-199-2708	18/Jul/2007
07-199-2708	18/Jul/2007

Sample

Record ALL positive cultures from 7 days prior to ICU admission until ICU discharge

Accession Number

Date Culture taken Time (24 hrs)

Sample Type

Organisms

Pseudomonas sp. / Aeruginosa , Results: Sensitive: Ceftazidime, Ciprofloxacin, Meropenem, Piperacillin, Tobramycin

Add Organism

Is this culture a manifestation of a previously diagnosed infection? Yes No

Is this a routine surveillance swab? Yes No

Antibiotics

Period of data collection starts 7 days prior to ICU admission and may extend beyond ICU discharge.

ONLY THOSE STARTED BEFORE DAY 30

If abx started > 72 hr ICU admission, 2 questions will be asked to help determine suspicion of ICU acquired infection.

The screenshot shows a web browser window displaying the 'Antibiotics' form for the REDOX Study. The browser address bar shows the URL: https://ceru.hpcvl.queensu.ca/REDOXS/newAntibiotic.do?id=53. The page header includes the study logo and name: 'The REDOX Study - REducing Deaths due to OXidative Stress'. The form is titled 'Antibiotics' and includes a navigation menu on the left with options: Home, Patient Status, Site Status, Contact Us, and Logout. The main form area contains a table with columns for Antibiotic, Date first dose received, and Date last dose received. Below the table is a form for entering antibiotic details, including fields for Antibiotic (dropdown), Dose, Route (IV or PO/NG), Frequency, and three date-time pairs for 'Date antibiotics ordered', 'Date first dose received', and 'Date last dose received'. There are also three yes/no questions: 'Is this antibiotic prescribed for prophylaxis?', 'Is this a dose adjustment of an antibiotic previously ordered for an infection?', and 'Is this antibiotic a substitute for an antibiotic previously ordered for an infection?'. The form includes 'Save Antibiotic', 'Reset Form', and 'New Antibiotic' buttons. The footer of the page reads 'Copyright © Critical Care Connections Inc. All rights Reserved.'

Antibiotic	Date first dose received	Date last dose received
Acyclovir	02/Mar/2007	02/Feb/2007

Antibiotics

Antibiotic: [dropdown]
Dose: [input]
Route: IV PO/NG
Frequency: [input]
Date antibiotics ordered: [dropdown] [dropdown] [dropdown] Time (24 hrs): [input]
Date first dose received: [dropdown] [dropdown] [dropdown] Time (24 hrs): [input]
Date last dose received: [dropdown] [dropdown] [dropdown] Time (24 hrs): [input]

Is this antibiotic prescribed for prophylaxis? Yes No
Is this a dose adjustment of an antibiotic previously ordered for an infection? Yes No
Is this antibiotic a substitute for an antibiotic previously ordered for an infection? Yes No

Save Antibiotic Reset Form New Antibiotic

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Suspicion of ICU Infection

- Is this antibiotic prescribed for prophylaxis?
- Is this a substitute for an antibiotic ordered for a previous infection?

NEED TO ASK SITE INVESTIGATOR

- If NO to ALL.....flag for adjudication (to be done after ICU outcomes).

The REDOX^S Study

REducing DEaths due to OXidative Stress

- Home
- Patient Status
- Site Status
- Contact Us
- Logout

Screening #:13
Enrolment #:11

Antibiotics

[Help](#)

Antibiotic	Date first dose received	Date last dose received
Piperacillin/Tazobactam	13/Aug/2007	18/Aug/2007
Ciprofloxacin	18/Aug/2007	24/Aug/2007
Cloxacillin	20/Aug/2007	22/Aug/2007
Vancomycin	20/Aug/2007	20/Aug/2007

Antibiotic

Record all antibiotics started 7 days prior to ICU admission and those during ICU stay.

Antibiotic:

Dose:

Route: IV PO/NG

Frequency:

Date antibiotics ordered: Time (24 hrs): No Time available

Date first dose received: Time (24 hrs):

Date last dose received: Time (24 hrs):

Is this antibiotic prescribed for prophylaxis? Yes No

Is this a dose adjustment of an antibiotic previously ordered for an infection? Yes No

Is this antibiotic a substitute for an antibiotic previously ordered for an infection? Yes No

Comments:

Infection Adjudication

All input warnings must be resolved

The screenshot shows a web browser window titled "Patient View - Windows Internet Explorer" with the URL "https://ceru.hpcvl.queensu.ca/REDOXS/patientMain.do?id=64". The page displays a table of dates from 18/Apr/2007 to 21/Apr/2007, each with a yellow warning icon. Below this are three main sections: "Microbiology", "Antibiotics", and "Outcomes and Follow Up".

Microbiology

Accession #	Date
123	10/Apr/2007
234	14/Apr/2007
1145	12/Apr/2007
1459	15/Apr/2007
	26/Feb/2007

Antibiotics

Antibiotic	Date first received	Date last received
Bacitracin	15/Apr/2007	20/Apr/2007
Cefazolin	15/Apr/2007	16/Apr/2007
Erythromycin	14/Apr/2007	18/Apr/2007
Ampicillin	16/Apr/2007	22/Apr/2007

Outcomes and Follow Up

- [ICU Outcome information](#)
- [ADJUDICATION Form](#)
- [Hospital Outcome information](#)
- [3 month follow up information](#)
- [6 month follow up information](#)

SF 36 - 3 Month survey [Edit SF36 Page 1](#)
[Edit SF36 Page 2](#)
[Edit SF36 Page 3](#)

[Click here to enter SF36 \(6 month\)](#)
[Investigator's Confirmation form](#)

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Automatic listing of relevant clinical data (microbiology, antibiotics, daily data) that will enable the Site Investigator to adjudicate newly acquired ICU infections.

REDOXS Study - Microsoft Internet Explorer

Address: <https://ceru.hpcvl.queensu.ca/REDOXS/loadAdjudication.do?id=95>

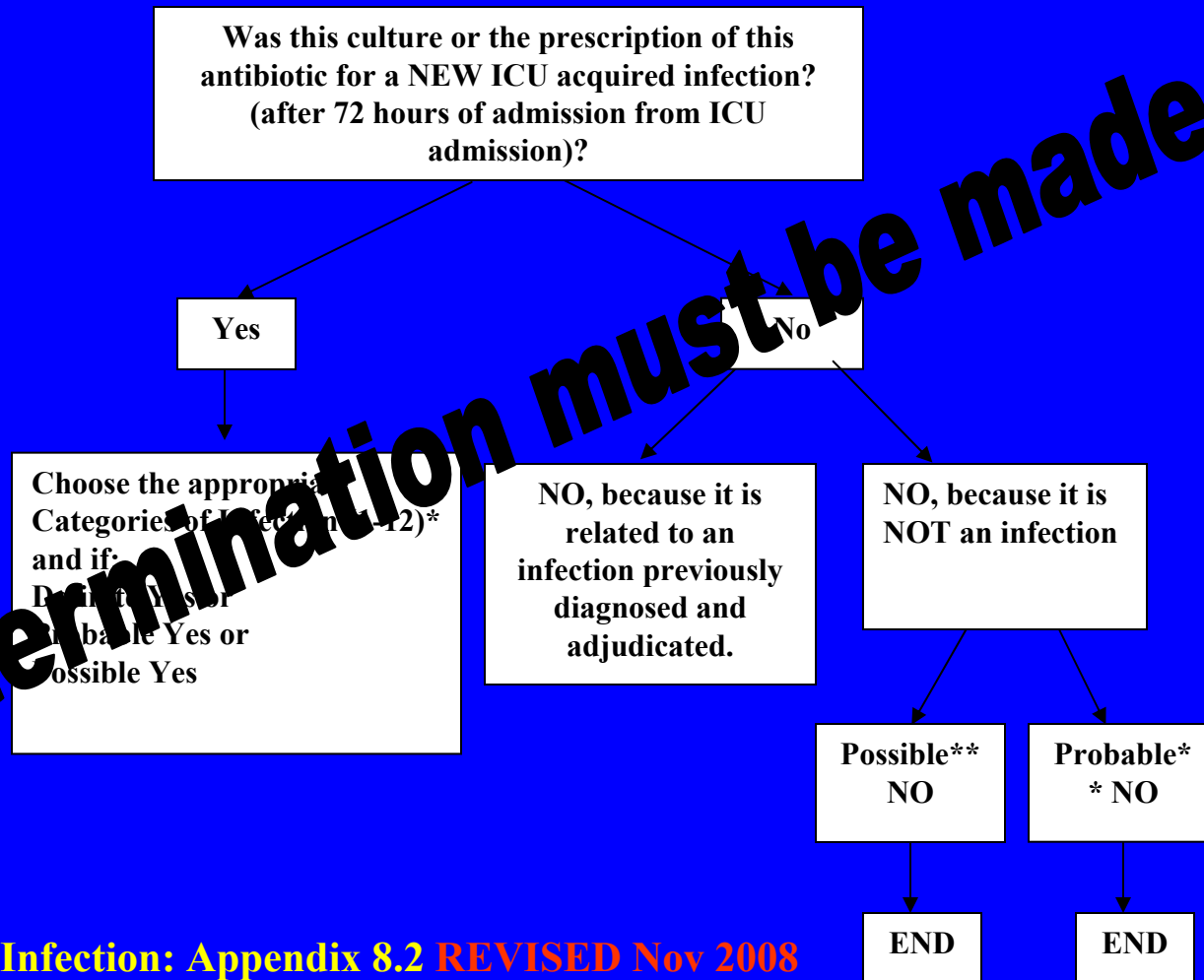
The REDOXS[®] Study
 REducing DEaths due to OXidative Stress

Infection Adjudication
 Patient: 4
 Admission Diagnosis: Valvular heart surgery/CABG
 ICU admission date: 08/May/2007 16:39

Date	Temp	Worst PF ratio	WBC	Pressors	Vented	Microbiology		Antibiotic				Newly Acquired Infection	
						Sample	Organism	Antibiotic	Dose	Unit	Frequency		Route
08 May 2007	38.5	77.0	High=11.2 Low=6.3	YES	YES								
08 May 2007	38.5	77.0	High=11.2 Low=6.3	YES	YES								
09 May 2007	38.7	147.0	High=16.3 Low=9.9	YES	YES			Ceftazidime	1.0	g	q12 hrs	IV	
10 May 2007	38.2	130.0	High=17.5 Low=14.0	YES	YES			Ceftazidime	1.0	g	q12 hrs	IV	
11 May 2007	38.0	105.0	High=18.2 Low=18.2	NO	YES								
12 May 2007	38.6	104.0	High=16.4 Low=16.4	NO	YES								
13 May 2007	37.8	128.0	High=19.7 Low=18.9	NO	YES	Other	30a Pylori						<input type="radio"/> This is a newly acquired infection <input type="radio"/> This is NOT a newly acquired infection <input type="radio"/> This is a previously adjudicated infection

Done

Determination of ICU Infection



*Categories of Infection: Appendix 8.2 REVISED Nov 2008

**Definition of No: Appendix 8.3

Input Warnings (must address before ICU Outcomes)

The screenshot shows the 'Patient Status Page' for the REDOX Study. The page title is 'The REDOX Study' with the tagline 'Reducing Deaths due to Oxidative Stress'. The site name is 'TEST'. The page is titled 'Patient Status Page' and features a navigation menu on the left with options: Home, Site Status, Contact Us, and Logout. The main content area is divided into several sections:

- Input Warnings:** This section is circled in red and contains three bullet points:
 - ICU admit Date must be within 24 hours prior of randomization Date [View/Edit](#)
 - ICU admit Date must be within 3 days after or 1 day before Date of onset of hypoperfusion failure [View/Edit](#) [Accept](#)
 - Stop date for EN study supplement is not consistent with compliance data for day #17 [View/Edit](#)
- Screening/Baseline forms:** This section displays the status of various forms:
 - Screening (1 of 2) ✓
 - Screening (2 of 2) ✓
 - Pre-Randomization ✓
 - Randomization ✓
 - Patient Baseline ⚠
 - APACHE II Worksheet ✓
 - Study Supplement Timelines ✓
 - Baseline Nutrition ✗
- Daily data:** A table with columns for Day #, Date, Daily data, Study Supplement Compliance, Daily Nutrition Data, Vasopressor, and Concomitant Medications. The first row shows data for Day # 1 on 04/May/2007, with 'Add' links for Daily data, Study Supplement Compliance, Daily Nutrition Data, Vasopressor, and Concomitant Medications.
- Microbiology:** A section with fields for Accession # and Date, and an 'Add Microbiology' button.
- Antibiotics:** A section with fields for Antibiotic, Date first received, and Date last received, and an 'Add Antibiotic' button.

The Windows taskbar at the bottom shows the Start button, a folder named 'SAE', and the active window 'REDOX Study Patien...'. A yellow banner at the bottom right contains the text 'Imp Manual: p 47'.

ICU Outcomes

This page **MUST** be completed before you can proceed to the next web pages

The screenshot shows a Microsoft Internet Explorer browser window displaying the ICU Outcomes form for The REDOX Study. The browser's address bar shows the URL: <https://ceru.hpcvl.queensu.ca/REDOXS/loadicuOutcome.do?id=7>. The page header includes the logo for The REDOX Study and the tagline "REDucing Deaths due to OXidative Stress". The form is titled "ICU Outcomes" and includes the following fields and options:

- Screening #: 19
- Enrolment #: 6
- Site name: KGH
- Form title: ICU Outcomes
- Question: "Did patient die in ICU?" with radio buttons for YES (selected) and NO.
- Field: "Provide date of actual death" with a date picker and a "Time (24 hrs)" input field.
- Question: "Is the date and time of final ventilation discontinuation the same as death date and time?" with radio buttons for YES and NO.
- Buttons: "Save" and "Reset Form".

The browser's taskbar at the bottom shows several open applications: "Inbox - Microso...", "CRFs", "Critical Care ...", and "3 Microsoft Of...". The system clock indicates the time is 2:27 PM.

Imp Manual: p 47

Locking of data

Study ICU Outcomes - Internet Explorer provided by Sympatico

https://ceru.hpcvl.queensu.ca/REDOXS/loadIcuOutcome.do?id=24

View Favorites Tools Help

REDOXS Study ICU Outcomes

The **REDOXS**® Study
REducing DEaths due to OXidative Stress

Screening #:43
Enrolment #:24

ICU Outcomes Site name:TEST
KGH

ICU Outcomes

Did patient die in ICU? YES NO

Provide date of actual ICU discharge 05 May 2007 Time 12:58 (24 hrs)

Provide date of final ventilator discontinuation 04 May 2007 Time 12:58 (24 hrs)

Windows Internet Explorer

Are you ready to lock all the data entered for this patient?
Note: Once patient is locked, access to the data can only be granted by CERU.

OK Cancel

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OR
**after ICU
infection
adjudication**

Can ask CERU to unlock the data to make changes

Imp Manual: p 50


Hospital Outcomes

Critical Care Nutrition Survey Hospital Outcomes - Microsoft Internet Explorer

File Edit View Favorites Tools Help

Address <https://ceru.hpcvl.queensu.ca/REDOXS/loadHospOutcome.do?id=5>

Google G Go Bookmarks 4 blocked Check AutoLink AutoFill Send to Settings



The **REDOXS** Study
REducing DEaths due to OXidative Stress

Screening #: 18
Enrolment #: 13

Hospital Outcomes

Site name: KGH

- Home
- Patient Status
- Site Status
- Contact Us
- Logout

Did patient die? YES NO

Provide date of actual hospital discharge: 02 Feb 2007 Time (24 hrs): 12:34

Is patient still on dialysis upon discharge from Hospital: YES NO

Comments:

Save Reset Form

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Start 2 Microsoft Of... Critical Care ... Microsoft Excel 2 Micros Internet

3 and 6 month follow up

SF-36 at 3 and 6 months

LONG TERM FOLLOW-UP: SF36

- Multi-purpose, short-form health survey
- 36 questions
- A generic measure
 - Health and well-being scores
 - Physical and mental health summary
 - Health utility index

(www.sf36.org)

REDOXS[©] & the SF36

- Administered by the Research Coordinator
- Conducted at 3 month and 6 month (from ICU admission)
- ± 2 weeks from target date
- Schedule reminders for yourself

Points of Contact

1. Time of consent
2. Time of pre-interview
3. Time of interview

Time of Consent

Contact information

- Patient
- Substitute decision maker
- Alternate family member

Time of Pre-interview

- The period of time between ICU discharge and hospital discharge
- Contact patient
 - Orient patient to the study
 - Discuss purpose of SF36
 - Suggest contact times

Time of Interview

- Telephone or in-person (if still in the hospital)
- 4 attempts to contact at different intervals throughout and at different times of day (over 2 week period)

With whom?

➤ Patient

OR

➤ Substitute respondent

- someone who knows the patient's condition the best

Contact is made with patient (substitute)

- Introduce yourself and why you are calling
- Remind them consent was signed
- Ask if it is an appropriate time:
 - Yes – outline the purpose of the SF36 & proceed with SF36 script
 - No – suggest alternate time; attempt to re-connect

If you cannot conduct the interview

➤ Identify reason:

- Patient died
- Patient refused/withdrew
- Patient lost to follow-up

Administering the questionnaire

- Outline the purpose of the SF36
- Follow the script
- Read each question and available response options

Clarification of questions

- Re-read the question verbatim
- Do not interpret for them
- Encourage them to use their own interpretation

Clarification of response options

- Direct them to select the category that most closely represents what they are thinking or feeling.

Survey completion

- Thank the participant
- Negotiate next interview (if applicable)
- Paper copy **MUST** be used to record responses
- Paper copy **MUST** be kept for source verification

Entering 3/6 month data into the eCRF

The screenshot shows a web browser window displaying the REDOX Study eCRF. The browser's address bar shows "Go", "Bookmarks", "4 blocked", "Check", "AutoLink", "AutoFill", and "Send to". The page header includes the REDOX logo and the text "The REDOX Study" and "REducing Deaths due to OXidative Stress".

On the left side, there is a navigation menu with the following items: Home, Patient Status, Site Status, Contact Us, and Logout. The "Patient Status" item is currently selected.

The main content area is titled "3 Month Follow Up" and includes the following information:

- Screening #: 23
- Enrolment #: 8
- Site name: KGH

The form is titled "3 Month Follow up" and asks "Were you able to conduct the follow-up interview?". The form contains the following fields and options:


- Yes
- Date of interview: [Month] [Day] [Year] Time (24 hrs) [Time]
- With whom? Patient Family/Caregiver
- No, Patient Died
- Date of death: [Month] [Day] [Year] Time (24 hrs) [Time]
- No, Patient refused or withdrew
- Date of refusal: [Month] [Day] [Year] Time (24 hrs) [Time]
- No, Patient lost to follow-up
- Date patient last known to be alive: [Month] [Day] [Year] Time (24 hrs) [Time]
- Is patient still on dialysis upon discharge from Hospital: YES NO

At the bottom of the form, there are "Save" and "Reset Form" buttons. Below the buttons, there is a link: "Click here to enter SF36 (3 month)".

The footer of the page contains the text: "Copyright © Critical Care Connections Inc. All rights Reserved."

Imp. Manual pg 57-60

Entering 3/6 month data into the eCRF



The **REDOX** Study
REducing DEaths due to OXidative Stress

15. Your Health and Well-Being

Page 1 of 3

Screening #:18
 Enrolment #:3

Site name:KGH

Indicate 3 or 6 Month Survey

This survey asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities. Thank you for completing this survey!

1. In general, would you say your health is:

Excellent	Very good	Good	Fair	Poor
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

2. Compared to one year ago, how would you rate your health in general now ?

Much better now than one year ago	Somewhat better now than one year ago	About the same as one year ago	Somewhat worse now than one year ago	Much worse now than one year ago
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

3. The following questions are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

	Yes, limited a lot	Yes, limited a little	No, not limited at all
<u>Vigorous activities</u> , such as running, lifting heavy objects, participating in strenuous sports	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<u>Moderate activities</u> , such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Lifting or carrying groceries	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Climbing <u>several</u> flights of stairs	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Climbing <u>one</u> flight of stairs	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Bending, kneeling, or stooping	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Walking <u>more than a kilometre</u>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Walking <u>several hundred metres</u>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Walking <u>one hundred metres</u>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Bathing or dressing yourself	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

- Home
- Patient Status
- Site Status
- Contact Us
- Logout

Entering 3/6 month data into the eCRF

- Implementation Manual pages 57-60
- If patient dies in ICU/hospital forms are disabled
- Must enter discharge dates in order to enter SF36 responses onto the eCRF.

General Rules for Data Collection

- CERU to assign passwords, site #
- Dates DD/MMM/YYYY, 00:00
- Click on + to expand menu or taxonomy
- Site Status Page: shows all patients
- Patient Status Page : colour coding
- Input warnings : help with query process

Investigator's Confirmation


Only appears once the ICU and Hospital outcomes have been completed and all input warnings have been resolved (Patient Status Page).

REDOXS Study - Microsoft Internet Explorer

File Edit View Favorites Tools Help

Back Forward Stop Home Search Favorites

Address <https://ceru.hpcvl.queensu.ca/REDOXS/loadInvestigator.do?id=60>

 The *REDOXS*® Study
REducing DEaths due to OXidative Stress

Site #:4
Enrolment #:10
Enrollment Date:03/Apr/2007
13:56

Investigator's Confirmation

The electronic data collection was conducted under my supervision according to the protocol during the entire study.

Fax to CERU and keep as source

The data and statements, including ICU acquired infection adjudication are complete and accurate to the best of my knowledge

Full Name of Investigator _____

Done

Do you want to finalize patient ?

Yes...only if sure that no more changes

Imp Manual: p 61

Resources online

www.criticalcarenutrition.com>REDOXS Study>Resources

Critical Care Nutrition

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Glutamine $C_5H_{10}N_2O_3$

The resources below have been provided for the sites actively participating in the REDOXS@ Study. The information will be useful for Site Investigators, Research Coordinators, Dietitians, Pharmacists and Pharmacy Technicians.

Study Procedures Manual

- Administration of Study Supplements pdf
- Administration of Study Supplements - EU version pdf
- Implementation Manual
 - Part 1 pdf
 - Part 2 pdf
 - Part 3 pdf
- Protocol Violations pdf
- Serious Adverse Events pdf
- Pharmacy Manual pdf
- Pharmacy Manual - EU version pdf
- Pharmacy Worksheets pdf
- Pharmacy Worksheets - EU version pdf
- Dietitian Manual pdf
- Research Coordinator Worksheets
 - Daily Monitoring log pdf
 - Checklists pdf

NEW
International 2008
REDOXS@ CIHR fund
Attitudes
Join the C Discussion

Address http://www.criticalcarenutrition.com/index.php?option=com_content&task=view&id=52&Itemid=81

2008
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The REDOXS@ Circular provides invaluable updates on enrollment data entry, regulatory and pharmacy issues, reminders and Frequently Asked Questions. The REDOXS@ Bulletin provides in depth coverage of current issues of interest.

All documents are in the .pdf format.

REDOXS@ Circular

- Issue #1 : June 2007
- Issue #2 : July 2007
- Issue #3 : September 2007
- Issue #4 : November 2007
- Issue #5 : December 2007
- Issue #6 : January 2008
- Issue #7 : February 2008
- Issue #8 : March 2008
- Issue #9 : April 2008 *new*
- Issue #10: June 2008 *new*

REDOXS@ Bulletin

- Study Days
- Delegation of Log
- Tiger Tubes
- Serious Adverse Events
- Research Coordinators - Updates *new*

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Done

Questions??

Imp Manual Tools

The REDOXS® Circular June 2007 Issue # 1

Clinical Evaluation Research Unit

We are very pleased to bring to you the newsletter for the REDOXS® Multicentre trial. Please Read on for an update of how the study is progressing.

Staggered Start Dates

May 1 st 2007	Kingston General started screening.
June 4 th 2007	Ottawa General, Ottawa Civic, Sacre-Coeur
Mid-end June 2007	St. Joseph's Hamilton, Royal Victoria, M. Royal Alexandra Edmonton and Charles
June-Sep 2007	Remaining sites expected to start.

Enrolment Update

Period	# patients enrolled	Site
May 1 st - June 7 th 2007	4	Kingston General
June 4 th - June 7 th 2007	1	Ottawa Civic
June 4 th - June 11 th 2007	1	Ottawa General

Worried about poor enrollment? Too many studies?

Enrollment at Kingston General started on May 1st and other sites are involved in studies such as PROTECT (2 patients in Kingston were SUGAR (co-enrollment not allowed), to date a total of 6 patients have illustrating that recruitment to REDOXS® is feasible even with competing studies!

Concerned about Antioxidants?

Some of you may be aware of the media attention that focused on We would like to point out that this report was based on studies that patients and hence the results cannot be extrapolated to ICU patients. Based on extensive work in critically ill patients, including our own worry. Please be prepared to address this should you be questioned consent.

The REDOXS® Circular July 2007 Issue # 2

Clinical Evaluation Research Unit

We have had a productive month and we are now actively enrolling at 9 sites across Canada. Thanks to our busy research coordinators we have managed to enrol 28 patients within the last 12 weeks!

Enrolment Update

# patients enrolled	Site	# patients to go
10	Kingston General	1092
1	St. Joseph's Hamilton	
7	Ottawa General	
3	Ottawa Civic	
4	Sacre Coeur	
2	Maisonneuve-Rosemont	
1	Royal Alexandra	
28	TOTAL	

Are you checking for these daily?

Volumes of study supplements received

The volumes of the enteral and parenteral study supplements actually received must be checked daily using the checklist provided or your own worksheets. If the volumes received are less than 80-90% of the prescribed volumes, you must complete a protocol violation form and send it to CERU within 24 hrs of becoming aware of the violation. Refer to the Protocol Violation section of your Study Procedures Manual for more details. The protocol violation form can be downloaded from the REDOXS® website after you log in.

Serious Adverse Events

Check for adverse events that are serious and unexpected on a daily basis using the checklists provided or your own worksheets. "Unexpected" means events that are NOT expected due to the progression of the underlying disease. Refer to the SAE section of your Study Procedures Manual.

Worried about high doses of selenium?

Some of you may have read about a recent randomized controlled trial (Stranges et al Annals of Internal Medicine Aug 2007) that concluded that long-term use of selenium supplements increased the risk of diabetes. Please note that the population in this study were outpatients seen in a dermatology clinic not acute critically ill patients with organ failures. Please be prepared to address this should you be questioned about this by a family member at the time of obtaining consent.

The REDOXS® Circular September 2007 Issue # 3

Clinical Evaluation Research Unit

The REDOXS® Study
Reducing Deaths due to Oxidative Stress

After a busy summer, we are happy to bring you the next issue of the REDOXS® Circular. Read along for an update on enrolment, important notices and frequently asked questions!

Enrolment Update

# patients enrolled	Site
14	Kingston General
2	St. Joseph's Hamilton
16	Ottawa General
5	Ottawa Civic
11	Sacre Coeur, Montreal
3	Maisonneuve-Rosemont, Montreal
2	Royal Victoria, Montreal
2	Royal Alexandra, Edmonton
55 + 80 (from pilot) = TOTAL 135	

1065 patients to go

Research Team at CERU

- Daren Heyland
- Rupinder Dhalwal
- John Muscedere
- Jennifer Korol
- Suzanne Biro

Did you know?

The next start date for new sites is October 2007. We anticipate that another 10 sites will be ready within the next month !!

How to Maximize delivery of enteral study supplements? Discuss these new approaches with your research team

NPO for prolonged periods: To reduce the interruptions to the enteral study supplements, try to limit the NPO period to 2 hours for non-operative procedures, and 6 hours for operative procedures. If you know that the patient is going to be NPO, consider doubling the study supplements in advance. Make sure that the infusion is returned to the regular rate after the "doubling up" to avoid infusing volumes higher than those prescribed.

High gastric residual volumes: High gastric residual volumes are common in critically ill patients and the use of motility agents is recommended as a strategy to minimize these. The combination of erythromycin plus metoclopramide in particular, is considered to be safe and effective in such patients. Please discuss the option of prescribing this combination with your site investigator.

Small Bowel Feeding: Feeding REDOXS® patients via the small bowel may be beneficial in improving the delivery of not only the enteral study supplements, but also enteral nutrition. We are working with Cook Medical to supply interested REDOXS® sites with a few self-advancing nasal jejunal feeding tubes (Tiger Tubes™). The use of these tubes is completely voluntary and they are to be considered a "tool" to optimize the delivery of enteral study supplements/enteral nutrition. If you are interested, please contact Rupinder Dhalwal to arrange inservices by Cook Medical. Look out for our REDOXS® Bulletin Small Bowel Feeding, coming soon.

www.criticalcarenutrition.com
click on **THE REDOXS® Study**

New Resources on our website

Coming soon
Revised Study Procedures Manuals and other tools
(version September 21st 2007)

The REDOXS® Circular

REDOXS® Circular and Bulletin