TheREDOXS® Study
REducing Deaths due to OXidative Stress

Pharmacy Logs and Worksheets

TheREDOXS® Study
REducing Deaths due to OXidative Stress

Monthly Site Inventory Log

Month_____Year_____

To be filled out by Site Pharmacy monthly and faxed to Clinical Evaluation Research Unit (CERU).

Name of Site: _____
Pharmacist: _____
Phone: _____

Product	Supplier	Minimum Supply needed	Actual supplies	Amount needed	Checked by CERU Project Assistant
Dipeptiven (100 ml bottles) (10 bottles per carton)	Fresenius Kabi (FK)	80 bottles*	____bottles	____bottles	
EN REDOXS formula (500 mls bottles) (12 bottles per carton)					
AOX + GLN	FK	36 bottles$^{\alpha}$	____bottles	____bottles	
AOX	FK	36 bottles$^{\alpha}$	____bottles	____bottles	
GLN	FK	36 bottles$^{\alpha}$	____bottles	____bottles	
Placebo	FK	36 bottles$^{\alpha}$	____bottles	____bottles	
Selenase(10 ml vials)	Biosyn	40 vials$^{\beta}$	____vials	____vials	

* based on 4 patients, each needing 2 bottles per day for 10 days
$^{\alpha}$ based on 4 patients, each needing 1 bottle per day for 9 days
$^{\beta}$ based on 4 patients, each needing approximately 1 vials/day per day for 10 days

Signature of person completing log:_____
Date_____

Fax completed form to: CERU (613) 548-2428
Attention: REDOXS© Study (613) 549-6666 ext 6686 or 4847

TheREDOXS® Study
REducing Deaths due to OXidative Stress

Monthly Site Temperature Log

Month _____Year_____

To be filled out by Site Pharmacy daily and faxed to Clinical Evaluation Research Unit (CERU) monthly.

Name of Site: _____ **Pharmacist:** _____ **Phone:** _____

Date	Temperature Low Température Bas	Temperature Current Température Présent	Temperature High Température Haut	Date	Temperature Low Température Bas	Temperature Current Température Présent	Temperature High Température Haut
01				16			
02				17			
03				18			
04				19			
05				20			
06				21			
07				22			
08				23			
09				24			
10				25			
11				26			
12				27			
13				28			
14				29			
15				30			
				31			

Signature of person submitting log: _____

Fax completed form to: CERU (613) 548-2428
Attention: REDOXS© Study (613) 549-6666 ext 6686 or 4847

Enteral Product Label Log Page ___of _____

Pharmacist to place removable labels here daily ***(use one page is for 3 days)***

Patient ID #:_____ Patient Initials:_____ Enrollment#:_____

Treatment Group (circle one): AOX GLN AOX+ GLN Placebo

Date dd/mm/yyyy

Date dd/mm/yyyy

Date dd/mm/yyyy

Enteral Study Supplement Dispensing Log Page___of___

To be filled out by Pharmacist

Patient ID # _____Patient Initials: _____ Enrollment #: _____

Dose: 480 mls/day Infusion Rate: 20 mls/hour

Treatment Group (circle one): AOX GLN AOX+ GLN Placebo

Date dd/mm/yyyy	*Lot #*	*Expiry*	Prepared by	Checked by	Checked by study monitor

TheREDOXS® Study
REducing Deaths due to OXidative Stress

Parenteral Study Supplement Dispensing Log

To be filled out by Pharmacist

Patient ID #:_____Patient Initials:____ Height:_____cms Enrollment #:_____

Treatment Group: (circle one): AOX GLN AOX+ GLN Placebo Infusion Rate of Final Product: 10 ml/hr (or > if tall)

	Dipeptiven		Selenium		Saline/D5W			Signatures	
Date	**dose (mls)**	**Lot # & expiry**	**dose (mls)**	**Lot # & expiry**	**dose (mls)**	**Lot # & expiry**	**Manufacturer**	**Prepared by**	**Checked by**

Audited by: _____

Nutrient Accountability Log Enteral AOX

Page___of ___

Site #:_____ To be filled out by Pharmacist

Date	Quantity received or destroyed	Lot #	Expiry date	Quantity dispensed	Patient enrollment #	Balance of Product	Signature

Nutrient Accountability Log Enteral GLN

Page___of ___

Site #:_____ To be filled out by Pharmacist

Date	Quantity received or destroyed	Lot #	Expiry date	Quantity dispensed	Patient enrollment #	Balance of Product	Signature

Audited by: _____

Nutrient Accountability Log Enteral AOX+GLN

Page___of ___

Site #:_____ To be filled out by Pharmacist

Date	Quantity received or destroyed	Lot #	Expiry date	Quantity dispensed	Patient enrollment #	Balance of Product	Signature

Audited by: _____

Nutrient Accountability Log Enteral Placebo

Page___of ___

Site #:_____ To be filled out by Pharmacist

Date	Quantity received or destroyed	Lot #	Expiry date	Quantity dispensed	Patient enrollment #	Balance of Product	Signature

Audited by: _____

Nutrient Accountability Log Dipeptiven **Page___of ___**

Site #:_____ To be filled out by Pharmacist

Date	Quantity received or destroyed	Lot #	Expiry date	Quantity dispensed	Patient enrollment #	Balance of Product	Signature

Audited by: _____

Nutrient Accountability Log Selenase

Page___of ___

Site #:_____ To be filled out by Pharmacist

Date	Quantity received or destroyed	Lot #	Expiry date	Quantity dispensed	Patient enrollment #	Balance of Product	Signature

Audited by: _____

Appendices

Appendix A.

TheREDOXS® Study

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.

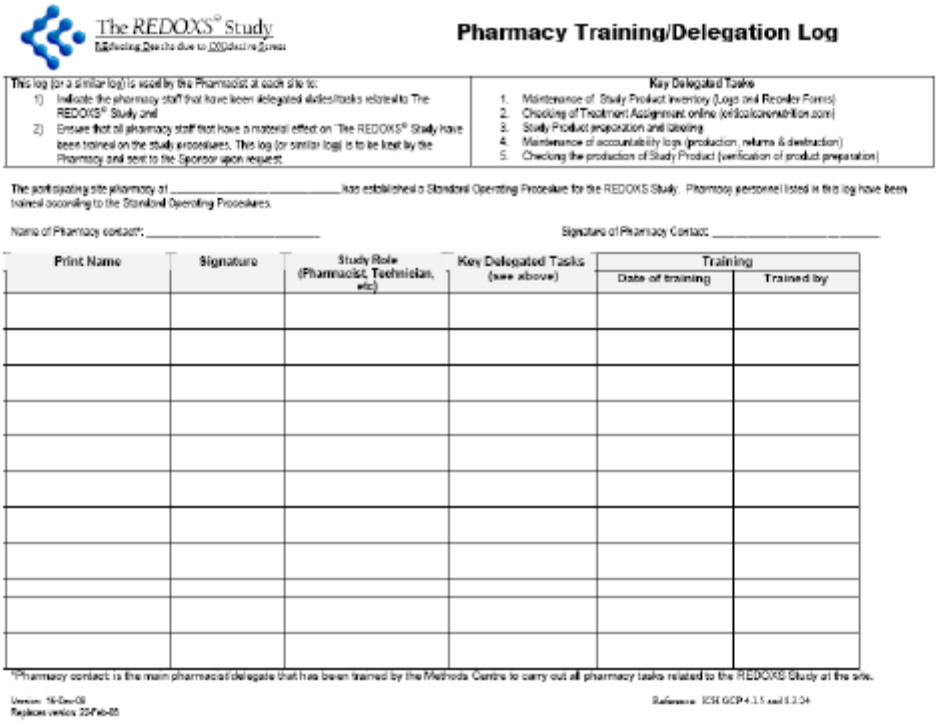
Name of Qualified Investigator: _____ Signature of Qualified Investigator: _____

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

*Qualified Investigator: the Site Investigator responsible for the conduct of the REDOXS® study at your site.
*Sub GI: Investigator other than the Qualified Investigator that is responsible for tasks related to the REDOXS® study at your site.

October 24th 2007 Reference: ICH GCP 4.1.5 and 5.5.24 1

Appendix B



The REDOXS® Study
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Pharmacy Training/Delegation Log

This log (or a similar log) is used by the Pharmacist at each site to:	Key Delegated Tasks
1) Indicate the pharmacy staff that have been delegated duties/tasks related to The REDOXS® Study and 2) Ensure that all pharmacy staff that have a material effect on The REDOXS® Study have been trained on the study procedures. This log (or similar log) is to be kept by the Pharmacy and sent to the Sponsor upon request.	1. Maintenance of Study Product inventory (Logs and Reorder Forms) 2. Checking of Treatment Assignment online (criticalcare-nutrition.com) 3. Study Product preparation and labeling 4. Maintenance of accountability logs (production, returns & destruction) 5. Checking the production of Study Product (verification of product preparation)

The participating site pharmacy at _____ has established a Standard Operating Procedure for the REDOXS Study. Pharmacy personnel listed in this log have been trained according to the Standard Operating Procedures.

Name of Pharmacy contact*: _____ Signature of Pharmacy Contact: _____

Print Name	Signature	Study Role (Pharmacist, Technician, etc)	Key Delegated Tasks (see above)	Training	
				Date of training	Trained by

*Pharmacy contact: is the main pharmacist delegate that has been trained by the Methods Centre to carry out all pharmacy tasks related to the REDOXS Study at the site.

Version: 16-Dec-08
Replaces version: 22-Feb-08

Reference: ICH GCP 4.1.5 and 8.2.24

Pharmacy Web access Signature Log

INSTITUTION: SITE NUMBER:
INVESTIGATOR:

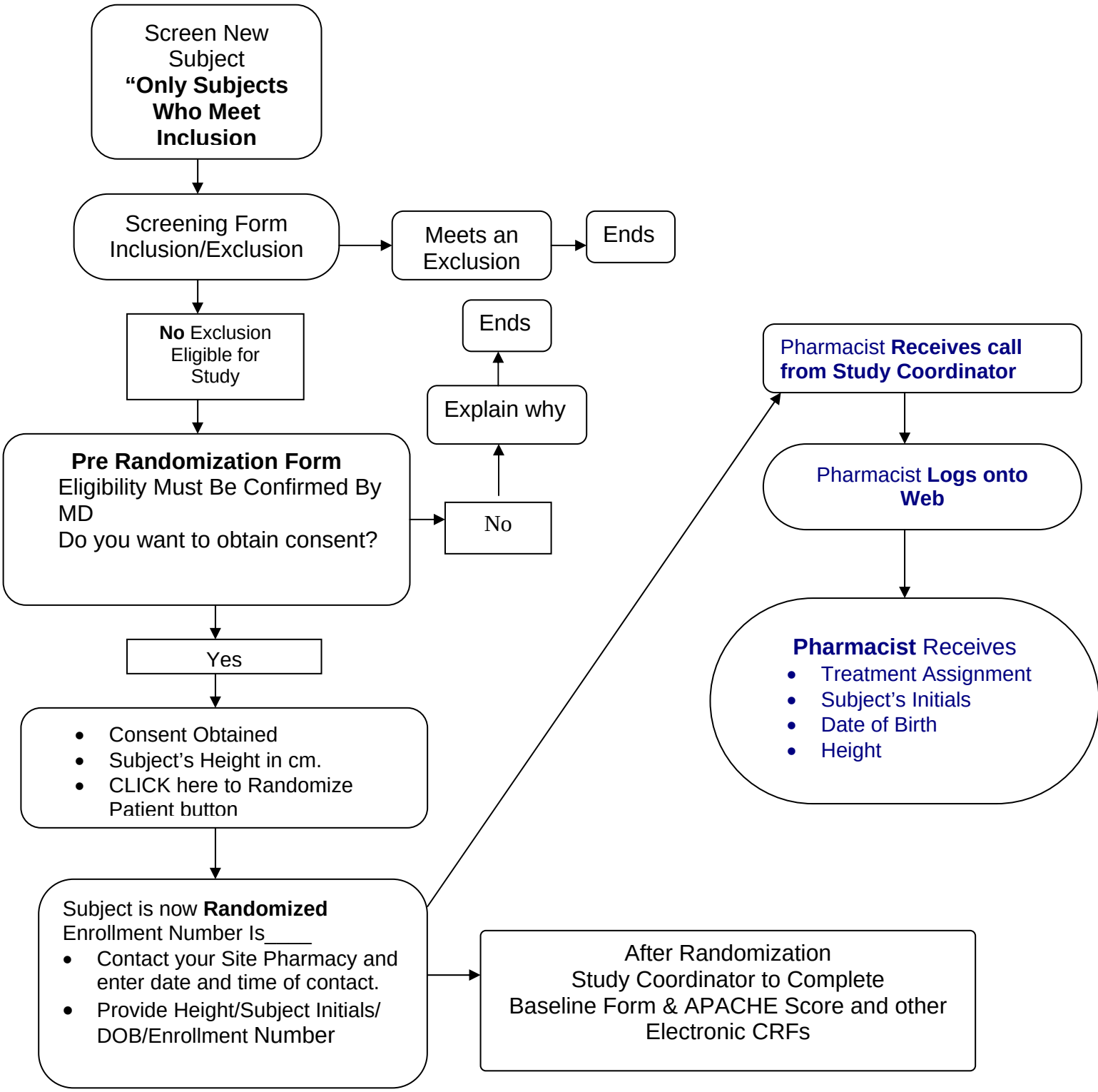
Please complete the Electronic Data Capture (EDC) System Access Signature Sheet for each Pharmacist/technician at your site who will be checking the randomization or dispensing/checking study supplements. A signature and email address is required to create user accounts for the web based system for the REDOXS© Study.

NAME	TITLE	SIGNATURE	EMAIL	DATE

NOTE:
By completing the information in the table above, the individual confirms they have been delegated the responsibility of checking the randomization and dispensing/verifying study supplements for the REDOXS© Study.

Reference: ICH GCP 5.5.3

Appendix D
Randomization Process on Web



Appendix E

Enteral Study Supplement
Study: REDOXS©
Enteral Component

For Clinical trial Use Only

Enrollment #:
Patient ID/CR#:
Patient Name:
Physician:

Date:

Directions: Infuse at 20 mL/hr
Storage: keep between 15-25 C
Expiry: use within 24 hours

Appendix F

Parenteral Study Supplement Worksheets

Use the appropriate worksheet according to the group the patient has been randomized to.

These worksheets will assist in calculating the volumes of the parenteral study supplements and normal saline or D5W needed.

Worksheet for Antioxidants (AOX)

Worksheet for Glutamine (GLN)

Worksheet for (Antioxidant + Glutamine) AOX + GLN

Worksheet for Placebo

Parenteral Supplements Worksheet

Patient CR# / ID#	Patient Initials	Enrolment #

Antioxidants (AOX)

Patient will receive Selenium (Antioxidants) and normal saline (or if hypernatremic D5W)

Begin with a bag containing exactly 250 mL of normal saline (i.e. account for overfill):

1. Volume of Dipeptiven† to be added = **0** mL
2. Volume of Selenium to be added = **10 mL**
3. Total Volume to be removed from 250 mL normal saline bag before adding study supplements:

   (# 1) + (# 2) = **10 mL**
   volume of dipeptiven; volume of selenium
4. Add (#1) + (#2) + normal saline **= 250 mL**
5. Record the volumes of Selenium and Normal Saline on the Parenteral Study Supplement Log for this patient daily.
6. Generate a label and attach to bag.

†Dipeptiven not required for this treatment arm

Note: Height of the patient not required to calculate the AOX dose

Parenteral Supplements Worksheet (Patients > 196 cm tall)

Patient CR# / ID#	Patient Initials	Enrolment #

Antioxidants (AOX)

Patient will receive Selenium (Antioxidants) and normal saline (or if hypernatremic D5W)

Dosing:

1. **Dosage of Selenium = 500mcg/day = 10mL/day regardless of height**
2. **Rate of infusion determined from chart below.**
3. Dose will be diluted in a NS bag to a final volume indicated in the chart below.
4. You **must account for overfill** in the normal saline bags as per table below.

Beginning with a bag of exactly 250 mL of normal saline:

Go to height chart (see below). Record:

1. Patient height = _____ cm
2. Final total volume of the bag (from chart below) = _____ mL
3. Rate to be infused (from chart below) = _____ mL/hr
4. Volume of Selenium to be added = **10 mL**

Height	Final Total Volume of Bag	Rate to be Infused	Volume of Selenium to be Added	Amount of Normal Saline	
				To be removed	To be added
196 cm	250 mL	10.4 mL/hr	10 mL	10.0 mL	
198 cm	255 mL	10.6 mL/hr	10 mL	15.0 mL	
201cm	263 mL	11.0 mL/hr	10 mL		3.0 mL
203 cm	268 mL	11.2 mL/hr	10 mL		8.0 mL
206 cm	275 mL	11.5 mL/hr	10 mL		15.0 mL
208 cm	280 mL	11.7 mL/hr	10 mL		20.0 mL
211 cm	288 mL	12.0 mL/hr	10 mL		28.0 mL
213 cm	293 mL	12.2 mL/hr	10 mL		33.0 mL

5. Volume of NS to be removed or added to bag = _____ mL
6. Add Selenium (#4), as per chart, to normal saline bag. Mix.
7. Record the volumes of Selenium and Normal Saline on the Parenteral Study Supplement Log for this patient daily.
8. Generate a label and attach to bag.

Version: 3-Jul-09 (EU)
Replaces version: 6-Dec-07 (EU)

Parenteral Supplements Worksheet

Patient CR# / ID#	Patient Initials	Enrolment #

Glutamine (GLN)

Patient will receive Dipeptiven (Glutamine) and normal saline (or if hypernatremic DSW)

Begin with a bag containing exactly 250 mL of normal saline (i.e. account for overfill):

1. Patient's height = _____ **cm**
2. Normal Body Weight = (#1) – 100 cm = _____ **kg**
3. Volume of Dipeptiven† to be added = (#2) x 2.5 mL = _____ **mL**
4. Volume of Selenium§ to be added = **0 mL**
5. Total Volume to be removed from 250 mL normal saline bag before adding study supplements:

   (# 3) + (# 4) = _____ **mL**
   volume of dipeptiven; volume of selenium

7. Add (#3) + (#4) + normal saline **= 250 mL**
8. Record the volumes of Dipeptiven and Normal Saline on the Parenteral Study Supplement Log for this patient daily.
9. Generate a label and attach to bag.

†Dipeptiven 2.5 mL/kg/day =Glutamine 0.35 g/kg/day = L-alanyl-L-glutamine 0.5 g/kg/day

§Selenium not required for this treatment arm

version: 3-Jul-09 (EU)
Replaces version: 9-Sept-07 (EU)

Patient CR# / ID#	Patient Initials	Enrolment #

Parenteral Supplements Worksheet (Patients > 196 cm tall)

Glutamine (GLN)

Patient will receive Dipeptiven (Glutamine) and normal saline (or if hypernatremic D5W)

Dosing:

1. **Dosage of Glutamine =** 0.35g/kg/day = L-alanyl-L-glutamine 0.5g/kg/day**= Dipeptivan®2.5mL/kg/day**
2. **Dosing will be based on patient's Normal Body Weight using Broca Formula as follows:**
   Normal Weight (kg)= Patient's Height (cm) - 100
3. Dose will be diluted in a NS bag to a final volume indicated in the chart below.
4. **Rate of infusion determined from chart below.**
5. You **must account for overfill** in the normal saline bags as per table below.

Beginning with a bag of exactly 250 mL of normal saline:

Go to height chart (see below). Record:

1. Patient height = _____ cm
2. Final total volume of the bag (from chart below) = _____ mL
3. Rate to be infused (from chart below) = _____ mL/hr
4. Volume of Glutamine (Dipeptiven®) to be added = _____ mL

Height	Final Total Volume of Bag	Rate to be Infused	Volume of Glutamine to be Added	Amount of Normal Saline to be removed
196 cm	253 mL	10.5 mL/hr	240 mL	237 mL
198 cm	258 mL	10.8 mL/hr	245 mL	237 mL
201cm	266 mL	11.1 mL/hr	253 mL	237 mL
203 cm	271 mL	11.3 mL/hr	258 mL	237 mL
206 cm	278 mL	11.6 mL/hr	265 mL	237 mL
208 cm	283 mL	11.8 mL/hr	270 mL	237 mL
211 cm	291 mL	12.1/mL/hr	278 mL	237 mL
213 cm	296 mL	12.3 mL/hr	283 mL	237 mL

5. Volume of NS to be removed from bag = _____ mL
6. Add Dipeptiven® (#4), as per chart, to normal saline bag. Mix.
7. Expiry dating = 96 hours at room temperature.
8. Generate a label and attach to bag.

Version: 3-Jul-09 (EU)
Replaces version: 6-Dec-07 (EU)

Parenteral Supplements Worksheet

Patient CR# / ID#	Patient Initials	Enrolment #

Antioxidants + Glutamine (AOX+GLN)

Patient will receive Selenium (AOX), Dipeptiven (GLN) and normal saline (or if hypernatremic DSW)

Begin with a bag containing exactly 250 mL of normal saline (i.e. account for overfill):

1. Patient's height = _____ cm
2. Normal Body Weight = (#1) – 100 cm = _____ kg
3. Volume of Dipeptiven† to be added = (#2) x 2.5 mL = _____ mL
4. Volume of Selenium to be added = 10 mL
5. Total Volume to be removed from 250 mL normal saline bag before adding study supplements:

   _____(#3)_____ + ____(#4)____ = _____ mL
   volume of dipeptiven volume of selenium
6. Add (#3) + (#4) + normal saline = 250 mL
7. Record the volumes of Dipeptiven, Selenium and Normal Saline on the Parenteral Study Supplement Log for this patient daily.
8. Generate a label and attach to bag.

†Dipeptiven 2.5 mL/kg/day =Glutamine 0.35 g/kg/day = L-alanyl-L-glutamine 0.5 g/kg/day

version: 3-Jul-09 (EU)
Replaces version: 9-Sept-07 (EU)

Patient CR# / ID#	Patient Initials	Enrolment #

Parenteral Supplements Worksheet (Patients > 196 cm tall)

ormal Saline on the Parenteral Study Supplement Log for this

Antioxidants + Glutamine (AOX+GLN)

Patient will receive Selenium (AOX), Dipeptiven (GLN) and normal saline (or if hypernatremic D5W)

Dosing:

1. **Dosage of Selenium = 500mcg/day = 10mL/day regardless of height;**
2. **Dosage of Glutamine** 0.35g/kg/day = L-alanyl-L-glutamine 0.5g/kg/day**= Dipeptivan®2.5mL/kg/day**
3. Dosing will be based on patient's Normal Body Weight using Broca Formula as follows: Normal Weight (kg) = Patient's Height(cm) - 100
4. Dose will be diluted in a NS bag to a final volume indicated in the chart below.
5. **Rate of infusion determined from chart below.** (rate may be increased up to 2x the amount on day 1 for hours missed to conform to standard dosing times)
6. You **must account for overfill** in the normal saline bags as per table below.

Beginning with a bag of exactly 250 mL of normal saline:

Go to height chart (see below). Record:

1. Patient height = _____ cm
2. Final total volume of the bag (from chart below) = _____ mL
3. Rate to be infused (from chart below) = _____ mL/hr
4. Volume of Selenium to be added = 10.0 **mL**
5. Volume of Glutamine (Dipeptiven®) to be added = _____ mL

Height	Final Total Volume of Bag	Rate to be Infused	Volume of Selenium to be Added	Volume of Glutamine to be Added
196 cm	250 ml	10.4 mL/hr	10 mL	240 mL
198 cm	255 ml	10.6 mL/hr	10 mL	245 mL
201cm	263 ml	11.0 mL/hr	10 mL	253 mL
203 cm	268 ml	11.2 mL/hr	10 mL	258 mL
206 cm	275 ml	11.5 mL/hr	10 mL	265 mL
208 cm	280 ml	11.7 mL/hr	10 mL	270 mL
211 cm	288 ml	12.0 mL/hr	10 mL	278 mL
213 cm	293 ml	12.2 mL/hr	10 mL	283 mL

6. Begin with an empty sterile bag, draw up: Selenium (#4) and Glutamine (#5). Add to the bag and mix.
7. Expiry dating = 96 hours at room temperature.
8. Generate a label and attach to bag.

Version: 3-Jul-09 (EU)
Replaces version: 6-Dec-07 (EU)

Parenteral Supplements Worksheet

Patient CR# / ID#	Patient Initials	Enrolment #

Placebo **Patient will only receive normal saline (or if hypernatremic D5W)**

Begin with a bag containing exactly 250 mL of normal saline (i.e. account for overfill):

1. Volume of Dipeptiven† to be added = **0 mL**
2. Volume of Selenium§ to be added = **0 mL**
3. No mixing needed. The patient will receive a 250 mL bag of normal saline.
4. Record the volume of Normal Saline (=250 mL) on the Parenteral Study Supplement Log, for this patient daily.
5. Generate a label and attach to bag.

†§Dipeptiven and Selenium not required for this treatment arm.

Patient CR# / ID#	Patient Initials	Enrolment #

Parenteral Supplements Worksheet (Patients > 196 cm tall)

l Dipeptiven on the Parenteral Study Supplement Log for this

Placebo **Patient will only receive normal saline (or if hypernatremic D5W)**

Dosing:

1. Dose will consist of a 250mL NS bag with added NS to a final volume as indicated in chart below.
2. **Rate of infusion determined from chart below**

Beginning with a bag of exactly 250 mL of normal saline:

Go to height chart (see below). Record:

1. Patient height = _____ cm
2. Final total volume of the bag (from chart below) = _____ mL
3. Rate to be infused (from chart below) = _____ mL/hr
4. Volume of normal saline to be added = _____ mL

Height	Final total volume of bag	Rate to be infused	Amount of normal saline to be added
196 cm	250 mL	10.4 mL/hr	
198 cm	255 mL	10.6 mL/hr	5 mL
201 cm	263 mL	11.0 mL/hr	13 mL
203 cm	268 mL	11.2 mL/hr	18 mL
206 cm	275 mL	11.5 mL/hr	25 mL
208 cm	280 mL	11.7 mL/hr	30 mL
211 cm	288 mL	12.0 mL/hr	38 mL
213 cm	293 mL	12.2 mL/hr	43 mL

5. Record the volume of Normal Saline (as per final volume on chart above) on the Parenteral Study Supplement Log, for this patient daily.
6. Generate a label and attach to the bag.

Appendix G

Parenteral Study Supplement
Study: REDOXS©
Parenteral Component

For Clinical trial Use Only

Enrollment #:
Patient CR#/ID#:
Patient Name:
Physician:

Date:

Directions: Infuse at 10 mL/hr
Storage: keep between 15-25
Expiry:

Appendix H. Height and Dose of Dipeptiven

Ht (ft in)	Ht (cms)	Dipeptiven mls	Se mls	N/S mls	Total mls
6'0"	183	208	10	32	250
6'1"	185	212	10	28	250
6'2"	188	220	10	20	250
6'3"	191	228	10	12	250
6'4"	193	233	10	7	250
6'5"	196	240	10	---	250
6'6"	198	245	10	---	255
6'7"	201	253	10	---	263
6'8"	203	258	10	---	268
6"9"	206	265	10	---	275
6'10"	208	270	10	---	280
6'11"	211	278	10	---	288
7'0"	213	283	10	---	293