



The **REDOXS**<sup>®</sup> Study  
REDucing DEaths due to OXidative STress

## Pharmacy Logs and Worksheets



### 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 Leader/delegate
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 <sup>α</sup>	____ bottles	____ bottles	
AOX	FK	36 bottles <sup>α</sup>	____ bottles	____ bottles	
GLN	FK	36 bottles <sup>α</sup>	____ bottles	____ bottles	
Placebo	FK	36 bottles <sup>α</sup>	____ bottles	____ bottles	
Selenase(10 ml vials)	Biosyn	40 vials <sup>β</sup>	____ vials	____ vials	

\* based on 4 patients, each needing 2 bottles per day for 10 days

<sup>α</sup> based on 4 patients, each needing 1 bottle per day for 9 days

<sup>β</sup> 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: REDOX<sup>®</sup> Study (613) 549-6666 ext 3830



The REDOX<sup>®</sup> 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: Rupinder Dhaliwal (613) 549-6666 ext 3830



**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



















The REDOX<sup>®</sup> Study  
REDucing Deaths due to OXidative Stress

## Appendices

Appendix A: Pharmacy Web Access Signature Log

Appendix B: Randomization Process on Web

Appendix C: Enteral Study Supplement Label Template

Appendix D: Parenteral Study Supplement Worksheets

Appendix E: Parenteral Study Supplement Label Template

Appendix F: Height and Dose of Dipeptiven



## Pharmacy Web access Signature Log

INSTITUTION:  
INVESTIGATOR:

SITE NUMBER:

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<sup>®</sup> Study.

NAME	TITLE	SIGNATURE	EMAIL	DATE

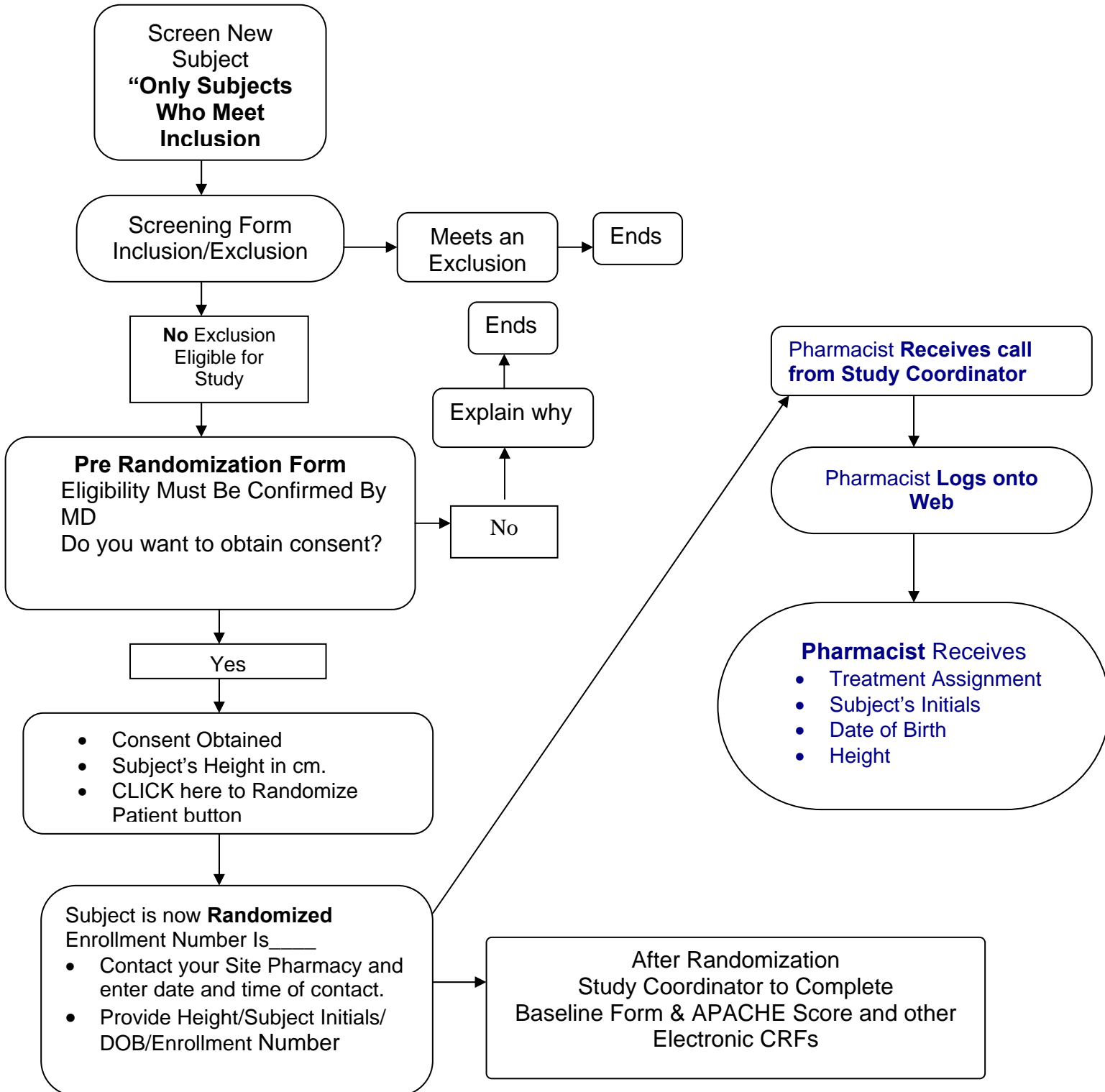
NOTE:

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<sup>®</sup> Study.

Reference: ICH GCP 5.5.3



## Appendix B Randomization Process on Web





The **REDOXS**<sup>®</sup> Study  
REDucing Deaths due to OXidative Stress

## Appendix C

**Enteral Study Supplement**  
**Study: REDOX<sup>®</sup>**  
*Enteral Component*

**For Clinical trial Use Only**

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

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

**Date:**



## **Appendix D**

### **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 Antioxidants (AOX)

### Patient will receive Selenium (Antioxidants) and Normal Saline

Patient ID #: \_\_\_\_\_ Patient Initials: \_\_\_\_\_ Enrollment #: \_\_\_\_\_

1. Patient's height = **Not needed for calculating AOX dose** \_\_\_\_\_ cms
2. Dosing Body Weight = (#1) minus 100 cms = **Not needed** \_\_\_\_\_ kgms
3. Dose of Dipeptiven\* to be added = 0 mL
4. Dose of Selenium to be added = 10 mL  
(Volume to be removed from 250mL normal saline)
5. Total Volume to be removed from 250mL normal saline bag before adding study supplements = 10 mL (add #3 and #4)
6. Add (#3) + (#4) + normal saline = 250 mL
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.

The parenteral study supplements are to be mixed with saline but in the event of concerns of hypernatremia, the supplements can be mixed with D5W instead of saline. Compatibility studies of Dipeptiven and Selenium show that they are compatibility with saline and D5W.



## Parenteral Supplements Worksheet for patients $\geq 196$ cm tall

### Antioxidants (AOX)

Patient CR #: \_\_\_\_\_ Patient Initials: \_\_\_\_\_ Enrollment #: \_\_\_\_\_

#### Dosing:

1. **Dosage of Selenium = 500mcg/day = 10mL/day regardless of height**
2. **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)
3. Dose will be diluted in a normal saline (NS) bag to a final volume indicated in chart below. Inherent overfill of bag to be ignored.

---

Go to Height Chart (see below). Record:

1. Patient Height \_\_\_\_\_ cm
2. Final Total Volume of bag (from chart below) \_\_\_\_\_ ml
3. Rate to be infused (from chart below) \_\_\_\_\_ ml/hr
4. Volume of Selenium to be added \_\_\_\_\_ 10 \_\_\_\_\_ mL
5. Amount of NS to be removed \_\_\_\_\_ mL OR added \_\_\_\_\_ mL  
(circle one)

Height	Final Total Volume of Bag	Rate to be Infused	Volume of Selenium to be added	Amount of NS to be removed	Amount of NS to be added
196 cm	250 mL	10.4 mL/hr	10mL	10 mL	
198 cm	255 mL	10.6 mL/hr	10mL	5 mL	
201 cm	263 mL	11.0 mL/hr	10mL		3 mL
203 cm	268 mL	11.2 mL/hr	10mL		8 mL
206 cm	275 mL	11.5 mL/hr	10mL		15 mL
208 cm	280 mL	11.7 mL/hr	10mL		20 mL
211 cm	288 mL	12.0 mL/hr	10mL		28 mL
213 cm	293 mL	12.2 mL/hr	10mL		33 mL



6. Retrieve 250mL bag of NS and appropriate amount of selenium required.
7. Remove or add appropriate amount from 250mL NS bag.
8. Draw up 10mL Selenium and add to above NS bag. Mix.
9. Final total volume= \_\_\_\_\_ mL (As per chart -Ignore overflow)
10. Infusion rate \_\_\_\_\_ mL/hr.(As per chart)
11. Expiry Dating= 96 hrs at room temperature.
12. Generate a label and attach to bag.
13. Record the volumes of Selenium and NS on the Parenteral Study Supplement Log for this patient daily.



## Parenteral Supplements Worksheet Glutamine (GLN)

Patient will receive Dipeptiven (Glutamine) and normal saline

Patient ID #: \_\_\_\_\_ Patient Initials: \_\_\_\_\_ Enrollment #: \_\_\_\_\_

1. Patient's height = \_\_\_\_\_ cms
2. Dosing Body Weight = (#1) minus 100 cms = \_\_\_\_\_ kgms
3. Dose of Dipeptiven\* to be added = (#2) x 2.5 mL \_\_\_\_\_ mL  
(Volume to be removed from 250mL normal saline)
4. Dose of Selenium to be added =  0  mL
5. Total Volume to be removed from 250 ml normal saline bag before adding study supplements = \_\_\_\_\_ mL (add #3 and #4)
6. Add (#3) + (#4) + normal saline =  250 mL
7. Record the volumes of Dipeptiven 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**

The parenteral study supplements are to be mixed with saline but in the event of concerns of hypernatremia, the supplements can be mixed with D5W instead of saline. Compatibility studies of Dipeptiven and Selenium show that they are compatibility with saline and D5W.



## Parenteral Supplements Worksheet for patients ≥ 196 cm tall Glutamine (GLN)

Patient ID #: \_\_\_\_\_ Patient Initials: \_\_\_\_\_ Enrollment #: \_\_\_\_\_

### Dosing:

- **Dosage of Glutamine** 0.35g/kg/day = L-alanyl-L-glutamine 0.5g/kg/day=  
**Dipeptivan®2.5mL/kg/day**
- **Dosing will be based on patient's Normal Body Weight using Broca Formula as follows:**
  - Normal Weight (kg)= Patient's Height(cm) - 100
- Dose will be diluted in a NS bag to a final volume indicated in chart below. (Volume of NS to be removed from 250mL NS bag = 240mL). Inherent overfill of bag to be ignored.
- **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)

Go to Height Chart (see below). Record:

1. Patient Height \_\_\_\_\_ cm
2. Final Total Volume of bag (from chart below) \_\_\_\_\_ ml
3. Rate to be infused (from chart below) \_\_\_\_\_ ml/hr
4. Volume of Glutamine (Dipeptiven®) to be added \_\_\_\_\_ mL  
(from chart below)

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	250 mL	10.4 mL/hr	240 mL	240 mL
198 cm	255 mL	10.6 mL/hr	245 mL	240 mL
201 cm	263 mL	11.0 mL/hr	253 mL	240 mL
203 cm	268 mL	11.2 mL/hr	258 mL	240 mL
206 cm	275 mL	11.5 mL/hr	265 mL	240 mL
208 cm	280 mL	11.7 mL/hr	270 mL	240 mL
211 cm	288 mL	12.0 mL/hr	278 mL	240 mL
213 cm	293 mL	12.2 mL/hr	283 mL	240 mL



5. Retrieve 250mL bag of NS and appropriate amount of Dipeptiven®  
**NOTE:** Dipeptiven® bottles can be shared between multiple patients if needed. Eg. If one patient needs 150ml Dipeptiven and the next patient needs 130ml please use 3 bottles(100ml each) for both instead of using 4 bottles (100mL each)for both patients. Once opened, the Dipeptiven is to be mixed into the other parenteral components immediately.
6. Remove 240 mL of NS from 250mL NS bag.
7. Draw up \_\_\_\_\_mL of Dipeptiven®(as per chart) and add to above normal saline bag. Mix.
8. Total final volume = \_\_\_\_\_ mL(as per chart -ignore overflow)
9. Infusion rate = \_\_\_\_\_mL/hr (as per chart)
10. Expiry dating = 96 hours at room temperature.
11. Generate a label and attach to bag.
12. Record the volumes of Dipeptiven and Normal Saline on the Parenteral Study Supplement Log for this patient daily.



## Parenteral Supplements Worksheet Antioxidants + Glutamine (AOX+GLN)

Patient will receive Selenium (Antioxidants), Dipeptiven (Glutamine) and normal saline

Patient ID #: \_\_\_\_\_ Patient Initials: \_\_\_\_\_ Enrollment #: \_\_\_\_\_

1. Patient's height = \_\_\_\_\_ cms
2. Normal Body Weight = (#1) minus 100 cms = \_\_\_\_\_ kgms
3. Dose of Dipeptiven\* to be added = (#2) x 2.5 mL \_\_\_\_\_ mL
4. Dose of Selenium to be added = 10 mL mL
5. Total Volume to be removed from 250 ml normal saline bag before adding study supplements = \_\_\_\_\_ mL (add #3 and #4)
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**

The parenteral study supplements are to be mixed with saline but in the event of concerns of hypernatremia, the supplements can be mixed with D5W instead of saline. Compatibility studies of Dipeptiven and Selenium show that they are compatibility with saline and D5W.



## **Parenteral Supplements Worksheet for patients $\geq$ 196 cm tall** **Antioxidants + Glutamine (AOX+GLN)**

Patient ID #: \_\_\_\_\_ Patient Initials: \_\_\_\_\_ Enrollment #: \_\_\_\_\_

### **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:**

$$\text{Normal Weight (kg)} = \text{Patient's Height(cm)} - 100$$

4. Dose will be diluted in a NS bag to a final volume indicated in chart below. Inherent overfill of bag to be ignored.
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)

---

Go to Height Chart (see below). Record:

1. Patient Height \_\_\_\_\_ cm
2. Final Total Volume of bag (from chart below) \_\_\_\_\_ mL
3. Rate to be infused (from chart below) \_\_\_\_\_ ml/hr
4. Volume of Selenium to be added \_\_\_\_\_ 10 \_\_\_\_\_ mL
5. Volume of Glutamine (Dipeptivan®) to be added \_\_\_\_\_ mL  
(from chart below)



Height	Final total volume of bag	Rate to be infused	Volume of Selenium to be added	Volume of Glutamine to be added	Amount of normal saline to be removed
196 cm	250 ml	10.4 mL/hr	10ml	240 ml	250 ml
198 cm	255 ml	10.6 mL/hr	10ml	245 ml	250 ml
201 cm	263 ml	11.0 mL/hr	10ml	253 ml	250 ml
203 cm	268 ml	11.2 mL/hr	10ml	258 ml	250 ml
206 cm	275 ml	11.5 mL/hr	10ml	265 ml	250 ml
208 cm	280 ml	11.7 mL/hr	10ml	270 ml	250 ml
211 cm	288 ml	12.0 mL/hr	10ml	278 ml	250 ml
213 cm	293 ml	12.2 mL/hr	10ml	283 ml	250 ml

- Retrieve 250mL bag of NS and appropriate amount of selenium and Dipeptiven®

**NOTE:** Dipeptiven® bottles can be shared between multiple patients if needed. Eg. If one patient needs 150ml Dipeptiven® and the next patient needs 130ml please use 3 bottles(100ml each) for both instead of using 4 bottles (100mL each)for both patients. Once opened, the Dipeptiven® is to be mixed into the other parenteral components immediately.

- Remove 250mL of NS from a 250mL NS bag.
- Draw up 10mL Selenium and add to above NS bag. Mix.
- Draw up \_\_\_\_\_mL of Dipeptiven®(as per chart) and add to above NS bag. Mix.
- Final total volume= \_\_\_\_\_ mL (As per chart -Ignore overflow)
- Infusion rate \_\_\_\_\_ mL/hr.(As per chart)
- Expiry Dating= 96 hrs at room temperature.
- Generate a label and attach to bag.
- Record the volumes of Dipeptiven, Selenium and Normal Saline on the Parenteral Study Supplement Log for this patient daily.



## Parenteral Supplements Worksheet Placebo

**Patient will only receive normal saline**

Patient ID #: \_\_\_\_\_ Patient Initials: \_\_\_\_\_ Enrollment #: \_\_\_\_\_

1. Patient's height = **Not needed for calculating dose** \_\_\_\_\_ cms
2. Normal Body Weight = (#1) minus 100 cms = **Not needed** \_\_\_\_\_ kgms
3. Dose of Dipeptiven\* to be added = **0** mL
4. Dose of Selenium to be added = **0** mL
5. Total Volume to be removed from 250 ml normal saline bag before adding study supplements = **0** mL (add #3 and #4)
6. No mixing needed. The patient will receive a 250 ml bag of normal saline.
7. Record the volume of Normal Saline (=250 mls) on the Parenteral Study Supplement Log, for this patient daily.
8. Generate a label and attach to bag.

The parenteral study supplements are to be mixed with saline but in the event of concerns of hypernatremia, the supplements can be mixed with D5W instead of saline. Compatibility studies of Dipeptiven and Selenium show that they are compatibility with saline and D5W.



## Parenteral Supplements Worksheet for patients $\geq 196$ cm tall Placebo

Patient ID #: \_\_\_\_\_ Patient Initials: \_\_\_\_\_ Enrollment #: \_\_\_\_\_

### Dosing:

1. Dose will consist of a 250mL NS bag with added NS to a final volume as indicated in chart below. Inherent overfill of bag to be ignored.
2. **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)

Go to Height chart (see below. Record:

1. Patient Height \_\_\_\_\_ cm
2. Final Total Volume of bag (from chart below) \_\_\_\_\_ mL
3. Rate to be infused (from chart below) \_\_\_\_\_ mL
4. Amount of NS to be added to 250mL bag \_\_\_\_\_ 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	0 mL
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. Retrieve 250mL bag of normal saline.
6. Add \_\_\_\_\_ mL normal saline to the above 250mL NS bag.
7. Final total volume= \_\_\_\_\_ mL (As per chart -Ignore overfill)
8. Infusion rate \_\_\_\_\_ mL/hr.(As per chart)
9. Expiry Dating= 96 hrs at room temperature.



The **REDOXS**<sup>®</sup> Study  
REDucing Deaths due to OXidative Stress

10. Record the volume of Normal Saline on the Parenteral Study Supplement Log, for this patient daily.
11. Generate a label and attach to bag.



The REDOX<sup>®</sup> Study  
REDucing Deaths due to OXidative Stress

## Appendix E

**Parenteral Study Supplement**  
**Study: REDOX<sup>®</sup>**  
***Parenteral Component***

**For Clinical trial Use Only**

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

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

**Date:**



## Appendix F. 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