



The **REDOXS**[®] 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 Assistant |
|---|----------|-------------------------|-----------------|---------------|-----------------------------------|
| Dipeptiven (100 ml bottles) (10 bottles per carton) | Calea | 80 bottles* | ____ bottles | ____ bottles | |
| EN REDOXS formula (500 mls bottles) (12 bottles per carton) | | | | | |
| AOX + GLN | Calea | 36 bottles ^α | ____ bottles | ____ bottles | |
| AOX | Calea | 36 bottles ^α | ____ bottles | ____ bottles | |
| GLN | Calea | 36 bottles ^α | ____ bottles | ____ bottles | |
| Placebo | Calea | 36 bottles ^α | ____ bottles | ____ bottles | |
| Selenium (10 ml vials) | Baxter | 50 vials ^β | ____ vials | ____ vials | |

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

^α based on 4 patients, each needing 1 bottle per day for 9 days

^β based on 4 patients, each needing approximately 1.5 vials/day per day for 8 days

Signature of person completing log: _____

Date _____

Fax completed form to: CERU (613) 548-2428

Attention: REDOX[®] Study (613) 549-6666 ext 6686 or 4847



The REDOX[®] 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 |
|------|------------------------------------|--|--------------------------------------|------|------------------------------------|--|--------------------------------------|
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| 15 | | | | 30 | | | |
| | | | | 31 | | | |

Signature of person submitting log: _____

Fax completed form to: CERU (613) 548-2428
Attention: REDOX[®] 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 CR #/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 CR #/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 |
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Parenteral Study Supplement Dispensing Log

Page ___ of ___

To be filled out by Pharmacist

Patient CR #/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)

| Date | Dipeptiven | | Selenium | | Saline | | | Signatures | |
|------|------------|----------------|------------|----------------|------------|----------------|--------------|-------------|------------|
| | dose (mls) | Lot # & expiry | dose (mls) | Lot # & expiry | dose (mls) | Lot # & expiry | Manufacturer | Prepared by | Checked by |
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Audited by: _____



Nutrient Accountability Log Enteral AOX

Site #: _____

To be filled out by Pharmacist

| Date | Quantity received or destroyed | Lot # | Expiry date | Quantity dispensed | Patient enrollment # | Balance of Product | Signature |
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Nutrient Accountability Log *Enteral GLN*

Site #: _____

To be filled out by Pharmacist

| Date | Quantity received or destroyed | Lot # | Expiry date | Quantity dispensed | Patient enrollment # | Balance of Product | Signature |
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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 |
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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 |
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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 |
|------|--------------------------------|-------|-------------|--------------------|----------------------|--------------------|-----------|
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Audited by: _____



Nutrient Accountability Log Selenium

Site #: _____

To be filled out by Pharmacist

| Date | Quantity received or destroyed | Lot # | Expiry date | Quantity dispensed | Patient enrollment # | Balance of Product | Signature |
|------|--------------------------------|-------|-------------|--------------------|----------------------|--------------------|-----------|
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Audited by: _____



The REDOX[®] Study
REDucing Deaths due to OXidative Stress

Appendices

Appendix A: Site Investigator Delegation of Authority Log

Appendix B: Pharmacy Training/Delegation of Authority Log

Appendix C: Pharmacy Web Access Signature Log

Appendix D: Randomization Process on Web

Appendix E: Enteral Study Supplement Label Template

Appendix F: Parenteral Study Supplement Worksheets

Appendix G: Parenteral Study Supplement Label Template

Appendix H: Height and Dose of Dipeptiven



Appendix A.



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 write/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, Nurse) | Key Delegated Tasks (see next page) | Dates | |
|------------|-----------|----------|---|--|-------|-----|
| | | | | | Start | End |
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*Qualified Investigator: the Site Investigator responsible for the conduct of the REDOX[®] study at your site.
 *Sub QI: Investigator other than the Qualified Investigator that is responsible for tasks related to the REDOX[®] study at your site.



Appendix B



Pharmacy Training/Delegation Log

| | |
|--|---|
| This log (or a similar log) is used by the Pharmacist at each site to: 1) Indicate the pharmacy staff that have been delegated duties/tasks related to The REDOX [®] Study and 2) Ensure that all pharmacy staff that have a material effect on The REDOX [®] 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. | Key Delegated Tasks 1. Maintenance of Study Product Inventory Logs and Receipt Forms 2. Checking of Treatment Assignments online (vtrials.com/medkit.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 REDOX 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 |
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*Pharmacy contact is the main pharmaceutical delegate that has been trained by the Methods Centre to carry out all pharmacy tasks related to the REDOX Study at the site.



The REDOX[®] Study
Reducing Deaths due to Oxidative Stress

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 REDOX[®] Study.

| NAME | TITLE | SIGNATURE | EMAIL | DATE |
|------|-------|-----------|-------|------|
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NOTE:

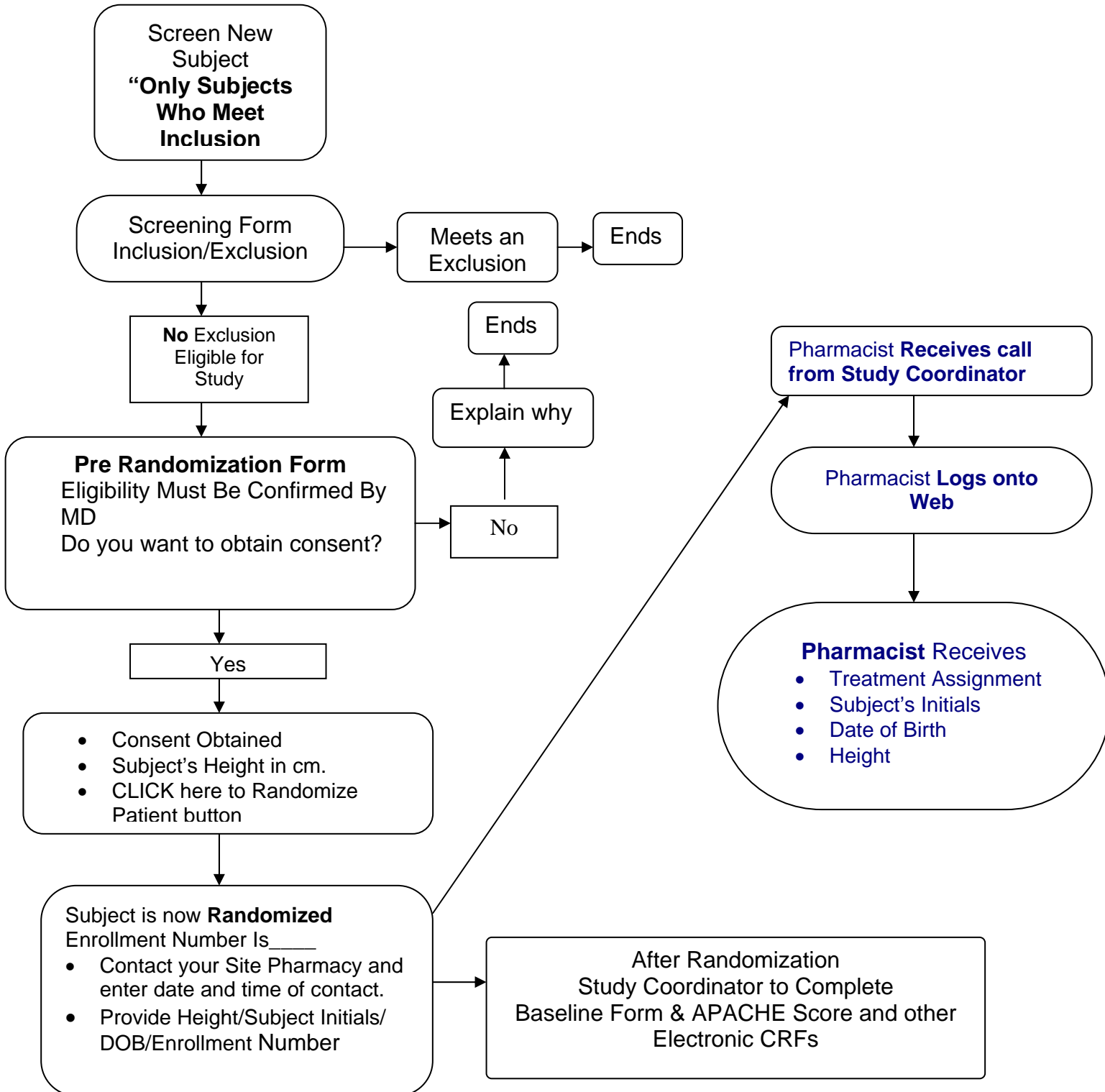
By completing the information in the table above, the individual confirms they have been delegated the responsibility of checking the randomization and dispensing/verifying study supplements for the REDOX[®] Study.

The individual agrees to keep their password confidential to prevent unauthorized access to the data.

Reference: ICH GCP 5.5.3



Appendix D Randomization Process on Web





The REDOX[®] Study
REDucing Deaths due to OXidative Stress

Appendix E

Enteral Study Supplement
Study: REDOX[®]
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 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 needed.

Worksheet for Antioxidants (AOX)

Worksheet for Glutamine (GLN)

Worksheet for (Antioxidant + Glutamine) AOX + GLN

Worksheet for Placebo



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

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 (cm) | Dipeptiven mL | Se mL | N/S mL | Total mL |
|------------|---------|------------------|----------|-----------|-------------|
| 6'0" | 183 | 208 | 12.5 | 30 | 250 |
| 6'1" | 185 | 212 | 12.5 | 25 | 250 |
| 6'2" | 188 | 220 | 12.5 | 18 | 250 |
| 6'3" | 191 | 228 | 12.5 | 10 | 250 |
| 6'4" | 193 | 233 | 12.5 | 5 | 250 |
| 6'5" | 196 | 240 | 12.5 | --- | 253 |
| 6'6" | 198 | 245 | 12.5 | --- | 258 |
| 6'7" | 201 | 253 | 12.5 | --- | 266 |
| 6'8" | 203 | 258 | 12.5 | --- | 271 |
| 6'9" | 206 | 265 | 12.5 | --- | 278 |
| 6'10" | 208 | 270 | 12.5 | --- | 283 |
| 6'11" | 211 | 278 | 12.5 | --- | 291 |
| 7'0" | 213 | 283 | 12.5 | --- | 296 |