

# Protocol Violation Form

The REDOXS<sup>®</sup> Study

## Instructions

1. A protocol violation form does not need to be completed on the following days:
    - (a) day of randomization
    - (b) days subsequent to the day of mechanical ventilation discontinuation (and feeding tube removal)
    - (c) day of discharge from the ICU (unless the patient has received less than 5 days of study supplements)
    - (d) day of death
  2. Complete the Protocol Violation Form.
  3. Use the PRINT FORM button at the bottom of the page to print a copy and file with the patient's study file.
  4. Return to the Project Leader by clicking on the SUBMIT BY EMAIL button at the bottom of the page.
- (If the form is printed then completed with hand written responses, it can be faxed back to the Project Leader at (613) 548-2428.)

Site #: \_\_\_\_\_ Study Coordinator Reporting: \_\_\_\_\_

Patient Enrolment #: \_\_\_\_\_ Site Investigator: \_\_\_\_\_

Date violation occurred: \_\_\_\_\_ Time violation occurred (24 hour clock): \_\_\_\_\_

Date violation discovered: \_\_\_\_\_ Time violation discovered (24 hour clock): \_\_\_\_\_

### Type of violation: (check one or both)

**Enteral Supplement < 80%**  
(< 384 mls/day)

**Parenteral Supplement < 90%**  
(< 216 mls/day \*exceptions height  $\geq$  196 cm)

Is the local Site Investigator aware of the violation?  Yes

No If No, explain:

### 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):<br>_____ |   |

### Action Taken by Study Coordinator (check all that apply):

Enteral Feeding Protocol reviewed:  Yes  No

Motility agents recommended:  Yes  No

Small bowel feeding recommended:  Yes  No

Rate of supplements doubled:  Yes  No

Comments:

## For CERU use only

Further action required:  Yes  No

Reviewed By: \_\_\_\_\_

Date Reviewed: \_\_\_\_\_

Action to be Taken: