



Protocol Violation Form

Study Coordinator Reporting: _____ Site Investigator _____

Date and time violation occurred:

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dd mmm yyyy 24 hr clock

Date and time violation discovered:

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

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: _____

Complete this form and fax to Project Leader, REDOX[®] study at 613-548-2428 within 24 hours of becoming aware of the Protocol Violation.



Enteral Feeding Protocol

