



Randomization Number \_\_\_\_\_

## Protocol Violation Form

Page #: \_\_\_\_\_

Date violation occurred (yyyy-mm-dd) \_\_\_\_\_

Date violation discovered (yyyy-mm-dd) \_\_\_\_\_

Is the local site investigator aware of the violation?  Yes  No

Protocol Violation # \_\_\_\_\_ for this date

- 1) Dose delivered is <80% prescribed over a 3 day average: \_\_\_\_\_ % received on indicated day  
\_\_\_\_\_ % received over 3 day average
- 2) Dispensing/Dosing error
- 3) Accidental unblinding
- 4) Enrollment of ineligible patient
- 5) Open label glutamine given
- 6) Unapproved EN formula given
- 7) Other, please specify: \_\_\_\_\_  
\_\_\_\_\_

Reason for violation (check all that apply)

- High gastric residual volumes
- Bowel perforation/obstruction
- Held for procedure/OR
- Other, specify details or attach Note to File/Incident Report: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Action taken by Research Coordinator/Responsible Delegate Feeding protocol reviewed, RN education, REB notification, Note To File, etc...  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

For CERU use only:

Date reviewed: \_\_\_\_\_

Reviewed by: \_\_\_\_\_

Further action required:  Yes  No

Action to be taken: \_\_\_\_\_  
\_\_\_\_\_