Protocol Violation/Incident Form

Date violation/incident occurred: D M M 20 Y
Date violation/incident discovered: D M M 20 Y

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

What are you reporting (check one)?

Protocol Violation # [ ] for this date
- 1) Dose delivered is <80% prescribed: ___ of ___ packets received
- 2) Dispensing/Dosing error
- 3) Accidental unblinding
- 4) Enrollment of ineligible patient
- 5) Unapproved procedures performed
- 6) 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:

Incident Report # [ ] for this date

Unanticipated problems (involving risk to subjects or others participating in the study)
Please specify: ____________________________

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

Action to be taken: ____________________________

For CERU use only:
Date reviewed: D M M 20 Y
Reviewed by: ____________________________

Further action required: Yes No

Version: Aug 17, 2011
**Protocol Violation Instructions**

<table>
<thead>
<tr>
<th>Protocol Violation Definition</th>
<th>A Protocol Violation is defined as non-compliance with the study protocol and/or procedures that may impact study participant safety, the integrity of study data and/or study participant willingness to participate in the study.</th>
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| Incident Reports            | **For THE RE-ENERGIZE Study, a Protocol Violation occurs when any of the following have occurred:**  
  1) Investigational Product (IP) Daily dose delivered is < 80% prescribed.  
     Example: if the daily dose is 5 packages and the daily dose delivered is less than 4 packets (80%), this is a protocol violation.  
  2) IP dispensing/dosing error  
  3) Accidental unblinding of IP  
  4) Enrollment of a patient that does not fulfill inclusion/exclusion criteria  
  5) Unapproved procedures performed  
  6) Other, please specify in the space provided. |
| General Instructions        | All **unanticipated problems** involving risk to subjects or others participating in the study MUST be reported to the Project Leader for reporting to the Department of Defense. These are to be reported as Incident Reports. |
| When to report              | Complete Protocol Violation forms and fax a copy to the Project Leader at (613) 548-2428 within 24 hours of becoming aware of the violation. |
| Date Violation/incident     | Enter the date when the violation/incident occurred. |
| Incident Occurred/Discovered | Enter the date when the violation/incident was identified by site research staff. |
| Local Investigator Aware?   | Indicate whether the local qualified investigator has been made aware of this violation/incident, Yes or No. |
| Protocol Violation or Incident | Check the box to indicate whether you are reporting a Protocol Violation or Incident |
| PV/Incident #               | Enter the number of the protocol violation or incident being reported for the date specified |
| Type of violation or incident | Using the options provided, check the box for the type of violation/incident:  
  ♦ Dose delivered is <80% prescribed (according to # packets given).  
  ♦ Dispensing/dosing error (an incorrect dose/product was given to patient)  
  ♦ Accidental unblinding (the integrity of the study blind has been compromised)  
  ♦ Enrollment of a patient that does not fulfill inclusion/exclusion criteria  
  ♦ Unapproved procedures performed (failure to obtain consent, taking blood draw on an extra day, etc)  
  ♦ Other, please specify (briefly describe the type of protocol violation)  
  ♦ Incident Reports (involves risk to subjects or others participating in the study) |
| Reason for the Violation    | Check the appropriate box and briefly describe the reason for the violation on the lines provided. Describe the circumstances surrounding these violations. |
| Action taken by Research Coordinator | Describe the action taken by the Research Coordinator/responsible delegate to prevent violation/problem from recurring. |