

July 25, 2008

## FORMS PACKET

N06CA, The Use of Topical Baclofen, Amitriptyline HCl, and Ketamine (BAK) in a PLO Gel vs. Placebo for the Treatment of Chemotherapy Induced Peripheral Neuropathy: A Phase III Randomized Double-Blind Placebo Controlled Study

- Contents:
- ✓ Eligibility checklist (7/25/2008)
  - ✓ Continuation phase eligibility checklist (7/25/2008)
    - On-study form (4/8/2008)
    - Baseline adverse events form (9/10/2007)
    - Adverse event form (9/10/2007)
    - Concurrent treatment form (baseline) (9/10/2007)
    - Concurrent treatment form (active monitoring phase) (2/8/2008)
    - Evaluation/treatment form (2/8/2008)
    - End of active treatment/cancel notification form (2/12/2008)
  - ✓ Continuation Phase Rochester Patients Only Optional Collection Blood Specimen Submission Form (7/15/2008)
    - Patient Questionnaire Booklet Compliance Form (2/12/2008)
    - Grade 4 or 5 non-AER reportable events/hospitalization form (1/30/2008)
    - Booklet order form (2/22/2008)
  - \* N06CA forms completion instructions (2/14/2008)

✓ Designates new/revised form.

\*Generic forms completion instructions are available on the NCCTG web site under “the CRA link in the Remote Registration and Data Entry section and are titled “Remote Data Entry Screen Instructions (Forms Completion).”

The specific forms instructions take precedence over the generic forms instructions, so it is very important to review them in addition to the generic forms instructions.

NORTH CENTRAL CANCER TREATMENT GROUP  
N06CA Eligibility Checklist

7/25/2008  
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**N06CA: The Use of Topical Baclofen, amitriptyline HCl, and Ketamine (BAK) in a PLO Gel vs. Placebo for the Treatment of Chemotherapy Induced Peripheral Neuropathy: A Phase III Randomized Double-Blind Placebo Controlled Study**

***This study is open to RMC Patients only. To register a patient, access the NCCTG web page at <https://ncctg.mayo.edu/training> and enter the remote registration/randomization application.***

Has the patient ever been on a prior study entered through this Registration Office?  Yes  No

If yes: Prior study number \_\_\_\_\_; prior patient study ID number \_\_\_\_\_

Registration date (date on) (mm/dd/yyyy) __ __ / __ __ / __ __ __ __
Patient study ID number (provided at time of Reg/Random) _____
NCCTG member (participant sponsor) _____
NCCTG treating location _____
NCCTG treating physician/Allied health professional _____
Institution patient number (local subject number) _____
IRB approval date (mm/dd/yyyy) __ __ / __ __ / __ __ __ __

Patients initials (last, first, middle) _____ (For Mayo Rochester patients, include first four letters of last name.)	Race (check all that apply)
Gender (check one) <input type="checkbox"/> Male <input type="checkbox"/> Female <input type="checkbox"/> Unknown	<input type="checkbox"/> White
Patient's Date of Birth (mm/dd/yyyy) __ __ / __ __ / __ __ __ __	<input type="checkbox"/> Black or African American
Patient's Zip code (USA) _____	<input type="checkbox"/> Native Hawaiian or Other Pacific Islander
Country of Residence (if not USA) _____	<input type="checkbox"/> Asian
Method of payment (check one)	<input type="checkbox"/> American Indian or Alaska Native
<input type="checkbox"/> PI (Private Insurance)	<input type="checkbox"/> Not reported: Patient refused or data not available
<input type="checkbox"/> MR (Medicare)	<input type="checkbox"/> Unknown: Patient is unsure of race
<input type="checkbox"/> MRP (Medicare and Private Insurance)	
<input type="checkbox"/> MD (Medicaid)	Ethnicity (check one)
<input type="checkbox"/> MM (Medicaid and Medicare)	<input type="checkbox"/> Not Hispanic or Latino
<input type="checkbox"/> MVA (Military or Veterans Sponsored, Not Otherwise Specified (NOS))	<input type="checkbox"/> Hispanic or Latino
<input type="checkbox"/> MS (Military Sponsored [including CHAMPUS & TRCARE])	<input type="checkbox"/> Not reported: Patient refused or data not available
<input type="checkbox"/> MV (Veterans Sponsored)	<input type="checkbox"/> Unknown: Patient is unsure of their ethnicity
<input type="checkbox"/> SP (Self pay [no insurance])	
<input type="checkbox"/> NP (No means of payment [no insurance])	
<input type="checkbox"/> OTH (Other)	
<input type="checkbox"/> UNK (Unknown)	

NCCTG Eligibility Checklist N06CA

7/25/2008  
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Patient study ID number \_\_\_\_\_

Eligibility Check - Answer questions below (yes/no). All requirements must be confirmed. All dates are to be *mm/dd/yyyy*.

**Required Characteristics**

Yes No NA

Received, or are currently receiving, neurotoxic chemotherapy (including but not limited to taxanes such as paclitaxel or docetaxel; platinum-based compounds such as carboplatin, cisplatin, or oxaliplatin; or vinca alkaloids such as vincristine or vinblastine, or other neurotoxic chemotherapy agents such as bortezomib, lenalidomide or thalidomide). <b>Note:</b> Patients on daily chemotherapy will not be eligible for this trial.	_____	_____	
Pain or symptoms of peripheral neuropathy of duration $\geq$ 1 month attributed to chemotherapy.	_____	_____	
A score of $\geq$ 4 out of 10 on the numbness/tingling/pain numeric analogue scale (see Appendix VII). Score: _____	_____	_____	
$\geq$ 18 years of age. Age = _____.	_____	_____	
Ability to sign informed consent and understand the nature of a placebo-controlled trial.	_____	_____	
ECOG Performance Status (PS) of 0, 1, or 2. PS = _____.	_____	_____	
Ability to complete questionnaires by themselves or with assistance.	_____	_____	
Life expectancy $\geq$ 4 months.	_____	_____	
Creatinine $\leq$ 1.5 X UNL obtained $\leq$ 90 days prior to registration. Creatinine = _____; UNL = _____ Creatinine Date ( <i>mm/dd/yyyy</i> ): ____ / ____ / ____	_____	_____	
Neuropathy limited to either hands or feet (or both) where gel can be applied.	_____	_____	
Women who are not able to bear children. Note: This is defined by those who are menopausal (12 months and no menstrual period if natural menopause), have had a hysterectomy and/or oophorectomy, permanent surgical sterilization (tubal ligation).	_____	_____	

**All responses in above section must be “Yes” unless specified as “NA.”**

**Contraindications**

Yes No NA

Pre-existing or history of peripheral neuropathy due to any cause other than chemotherapy (diabetes, alcohol, toxin, hereditary, etc.).	_____	_____	
History of an allergic reaction to amitriptyline HCl, baclofen, and/or ketamine.	_____	_____	
Treatment $\leq$ 30 days with anticonvulsants, tricyclic antidepressants, MAO inhibitor, or other neuropathic pain medication agents such as carbamazepine, phenytoin, valproic acid, gabapentin, lamotrigine, topical lidocaine patch or gel, capsaicin cream, amifostine, etc. <b>Note:</b> Patients who have taken any of these agents for peripheral neuropathy for $\leq$ 1 week during the past 30 days, but are no longer taking the agent, are not excluded.	_____	_____	
Diagnosis of coronary artery disease including but not limited to MI, PTCA, or CABG $\leq$ 5 years or diagnosis of congestive heart failure of any NY heart class I-IV. <b>Note:</b> Valve replacements are permitted as long as patient has fully recovered from the surgery.	_____	_____	
Other medical conditions, which in the opinion of the treating physician/allied health professional would make this protocol unreasonably hazardous for the patient.	_____	_____	
Current use of any of the study agents in any manner.	_____	_____	
Skin abnormalities at the intended application sites (hands and feet) of study gel (i.e.: skin breakdown)	_____	_____	
Any of the following: <ul style="list-style-type: none"> <li>• Pregnant</li> <li>• Nursing women</li> <li>• Women of childbearing potential</li> </ul>	_____	_____	

**All responses in above section must be “No” unless specified as “NA.”**

NCCTG Eligibility Checklist N06CA

7/25/2008  
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Patient study ID number \_\_\_\_\_

Registration Check - Answer questions below (yes/no). All requirements must be confirmed. All dates are to be mm/dd/yyyy.

	Yes	No	NA
Consent form signed and dated. Date of consent ___/___/____.	___	___	___
Authorization for use and disclosure of protected health information signed and dated. <b>Non-USA institution only</b> (check NA) vs. Date of authorization ___/___/____.	___	___	___
Treatment on this protocol must commence at the accruing membership under the supervision of an NCCTG member physician or allied health professional.	___	___	___
Treatment cannot begin prior to registration and must begin ≤28 days after registration.	___	___	___
Pretreatment tests/procedures (see Section 4.0) must be completed ≤30 days prior to registration. Earliest pretreatment test date ___/___/____; latest pretreatment test date ___/___/____	___	___	___
All required baseline symptoms (see Section 10.3) must be documented and graded.	___	___	___
Study drug availability is checked.	___	___	___
Patient questionnaire booklet availability checked; copies are not acceptable for this submission.	___	___	___
<b>Translational Research (Mayo Clinic Rochester patients only):</b> An optional translational research component is part of the Continuation Phase of the study for Mayo Clinic Rochester patients only. There will be an option to select if the patient is to be registered onto this component (Section 14.0). • Patient has/has not given permission to give a blood sample for research testing. <b>Not a Mayo Clinic Rochester Patient</b> (check NA).	___	___	___

All responses in above section must be “Yes” unless specified as “NA.”

Stratification Factors

Chemotherapy with a neurotoxic agent (select one):

- \_\_\_ Active (completed)
- \_\_\_ Non-active (discontinued)

Use of opioids or oral pain medications (select one):

- \_\_\_ Yes
- \_\_\_ No

Eligibility Pain Rating (select one – see Section 3.13 and Appendix VII):

- \_\_\_ 4 - 7
- \_\_\_ 8 – 10

Previous ineffective pharmacologic treatment for peripheral neuropathy (select one):

- \_\_\_ Yes
- \_\_\_ No

Assigned Treatment

\_\_\_\_\_ Amitriptyline HCL/baclofen/ketamine gel vs. placebo

Person registering \_\_\_\_\_ Signature Reg. office specialist \_\_\_\_\_ initials

Physician \_\_\_\_\_ Signature \_\_\_\_\_ M - D - Y

**N06CA: The Use of Topical Baclofen, amitriptyline HCl, and Ketamine (BAK) in a PLO Gel vs. Placebo for the Treatment of Chemotherapy Induced Peripheral Neuropathy: A Phase III Randomized Double-Blind Placebo Controlled Study**

***This study is open to MCR patients only. If the patient and physician want to continue with the active gel, or if on the placebo, begin the active gel, call (507/248-4130) or fax (507/284-0885) a completed continuation phase eligibility checklist to the Registration Office between 8 a.m. and 4:30 p.m. central time Monday through Friday.***

Has the patient ever been on a prior study entered through this Registration Office? \_\_\_\_ Yes \_\_\_\_ No

If yes: Prior study number \_\_\_\_\_; prior patient study ID number \_\_\_\_\_

Registration date (date on) (mm/dd/yyyy) __ __/__ __/__ __ __ __
Patient study ID number (provided at time of Reg/Random) _____
NCCTG member (participant sponsor) _____
NCCTG treating location _____
NCCTG treating physician/allied health professional _____
Institution patient number (local subject number) _____
IRB approval date (mm/dd/yyyy) __ __/__ __/__ __ __ __

Patient study ID number \_\_\_\_\_

Eligibility Check - Answer questions below (yes/no). All requirements must be confirmed. All dates are to be mm/dd/yyyy.

**Registration Check**

Yes No

The double-blind phase of the study must be completed prior to the treatment code being broken; that is, after the treating site has received the completed patient questionnaire booklet.	____	____
--	------	------

**All responses in above section must be "Yes"**

Assigned Treatment

\_\_\_\_\_ Amitriptyline HCL/baclofen/ketamine gel

Person registering \_\_\_\_\_ Signature \_\_\_\_\_ Registration Office Specialist \_\_\_\_\_ initials

Physician \_\_\_\_\_ Signature \_\_\_\_\_ M D Y

PLACE LABEL HERE

**NORTH CENTRAL CANCER TREATMENT GROUP**

Protocol Number:   N06CA  

**ON-STUDY FORM**

Patient ID Number: \_\_\_\_\_ Patient Initials: \_\_\_\_\_

L F M

Institution Number: \_\_\_\_\_

Institution: \_\_\_\_\_

**ALL ITEMS MUST BE COMPLETED**

**Are data amended? (check one)**  Yes  No  
*(if data are amended, please circle in red when using paper form)*

MedDRA code: 10007423 (*Carcinoma NOS*)

Primary Tumor Site: \_\_\_\_\_

Status Of Primary Tumor: (*check one*)

Distant Metastases: (*check all that apply*)

- 1  Resected with no residual
- 2  Resected with known residual
- 3  Unresected
- 4  Recurrent

- Abdominal
- Bone
- Brain
- (Sub)cutaneous
- Liver
- Lung
- Nodal
- Other, \_\_\_\_\_

Weight (kg): \_\_\_\_ . \_\_\_\_

**Chemotherapy**

Neurotoxic chemotherapy agent exposure (*check all that apply*)

- |   |                |                                     |                                       |
|---|----------------|-------------------------------------|---------------------------------------|
| <input type="checkbox"/> Oxaliplatin            | If applicable: | 1 <input type="checkbox"/> Previous | 2 <input type="checkbox"/> Concurrent |
| <input type="checkbox"/> Vincristine:           | If applicable: | 1 <input type="checkbox"/> Previous | 2 <input type="checkbox"/> Concurrent |
| <input type="checkbox"/> Other vinca alkaloids: | If applicable: | 1 <input type="checkbox"/> Previous | 2 <input type="checkbox"/> Concurrent |
| <input type="checkbox"/> Taxanes:               | If applicable: | 1 <input type="checkbox"/> Previous | 2 <input type="checkbox"/> Concurrent |
| <input type="checkbox"/> Platinums              | If applicable: | 1 <input type="checkbox"/> Previous | 2 <input type="checkbox"/> Concurrent |
| <input type="checkbox"/> Thalidomide:           | If applicable: | 1 <input type="checkbox"/> Previous | 2 <input type="checkbox"/> Concurrent |
| <input type="checkbox"/> Other, specify _____   | If applicable: | 1 <input type="checkbox"/> Previous | 2 <input type="checkbox"/> Concurrent |

Duration of pain or neuropathy symptoms in months at baseline: (*check one*)

- 1  1 to ≤3
- 2  >3 to ≤6
- 3  >6

Exposure to neurotoxic agents over lifetime (*check one*)    1  Single agent    2  Multiple agents

Gender: (*check one*)    1  Male    2  Female

Age: (*check one*)    1  <70    2  ≥70

Neurotoxicity Evaluation (*see Appendix XI*) (*check one*)

- 1  Grade I (loss of deep tendon reflexes or paresthesia, including tingling, but not interfering with function)
- 2  Grade II (objective sensory alteration or paresthesia, including tingling, interfering with function, but not with activities of daily living)
- 3  Grade III (sensory alteration or paresthesia interfering with activities of daily living)
- 4  Grade IV (permanent sensory losses that are disabling)

PLACE LABEL HERE

**NORTH CENTRAL CANCER TREATMENT GROUP**

Protocol Number: N06CA

Patient ID: \_\_\_\_\_ Patient Initials: \_\_\_\_\_

L F M

Institution Number: \_\_\_\_\_

Institution: \_\_\_\_\_

**BASELINE  
ADVERSE EVENTS FORM**

**ALL ITEMS MUST BE COMPLETED**

Are data amended? (*check one*)  Yes  No  
(if data are amended, please circle in red when using paper form)

<b>Required Baseline Adverse Events from Section 10.0 of Protocol</b>		
<b>CTC Adverse Events Term</b>	<b>MedDRA Code (v. 10.0)</b>	<b>CTC Adverse Event Grade</b>
Rash: hand-foot skin reaction	10019126	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3
Constipation	10010774	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4
Dry mouth/salivary gland (xerostomia)	10013781	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3
Confusion	10010300	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4
Somnolence/depressed level of consciousness	10012373	<input type="checkbox"/> 0 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4

PLACE LABEL HERE

**NORTH CENTRAL CANCER TREATMENT GROUP**

Protocol Number: N06CA

Patient ID: \_\_\_\_\_ Patient Initials: \_\_\_\_\_

L F M

Institution Number: \_\_\_\_\_

Institution: \_\_\_\_\_

**ADVERSE EVENT FORM**

**ALL ITEMS MUST BE COMPLETED**

Pg. 1 of 2

**Are data amended? (check one)**  Yes  No  
*(if data are amended, please circle in red when using paper form)*

Current Cycle Number (*adverse events associated with this cycle*): \_\_\_\_\_

Evaluation Date: (*mm/dd/yyyy*) \_\_\_\_/\_\_\_\_/\_\_\_\_

NOTE: Cycle 1 = Week 1  
 Cycle 2 = Week 2  
 Cycle 3 = Week 3  
 Cycle 4 = Week 4, etc.

CTC Adverse Event Term	MedDRA Code (v. 10.0) (must be completed)	CTC Adverse Event Grade (highest grade this cycle)  <b>INCLUDE GRADE 0's</b>	CTC AE Attribution Code (If Grade > 0)  1 = Unrelated 2 = Unlikely 3 = Possible 4 = Probable 5 = Definite	Has an adverse event expedited report been submitted?*( Enter 1 for Yes or 2 for No)
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**Required Adverse Events from Section 10.0 of Protocol**

Rash: hand-foot skin reaction	10019126	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	_____
Constipation	10010774	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 (death)	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	_____
Dry mouth/salivary gland (xerostomia)	10013781	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	_____
Confusion	10010300	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 (death)	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	_____
Somnolence/depressed level of consciousness	10012373	<input type="checkbox"/> 0 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 (death)	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	_____

\* See Section 10.0 of the protocol.

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

Protocol Number: N06CA

Patient ID: Patient Initials: L F M

Institution Number:

Institution:

ADVERSE EVENT FORM

ALL ITEMS MUST BE COMPLETED

Pg. 2 of 2

Are data amended? (check one) Yes No (if data are amended, please circle in red when using paper form)

Current Cycle Number (adverse events associated with this cycle):

NOTE: Cycle 1 = Week 1, Cycle 2 = Week 2, Cycle 3 = Week 3, Cycle 4 = Week 4, etc.

Were (other) adverse events assessed during this report period?

1 Yes, and reportable adverse events occurred

3 Yes, but no reportable adverse events occurred (Stop here)

2 No (Stop here)

Adverse Events\*\* beyond those required in Section 10.0 of the protocol. Record grade 2 with attribution of possible, probable or definite and all grade 3, 4 and 5 regardless of attribution.

Table with 5 columns: Other CTC Adverse Event Terms not listed, MedDRA Code (v. 10.0) (must be completed), CTC Adverse Event Grade (highest grade this cycle), CTC AE Attribution Code (If Grade > 0), Has an adverse event expedited report been submitted?\*

\* See Section 10.0 of the protocol.

\*\* Both hematologic and nonhematologic Adverse Events must be graded on this form as applicable.

PLACE LABEL HERE

**NORTH CENTRAL CANCER TREATMENT GROUP**

**CONCURRENT TREATMENT FORM  
(BASELINE)**

**ALL ITEMS MUST BE COMPLETED**

**Are data amended? (check one)**  Yes  No  
*(if data are amended, please circle in red when using paper form)*

Protocol Number: N06CA

Patient ID: \_\_\_\_\_ Patient Initials: \_\_\_\_\_  
L F M

Institution Number: \_\_\_\_\_

Institution: \_\_\_\_\_

Evaluation Date: (mm/dd/yyyy) \_\_\_/\_\_\_/\_\_\_\_\_

Concomitant medications? (check one)

1  Yes      2  No (Stop here)

If yes, enter all medications (including prescription, over-the-counter, and alternative medications).

Concomitant Treatment	Dose and Schedule	Reason for Use

PLACE LABEL HERE

**NORTH CENTRAL CANCER TREATMENT GROUP**

**CONCURRENT TREATMENT FORM  
(ACTIVE MONITORING PHASE)**

**ALL ITEMS MUST BE COMPLETED**

**Are data amended? (check one)**  Yes  No  
*(if data are amended, please circle in red when using paper form)*

Protocol Number: N06CA

Patient ID: \_\_\_\_\_ Patient Initials: \_\_\_\_\_

L F M

Institution Number: \_\_\_\_\_

Institution: \_\_\_\_\_

Current Cycle Number: \_\_\_\_\_

Evaluation Date: (mm/dd/yyyy) \_\_\_/\_\_\_/\_\_\_\_\_

Has there been any change in medications since the previous visit?

1  Yes      2  No (*Stop here*)

NOTE: Cycle 1 = Week 1  
Cycle 2 = Week 2  
Cycle 3 = Week 3  
Cycle 4 = Week 4, etc.

If Yes, enter all medications (*including prescription, over-the-counter, and alternative medications*) that have not been previously reported, no longer being taken, or have a dose and/or schedule change.

Concomitant Treatment	Reason for entry: 1=New medication 2=Medication no longer being taken 3=Dose and /or schedule change	Dose and Schedule	Reason for Use
	_____		
	_____		
	_____		
	_____		
	_____		
	_____		
	_____		
	_____		
	_____		

PLACE LABEL HERE

**NORTH CENTRAL CANCER TREATMENT GROUP**

**EVALUATION/TREATMENT FORM**

**ALL ITEMS MUST BE COMPLETED**

**Are data amended? (check one)**  Yes  No  
*(if data are amended, please circle in red when using paper form)*

Protocol Number: N06CA

Patient ID Number: \_\_\_\_\_ Patient Initials: \_\_\_\_\_  
L F M

Institution Number: \_\_\_\_\_

Institution: \_\_\_\_\_

Current Cycle Number: \_\_\_\_\_

Evaluation Date: (mm/dd/yyyy) \_\_\_/\_\_\_/\_\_\_\_\_

Container Number: \_\_\_\_\_

Was treatment held/stopped? (check one) 1  Yes 2  No

If Yes, reason: \_\_\_\_\_

In the past 1 week what percentage of time has the patient taken the medication as prescribed: (check one answer)

- 1  95-100% (always or missed 1-2 doses over the past week)
- 2  85-94% (almost always or missed no more than twice per week)
- 3  75-84% (usually or missed 3-4 doses per week)
- 4  60-74% (occasionally or missed 5-6 doses per week)
- 5  50-59% (about half of the time)
- 6  25-49% (almost never or applied only 3-5 times per week)
- 7  <25% (never or applied no more than twice per week)

Neurotoxicity Evaluation (see Appendix XI) (check one)

- 1  Grade I (loss of deep tendon reflexes or paresthesia, including tingling, but not interfering with function)
- 2  Grade II (objective sensory alteration or paresthesia, including tingling, interfering with function, but not with activities of daily living)
- 3  Grade III (sensory alteration or paresthesia interfering with activities of daily living)
- 4  Grade IV (permanent sensory losses that are disabling)

PLACE LABEL HERE

**NORTH CENTRAL CANCER TREATMENT GROUP**

**END OF ACTIVE TREATMENT/CANCEL  
NOTIFICATION FORM  
Submit Once Per Patient**

**ALL ITEMS MUST BE COMPLETED**

**Are data amended? (check one)**  Yes  No  
*(if data are amended, please circle in red when using paper form)*

Protocol Number: N06CA  
Patient ID: \_\_\_\_\_ Patient Initials: \_\_\_\_\_  
L F M  
Institution Number: \_\_\_\_\_  
Institution: \_\_\_\_\_

Last Date (any modality of) protocol therapy was given: (mm/dd/yyyy) \_\_\_/\_\_\_/\_\_\_\_\_  
*[last date study gel was used (continuation phase included if applicable) or date decision made not to initiate protocol treatment (cancel)]*

Off Treatment Date: (mm/dd/yyyy) \_\_\_/\_\_\_/\_\_\_\_\_  
*[date decision was made to end active treatment or date decision made not to initiate protocol treatment (cancel)]*

This patient will now go to: 9  Off Study/Off Study (cancel)  
*(See Schema and Section 13.0 of the protocol)*

Reason Treatment Ended <i>(check one)</i>	COMMENTS
1 <input type="checkbox"/> Treatment Completed Per Protocol Criteria	
2 <input type="checkbox"/> Patient Withdrawal/Refusal <b>After</b> Beginning Protocol Therapy	Specify:
24 <input type="checkbox"/> Patient Withdrawal/Refusal <b>Prior To</b> Beginning Protocol Therapy <i>(cancel)</i>	Specify:
3 <input type="checkbox"/> Adverse Event/Side Effects/Complications	Specify:
7 <input type="checkbox"/> Death On Study	
8 <input type="checkbox"/> Other	Specify:

PLACE LABEL HERE

**NORTH CENTRAL CANCER TREATMENT GROUP**

**ROCHESTER PATIENTS ONLY  
BLOOD SPECIMEN SUBMISSION FORM**

**ALL ITEMS MUST BE COMPLETED**  
**Are data amended? (check one)  Yes  No**

*(if data are amended, please circle in red when using paper form)*

Protocol Number: N06CA

Patient ID: \_\_\_\_\_ Patient Initials: \_\_\_\_\_  
L F M

Institution Number: \_\_\_\_\_

Institution: \_\_\_\_\_

Current Cycle Number: \_\_\_\_\_

**INSTRUCTIONS:**

*This form is only completed once during weeks 3-4 of double-blind phase. Complete this form for **Rochester patients** and enter into the remote data entry system within 7 days of specimen collection. See Section 14 of the protocol for specimen requirements and shipment.*

Did this patient provide written consent to give blood specimen(s) for research? *(check one)*

1  Yes. If Yes, complete rest of form.

2  No. If No, end form.

Was a research blood specimen collected? *(check one)*

1  Yes. If Yes: Date of collection: *(mm/dd/yyyy)* \_\_\_/\_\_\_/\_\_\_\_

Date Specimen Shipped: *(mm/dd/yyyy)* \_\_\_/\_\_\_/\_\_\_\_

2  No. If No, reason: \_\_\_\_\_

PLACE LABEL HERE

Protocol Number: N06CA

Patient ID: \_\_\_\_\_ Patient Initials: \_\_\_\_\_

L F M

Institution Number: \_\_\_\_\_

Institution: \_\_\_\_\_

**NORTH CENTRAL CANCER TREATMENT GROUP**

**PATIENT QUESTIONNAIRE BOOKLET COMPLIANCE FORM**

**ALL ITEMS MUST BE COMPLETED**

**Are data amended? (check one)**  Yes  No  
*(if data are amended, please circle in red when using paper form)*

Current Cycle Number: \_\_\_\_

NOTE: Cycle 0 = Baseline  
Cycle 4 = Double-blind phase  
Cycle 12 = Optional continuation phase

***Complete this form only if the entire Patient Questionnaire booklet contains absolutely NO patient provided assessment information.***

***Reason Patient Questionnaire booklet was not completed. (check one)***

- 1  Patient refusal
- 2  Unable to accommodate disability or language needs
- 3  Staff unavailable
- 4  Patient not given form by staff
- 5  Patient did not like content of questions
- 6  Site did not like content of questions
- 7  Other reason, specify \_\_\_\_\_

PLACE LABEL HERE

**NORTH CENTRAL CANCER TREATMENT GROUP**

Protocol Number: N06CA

Patient ID: \_\_\_\_\_ Patient Initials: \_\_\_\_\_

L F M

Institution Number: \_\_\_\_\_

Institution: \_\_\_\_\_

**NOTIFICATION FORM**  
**Grade 4 or 5 Non-AER Reportable Events/Hospitalization**  
**ALL ITEMS MUST BE COMPLETED**

**INSTRUCTIONS:**

- Use this form to report all known information on non-AER reportable grade 4 or 5 adverse events or any hospitalization during active treatment.
- Verify reporting requirements listed within the study protocol, prior to entering into the remote data entry system.
- If AER has been submitted for this event do not enter this form.
- Fill out all information known.
- Enter into the remote data entry system within 5 working days of notification.
- These events must also be reported on the Nadir/Adverse Event Form.

Date membership CRA aware of event(s): (mm/dd/yyyy) \_\_\_/\_\_\_/\_\_\_\_\_

Name of Person Completing Form: \_\_\_\_\_ Phone: (\_\_\_\_\_) \_\_\_\_\_ - \_\_\_\_\_

Current Cycle Number: \_\_\_\_\_ Assigned Treatment Arm: \_\_\_\_\_

Event ≥ Grade 4: (check one) 1  Yes 2  No

Date of First Occurrence of Adverse Event (mm/dd/yyyy)	CTC Adverse Event Term (only one event per line)	CTC Adverse Event Grade	In your opinion, is this related to the study medication?*
___/___/_____		<input type="checkbox"/> 4 <input type="checkbox"/> 5	4 <input type="checkbox"/> Yes: Unlikely 1 <input type="checkbox"/> Yes: Possible, probable, or definite 2 <input type="checkbox"/> No 3 <input type="checkbox"/> Unknown
___/___/_____		<input type="checkbox"/> 4 <input type="checkbox"/> 5	4 <input type="checkbox"/> Yes: Unlikely 1 <input type="checkbox"/> Yes: Possible, probable, or definite 2 <input type="checkbox"/> No 3 <input type="checkbox"/> Unknown
___/___/_____		<input type="checkbox"/> 4 <input type="checkbox"/> 5	4 <input type="checkbox"/> Yes: Unlikely 1 <input type="checkbox"/> Yes: Possible, probable, or definite 2 <input type="checkbox"/> No 3 <input type="checkbox"/> Unknown
___/___/_____		<input type="checkbox"/> 4 <input type="checkbox"/> 5	4 <input type="checkbox"/> Yes: Unlikely 1 <input type="checkbox"/> Yes: Possible, probable, or definite 2 <input type="checkbox"/> No 3 <input type="checkbox"/> Unknown
___/___/_____		<input type="checkbox"/> 4 <input type="checkbox"/> 5	4 <input type="checkbox"/> Yes: Unlikely 1 <input type="checkbox"/> Yes: Possible, probable, or definite 2 <input type="checkbox"/> No 3 <input type="checkbox"/> Unknown

\*Answer YES if attribution is unlikely, possible, probable or definite; answer NO if unrelated; answer UNKNOWN if you are not sure. Verify if expedited reporting (e.g. ADEERS) is required (see protocol), based on relationship to study treatment.

**Hospitalization:** (check one) 1  Yes 2  No

If Yes: Hospital Admission Date: (mm/dd/yyyy) \_\_\_/\_\_\_/\_\_\_\_\_

Reason(s) for Hospitalization:

- 1  Adverse Event, specify type and grade: \_\_\_\_\_
- 2  Prophylactic, specify: \_\_\_\_\_
- 3  Other reason, specify \_\_\_\_\_



# NCCTG

NORTH CENTRAL CANCER TREATMENT GROUP

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February 22, 2008

## Order Form

### Quality-of-Life Booklets

N06CA, The Use of Topical Baclofen, Amitriptyline HCl, and Ketamine (BAK) in a PLO Gel vs. Placebo for the Treatment of Chemotherapy Induced Peripheral Neuropathy: A Phase III Randomized Double-Blind Placebo Controlled Study

#### **Baseline Patient Questionnaire**

Number of booklets needed: \_\_\_\_\_

#### **Week 1-4 Patient Questionnaire**

Number of booklets needed: \_\_\_\_\_

#### **Week 5-12 Patient Questionnaire**

Number of booklets needed: \_\_\_\_\_

Fax form to: 507-284-1902

Attention of NCCTG Operational Support Clerk

Requestor: \_\_\_\_\_ Phone: \_\_\_\_\_

Affiliate/Membership: \_\_\_\_\_/\_\_\_\_\_

Shipping address: \_\_\_\_\_

\_\_\_\_\_

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

## **N06CA: Cancer Control Specific Forms Instructions**

*All material and questionnaires are to be entered in the remote data entry system*

<b><i>General Information</i></b>	<ul style="list-style-type: none"><li>• Refer to the <b><i>Remote Data Entry Screen Instructions (Forms Completion)</i></b> on the NCCTG website for additional, non-specific forms instructions.</li> <li>• <b>The study is cycled as followed:</b><ul style="list-style-type: none"><li>➤ <b>Cycle 1 = Week 1 (Double-Blind Phase)</b></li><li>➤ <b>Cycle 2 = Week 2 (Double-Blind Phase)</b></li><li>➤ <b>Cycle 3 = Week 3 (Double-Blind Phase)</b></li><li>➤ <b>Cycle 4 = Week 4 (Double-Blind Phase)</b></li><li>➤ <b>Cycle 5 = Week 5 (Optional Continuation Phase)</b></li><li>➤ <b>Cycle 6 = Week 6 (Optional Continuation Phase)</b></li><li>➤ <b>Cycle 7 = Week 7 (Optional Continuation Phase)</b></li><li>➤ <b>Cycle 8 = Week 8 (Optional Continuation Phase)</b></li><li>➤ <b>Cycle 9 = Week 9 (Optional Continuation Phase)</b></li><li>➤ <b>Cycle 10 = Week 10 (Optional Continuation Phase)</b></li><li>➤ <b>Cycle 11 = Week 11 (Optional Continuation Phase)</b></li><li>➤ <b>Cycle 12 = Week 12 (Optional Continuation Phase)</b></li></ul></li></ul>
<b><i>Evaluation/Treatment Form</i></b>	<ul style="list-style-type: none"><li>• This form is completed for each cycle (weekly). If the patient is evaluated more than once during the cycle, the evaluations should be combined as one.</li> <li>• The “Evaluation Date” is the date of the CRA/Nurse phone call or the date the patient was seen in the clinic.</li></ul>
<b><i>Adverse Event Form</i></b>	<ul style="list-style-type: none"><li>• This form is completed at baseline (initial material) and for each cycle (weekly). If the patient is assessed more than once during a cycle, the assessments should be combined as one and the highest grade and attribution reported.</li> <li>• The “Evaluation Date” is the date of the CRA/Nurse phone call or the date the patient was seen in the clinic.</li> <li>• You are now required to grade all “Required Adverse Events” even if all are a grade 0.</li></ul>

<p><b><i>Concurrent Treatment Form</i></b></p>	<ul style="list-style-type: none"> <li>• This form is submitted at baseline (initial material) and for each cycle (weekly). If the patient is evaluated more than once during the cycle, the evaluations should be combined as one.</li> <li>• The “Evaluation Date” is the date of the CRA/Nurse phone call or the date the patient was seen in the clinic.</li> <li>• You will need to enter all medications on the baseline form. On the active monitoring phase form you will only need to enter the medications that have not been previously reported, no longer being taken, or have a dose and/or schedule change.</li> </ul>
<p><b><i>Patient Questionnaires</i></b></p>	<ul style="list-style-type: none"> <li>• There are three Patient Questionnaires in this study: <ul style="list-style-type: none"> <li>➤ <i>Patient Questionnaire (Baseline)</i> – to be completed prior to treatment.</li> <li>➤ <i>Patient Questionnaire: Double-Blind Phase (Weeks 1-4)</i> – to be completed weekly during the 4 week Double-Blind Phase. This booklet has tabs enclosed stating how to cycle this in the remote data system. <ul style="list-style-type: none"> <li>Cycle 1, Sequence 1 = Week 1</li> <li>Cycle 2, Sequence 1 = Week 2</li> <li>Cycle 3, Sequence 1 = Week 3</li> <li>Cycle 4, Sequence 1 = Week 4</li> </ul> </li> <li>➤ <i>Patient Questionnaire: Optional Continuation Phase (Weeks 5-12)</i> – to be completed weekly during the 8 week Optional Continuation Phase. This booklet has tabs enclosed stating how to cycle this in the remote data system. <ul style="list-style-type: none"> <li>Cycle 5, Sequence 1 = Week 5</li> <li>Cycle 6, Sequence 1 = Week 6</li> <li>Cycle 7, Sequence 1 = Week 7</li> <li>Cycle 8, Sequence 1 = Week 8</li> <li>Cycle 9, Sequence 1 = Week 9</li> <li>Cycle 10, Sequence 1 = Week 10</li> <li>Cycle 11, Sequence 1 = Week 11</li> <li>Cycle 12, Sequence 1 = Week 12</li> </ul> </li> </ul> </li> <li>• Please refer to the <b><i>Guidelines for Entering QOL Booklets</i></b> on the NCCTG website for additional information/instructions.</li> </ul>

<p><b><i>Patient Questionnaire Booklet Compliance Form</i></b></p>	<ul style="list-style-type: none"> <li>• Only complete this form if an <b>entire</b> booklet was not completed. If a portion of the booklet was completed, then this form <b>does not</b> need to be completed.</li> <li>• When entering <u>this</u> form in the database, please cycle as follows: <ul style="list-style-type: none"> <li>➤ <i>Patient Questionnaire (Baseline)</i> = <b>Cycle 0 (Sequence 1)</b></li> <li>➤ <i>Patient Questionnaire: Double-Blind Phase (Weeks 1-4)</i> = <b>Cycle 4.</b></li> <li>➤ <i>Patient Questionnaire: Optional Continuation Phase (Weeks 5-12)</i> = <b>Cycle 12</b></li> </ul> </li> </ul>
<p><b><i>End of Active Treatment/Cancel Notification Form</i></b></p>	<ul style="list-style-type: none"> <li>• The End of Active Treatment Form is submitted <b>once</b> per patient following the discontinuation of study treatment or if the patient withdraws/cancels prior to treatment.</li> <li>• The End of Active Treatment Form should be completed at the end of double-blind phase <u>only</u> if they do not go onto the continuation phase <u>or</u> at the end of the optional continuation phase (if applicable).</li> </ul>