

NCCTG

NORTH CENTRAL CANCER TREATMENT GROUP

Date: February 22, 2008

To: Primary Clinical Research Associates

From: Daniel Satele
Protocol Development Coordinator

Re: 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

The above study is now active. This study was previously distributed as a pre-activation on January 25, 2008. No further changes have been made to the protocol. Therefore, the only material being distributed is an updated title page reflecting the activation date and the forms packet.

If you have any questions, please feel free to contact me.

Enclosure

North Central Cancer Treatment Group

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

*For any communications regarding this protocol,
please call the protocol resource person on the following page.*

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(507) 266-2380

***Investigator having NCI responsibility for this protocol**

√Study contributor(s) not responsible for patient care.

Document History	(Effective Date)
Activation	February 22, 2008

<u>Study Participants</u>	<u>Date Activated</u>
Entire NCCTG	Feb 22 2008

NCI Version Date: February 18, 2008

February 22, 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 (2/22/2008)
- Continuation phase eligibility checklist (2/22/2008)
- On-study form (10/17/2007)
- 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 (2/13/2008)
- 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)

*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

02/22/2008

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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

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

02/22/2008
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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). Note: 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.	___	___	___
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 (mm/dd/yyyy): ____ / ____ / ____	___	___	___
Neuropathy limited to either hands or feet (or both) where gel can be applied.	___	___	___
Negative pregnancy test done \leq 7 days prior to registration, for women of childbearing potential only. Not a woman of childbearing potential (<i>check NA</i>) vs. negative pregnancy test date ____ / ____ / ____	___	___	___

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. Note: 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. Note: 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"> • Pregnant • Nursing women • Women of childbearing potential 	___	___	___

All responses in above section must be "No" unless specified as "NA."

NCCTG Eligibility Checklist N06CA

02/22/2008

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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.			
Non-USA institution only (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.			

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 _____

NORTH CENTRAL CANCER TREATMENT GROUP

N06CA Continuation Phase Eligibility Checklist

02/22/2008

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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

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 Randomization Center 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 Randomization Center? ____ 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"

Yes No

<p>Translational Research (Mayo Clinic Rochester patients only): 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).</p> <ul style="list-style-type: none"> • Patient has/has not given permission to give a blood sample for research testing. 	____	____
--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	------	------

All responses in above section must be "Yes" or "No"

NORTH CENTRAL CANCER TREATMENT GROUP

N06CA Continuation Phase Eligibility Checklist

02/22/2008
Page 2 of 2

Assigned Treatment

_____ Amitriptyline HCL/baclofen/ketamine gel

Person registering _____ Random. Specialist _____
Signature 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: _____

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

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)

Required Baseline Adverse Events from Section 10.0 of Protocol		
CTC Adverse Events Term	MedDRA Code (v. 10.0)	CTC Adverse Event Grade
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

Protocol Number: N06CA

Patient ID: _____ Patient Initials: _____

L F M

Institution Number: _____

Institution: _____

NORTH CENTRAL CANCER TREATMENT GROUP

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

Required Adverse Events from Section 10.0 of Protocol

Rash: hand-foot skin reaction	10019126	0 1 2 3	1 2 3 4 5	___
Constipation	10010774	0 1 2 3 4 5 (death)	1 2 3 4 5	___
Dry mouth/salivary gland (xerostomia)	10013781	0 1 2 3	1 2 3 4 5	___
Confusion	10010300	0 1 2 3 4 5 (death)	1 2 3 4 5	___
Somnolence/depressed level of consciousness	10012373	0 2 3 4 5 (death)	1 2 3 4 5	___

* See Section 10.0 of the protocol.

PLACE LABEL HERE

Protocol Number: N06CA

Patient ID: _____ Patient Initials: _____

L F M

Institution Number: _____

Institution: _____

NORTH CENTRAL CANCER TREATMENT GROUP

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.**

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) 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)
	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<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	—
	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<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	—
	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<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	—
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	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<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	—
	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<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	—
	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<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	—
	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<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	—
	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<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	—
	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<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.

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

PLACE LABEL HERE

Protocol Number: N06CA

Patient ID: _____ Patient Initials: _____

L F M

Institution Number: _____

Institution: _____

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)

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

Protocol Number: N06CA

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

Patient ID: _____ Patient Initials: _____
L F M

ALL ITEMS MUST BE COMPLETED

Institution Number: _____

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

Institution: _____

Current Cycle Number: _____

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

Evaluation Date: (mm/dd/yyyy) ____/____/____

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

1 Yes 2 No (*Stop here*)

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

Protocol Number: N06CA

EVALUATION/TREATMENT FORM

Patient ID Number: _____ Patient Initials: _____

L F M

Institution Number: _____

ALL ITEMS MUST BE COMPLETED

Institution: _____

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

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

Protocol Number: N06CA

**END OF ACTIVE TREATMENT/CANCEL
NOTIFICATION FORM**

Patient ID: _____ Patient Initials: _____

Submit Once Per Patient

L F M

Institution Number: _____

ALL ITEMS MUST BE COMPLETED

Institution: _____

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

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 After Beginning Protocol Therapy	Specify:
24 <input type="checkbox"/> Patient Withdrawal/Refusal Prior To 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

Protocol Number: N06CA

Patient ID: _____ Patient Initials: _____
L F M

Institution Number: _____

Institution: _____

NORTH CENTRAL CANCER TREATMENT GROUP

**CONTINUATION PHASE
ROCHESTER PATIENTS ONLY
OPTIONAL COLLECTION
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)

Current Cycle Number: _____

INSTRUCTIONS:

This form is only completed once during weeks 6-12 of continuation 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

Protocol Number: N06CA

Patient ID: _____ Patient Initials: _____
L F M

Institution Number: _____

Institution: _____

NORTH CENTRAL CANCER TREATMENT GROUP

**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

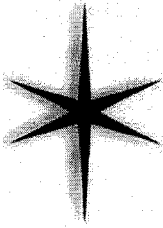
*Answer YES if attribution is unlikely, possible, probable or definite; answer NO if unrelated; answer UNKNOWN if you are not sure. Verify if expedited reporting (e.g. ADEERS) is required (see protocol), based on relationship to study treatment.

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

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

<i>General Information</i>	<ul style="list-style-type: none">• Refer to the <i>Remote Data Entry Screen Instructions (Forms Completion)</i> on the NCCTG website for additional, non-specific forms instructions.• The study is cycled as followed:<ul style="list-style-type: none">➤ Cycle 1 = Week 1 (Double-Blind Phase)➤ Cycle 2 = Week 2 (Double-Blind Phase)➤ Cycle 3 = Week 3 (Double-Blind Phase)➤ Cycle 4 = Week 4 (Double-Blind Phase)➤ Cycle 5 = Week 5 (Optional Continuation Phase)➤ Cycle 6 = Week 6 (Optional Continuation Phase)➤ Cycle 7 = Week 7 (Optional Continuation Phase)➤ Cycle 8 = Week 8 (Optional Continuation Phase)➤ Cycle 9 = Week 9 (Optional Continuation Phase)➤ Cycle 10 = Week 10 (Optional Continuation Phase)➤ Cycle 11 = Week 11 (Optional Continuation Phase)➤ Cycle 12 = Week 12 (Optional Continuation Phase)
<i>Evaluation/Treatment Form</i>	<ul style="list-style-type: none">• 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.• The “Evaluation Date” is the date of the CRA/Nurse phone call or the date the patient was seen in the clinic.
<i>Adverse Event Form</i>	<ul style="list-style-type: none">• 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.• The “Evaluation Date” is the date of the CRA/Nurse phone call or the date the patient was seen in the clinic.• You are now required to grade all “Required Adverse Events” even if all are a grade 0.

<p><i>Concurrent Treatment Form</i></p>	<ul style="list-style-type: none"> • 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. • The “Evaluation Date” is the date of the CRA/Nurse phone call or the date the patient was seen in the clinic. • 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.
<p><i>Patient Questionnaires</i></p>	<ul style="list-style-type: none"> • There are three Patient Questionnaires in this study: <ul style="list-style-type: none"> ➤ <i>Patient Questionnaire (Baseline)</i> – to be completed prior to treatment. ➤ <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"> Cycle 1, Sequence 1 = Week 1 Cycle 2, Sequence 1 = Week 2 Cycle 3, Sequence 1 = Week 3 Cycle 4, Sequence 1 = Week 4 ➤ <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"> Cycle 5, Sequence 1 = Week 5 Cycle 6, Sequence 1 = Week 6 Cycle 7, Sequence 1 = Week 7 Cycle 8, Sequence 1 = Week 8 Cycle 9, Sequence 1 = Week 9 Cycle 10, Sequence 1 = Week 10 Cycle 11, Sequence 1 = Week 11 Cycle 12, Sequence 1 = Week 12 • Please refer to the <i>Guidelines for Entering QOL Booklets</i> on the NCCTG website for additional information/instructions.

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