

NORTH CENTRAL CANCER TREATMENT GROUP

Eligibility Checklist

12/18/2009

Page 1 of 3

N08C1: Paclitaxel-Associated Acute Pain Syndrome Natural History 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 _____

Institution patient number (local subject number) _____

IRB approval date (mm/dd/yyyy) ___/___/_____

Person Completing Form:

Last Name: **(print)** _____ First Name: **(print)** _____

Phone: _____ Fax: _____ Email: _____

Patient 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
Date of birth (mm/dd/yyyy) ___/___/_____	<input type="checkbox"/> Black or African American
ZIP code _____	<input type="checkbox"/> Native Hawaiian or Other Pacific Islander
Country of Residence _____	<input type="checkbox"/> Asian
	<input type="checkbox"/> American Indian or Alaska Native
	<input type="checkbox"/> Not reported: Patient refused or not available
	<input type="checkbox"/> Unknown: Patient unsure
Method of payment (check one)	Ethnicity (check one)
<input type="checkbox"/> PI (Private Insurance)	<input type="checkbox"/> Not Hispanic or Latino
<input type="checkbox"/> MR (Medicare)	<input type="checkbox"/> Hispanic or Latino
<input type="checkbox"/> MRP (Medicare and Private Insurance)	<input type="checkbox"/> Not reported: Refused or data not available
<input type="checkbox"/> MD (Medicaid)	<input type="checkbox"/> Unknown: Unsure of their ethnicity
<input type="checkbox"/> MM (Medicaid and Medicare)	
<input type="checkbox"/> MVA (Military or Veterans Sponsored, Not Otherwise Specified (NOS))	
<input type="checkbox"/> MS (Military Sponsored [including CHAMPUS & TRCARE])	
<input type="checkbox"/> MV (Veterans Sponsored)	
<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 N08C1

12/18/2009
Page 2 of 3

Patient study ID number _____

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

Inclusion Criteria

Yes No NA

≥18 years of age and be diagnosed with cancer. Age = _____.	___	___	___
Provide informed written consent.	___	___	___
Ability to complete questionnaire(s) by themselves or with assistance.	___	___	___
Planned use of intravenous (IV) paclitaxel (not nab-paclitaxel) at one of the following doses: <ul style="list-style-type: none"> At least 175 mg/m² and planned at 2-4 week intervals (cycles being 2, 3, or 4 weeks, respectively) 70-90 mg/m² planned weekly (3 out of 4 weeks is OK) 	___	___	___
Life expectancy >6 months.	___	___	___
ECOG performance status 0 or 1. ECOG performance status = _____.	___	___	___
Willingness to provide the biologic specimens as required by the protocol (see Sections 6.16, 14.0).	___	___	___

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

Exclusion Criteria

Yes No NA

Diagnosis (current or previous) of peripheral neuropathy (from diabetes or other causes).	___	___	___
Diagnosis (current or previous) of fibromyalgia.	___	___	___
Concurrent planned neutrophil colony stimulating factor therapy.	___	___	___
Previous exposure to paclitaxel, or neurotoxic chemotherapy drugs including other taxanes, platinum agents, vinca alkaloids, or epothilones.	___	___	___

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

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 informed consent signed ___/___/_____	___	___	___
Authorization for use and disclosure of protected health information (<i>U.S.A. institutions only</i>) signed and dated. If not a USA institution (<i>check NA</i>) If a USA institution - Date of authorization ___/___/_____	___	___	___
Study procedures on this protocol must commence at the accruing membership under the supervision of an NCCTG member physician or allied health staff.	___	___	___
Study procedures cannot begin prior to registration and must begin ≤28 days after registration.	___	___	___
A mandatory translational research component is part of this study the patient will be automatically registered onto this component (Sections 3.16, 14.0).	___	___	___
Patient questionnaire booklets confirmed to be available.	___	___	___

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

Yes No NA

At the time of registration/randomization, the following will also be recorded:	___	___	___
<ul style="list-style-type: none"> Patient has given permission for blood sample(s) to be stored and used for future research to learn about, prevent, or treat cancer. 	___	___	___
<ul style="list-style-type: none"> Patient has given permission for blood sample(s) to be stored and used for future research to learn about, prevent, or treat other health problems (for example: diabetes, Alzheimer’s disease, or heart disease). 	___	___	___
<ul style="list-style-type: none"> Patient has given permission to give samples to outside researchers. 	___	___	___

All responses in above section may be “Yes” or “No”.

Patient study ID number _____

Grouping Factors

Paclitaxel Schedule

- _____ Weekly paclitaxel given in combination with a neurotoxic agent (Arm A)
- _____ ~~Weekly paclitaxel not given in combination with a neurotoxic agent (Arm B)~~ **Note: This arm is permanently closed effective Friday, December 11, 2009**
- _____ q 2-4 week paclitaxel given in combination with a neurotoxic agent (Arm C) **Note: This arm is open to minority accrual only as of August 7, 2009, per the Notice of Status Change.**
- _____ q 2-4 week paclitaxel not given in combination with a neurotoxic agent (Arm D)

Assigned Treatment

- _____ A) Questionnaires day 2-8 after each weekly paclitaxel treatment given in combination with a neurotoxic agent
- _____ ~~B) Questionnaires day 2-8 after each weekly paclitaxel treatment not given in combination with a neurotoxic agent~~ **Note: This arm is permanently closed effective Friday, December 11, 2009.**
- _____ C) Questionnaires day 2-8 after q 2-4 week paclitaxel treatment given in combination with a neurotoxic agent **Note: This arm is open to minority accrual only as of August 7, 2009, per the Notice of Status Change.**
- _____ D) Questionnaires day 2-8 after q 2-4 week paclitaxel treatment not given in combination with a neurotoxic agent

Person registering Signature _____ Registration Office specialist initials _____

Physician or Allied Health Staff Signature _____ Date (mm/dd/yyyy) ___/___/___