

FORMS PACKET

N07C2, The Use of Wisconsin Ginseng (*panax quinquefolius*) to Improve Cancer-Related Fatigue: A Randomized, Double-Blind, Placebo-Controlled Phase III Study

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*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.

CENTRAL CANCER TREATMENT GROUP

Eligibility Checklist

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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 _____

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)	

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

≥ 18 years of age. Age = _____.	___ ___
Men or women with a history of cancer-related fatigue as defined by an average score ≥4 over the past 30 days on the numeric analogue scale (1-10) (Linear Analogue Scale Fatigue Question 1; Appendix II). Fatigue Score = _____.	___ ___
The presence of fatigue ≥1 month prior to randomization.	___ ___
ECOG performance score 0, 1, 2. PS = _____.	___ ___
Histologic or cytologic proven cancer other than brain cancer or CNS lymphoma, undergoing curative intent therapy (including anti-hormonal therapies such as tamoxifen or leuprolide) or those having completed curative intent therapy who were diagnosed within the past 2 years. Note: If a patient is receiving treatment for their disease such as chemotherapy, targeted therapies, immunotherapy therapy or radiation therapy then, the patient must have completed ≥1 cycle of chemotherapy, targeted therapy, or ≥1 week of radiation treatment.	___ ___
Laboratory values obtained prior to randomization.	___ ___
<ul style="list-style-type: none"> Hgb ≥11 (must be obtained ≤30 days; patients must not be transfused ≤30 days to meet this criterion). Hgb date ___/___/____. Hgb = _____. 	___ ___
<ul style="list-style-type: none"> Creatinine ≤ 1.2 x UNL (must be obtained ≤180 days prior to randomization). Creatinine date ___/___/____. Creatinine = _____. UNL = _____. 	___ ___
<ul style="list-style-type: none"> AST (SGOT) or ALT (SGPT) ≤ 1.5 x UNL (must be obtained ≤180 prior to randomization). Which was done? ___ AST (SGOT) date ___/___/____. AST (SGOT) = _____. UNL = _____. ___ ALT (SGPT) date ___/___/____. ALT (SGPT) = _____. UNL = _____. Both → Complete AST (SGOT) and ALT (SGPT) fields above 	___ ___
Negative pregnancy test done ≤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 ___/___/____	___ ___
Ability to complete patient questionnaires alone or with assistance.	___ ___
Controlled: <ul style="list-style-type: none"> Pain (≤4 on Linear Analogue Scale Question 3 – Appendix II) Pain Score = _____ Insomnia (≤4 on Linear Analogue Scale Question 2 – Appendix II) Insomnia Score = _____ 	___ ___
Willingness to provide blood/saliva samples for correlative studies. Note: These samples are only required for those not receiving active treatment for their disease. Active treatment is defined as chemotherapy, radiation therapy, or immunotherapy, not anti-hormone therapy such as tamoxifen, aromatase inhibitors or leuprolide. If receiving active treatment for disease (<i>check NA</i>).	___ ___

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

Contraindications

Yes No NA

Hypersensitivity to ginseng.	___ ___
Prior use of ginseng capsules for fatigue in the past year. Note: Prior use of teas or drinks containing ginseng is allowed, however, patients will be asked to avoid these beverages while on the study.	___ ___
Uncontrolled hypertension on more than one occasion (diastolic blood pressure > 100, systolic > 160) measured ≤90 days prior to randomization.	___ ___
Currently using any other pharmacologic agents or nonpharmacologic interventions to specifically treat fatigue including psychostimulants, antidepressants, acupuncture, etc. Note: Antidepressants used to treat items other than fatigue (such as hot flashes) are allowed if the patient has been on a stable dose for ≥1 month and plans to continue for ≥1 month. Erythropoietin agents to treat anemia are allowed. Exercise is allowed.	___ ___
Known brain metastasis or primary CNS malignancy.	___ ___
Chronic systemic steroid use (including CHOP therapy or as part of any regular cancer treatment, however, steroids used as prophylaxis for nausea and vomiting are allowed). To prevent rash with Alimta, low dose dexamethasone will be allowed.	___ ___
Diabetes Type I or II (defined by being on oral hypoglycemics or insulin).	___ ___

Patient study ID number _____

Contraindications – (continued)

	Yes	No	NA
Psychiatric disorder such as severe depression, manic depressive disorder, obsessive compulsive disorder or schizophrenia. (Defined per medical history).	___	___	___
≤4 weeks from major surgery to randomization, including any procedure that requires general anesthetic.	___	___	___
Any of the following: <ul style="list-style-type: none"> • Pregnant women • Nursing women • Women of childbearing potential who are unwilling to employ adequate contraception 	___	___	___
Pain requiring opioid pain medication, however, over the counter analgesics such as Tylenol or ibuprofen are allowed.	___	___	___
Use of full dose of anticoagulant therapy (Exception: 1 mg/day of Coumadin for preventing catheter clots is allowed).	___	___	___
Use of MAO inhibitors.	___	___	___
Planning to start or complete any type of cancer therapy during the 8 week, double blind, course of the study, once randomized on the study. Note: If not currently getting treatment, no chemotherapy agents ≤ 21 days prior to randomization. Combination treatment regimens that have components ending at different times are allowed, as long as any part of the initially started treatment continues through the double blind portion of the study.	___	___	___
Malnutrition, active infection, significant pulmonary disease and cardiovascular disease as determined by the physician, as they could impact fatigue.	___	___	___
Use of any over the counter herbal/dietary supplement marketed for fatigue or energy (for example, products containing any type of ginseng, rhodiola rosea, high doses of caffeine, guarana, or anything called an “adaptogen”).	___	___	___
Uncontrolled nausea or vomiting or any symptom that would prevent the ability to comply with daily oral ginseng/placebo treatment.	___	___	___
Uncontrolled thyroid disorder.	___	___	___
Currently receiving single agent on blinded placebo controlled treatment trials.	___	___	___

All responses in above section must be “No.”

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

	Yes	No	NA
A mandatory translational research component is part of this study for patients NOT receiving chemotherapy or radiation therapy. Patients not receiving chemotherapy or radiation therapy must agree to do both the saliva and the blood sampling to participate. There will be an option to select if the patient is to be registered onto this component (Section 14.0). <ul style="list-style-type: none"> • Patient is receiving active treatment and will not provide blood/saliva for research testing (<i>check NA</i>). • Patient is not receiving active treatment and will provide blood/saliva for research testing 	___	___	___
Consent form signed and dated. Date of consent ___/___/____.	___	___	___
Authorization for use and disclosure of protected health information signed and dated. Non-USA institution only (<i>check NA</i>) vs. Date of authorization ___/___/____.	___	___	___
Treatment on this protocol must commence at the accruing membership under the supervision of an NCCTG member physician.	___	___	___
Treatment cannot begin prior to registration and must begin ≤30 days after randomization.	___	___	___
Pretreatment tests/procedures (see Section 4.0) must be completed within the guidelines specified in the test schedule.	___	___	___
All required baseline symptoms (see Section 10.3) must be documented and graded.	___	___	___
Study drug availability checked.	___	___	___

NCCTG Eligibility Checklist N07C2

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Patient study ID number _____

Registration Check (*continued*)

Yes No NA

Blood draw kit and saliva collection kit availability checked. If not applicable (<i>check NA</i>)	___	___	___
Patient questionnaire booklet availability checked; copies are not acceptable for this submission.	___	___	

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

<p>Is patient receiving active treatment? ___ Yes. If yes, go to Stratification factors. ___ No. If no, continue with Registration questions.</p>	
<p>At the time of registration/randomization, the following will also be recorded:</p> <ul style="list-style-type: none"> • Patient has given permission to keep blood sample(s) for use in future research to learn about, prevent, or treat cancer. 	___ ___
<ul style="list-style-type: none"> • Patient has given permission to keep blood sample(s) for use in 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 NCCTG permission to give blood sample(s) to outside researchers. 	___ ___
<ul style="list-style-type: none"> • Patient has given permission to keep saliva sample(s) for use in future research to learn about, prevent, or treat cancer. 	___ ___
<ul style="list-style-type: none"> • Patient has given permission to keep saliva sample(s) for use in 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 NCCTG permission to give saliva sample(s) to outside researchers. 	___ ___

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

Stratification Factors

Baseline fatigue score
 ___ 4-7
 ___ 8-10

Duration of all prior cancer treatment in patients lifetime
 ___ None
 ___ ≤180 days
 ___ >180 days

Disease status of current cancer
 ___ Initial diagnosis
 ___ Recurrent disease

Current tumor type
 ___ Hematologic
 ___ Solid tumor malignancy

Note: Patients with both types of malignancies, select hematologic.

Current treatment (chemotherapy, radiation, immunotherapy):
 ___ Yes
 ___ No

Assigned Treatment

___ Panax quinquefolius (Wisconsin ginseng) vs. Placebo

Person registering _____ Signature Registration Office specialist _____ initials

Physician _____ Signature M - D - Y

NORTH CENTRAL CANCER TREATMENT GROUP

N07C2 Continuation Phase Eligibility Checklist

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If the patient and physician want to continue with the active agent, or if on placebo, begin the active agent, call (507/284-4130) 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 Randomization Center? ____ Yes ____ No

If yes: Prior study number _____; prior patient study ID number _____

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

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

	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.	____	____
Treatment cannot begin prior to registering to the continuation phase and must begin ≤ 28 days after registration.	____	____
Study drug availability checked.	____	____
Patient questionnaire booklet availability checked; copies are not acceptable for this submission.	____	____

All responses in above section must be “Yes”

N07C2 Continuation Phase Eligibility Checklist

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Patient study ID number _____

Assigned Treatment

_____ Panax quinquefolius (Wisconsin ginseng)

Person registering _____ Random. Specialist _____
Signature initials

Physician _____ M - D - Y
Signature

N07C2: Cancer Control Specific Forms Instructions

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

<p><i>General Information</i></p>	<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 follows:<ul style="list-style-type: none">➤ Cycle 1 = Week 1 & 2 (Double-Blind Phase)➤ Cycle 2 = Week 3 & 4 (Double-Blind Phase)➤ Cycle 3 = Week 5 & 6 (Double-Blind Phase)➤ Cycle 4 = Week 7 & 8 (Double-Blind Phase)➤ Cycle 5 = Week 9 & 10 (Optional Cont. Phase)➤ Cycle 6 = Week 11 & 12 (Optional Cont. Phase)
<p><i>Initial Material</i></p>	<ul style="list-style-type: none">• The following forms are to be completed within 14 days of registration:<ul style="list-style-type: none">➤ On-Study Form➤ Baseline Adverse Events Form➤ Baseline Concurrent Treatment Form➤ Baseline Patient Questionnaire
<p><i>Blood Specimen Submission Form</i> <i>(Baseline and Active Monitoring)</i></p>	<ul style="list-style-type: none">• This form is completed for all patients even if submission of a blood specimen was not required.• The form is completed at baseline and week 5 (Cycle 3)
<p><i>Saliva Specimen Submission Form</i> <i>(Baseline and Active Monitoring)</i></p>	<ul style="list-style-type: none">• This form is completed for all patients even if submission of a saliva specimen was not required.• The form is completed at baseline and week 5 (Cycle 3)
<p><i>Evaluation/Treatment Form</i> <i>(Double-Blind Phase and Optional Cont. Phase)</i></p>	<ul style="list-style-type: none">• There are two different forms for this study. One for the Double-Blind Phase and one for the Optional Continuation Phase.• This form is completed at the end of each two week cycle. 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.

<p><i>Patient Questionnaires</i></p>	<ul style="list-style-type: none"> • There are five 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 (Weeks 1-4):</i> 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 1, Sequence 2 = Week 2 Cycle 2, Sequence 1 = Week 3 Cycle 2, Sequence 2 = Week 4 ➤ <i>Patient Questionnaire (Weeks 5-8):</i> 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 3, Sequence 1 = Week 5 Cycle 3, Sequence 2 = Week 6 Cycle 4, Sequence 1 = Week 7 Cycle 4, Sequence 2 = Week 8 ➤ <i>Optional Continuation Booklet (Weeks 9-12)</i> – to be completed weekly during the 4 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 9 Cycle 5, Sequence 2 = Week 10 Cycle 6, Sequence 1 = Week 11 Cycle 6, Sequence 2 = Week 12 ➤ <i>Saliva Collection Diary</i> – is only required for patients who are not actively receiving chemotherapy, immunotherapy, or radiation therapy. A booklet is to be completed at baseline and week 5 (cycle 3). This booklet has tabs enclosed stating how to cycle this in the remote data system. <ul style="list-style-type: none"> Day 1, Sequence 1 Day 2, Sequence 2 • 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 this form in the database, please cycle as follows: <ul style="list-style-type: none"> ➤ <i>Patient Questionnaire (Baseline)</i> = Cycle 0 ➤ <i>Patient Questionnaire (Weeks 1-4)</i> = Cycle 2 ➤ <i>Patient Questionnaire (Weeks 5-8)</i> = Cycle 4 ➤ <i>Optional Continuation (Weeks 9-12)</i> = Cycle 6

<p><i>Adverse Event Form</i></p>	<ul style="list-style-type: none"> • This form is completed at the end of each two week cycle. 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. • The Phone Contact Guide (Appendix X) can be used as a template to gather the information required to complete this form.
<p><i>Concurrent Treatment Form (Active Monitoring)</i></p>	<ul style="list-style-type: none"> • This form is completed at the end of each two week cycle. If the patient is evaluated more than once during the cycle, the evaluations should be combined as one. • On the active monitoring phase form you will only need to enter the medications that have not been previously reported or no longer being taken. • The “Evaluation Date” is the date of the CRA/Nurse phone call or the date the patient was seen in the clinic. • The Phone Contact Guide (Appendix X) can be used as a template to gather the information required to complete this form. • Concurrent treatment does not have to be collected during the optional continuation phase.
<p><i>Continuation Phase Eligibility Checklist</i></p>	<ul style="list-style-type: none"> • If a patient elects to go to the Continuation Phase, you will need to submit a <i>hard copy</i> of this form to the Registration Office. The remote data entry system will not allow you to enter it remotely.
<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 <u>once</u> 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 they do not go onto the continuation phase <u>or</u> at the end of the optional continuation phase (if applicable).

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

Protocol Number: N07C2

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 (CTCAE v3.0)	MedDRA Code (v. 10.0)	CTC Adverse Event Grade
Nausea	10028813	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4
Vomiting	10047700	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4
Insomnia	10022437	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4
Mood Alteration - Selects		
- Agitation	10001497	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4
- Anxiety	10002855	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4

	1	2	3	4
Nausea	Loss of appetite without alteration in eating habits	Oral intake decreased without significant weight loss, dehydration or malnutrition; IV fluids indicated <24 hrs	Inadequate oral caloric or fluid intake; IV fluids, tube feedings, or TPN indicated ≥24 hrs	Life-threatening consequences
Vomiting	1 episode in 24 hrs	2 -5 episodes in 24 hrs; IV fluids indicated <24 hrs	≥6 episodes in 24 hrs; IV fluids, or TPN indicated ≥24 hrs	Life-threatening consequences
Insomnia	Occasional difficulty sleeping, not interfering with function	Difficulty sleeping, interfering with function but not interfering with ADL	Frequent difficulty sleeping, interfering with ADL	Disabling
Mood alteration - Agitation	Mild mood alteration not interfering with function	Moderate mood alteration interfering with function, but not interfering with ADL; medication indicated	Severe mood alteration interfering with ADL	Suicidal ideation; danger to self or others
Mood alteration - Anxiety	Mild mood alteration not interfering with function	Moderate mood alteration interfering with function, but not interfering with ADL; medication indicated	Severe mood alteration interfering with ADL	Suicidal ideation; danger to self or others

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: N07C2

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? (check one) 1 Yes 2 No

If Yes, enter medications (including prescription, over-the-counter, alternative medications, and cancer treatment medications) that have not been previously reported or no longer being taken.

Concomitant Treatment	Reason for entry: 1= New medication 2= Medication no longer being taken	Reason for use

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

**DURING WEEK 5
ACTIVE MONITORING
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: N07C2

Patient ID: _____ Patient Initials: _____

L F M

Institution Number: _____

Institution: _____

Current Cycle Number: 3

Was patient actively being treated with chemotherapy, radiation therapy or immunotherapy at baseline? *(check one)*

1 Yes. If Yes, End Form.

2 No. If No, complete this form.

INSTRUCTIONS:

Complete this form for all 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.

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

NORTH CENTRAL CANCER TREATMENT GROUP

Protocol Number: N07C2

Patient ID: _____ Patient Initials: _____

L F M

Institution Number: _____

Institution: _____

**BASELINE
SALIVA 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)

Required for patients who are **not** actively being treated with chemotherapy, radiation therapy or immunotherapy.

Is patient actively being treated with chemotherapy, radiation therapy, or immunotherapy? *(check one)*

1 Yes. If Yes, End Form.

2 No. If No, complete this form.

INSTRUCTIONS:

- Complete this form **for all patients** and enter into the remote data entry system within 7 days after specimen collection.
- See Section 14 of the protocol for specimen requirements and shipment.
- Include a copy of this form with saliva submission (see Section 14).

Were research saliva specimens collected? *(check one)*

1 Yes. If Yes: Dates of collection: (mm/dd/yyyy) __ __ / __ __ / __ __ __ __

(mm/dd/yyyy) __ __ / __ __ / __ __ __ __

Date Specimens Shipped: (mm/dd/yyyy) __ __ / __ __ / __ __ __ __

2 No. If No, reason: _____

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

Protocol Number: N07C2

Patient ID: _____ Patient Initials: _____

L F M

Institution Number: _____

Institution: _____

ADVERSE EVENT FORM

ALL ITEMS MUST BE COMPLETED

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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) ____/____/____

CTC Adverse Event Term (CTCAE v3.0)	MedDRA Code (v. 10.0) (must be completed)	CTC Adverse Event Grade (highest grade this cycle) INCLUDE GRADE 0's	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

Nausea	10028813	0 1 2 3 4 5 (death)	1 2 3 4 5	_____
Vomiting	10047700	0 1 2 3 4 5 (death)	1 2 3 4 5	_____
Insomnia	10022437	0 1 2 3 4	1 2 3 4 5	_____
Mood Alteration - Selects				
- Agitation	10001497	0 1 2 3 4 5 (death)	1 2 3 4 5	_____
- Anxiety	10002855	0 1 2 3 4 5 (death)	1 2 3 4 5	_____

* See Section 10.0 of the protocol.

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

Protocol Number: N07C2

Patient ID: _____ Patient Initials: _____

L F M

Institution Number: _____

Institution: _____

ADVERSE EVENT FORM

ALL ITEMS MUST BE COMPLETED

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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*): _____

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 (CTCAE v3.0)	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	—
	<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	—
	<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

NORTH CENTRAL CANCER TREATMENT GROUP

Protocol Number: N07C2

END OF ACTIVE TREATMENT/CANCEL NOTIFICATION FORM

Patient ID: _____ Patient Initials: _____

Submit Once Per Patient

Institution Number: _____ L F M

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) ___/___/___

(date of last treatment dose on this study or date decision made not to initiate protocol treatment)

(If patient is not going on continuation this is the last day they took drug on the double blind phase, if the patient is on continuation this would be the last day the patient took medication on the continuation phase.)

Off Treatment Date: (mm/dd/yyyy) ___/___/___

(date decision was made to end active treatment or not to initiate protocol treatment)

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:
4 <input type="checkbox"/> Disease Progression, Relapse During Active Treatment*	
10 <input type="checkbox"/> Disease Progression Before Active Treatment	
5 <input type="checkbox"/> Alternative Therapy	Specify:
6 <input type="checkbox"/> Patient Off-Treatment For Other Complicating Disease	Specify:
7 <input type="checkbox"/> Death On Study	
8 <input type="checkbox"/> Other	Specify:

* Submit documentation to verify progression. See Section 11.0 and Section 18.0 of protocol.

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

Protocol Number: N07C2

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 _____

PLACE LABEL HERE

Protocol Number: N07C2

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)

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

Baseline: _____ or Current Cycle Number: _____ *(prefill if possible)*

Date this form completed: (mm/dd/yyyy) ____/____/____

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
- 99 Other reason, specify _____



NCCTG

NORTH CENTRAL CANCER TREATMENT GROUP

October 10, 2008

Order Form for Quality-of-Life Booklets

N07C2, The Use of Wisconsin Ginseng (*panax quinquefolius*) to Improve Cancer-Related Fatigue: A Randomized, Double-Blind, Placebo-Controlled Phase III Study

Baseline Booklet

Number of booklets needed: _____

Saliva Collection Diary

Number of booklets needed: _____

Saliva Collection Diary Instructions

Number of booklets needed: _____

Week 1-4 Booklet

Number of booklets needed: _____

Week 5-8 Booklet

Number of booklets needed: _____

Week 9-12 Booklet – Optional Continuation

Number of booklets needed: _____

Fax form to: 507-284-1902

Attention of NCCTG Operational Support Clerk

Requestor: _____ Phone: _____

Affiliate/Membership: _____/_____

Shipping address: _____

Date: _____

Biospecimen Accessioning Processing
Fax Supply Order Form – No Cover Sheet Necessary
Fax to Research Kit Building @ 507-538-4103

NOTE: Form must be either typed or printed legibly and filled out completely.

Study ID: N07C2

Investigator: _____

Order Placed By: _____ **Phone #:** () _____

Email: _____ **Fax #:** () _____

Complete Address (kits sent to):

ALLOW AT LEAST TWO WEEKS TO RECEIVE THE KITS.

NOTE: Kits will be sent via FedEx® Ground at no additional cost to the participating institutions. Kits will not be sent via rush delivery service unless the participating institution provides their own FedEx® account number or alternate billing number for express service. **The study will not cover the cost for rush delivery of kits.**

Date Needed: _____
(Please be specific)

Fed Ex account number (Rush deliveries only) _____

<u>Type of Kits</u>	<u># of Kits Needed</u>
<u>N07C2 Research Blood Kit</u>	_____
<u>N07C2 Research Saliva Kit</u>	_____
Total Kits	_____

Questions? Contact the Biospecimen Resource Manager listed on the Protocol Resource page of the protocol.



NCCTG

NORTH CENTRAL CANCER TREATMENT GROUP

N07C2, The Use of Wisconsin Ginseng (*panax quinquefolius*) to Improve Cancer-Related Fatigue: A Randomized, Double-Blind, Placebo-Controlled Phase III Study

REIMBURSEMENT REQUEST

(form may be completed by member institution or their affiliate and sent to below address or email)

Today's Date: _____ NCCTG Patient ID (one patient per form): _____

NCCTG Member Institution Information (payment is made payable and sent to NCCTG member*):

Name of institution: _____

Attention to: _____

Address of institution: _____

Institutional TAX ID #: _____

Enrolling Institution Information:

Name of institution: _____

Contact CRA: _____

Phone: _____ Email: _____

Item(s) to be reimbursed	Max number per patient	Max \$ allowed per item	Date obtained or completed	Amount requested
Venipuncture	2	20.00		\$
				\$
Total amount requested:				\$

Submit to: NCCTG Operations Office, PL4
Attn: CRO Finance Coordinator
200 First Street SW
Rochester, MN 55905

OR

CROFinance@mayo.edu

Questions: Send email to CROFinance@mayo.edu

*Due to contractual obligations, payments may only be made to the NCCTG member site. No direct payment will be made to a member's affiliate from the NCCTG Operations Office.