

October 9, 2009

FORMS PACKET

N08C7, Phase III, Randomized, Placebo-controlled, Double-Blind Trial of Flaxseed for the Treatment of Hot Flashes

Contents:

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- Optional Continuation Eligibility Checklist (10/09/2009)
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- Concomitant Medication Form (Baseline) (08/24/2009)
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✓ designates revised/new forms

*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

Eligibility Checklist

10/9/2009

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N08C7: Phase III, Randomized, Placebo-Controlled, Double-Blind Trial of Flaxseed for the Treatment of Hot Flashes

To register a patient, access the NCCTG web page at <https://ncctg.mayo.edu/training> and enter the remote registration/randomization application.

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 care provider _____

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) ___ ___ ___

Gender (check one) ___ Male ___ Female ___ Unknown

Date of birth (mm/dd/yyyy) ___/___/___

ZIP code _____

Country of Residence _____

Race (check all that apply)

- White
- Black or African American
- Native Hawaiian or Other Pacific Islander
- Asian
- American Indian or Alaska Native
- Not reported: Patient refused or not available
- Unknown: Patient unsure

Method of payment (check one)

- PI (Private Insurance)
- MR (Medicare)
- MRP (Medicare and Private Insurance)
- MD (Medicaid)
- MM (Medicaid and Medicare)
- MVA (Military or Veterans Sponsored,
Not Otherwise Specified (NOS))
- MS (Military Sponsored [including CHAMPUS & TRCARE])
- MV (Veterans Sponsored)
- SP (Self pay [no insurance])
- NP (No means of payment [no insurance])
- OTH (Other)
- UNK (Unknown)

Ethnicity (check one)

- Not Hispanic or Latino
- Hispanic or Latino
- Not reported: Refused or data not available
- Unknown: Unsure of their ethnicity

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

≥18 years of age. Age = _____.	_____	_____
Women with a history of breast cancer or other cancer (currently without malignant disease) or women who have no history of breast cancer but who wish to avoid estrogen due to a perceived increased risk of breast cancer.	_____	_____
Bothersome hot flashes (defined by their occurrence ≥28 times per week and of sufficient severity to make the patient desire therapeutic intervention).	_____	_____
Women who are postmenopausal as defined by (1) absence of a period in the past 12 months; or (2) bilateral oophorectomy. Note: Women with at least one ovary but without a uterus should be deemed postmenopausal by either (1) age over 55 or (2) a combination of estrogen within a postmenopausal range (per local lab) and FSH over 40 mIU/mL.	_____	_____
Presence of hot flashes for ≥1 month prior to randomization.	_____	_____
Life expectancy ≥6 months.	_____	_____
ECOG Performance Status (PS) 0 or 1. PS = _____.	_____	_____
Ability to complete questionnaire(s) by themselves or with assistance.	_____	_____
Provide informed written consent.	_____	_____

All responses in above section must be “Yes.”

Exclusion Criteria

Yes No

Any of the following current (≤4 weeks) or planned therapies (EXCEPTION: tamoxifen, raloxifene, or aromatase inhibitors are allowed, but the patient must have been on a constant dose for ≥4 weeks and must not be expected to stop the medication during the study period): <ul style="list-style-type: none"> • Androgens • Estrogens • Progestational agents 	_____	_____
History of allergic or other adverse reaction to flaxseed.	_____	_____
Current (≤7 days prior to registration) or planned use of other agents for treating hot flashes (i.e.: gabapentin, clonidine, antidepressants) except stable dose of vitamin E (as a general vitamin supplement), if no more than 800 IU/day, is allowed as long as it was started >30 days prior to study initiation and is to be continued through the study period. Women who have been using antidepressants for mood and have been on a stable dose for over a month and meet the eligibility criteria for hot flash frequency and duration are eligible.	_____	_____
Women of childbearing potential, premenopausal women.	_____	_____
Other herbal supplements for any reason, including soy and soy supplements such as powders, pills and milk.	_____	_____
Diagnosis of irritable bowel syndrome, colitis, Crohns disease or any GI condition where the patient should not consume and/or has an intolerance/allergies to seeds or nuts.	_____	_____
Anticoagulant or anti-platelet (1 mg Coumadin for central line patency is allowed) therapy. Note: 81 mg and below aspirin is allowed.	_____	_____
Anti-hypertensives, as flaxseed may potentiate this therapy.	_____	_____
Diabetes requiring oral or injectable anti-hyperglycemics.	_____	_____
Treatment with anti-cancer therapies of any kind except trastuzumab and endocrine therapies are allowed (tamoxifen, aromatase inhibitors, raloxifene as defined in 3.21).	_____	_____

All responses in above section must be “No.”

NCCTG Eligibility Checklist N08C7

10/9/2009
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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 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 __ __/__ __/____	____	____	____
Treatment on this protocol must commence at the accruing membership under the supervision of an NCCTG member physician or allied health staff.	____	____	____
Study Week 2 treatment (date of first bar) cannot begin prior to registration and must begin ≤ 28 days after randomization.	____	____	____
Pretreatment tests/procedures must be completed ≤ 100 days prior to registration (see Section 4.0). Earliest pretreatment test/procedure date __ __/__ __/____; latest pretreatment test/procedure date __ __/__ __/____	____	____	____
All required baseline symptoms (see Section 10.3) must be documented and graded.	____	____	____
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

Age:
____ 18-49 years
____ ≥ 50 years

Duration of hot flashes:
____ ≤ 9 months
____ > 9 months

Tamoxifen/Selective Estrogen Receptor Modulator (SERM)/Aromatase Inhibitor (AI):
____ Yes
____ No

Daily frequency of hot flashes:
____ 4 to 9
____ ≥ 10

Assigned Treatment

____ Flaxseed vs. placebo

Person registering Signature _____ Registration Office specialist initials _____

Physician/Allied Health Care Provider Signature _____ Date (mm/dd/yyyy) __ __/__ __/____

NORTH CENTRAL CANCER TREATMENT GROUP

N08C7 Continuation Phase Eligibility Checklist

10/09/2009
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N08C7: Phase III, Randomized, Placebo-Controlled, Double-Blind Trial of Flaxseed for the Treatment of Hot Flashes

If the patient and physician/allied health staff want to continue with the active agent, or if on placebo, begin the active agent, 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.

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 care provider _____
Institution patient number (local subject number) _____
IRB approval date (mm/dd/yyyy) __ __/__ __/____
Person Completing Form:
Last Name: (print) _____ First Name: (print) _____
Phone: _____ Fax: _____ Email: _____

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.	____	____
Treatment cannot begin prior to registration and must begin \leq 28 days after registration to the continuation phase.	____	____

All responses in above section must be "Yes"

Assigned Treatment

_____ Flaxseed

Person registering Signature _____ Registration Office specialist initials _____

Physician/Allied Health Care Provider Signature _____ Date (mm/dd/yyyy) __ __/__ __/____

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

Protocol Number: N08C7

ON-STUDY FORM

Patient ID Number: _____ Patient Initials: _____

ALL ITEMS MUST BE COMPLETED

L F M

Institution Number: _____

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

Institution: _____

MedDRA code: *(check one or if healthy patient, leave blank)*

1 10029000 *[solid tumor; NOS]*

2 10006285 *[breast cancer; NOS]*

Descriptive Factors

Breast cancer history: *(check one)* 1 Yes 2 No

Time since menopause: *(check one)*
1 ≤1 year
2 > 1 year but ≤2 years
3 >2 years but ≤3 years
4 >3 years

Anti-estrogen therapy: *(check one)*
1 Aromatase inhibitor
2 Tamoxifen
3 Other, specify _____

On anti-depressive therapy: *(check one)* 1 Yes. If Yes *(check one)* 1 SSRI 2 Other
2 No

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

Protocol Number: N08C7

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 Event Term	MedDRA Code (v. 12.0)	CTC Adverse Event Grade
Baseline number of stools per day: _____		
Nausea	10028813	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3
Vomiting	10047700	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4
Abdominal distension	10000060	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3
Flatulence	10016766	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2
Rash maculo-papular	10037868	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3
Pruritus	10037087	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3
Hematoma	10019428	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4
Vascular disorders - Other (Specify)	10047065	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

Protocol Number: N08C7

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*): _____

Date of evaluation: (*mm/dd/yyyy*) ____/____/____

*Double-Blind Phase: Cycle 1 = Week 3
 Cycle 2 = Week 5
 Cycle 3 = Week 7
 *Continuation Phase: Cycle 4 = Week 2
 Cycle 5 = Week 4
 Cycle 6 = Week 6

CTC Adverse Event Term	MedDRA Code (v. 12.0) (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	<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	____
Vomiting	10047700	<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	____
Abdominal distension	10000060	<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	____
Flatulence	10016766	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	____
Diarrhea	10012727	<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	____
Rash maculo-papular	10037868	<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	____
Pruritus	10037087	<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	____
Hematoma	10019428	<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	____
Vascular disorders - Other (Specify)	10047065	<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	____

* See Section 10.0 of the protocol.

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

Protocol Number: N08C7

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*): _____

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 Term not listed	MedDRA Code (v. 12.0) (<i>must be completed</i>)	CTC Adverse Event Grade (<i>highest grade this cycle</i>)	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?*
	<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"/>	<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"/>	<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"/>	<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"/>	<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"/>	<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"/>	<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"/>	<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"/>	<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"/>	<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"/>	<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"/>	<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

**CONCOMITANT MEDICATION 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: N08C7

Patient ID: _____ Patient Initials: _____

L F M

Institution Number: _____

Institution: _____

Date of evaluation: (mm/dd/yyyy) ___/___/_____

Is the patient taking any concomitant medications? (check one)

1 Yes 2 No (Stop here)

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

Concomitant Medication

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

Protocol Number: N08C7

Patient ID: _____ Patient Initials: _____
L F M

Institution Number: _____

Institution: _____

**CONCOMITANT MEDICATION 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)

Current Cycle Number*: _____

Date of evaluation: (mm/dd/yyyy) ___/___/___

Has there been any change in medications since the previous visit? (check one)

1 Yes 2 No (Stop here)

*Double-Blind Phase:	Cycle 1 = Week 3
	Cycle 2 = Week 5
	Cycle 3 = Week 7
*Continuation Phase:	Cycle 4 = Week 2
	Cycle 5 = Week 4
	Cycle 6 = Week 6

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

Concomitant Medication	Concomitant Medication Reason: 1= New medication 2= Medication no longer being taken

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: N08C7

Patient ID: _____ Patient Initials: _____
L F M

Institution Number: _____

Institution: _____

Current Cycle Number*: _____

*Double-Blind Phase: Cycle 1=Week 3
Cycle 2=Week 5
Cycle 3=Week 7
*Continuation Phase: Cycle 4=Week 2
Cycle 5=Week 4
Cycle 6=Week 6

Date of Evaluation (*phone call*): (*mm/dd/yyyy*) ___/___/____

Treatment package number: _____
(not applicable at Cycle \geq 4)

Did patient stop taking the flaxseed/placebo bar? (*check one*)

1 Yes. If Yes, was patient taken off study due to dislike of taste/texture of flaxseed/placebo bar? (*check one*)

1 Yes

2 No. If No, Primary reason: (*check one*) 100 Per protocol
99 Other (not per protocol), specify _____

2 No. If No, was the bar decreased by one-half bar per day? (*check one*)

1 Yes. If Yes, Primary reason: (*check one*) 100 Per protocol
99 Other (not per protocol), specify _____

2 No

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

Protocol Number: N08C7

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 the study product on the double-blind phase; if the patient is on continuation, this would be the last day the patient took the study product 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: (check one) 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: N08C7

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: _____

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: N08C7

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*: _____

*Double-Blind Phase:	Cycle 1 = Week 3
	Cycle 2 = Week 5
	Cycle 3 = Week 7
*Continuation Phase:	Cycle 4 = Week 2
	Cycle 5 = Week 4
	Cycle 6 = Week 6

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

Study Phase: 1 Double-Blind Phase
2 Continuation Phase

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
- 99 Other reason, specify _____



NCCTG

NORTH CENTRAL CANCER TREATMENT GROUP

October 9, 2009

Order Form

Quality-of-Life Booklets

Title: N08C7, Phase III, Randomized, Placebo-controlled, Double-Blind Trial of Flaxseed for the Treatment of Hot Flashes

Patient Questionnaire - Double Blind Phase

Number of booklets needed: _____

Patient Questionnaire - Continuation Phase

Number of booklets needed: _____

Fax form to: 507-284-1902

Attention of NCCTG Operational Support Clerk

Requestor: _____ Phone: _____

Affiliate/Membership: _____/_____

Shipping address: _____

Date: _____