

North Central Cancer Treatment Group

N0392: Assessment of Patient Satisfaction with Participation in Phase II/III NCCTG Clinical Trials

Addendum 3– September 18, 2009

**Summary**

- Descriptive factors have been revised
- Administrative/Editorial changes

**Replacement pages are included. Please incorporate into the protocol and keep this addendum with your protocol.**

**Title page** Reflects the addition of Addendum 3.

**Protocol Resources page**

Page 2 Sara Braun's title has been updated from NCCTG *Research Base Protocol Development Coordinator* to NCCTG *Research Base Research Protocol Specialist*

**Section 9.0** **Descriptive Factors**

Page 11 Section 9.5 has been modified, "other" has been added as an alternative option for types of cancer that are staged differently than the typical staging of I, II, III, or IV. Changes are as follows:

Tumor stage: I vs. II vs. III vs. IV vs. **Other**.

## North Central Cancer Treatment Group

**Assessment of Patient Satisfaction with Participation in Phase II/III NCCTG Clinical Trials**

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

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<b>Document History</b>	<b>(Effective Date)</b>
Activation	June 7, 2006
Addendum 1	January 19, 2007
Addendum 2	November 16, 2007
Addendum 3	September 18, 2009

**Study**  
**Participants**  
Entire  
NCCTG

**Date**  
**Activated**  
June 7, 2006

**Protocol Resources**

	<b>Questions:</b>	<b>Contact Name:</b>
Add 1	Patient eligibility*, test schedule, forms completion	Carol A. Leonard NCCTG <i>Research Base</i> Quality Control Specialist Phone: 507/284-3121 Fax: 507/266-7240 E-mail: <a href="mailto:leonard@mayo.edu">leonard@mayo.edu</a>
Add 1	Forms completion and submission	Jill K. Burton NCCTG <i>Research Base</i> Clinical Research Associate Phone: 507/284-8440 Fax: 507/284-5280 E-mail: <a href="mailto:burton@mayo.edu">burton@mayo.edu</a>  M. Cathie Smith, CCRC NCCTG Member Clinical Research Associate Phone: 904/953-2865 Fax: 904/953-2675 E-mail: <a href="mailto:smith.marycatherine@mayo.edu">smith.marycatherine@mayo.edu</a>
Add 3	Protocol document, consent form, regulatory issues	Sara M. Braun NCCTG <i>Research Base</i> Research Protocol Specialist Phone: 507/538-8226 Fax: 507/284-5280 E-mail: <a href="mailto:braun.sara@mayo.edu">braun.sara@mayo.edu</a>
Add 1,2	Technical problems with electronic form entry.	Barbara A. Warren NCCTG <i>Research Base</i> Data Management Specialist Phone: 507/284-5901 Fax: 507/538-0906 E-mail: <a href="mailto:warren.barbara@mayo.edu">warren.barbara@mayo.edu</a>

\* No waivers of eligibility per NCI

**9.0 Descriptive Factors**

- 9.1 ECOG Performance Scale (PS): 0 vs. 1 vs. 2 vs. 3 vs. 4 vs. unknown.
- 9.2 Gender: Male vs. Female.
- 9.3 Age (years):  $\leq 65$  vs.  $> 65$ .
- 9.4 Tumor type.
- Add 2,3 9.5 Tumor stage: I vs. II vs. III vs. IV vs. Other.
- Add 2 9.6 NCCTG protocol number of current treatment study.
- Add 2 9.7 Phase: II vs. III.

September 18, 2009

## **FORMS PACKET**

### **N0392, Assessment of Patient Satisfaction with Participation in Phase II/III NCCTG Clinical Trials**

Contents:   ✓   Eligibility checklist (9/18/09)  
                  Patient Questionnaire Booklet Compliance Form (10/31/06)  
                  Booklet order form (6/13/06)

✓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.



Study reg. number \_\_\_\_\_

**Eligibility Check** - Answer questions below (yes/no). All requirements must be confirmed. All dates are to be M/D/Y.

Yes No

- \_\_\_\_ Enrollment on an NCCTG-sponsored clinical trial which has been designated as a parent study to N0392.
- \_\_\_\_ Ability to complete the questionnaire booklets. Can be done with the aid of an interpreter, family member or medical professional, if necessary.

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

- \_\_\_\_ Cognitive impairment. If patient is able to complete the questionnaire, it will be assumed that cognitive impairment does not exist.

**All responses in above section must be "No."**

- \_\_\_\_ Patient eligible.

**Registration Check** - Answer questions below (yes/no). All requirements must be confirmed. All dates are to be M/D/Y.

Yes No

- \_\_\_\_ Successful registration to the parent protocol.
- \_\_\_\_ **Is this an USA institution?** (This question may be answered yes or no.)
  - \_\_\_\_ Yes → Complete authorization question below.
  - \_\_\_\_ No → Check "not applicable (**Non-USA institution only**)" and go to next question.
- \_\_\_\_ Authorization for use and disclosure of protected health information signed and dated.
- \_\_\_\_ Date of authorization \_\_\_\_-\_\_\_\_-\_\_\_\_ vs. not applicable (**Non-USA institution only**) \_\_\_\_.
- \_\_\_\_ The administration of all assessments will commence at an NCCTG accruing membership under the supervision of an NCCTG member physician, nurse or clinical research assistant.

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

- \_\_\_\_ Randomization/registration allowed.

Descriptive Factors

ECOG PS

- \_\_\_\_ 0
- \_\_\_\_ 1
- \_\_\_\_ 2
- \_\_\_\_ 3
- \_\_\_\_ 4
- \_\_\_\_ Unknown

Gender

- \_\_\_\_ Male
- \_\_\_\_ Female

Age (years)

- \_\_\_\_ ≤65
- \_\_\_\_ >65

Tumor type: \_\_\_\_\_

Tumor stage

- \_\_\_\_ I
- \_\_\_\_ II
- \_\_\_\_ III
- \_\_\_\_ IV
- \_\_\_\_ Other

NCCTG protocol number of current treatment study:

\_\_\_\_\_

Phase

- \_\_\_\_ II
- \_\_\_\_ III

NCCTG Eligibility Checklist N0392

09/18/2009  
Page 3 of 3

Study reg. number \_\_\_\_\_

Assigned Treatment

\_\_\_\_\_ A) Assessments

Person registering \_\_\_\_\_ Random. specialist \_\_\_\_\_  
Signature initials

Physician/nurse/clinical research assistant \_\_\_\_\_  
Signature M D Y