

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
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Study reg. number _____

Assigned Treatment

_____ A) Assessments

Person registering _____ Random. specialist _____
Signature initials

Physician/nurse/clinical research assistant _____ M - D - Y
Signature

PLACE LABEL HERE

Protocol Number: N0392

Patient ID: _____ Patient Initials: _____

L F M

Institution Number: _____

Institution: _____

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: _____

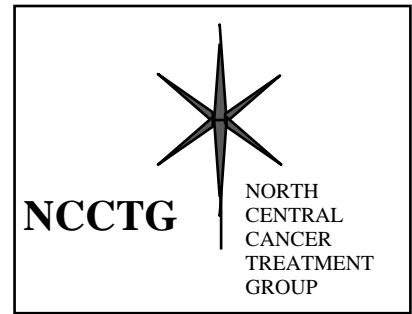
Date this form completed: (mm/dd/yyyy) ____/____/____

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
- 5 Patient did not like content of questions
- 6 Site did not like content of questions
- 7 Other reason, specify _____

Operations Office

Telephone (507) 284-3005



June 13, 2006

Order Form

Quality-of-Life Booklets

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

Patient Questionnaire: Baseline (Control Preference Form)

Number of booklets needed: _____

Patient Questionnaire: During Active Treatment (Was It Worth It Questionnaire)

Number of booklets needed: _____

Fax form to: 507-284-1902

Attention of NCCTG Operational Support Clerk

Requestor: _____ Phone: _____

Affiliate/Membership: _____/_____

Shipping address: _____

Date: _____