

North Central Cancer Treatment Group

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

Addendum 1– January 19, 2007

**Summary**

*Scientific Change:*

- Revisions made throughout protocol to allow for verbal or written consent.
- An **optional** model consent form has been added. Appendices have been renumbered accordingly.

*Administrative/Editorial Change:*

- Document history and resource page updated.
- Revisions made throughout protocol to switch to remote data entry.
- Revisions made to Sections 4.0 and 5.0 to clarify which treatment studies N0392 will be added to.
- In Section 8.0, correct template has been inserted for registration procedures.
- Submission timetable added to Section 12.0.
- Patient instructions added to Appendix III, Was It Worth It Questionnaire for clarity.
- Other editorial changes.

**A replacement protocol is provided. Please replace the current copy with the one attached. Please keep this addendum with your protocol.**

**Title page:** Document history updated.

**Protocol Resources:**

Page 2 The following editorial changes were made to the protocol resource page:

Carol A. Leonard

**Jill K. Burton**

**NCCTG *Research Base* Clinical Research Associate**

**Phone: 507/284-8440**

**E-mail: [burton@mayo.edu](mailto:burton@mayo.edu)**

~~Fax: 904/953-2675~~

**E-mail: smith.marycatherine@mayo.edu**

Barbara A. Warren

**Index:**

Page 3

An optional model consent form was added as some local IRB's are requiring written consent instead of verbal. The order of the other two appendices was switched and they were renumbered accordingly throughout the protocol.

**Appendix I – Consent form (optional)**

Appendix II – The Control Preferences Scale (CPS)

Appendix III – Was It Worth It (WIWI) Questionnaire

**Schema:**

Page 4

Step 3 revised for clarification

Patients registered/randomized to appropriate NCCTG treatment trials ~~after~~ **which has been designated as a parent trial to N0392 activation date** (see Section 4.0 for study approval process)

Step 4 revised to reflect that verbal or written consent is acceptable.

NCCTG Clinical Research Associate (CRA), Nurse, or MD discusses study participation and survey schedule with patient at study entry and documents discussion in the patient's medical record. Verbal **or written** consent is given and written HIPAA authorization is obtained. Both are documented in the patient's medical record.

Step 6 editorial revision

Patient completes baseline ~~questionnaire survey~~, Control Preferences Scale\* before beginning treatment on parent protocol.

Steps 7 & 9 revised to reflect that data will be entered electronically.

~~NCCTG CRA duplicates survey for own records, and mails original survey to NCCTG Operations Office for data entry~~ **Baseline data will be entered into the remote data entry system.**

~~NCCTG CRA duplicates questionnaire for own records, and mails original survey to NCCTG Operations Office for data entry~~ **Patient questionnaire data will be entered into the remote data entry system.**

**Section 4.0**

Page 8

**Study Design**

Revised for clarification and editorial changes.

Paragraph 1

We will seek to evaluate patient perceptions of their experience in clinical trials. The patient population includes all patients who enroll in ~~appropriate~~ **designated** NCCTG phase II or III **treatment** studies (~~treatment and control~~) for a period of 12 months....

Paragraph 2  
(~~Dillman, 200040~~)

Paragraph 5, second bullet

- The WIWI will be administered at the end of the 1<sup>st</sup> cycle of treatment (or at 1 month if cycle is not defined in the treatment protocol), and at the end of active treatment (or at 1 year from **registration**/randomization, whichever comes first).

Paragraph 8, revised to reflect that data will be entered electronically.

~~The NCCTG physician, Nurse, or Clinical Research Associate (CRA) will duplicate the questionnaire for own records, and mail original survey to NCCTG Operations Office for data entry.~~ **Patient questionnaire data will be entered into the remote data entry system.**

Paragraph 9

A separate **written** consent form is ~~optional~~**not necessary**, **verbal consent is acceptable** as this is a minimal risk study. **Note: If a written consent is required by your local IRB you may use the model consent form in this protocol or create your own consent form to meet the requirements of your local IRB.**

## Section 5.0

### Patient Eligibility

Page 9

Section 5.11: Revised for clarification.

Enrollment on an ~~appropriate~~ NCCTG-sponsored clinical trial **which has been designated as a parent study to after N0392 activation date** (~~this would exclude patients enrolled in an intergroup study where NCCTG is not the data center~~)

## Section 6.0

### Test Schedule

Table revised and footnotes added for clarification.

| Assessments            | Prior to start of treatment | End of 1 <sup>st</sup> cycle (or after 1 month) <sup>1</sup> of treatment | End of active treatment (or at 1 yr) <sup>2</sup> |
|------------------------|-----------------------------|---|---|
| CPS<br>(Appendix II)   | X                           |   |   |
| WIWI<br>(Appendix III) |                             | X   | X   |

**1 Time point of 1 month is used if cycle is not defined in the treatment protocol.**

**2 Time point of 1 year is used only if length of active treatment is  $\geq$  1 year.**

**Section 8.0 Registration/Randomization Procedures**

Page 10

Section 8.2: Registration information has been corrected to reflect that IRB approvals must be on file at the CTSU Regulatory Office.

~~IRB approval(s) is required for each treating site and a 310 form is to be on file at the NCCTG Randomization Center before patient accrual.~~ **IRB approval(s) is required for each treating site. A signed Cancer Trials Support Unit (CTSU) IRB Certification Form is to be on file at the CTSU Regulatory Office (fax 215-569-0206). This form can be found at the following Web site: [www.ctsu.org/rss2\\_page.asp](http://www.ctsu.org/rss2_page.asp). Guidelines can be found under Quick Fact Sheets.**

**In addition to submitting initial IRB approval documents, ongoing IRB approval documentation must be on file (no less than annually) at the CTSU Regulatory Office (fax 215-569-0206). If the necessary documentation is not submitted in advance of attempting patient registration, the registration will not be accepted and the patient may not be enrolled in the protocol until the situation is resolved.**

**When the study has been permanently closed to patient enrollment, submission of annual IRB approvals to the CTSU is no longer necessary.**

Section 8.3: Revised for clarification. Added 5<sup>th</sup> bullet.

- **Verbal or written consent given**

**Section 12.0 Data Collection Procedures**

Page 15

Reference corrected.

Questionnaires will be compiled into professionally prepared booklets as per the methods of Dillman (~~402000~~).

Revised to reflect that data will be entered electronically and a submission timetable has been added for clarify submission schedule.

~~Upon receipt, of completed booklets will be entered into the remote data entry system, the CRA, Nurse, or NCCTG physician will submit the completed booklet to the primary CRA. The CRA will duplicate questionnaire for own records, and mail original survey to NCCTG Operations Office for data entry.~~

Submission timetable:

| <b>Booklets/Forms</b>                                      | $\leq 2$ weeks after registration | At end of 1 <sup>st</sup> treatment cycle (or after 1 month of treatment) | At end of treatment or at 1 yr. (whichever occurs first) |
|--|-----------------------------------|---|--|
| Patient Questionnaire Booklet CPS (App II) <sup>1</sup>    | X                                 |   |  |
| Patient Questionnaire Booklet WIWI (App III) <sup>1</sup>  |                                   | X   | X  |
| Patient Questionnaire Booklet Compliance Form <sup>2</sup> |                                   | X   | X  |

1. Patient questionnaire booklets **must** be used; copies are not permitted.
2. This form must be completed **only** if the patient questionnaire contains absolutely **NO** patient provided assessment information.

~~The NCCTG Operations Office will provide completed booklets to the study coordinator for data entry. All of the data collected will be stored in secure areas and will be entered by the study coordinator at the clinical site or at the research base, as appropriate, via the JCCS data entry system at the clinical site.~~

**Appendix I**     **Consent form**  
Pages 1-5     An optional model consent form was added.

**Appendix II**     **The Control Preference Scale.** First sentence was removed to simplify questionnaire as it didn't contain any additional information for the patient.  
Page 1     ~~There are 5 major ways that patients could be involved in the choices about how to treat their illness.~~

**Appendix III**     **Was It Worth It**  
Page 1     Instructions were added for clarification. (Note: This change will not be implemented until new booklets are ordered.)

**Directions:** ~~Circle one response~~ **Please respond to the following 4 items as indicated.**

Overall, did your quality of life change by participating in this research study (**circle one response**)?

It improved

It stayed the same

It got worse

Overall, how was your experience of participating in this research study (**circle one response**)?

Better than I expected

The same as I expected

Worse than I expected

**Please note:** The changes to Appendices II & III will be incorporated into the next printing of the booklets. The changes were made strictly for clarification. It is acceptable to use either version.