

## APPENDIX X (5/16/07, 10/30/07)

### NCCTG GROUP-SPECIFIC INFORMATION

#### 1.0 REGISTRATION

##### Step 1

To register a patient, call (507/284-4130) or fax (507/284-0885) a completed Step 1 eligibility checklist to the Randomization Center between 8 a.m. and 3:30 p.m. central time Monday through Friday.

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.

Prior to accepting the registration, the NCCTG Randomization Center will verify the following:

- IRB approval at the registering institution
- Patient eligibility
- Existence of a signed consent form
- Existence of a signed authorization for use and disclosure of protected health information (*U.S.A. institutions only*)

The NCCTG Randomization Center will contact RTOG Headquarters to register the patient and will then contact the submitting institution. The site has reviewed and understands the central pathology review process.

***After the patient has been registered, the treating site must submit pathology material per Section 10 of the protocol.***

##### Step 2

Once the first segment of treatment has been completed, the submitting institution will submit the Step 2 eligibility checklist to the NCCTG Randomization Center between 8 a.m. and 3:30 p.m. central time Monday through Friday..

The NCCTG Randomization Center will contact RTOG Headquarters to randomize the patient to the adjuvant phase of treatment. NCCTG will then contact the submitting institution with the treatment assignment.

All investigators must be registered with CTEP, DCTD by the annual submission of the FDA Form 1572 and a current C.V. To obtain an NCI/CTEP investigator number, investigators should complete and submit (*by US Mail or Express Courier, faxes are not acceptable*) an FDA Form 1572, with an original signature, and a current curriculum vitae to the PMB at:

Pharmaceutical Management Branch, CTEP, DCTD, NCI  
6130 Executive Boulevard, Room 7149  
Rockville, MD 20852  
Phone: 301-496-5725

A copy of this submission should be sent to the NCCTG Operations Office.

The FDA Form 1572, with instructions, is available on the NCI home page (<http://ctep.info.nih.gov>) or by calling PMB at 301-496-5725.

## **2.0 DATA SUBMISSION**

Submit data to: RTOG Headquarters  
1818 Market Street, Suite 1600  
Philadelphia, PA 19103

## **3.0 NEUROCOGNITIVE FUNCTION FORMS**

Neurocognitive function forms are found in the Forms Packet available on the NCCTG website.

## **4.0 ADVERSE EVENT REPORTING**

Follow the guidelines as stated in the protocol.

## **5.0 TISSUE/SPECIMEN SUBMISSION**

Follow the guidelines as stated in the protocol.