



# NCCTG

NORTH CENTRAL CANCER TREATMENT GROUP

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Date: July 25, 2008

To: NCCTG Primary Clinical Research Associates

From: Sara Braun  
Protocol Development Coordinator

Subject: N0275, Phase II Trial Evaluating Resection followed by Adjuvant Radiation Therapy (RT) for Patients with Desmoplastic Melanoma

Attached is an updated eligibility checklist with the following revisions:

- Reference to the treating location, physician, and IRB approval date (chemo) have been deleted due to the only type of treatment given for this study is radiation therapy.
- **REGISTRATION/RANDOMIZATION INSTRUCTIONS:** The Registration/Randomization Application requires entry of both a Treating Location and Physician **and** Secondary Treating Location and Physician; enter your Radiation Therapy Treating Location and Physician twice.

If you have any questions, please contact me at 507/538-8226.

Thank you.

SB/dg  
Enclosure

July 25, 2008

## FORMS PACKET

**N0275:** Phase II Trial Evaluating Resection Followed by Adjuvant Radiation Therapy (RT) for Patients with Desmoplastic Melanoma

Contents ✓ Eligibility Checklist: 7-25-08  
\*Forms Completion Instructions: Please refer to general forms completion instructions on website. No protocol-specific instructions needed.  
Desmoplastic Melanoma On-study Form: 4-28-05  
Pathology Reporting Form: 3-17-08  
Pathology Submission Form: 3-17-08  
At Completion of Radiotherapy Form: 4-28-05  
Radiation Therapy Reporting Form: 4-28-05  
Observation Form: 7-25-03  
Post Radiotherapy Form: 4-28-05  
End of Active Treatment Form: 4-08-03  
Event Monitoring Form: 7-25-03  
Event Monitoring Continuation Form: 7-25-03  
Notification Form (Grade 4 or 5 Non-AER Reportable Events): 6-1-06  
NCCTG Brief Fatigue Inventory Questionnaire: 5-16-03

✓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.

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Eligibility Checklist

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**N0275: Phase II Trial Evaluating Resection followed by Adjuvant Radiation Therapy (RT) for Patients with  
Desmoplastic Melanoma**

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

Has the patient ever been on a prior study entered through this Registration Office?  Yes  No

If yes: Last protocol number \_\_\_\_\_; previous patient ID number \_\_\_\_\_

Registration date (date on) (mm/dd/yyyy) \_\_\_/\_\_\_/\_\_\_\_\_

Patient study ID number (provided at time of Registration) \_\_\_\_\_

NCCTG member (participant sponsor) \_\_\_\_\_

NCCTG treating location (RT) \_\_\_\_\_

NCCTG treating physician (RT) \_\_\_\_\_

Institution patient number (local subject number) \_\_\_\_\_

IRB approval date (RT) (mm/dd/yyyy) \_\_\_/\_\_\_/\_\_\_\_\_

Patient initials (last, first, middle) \_\_\_\_\_  
(For Mayo Rochester patients, include first four letters of last name.)

Gender (check one)  Male  Female  Unknown

Date of birth (mm/dd/yyyy) \_\_\_/\_\_\_/\_\_\_\_\_

Zip code \_\_\_\_\_

Country of Residence \_\_\_\_\_

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)

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

Ethnicity (check one)

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

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

- \_\_\_\_ \_\_\_\_ ≥18 years. Age = \_\_\_\_\_.
- \_\_\_\_ \_\_\_\_ ECOG performance status (PS) 0, 1, or 2. PS = \_\_\_\_\_.
- \_\_\_\_ \_\_\_\_ Pathologically proven DM ≥1 mm in depth or locally recurrent DM. Recurrent tumor is defined as a tumor found ≤2 cm from the previous excision or within the surgical bed (which includes the extent of previous skin flaps).
- \_\_\_\_ \_\_\_\_ DM resected with pathologically negative margins. Acceptable surgery includes standard wide local excision and Moh's surgery.
- Tumors on the trunk proximal extremities need to have a ≥2 cm negative margin. Tumors located on the head and neck and distal extremities will have an attempt at 2 cm negative margins but due to location and subsequent concern regarding cosmesis a margin <2 cm will be acceptable if margin is negative.
  - Margins from tumors resected using the Moh's techniques will be accepted if negative and best approximation of tumor with will be made.
- \_\_\_\_ \_\_\_\_ RT is to begin ≤8 weeks after definitive surgical resection. This will allow for definitive healing from the wide local excision. Due to the nature of the disease, there is the potential need for skin grafts and skin flaps to cover wounds which can be prone to wound healing issues. 8 weeks should allow adequate time for healing prior to radiation therapy.
- \_\_\_\_ \_\_\_\_ Adjuvant systemic therapy (immunotherapy or chemotherapy) must be postponed until irradiation is completed.

The utility of adjuvant systemic therapy is unknown for patients with desmoplastic melanoma. There is a benefit for patients with cutaneous melanoma who have stage III disease but due to the fact the subset of DM is so small it is impossible to evaluate that group. There are reports of increased in field toxicity in patients who receive adjuvant interferon therapy. Severe subacute and late complications were seen in 5 out of 10 patients who received concurrent or sequential alpha-interferon therapy. The decision to treat these patients will be left up to the treating physician.

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

- \_\_\_\_ \_\_\_\_ Previous irradiation to the same site.
- \_\_\_\_ \_\_\_\_ Non-healing surgical wound.
- \_\_\_\_ \_\_\_\_ Active infection at the surgical site.
- \_\_\_\_ \_\_\_\_ Evidence of metastatic disease. Local nodal disease is still eligible for the trial.
- \_\_\_\_ \_\_\_\_ Life expectancy <1 year.
- \_\_\_\_ \_\_\_\_ Melanoma with focally desmoplastic features, in which the desmoplastic melanoma is not the predominant histologic pattern of the tumor, will be excluded. Non-desmoplastic neurotropic melanoma and non-desmoplastic spindle cell melanoma are also excluded.
- \_\_\_\_ \_\_\_\_ Previous malignancy <5 years excluding basal cell carcinoma or squamous cell carcinoma of the skin or cervical carcinoma in situ (with the exception of patients who have stage I breast cancer who were adequately treated with adjuvant therapy and are currently disease free, and patients with stage I or II prostate cancer treated with prostatectomy or radiotherapy and are biochemically free of disease [for RRP PSA <0.3 and for radiotherapy PSA <2.0 above the post treatment nadir]).
- \_\_\_\_ \_\_\_\_ Any of the following:
- Pregnant women
  - Women of childbearing potential who are unwilling to employ adequate contraception (condoms, diaphragm, birth control pills, injections, intrauterine device [IUD], surgical sterilization, abstinence, etc.)

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

NCCTG Eligibility Checklist N0275

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

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

Yes No

- \_\_\_\_ Consent form signed and dated. Date of consent \_\_\_\_ - \_\_\_\_ - \_\_\_\_.
- \_\_\_\_ Authorization for use and disclosure of protected health information signed and dated.
- \_\_\_\_ Date of authorization \_\_\_\_ - \_\_\_\_ - \_\_\_\_ vs. Not applicable (Non-U.S.A. institution only) \_\_\_\_.
- \_\_\_\_ Treatment on this protocol must commence at the accruing membership under the supervision of a NCCTG member physician.
- \_\_\_\_ Treatment cannot begin prior to registration and must begin  $\leq 30$  days after registration.
- \_\_\_\_ Pretreatment tests must be completed within the guidelines specified on the test schedule (see Section 4.0).
  - Urine pregnancy test must be done  $\leq 7$  days prior to registration (see Section 4.0).
    - Urine pregnancy test date \_\_\_\_ - \_\_\_\_ - \_\_\_\_ vs. not done \_\_\_\_.
    - If urine pregnancy test not done, reason: \_\_\_\_\_.
- \_\_\_\_ All required baseline symptoms must be documented and graded on the on-study form.
- \_\_\_\_ A radiation oncologist has seen the patient and confirms the patient is a suitable candidate for this study.

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

Grouping Factor

- Desmoplastic melanoma type
- \_\_\_\_  $\geq 1$  mm deep
- \_\_\_\_ Locally recurrent

Assigned Treatment

\_\_\_\_ A) Radiotherapy

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

Physician \_\_\_\_\_ M - D - Y  
Signature