

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.
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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.

NORTH CENTRAL CANCER TREATMENT GROUP

Eligibility Checklist

07/25/2008
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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

07/25/2008
Page 3 of 3

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 ≤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 ≤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
- ____ ≥1 mm deep
- ____ Locally recurrent

Assigned Treatment

____ A) Radiotherapy

Person registering _____ Random. specialist _____
Signature Signature initials

Physician _____ M - D - Y
Signature

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

DESMOPLASTIC MELANOMA

ON-STUDY FORM

Protocol # N0275

Patient ID # _____ Initials: _____

L F M

Local ID # _____ Institution _____

Melanoma: Prior Treatment

Prior Radiation Therapy? 1 Yes 2 No

Radiation Therapy Sites (check all that apply)

Date Prior RT Ended

Date Prior RT Ended

Brain

mm dd yyyy grid

Lymph nodes

mm dd yyyy grid

Bone

mm dd yyyy grid

Other, specify _____

mm dd yyyy grid

Head/Neck

mm dd yyyy grid

Prior Vaccine Therapy? 1 Yes (If yes, provide treatment details below.) 2 No 3 Unknown

Prior Isolation Limb Perfusion? 1 Yes (If yes, provide treatment details below.) 2 No 3 Unknown

Prior Hormonal Therapy? 1 Yes (If yes, provide treatment details below.) 2 No 3 Unknown

Prior Systemic Chemotherapy? 1 Yes (If yes, provide treatment details below.) 2 No 3 Unknown

Prior Immunotherapy? 1 Yes (If yes, provide treatment details below.) 2 No 3 Unknown

Melanoma: Prior Treatment - Systemic Regimens

Table with 4 columns: Prior Treatment Regimen, Start Date (mm, dd, yyyy), End Date (mm, dd, yyyy), and Prior Treatment Regimen Type (Adjuvant, Metastatic). Includes 8 rows for data entry.

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP
DESMOPLASTIC MELANOMA
ON-STUDY FORM

Protocol # N0275

Patient ID # _____ Initials: _____

Local ID # _____ Institution _____ L F M

Cormorbid Conditions

Is the patient diabetic? 1 Yes 2 No

Is the patient currently receiving steroids? 1 Yes 2 No

Height (cm): .

Baseline Adverse Events/Symptoms

GRADE

Anorexia	<input type="text"/> 0	<input type="text"/> 1	<input type="text"/> 2	<input type="text"/> 3	<input type="text"/> 4
Nausea	<input type="text"/> 0	<input type="text"/> 1	<input type="text"/> 2	<input type="text"/> 3	<input type="text"/> 4
Odynophagia (painful swallowing)	<input type="text"/> 0	<input type="text"/> 1	<input type="text"/> 2	<input type="text"/> 3	<input type="text"/> 4
Vomiting	<input type="text"/> 0	<input type="text"/> 1	<input type="text"/> 2	<input type="text"/> 3	<input type="text"/> 4

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP
PATHOLOGY REPORTING FORM
MALIGNANT MELANOMA

I. CRA/RN

Protocol # N0275

Patient ID # _____ Initials: _____

L F M

Local ID # _____ Institution _____

Primary Pathologist: _____ No. of slides sent: _____

Clinic/Hospital: _____ Date sent: _____

Reviewer: _____ Slide No. _____ Sequence No. _____

_____ to _____

_____ to _____

II. Completed by the NCCCTG Central Pathology reviewer

Date of Initial Pathologic Diagnosis / /
m m d d y y y y

Desmoplastic histology? 1 Yes 2 No

Most Extensive Primary Surgery (check one) 1 Wide local excision of primary only 4 Mohs
2 Wide local excision of primary plus sentinel lymph node biopsy 5 Other, specify _____
3 Wide local excision of primary plus lymph node dissection

Primary Site (check one) 1 Head/Neck 5 Ocular 9 Unknown
2 Upper extremity 6 Subungual 10 Other, specify _____
3 Lower extremity 7 Mucosal
4 Trunk 8 Anogenital (non-mucosal)

Breslow Thickness (mm) .

Clark Level (Level of Invasion) (check one) 1 I - above basal lamina (in situ) 4 IV - reticular dermis
2 II - extension into papillary dermis 5 V - subcutaneous fat
3 III - interface papillary-reticular dermis

Ulceration? 1 Yes 2 No 3 Unknown

Surgical margin: (check one) 1 Positive 4 Negative, 1-1.9 cm clear
2 Negative, size not specified 5 Negative, ≥2 cm clear
3 Negative, <1 cm clear

Number of Sentinel Nodes Examined Number of Positive Sentinel Nodes
(if not done, enter 0)

Number of Lymph Nodes Examined Number of Positive Lymph Nodes
(if not done, enter 0) (including sentinel lymph node if done)

Serum Lactate Dehydrogenase (U/I)
(at time of diagnosis of distant metastases)

Date of Most Extensive Primary Surgery (if required, use last re-excision date) / /
m m d d y y y y

Regional Recurrence? 2 No 1 Yes → Date of First Regional Recurrence / /
m m d d y y y y

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

PATHOLOGY REPORTING FORM

MALIGNANT MELANOMA

I. CRA/RN

Protocol # N0275

Patient ID # _____ Initials: _____

L F M

Local ID # _____ Institution _____

Primary Pathologist: _____ No. of slides sent: _____

Clinic/Hospital: _____ Date sent: _____

Reviewer: _____ Slide No. _____ Sequence No. _____

_____ to _____

_____ to _____

II. Completed by the NCCTG Central Pathology reviewer

Metastatic Disease? 2 No

1 Yes → Date of First Metastasis

/ /
m m d d y y y y

Metastatic Site(s)
(check all that apply)

- Distant subcutaneous tissue
- Lung
- Liver
- Distant lymph nodes
- Distant soft tissue/skin metastasis
- Bone

- Brain
- Other CNS
- Other visceral, specify _____
- Other non-visceral, specify _____

III. Signatures

NCCTG Pathology Reviewer

/ /
Date

- 1. Agree with original local diagnosis
- 2. Minor disagreement with original local diagnosis
- 3. Substantial disagreement with original local diagnosis

Comments: _____

Research Base Advisor

/ /
Date

- 1. Agree with original local diagnosis
- 2. Minor disagreement with original local diagnosis
- 3. Substantial disagreement with original local diagnosis

Comments: _____

Committee Chairperson

/ /
Date

- 1. Agree with original local diagnosis
- 2. Minor disagreement with original local diagnosis
- 3. Substantial disagreement with original local diagnosis

Comments: _____

Block/Slide number(s) to be used for research/banking: _____

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

PATHOLOGY SUBMISSION FORM

(NOTE: This form is used to update the Outstanding Materials Report)

Protocol Number: N0275

Patient ID: _____ Patient Initials: _____

L F M

Institution Number: _____

Institution: _____

**** This form must be submitted to the NCCTG Operations Office at the time slides/blocks are sent to the NCCTG reviewer (see Pathology section of the protocol) ****

Date specimen shipped: (mm/dd/yyyy) ___/___/_____

Reviewer: (check one) Dr. David J. Di Caudo, NCCTG reviewer - Scottsdale, AZ

Dr. Lori Erickson, Mayo Clinic Rochester - Rochester, MN

(Note: For Mayo Clinic Rochester and its affiliate sites)

Number of slides sent: ___

Accession numbers on the slides sent:

_____	_____
_____	_____
_____	_____
_____	_____
_____	_____

Number of blocks sent: ___

Accession numbers on the blocks sent:

_____	_____
_____	_____
_____	_____
_____	_____
_____	_____

Comments:

Institution Contact Information: (Please Print)

CRA/Nurse Contact: _____

Institution Name: _____

Street Address: _____

City: _____

State: _____ Zip: _____

Phone Number: _____

Fax Number: _____

E-mail Address: _____

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

AT COMPLETION OF RADIOTHERAPY

Protocol # N0275

Patient ID # _____ Initials: _____

L F M

Local ID # _____ Institution _____

Adverse Events (use version 2.0 of the CTC grade 0-5)

Evaluation Date: / /
m m d d y y y y

Actual Weight (kg): .
 (used for this cycle, round to the nearest tenth)

ECOG Perf. Status (check one): 0 1 2 3 4
 (used for this cycle)

Adverse Event 1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No Adverse Events (stop here) GRADE ALL ADVERSE EVENTS BELOW	MedDRA Code (must be completed)	Grade (highest grade this cycle) INCLUDE GRADE 0's	Relationship to Study Medication If Grade > 0 1 = Not related 2 = Unlikely 3 = Possible 4 = Probable 5 = Definite	AER* Check if submitted
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Required Adverse Events from Section 10.0 of Protocol

Alopecia	1 0 0 0 1 7 6 0	0 1 2 ■ ■ ■	1 2 3 4 5	1 <input type="checkbox"/>
Radiation dermatitis	1 0 0 1 2 4 8 7	0 1 2 3 4 5 (death)	1 2 3 4 5	1 <input type="checkbox"/>
Anorexia	1 0 0 0 2 6 4 6	0 1 2 3 4 5 (death)	1 2 3 4 5	1 <input type="checkbox"/>
Nausea	1 0 0 2 8 8 1 3	0 1 2 3 ■ ■	1 2 3 4 5	1 <input type="checkbox"/>
Odynophagia (painful swallowing)	1 0 0 3 0 2 2 0	0 1 2 3 4 5 (death)	1 2 3 4 5	1 <input type="checkbox"/>
Vomiting	1 0 0 4 7 7 0 6	0 1 2 3 4 5 (death)	1 2 3 4 5	1 <input type="checkbox"/>
Pain due to radiation	1 0 0 3 7 7 5 5	0 1 2 3 4 5 (death)	1 2 3 4 5	1 <input type="checkbox"/>

Adverse Events beyond those required in Section 10.0 of the protocol. Record grade 2 with attribution of possible, probable or definite and all grade 3, 4 and 5 regardless of attribution.**

Other:	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	2 3 4 5 (death)	1 2 3 4 5	1 <input type="checkbox"/>
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* See Section 10.0 of the protocol.

** Both hematologic and nonhematologic Adverse Events must be graded on this form as applicable.

NORTH CENTRAL CANCER TREATMENT GROUP

AT COMPLETION OF RADIOTHERAPY

ALL ITEMS MUST BE COMPLETED

Amended Data: if yes, check box and **highlight** amended areas

Protocol # N0275

Patient ID # _____ Initials: _____

L F M

Local ID # _____ Institution _____

Adverse Event	MedDRA Code (must be completed)	Grade (highest grade this cycle)	Relationship to Study Medication If Grade > 0 1 = Not related 2 = Unlikely 3 = Possible 4 = Probable 5 = Definite	AER* Check if submitted
Other:	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 (death)	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	1 <input type="checkbox"/>
Other:	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 (death)	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	1 <input type="checkbox"/>
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Other:	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 (death)	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	1 <input type="checkbox"/>
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Other:	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 (death)	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	1 <input type="checkbox"/>
Other:	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 (death)	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	1 <input type="checkbox"/>
Other:	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 (death)	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	1 <input type="checkbox"/>

* See Section 10.0 of the protocol.

NORTH CENTRAL CANCER TREATMENT GROUP

RADIATION THERAPY REPORTING FORM

Protocol # N0275

Patient ID # _____ Initials: _____

L F M

Local ID # _____ Institution _____

Institution Name: _____

MELANOMA

Date Start of External Radiotherapy

		/			/				
m	m		d	d		y	y	y	y

Enclose copies:
See data collection procedures in protocol

Date End of External Radiotherapy

		/			/				
m	m		d	d		y	y	y	y

TREATMENT AREAS, DOSE AND TIME (Please indicate point of dose calculation on isodose distribution). All doses to be specified at isocenter for SAD treatments at intersection of axes for multi-field SSD treatments, and at midplane for parallel opposed SSD treatments.

Site Treated (check one) 1 Head/neck 4 Lower extremity
3 Trunk 5 Upper extremity 2 Other, specify _____

Treatment was delivered with (check one): 1 Photons
2 Electrons

	Tumor Dose (cGy)	# of Fractions	# of Fields	Elapsed Days	Beam Energy (MeV)	Treatment Distance	1 = SSD 2 = SAD
Total Cumulative External RT Dose							

Dose received 2 cm below tumor bed in center of field: Gy

Was RT given twice per week (Monday/Thursday or Tuesday/Friday)? 1 Yes 2 No

Did any spinal cord, lung, eye, or brain receive ≥ 24 Gy? 1 Yes 2 No

Size of margin from tumor bed: cm

UNSCHEDULED INTERRUPTIONS IN EXTERNAL RT?

1 = Yes, 2 = No
(Indicate days and reasons for each interruption)

	Days	Reasons	
1st Interruption			1 = Diarrhea
2nd Interruption			2 = Skin reaction
3rd Interruption			3 = Hematologic toxicity
			5 = Other, specify _____
			9 = Unknown

Discontinued early? (check one) 2 No 1 Yes → Reason: _____

RADIATION ONCOLOGIST'S COMMENTS

Radiation Oncologist's Signature

Date

4/28/05

NORTH CENTRAL CANCER TREATMENT GROUP

OBSERVATION FORM

ALL ITEMS MUST BE COMPLETED

Protocol # N0275

Patient ID # _____ Initials: _____

L F M

Local ID # _____ Institution _____

Amended Data: if yes, check box and **highlight** amended areas

Adverse Event	MedDRA Code (must be completed)	Grade (highest grade this cycle)	Relationship to Study Medication If Grade > 0 1 = Not related 2 = Unlikely 3 = Possible 4 = Probable 5 = Definite	AER* Check if submitted
Other:	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 (death)	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	1 <input type="checkbox"/>
Other:	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 (death)	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	1 <input type="checkbox"/>
Other:	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 (death)	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	1 <input type="checkbox"/>
Other:	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 (death)	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	1 <input type="checkbox"/>
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Other:	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 (death)	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	1 <input type="checkbox"/>
Other:	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 (death)	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	1 <input type="checkbox"/>
Other:	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 (death)	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	1 <input type="checkbox"/>
Other:	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 (death)	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	1 <input type="checkbox"/>
Other:	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 (death)	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	1 <input type="checkbox"/>
Other:	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 (death)	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	1 <input type="checkbox"/>
Other:	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 (death)	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	1 <input type="checkbox"/>
Other:	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 (death)	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	1 <input type="checkbox"/>
Other:	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 (death)	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	1 <input type="checkbox"/>

* See Section 10.0 of the protocol.

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

POST RADIOTHERAPY TREATMENT FORM

Protocol # N0275

Patient ID # _____ Initials: _____

Local ID # _____ Institution _____ L F M

Cycle #:

Evaluation Date: / /
m m d d y y y y

Has the patient received any additional treatments for melanoma following radiotherapy (but prior to progression)?

1 Yes 2 No (end form)

↓
(If yes, specify below)

Treatment Regimen	Treatment Regimen Start Date	Treatment Regimen End Date
_____	<input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> m m d d y y y y	<input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> m m d d y y y y
_____	<input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> m m d d y y y y	<input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> m m d d y y y y
_____	<input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> m m d d y y y y	<input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> m m d d y y y y
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_____	<input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> m m d d y y y y	<input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> m m d d y y y y
_____	<input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> m m d d y y y y	<input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> m m d d y y y y

NORTH CENTRAL CANCER TREATMENT GROUP

END OF ACTIVE MONITORING FORM

Submit Once Per Patient

Amended Data: if yes, check box and **highlight** amended areas

Protocol # N0275

Patient ID # _____ Initials: _____

L F M

Local ID # _____ Institution _____

Date of end of active monitoring:

/ /
 m m d d y y y y

This patient will now go to :

2 Event monitoring

PRIMARY REASON (check one)	COMMENTS
1 <input type="checkbox"/> Completed Treatment Per Protocol	
2 <input type="checkbox"/> Refused Further Treatment	Specify:
3 <input type="checkbox"/> Adverse Event	Specify:
4 <input type="checkbox"/> Disease Progression*	
5 <input type="checkbox"/> Alternative Treatment	Specify:
6 <input type="checkbox"/> Other Medical Problems	Specify:
7 <input type="checkbox"/> Died On Study	
9 <input type="checkbox"/> New Primary Cancer	
8 <input type="checkbox"/> Other	Specify:

* Submit documentation to verify PROG. See Section 11.0 of protocol.

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP
EVENT MONITORING FORM
(Progression/Recurrence, Follow-up, New Primary, Death)

Protocol # N0275

Patient ID # _____ Initials: _____

Local ID # _____ Institution _____ L F M

Amended Data: if yes, check box and **highlight** amended areas

Were you able to obtain any information about the patient since the last report?*

1 Yes 2 No → Date of last attempt to contact patient: / / → Return form to Operations Office
m m d d y y y y

VITAL STATUS

1 Alive } Date last known alive or death: / /
2 Dead } m m d d y y y y

Cause of death → 1 This cancer 4 Adverse Event (Late Adverse Event section below must be completed) 2 Other, specify _____

DISEASE FOLLOW-UP STATUS

Has the patient been assessed by a physician for this cancer since submission of the last event monitoring form?*

2 No → Go to Notice of New Primary. 1 Yes. If Yes, Date of Assessment: / /
m m d d y y y y

NOTICE OF RELAPSE/PROGRESSION

Has the patient had a recurrence of this cancer that has not been previously reported?

2 No 1 Yes → Date of recurrence: / /
Go to Notice of New Primary m m d d y y y y

Was the recurrence a local-regional recurrence?

2 No 1 Yes → Date of diagnosis: / /
m m d d y y y y

Sites (check all that apply) Head/neck Upper extremity
 Trunk Lymph nodes
 Lower extremity Other, specify _____

Method (check all that apply) Clinical exam Radiographic Pathologic

Was the recurrence a distant recurrence?

2 No 1 Yes → Date of diagnosis: / /
m m d d y y y y

Sites (check all that apply): Lung Other soft tissue
 Brain Other, specify _____

Method (check all that apply): Clinical exam Radiographic Pathologic

NOTICE OF NEW PRIMARY

Has the patient developed a new malignant neoplasm?

2 No 1 Yes → Date of diagnosis: / /
m m d d y y y y

Site of new primary: _____

LATE ADVERSE EVENT (post completion of active monitoring)

Has the patient developed any of the following not previously reported:

- Adverse events at least possibly attributed to treatment on this study.
- Death within 30 days of treatment not due to disease progression.
- Death any time at least possibly treatment related.

2 No 3 Unknown/ 1 Yes
Not evaluated ↓

* If this is the first event monitoring form check yes, enter assessment date and complete the rest of the form.

** Submit documentation to verify PROG

NORTH CENTRAL CANCER TREATMENT GROUP

EVENT MONITORING CONTINUATION FORM

(LATE ADVERSE EVENT REPORTING)

ALL ITEMS MUST BE COMPLETED

Protocol # N0275

Patient ID # _____ Initials: _____

L F M

Local ID # _____ Institution _____

Amended Data: if yes, check box and **highlight** amended areas

LATE ADVERSE EVENTS

The CTCAE Version 2.0 will be used to evaluate the following signs/symptoms:

Adverse Event	MedDRA Code (must be completed)	Highest Grade	Late Adverse Event Start Date (mm/dd/yyyy)
Other:	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 (death)	<input type="checkbox"/> <input type="checkbox"/> / <input type="checkbox"/> <input type="checkbox"/> / <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
Other:	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 (death)	<input type="checkbox"/> <input type="checkbox"/> / <input type="checkbox"/> <input type="checkbox"/> / <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
Other:	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 (death)	<input type="checkbox"/> <input type="checkbox"/> / <input type="checkbox"/> <input type="checkbox"/> / <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
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Other:	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 (death)	<input type="checkbox"/> <input type="checkbox"/> / <input type="checkbox"/> <input type="checkbox"/> / <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
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Other:	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 (death)	<input type="checkbox"/> <input type="checkbox"/> / <input type="checkbox"/> <input type="checkbox"/> / <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
Other:	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 (death)	<input type="checkbox"/> <input type="checkbox"/> / <input type="checkbox"/> <input type="checkbox"/> / <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
Other:	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 (death)	<input type="checkbox"/> <input type="checkbox"/> / <input type="checkbox"/> <input type="checkbox"/> / <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

NOTIFICATION FORM

Protocol # N0275

Patient ID # _____ Initials: _____

L F M

Local ID # _____ Institution _____

Grade 4 or 5 Non-AER Reportable Events/Hospitalization

INSTRUCTIONS:

- Use this form to report all known information on non-AER reportable grade 4 or 5 adverse events or any hospitalization during active treatment.
- If AER has been submitted for this event do not enter this form.
- Fill out all information known.
- Enter into the remote data entry system within 5 working days of notification.
- These events must also be reported on the Nadir/Adverse Event Form.

Date membership CRA aware of event(s): (mm/dd/yyyy) ___/___/___

Name of Person Completing Form: _____ Phone Number (____) _____ - _____

Cycle Number: _____ Assigned Treatment Arm: _____

Event ≥ Grade 4 1 Yes 2 No



Date of First Occurrence of Adverse Event (mm/dd/yyyy)	Common Toxicity Criteria Adverse Event Term Type (only one event per line)	CTC Adverse Event Grade	Relationship to study medication. In your opinion, is this related to the study medication? ¹
___/___/___		<input type="checkbox"/> 4 <input type="checkbox"/> 5	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No 3 <input type="checkbox"/> Unknown
___/___/___		<input type="checkbox"/> 4 <input type="checkbox"/> 5	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No 3 <input type="checkbox"/> Unknown
___/___/___		<input type="checkbox"/> 4 <input type="checkbox"/> 5	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No 3 <input type="checkbox"/> Unknown
___/___/___		<input type="checkbox"/> 4 <input type="checkbox"/> 5	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No 3 <input type="checkbox"/> Unknown
___/___/___		<input type="checkbox"/> 4 <input type="checkbox"/> 5	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No 3 <input type="checkbox"/> Unknown

1. Answer YES if attribution is unlikely, possible, probable or definite; answer NO if unrelated; answer UNKNOWN if you are not sure.

Hospitalization: 1 Yes 2 No



Hospital Admission Date: (mm/dd/yyyy) ___/___/___

Reason(s) for Hospitalization:

1 Adverse Event, specify type and grade: _____

2 Prophylactic, specify: _____

3 Other reason, specify _____

NORTH CENTRAL CANCER TREATMENT GROUP

BRIEF FATIGUE INVENTORY

APPENDIX III

Protocol # N0275

Patient ID # _____ Initials: _____

L F M

Local ID # _____ Institution _____

Date: / /
m m d d y y y y

Throughout our lives, most of us have times when we feel very tired or fatigued. Have you felt unusually tired or fatigued in the last week? Yes_____ No _____

1. Please rate your fatigue (weariness, tiredness) by circling the one number that best describes your fatigue right **NOW**.

0 1 2 3 4 5 6 7 8 9 10
No As bad as
fatigue you can imagine

2. Please rate your fatigue (weariness, tiredness) by circling the one number that best describes your **USUAL** level of fatigue during the past 24 hours.

0 1 2 3 4 5 6 7 8 9 10
No As bad as
fatigue you can imagine

3. Please rate your fatigue (weariness, tiredness) by circling the one number that best describes your **WORST** level of fatigue during the past 24 hours.

0 1 2 3 4 5 6 7 8 9 10
No As bad as
fatigue you can imagine