December 10, 2010

FORMS PACKET

N0775, A Randomized Phase II Trial of Temozolomide (TMZ) and Avastin® or ABI-007/Carboplatin (CBDCA) and Avastin® in Patients with Unresectable Stage IV Malignant Melanoma

Contents:

- Eligibility checklist (9/11/2009)
- * Forms completion instructions
- On-study form (3/28/2008)
- ✓ Baseline adverse events form (8/24/2010)
- ✓ Adverse event form (8/24/2010)
- Pretreatment RECIST measurement form (12/11/2007)
- Active monitoring RECIST measurement form (12/5/2007)
- Baseline blood specimen submission form (12/5/2007)
- Active monitoring blood specimen submission form (12/5/2007)
- Research Tissue Submission Form (11/19/2010)
- Regimen A evaluation/treatment form (3/28/2008)
- Regimen B evaluation/treatment form (7/20/2009)
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- Evaluation/observation form (3/28/2008)
- Event monitoring form (1/9/2008)
- Grade 4 or 5 non-AER reportable events/hospitalization form (2/6/2008)

✓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.

N0775: A Randomized Phase II Trial of Temozolomide (TMZ) and Avastin® or ABI-007/Carboplatin (CBDCA) and Avastin® in Patients with Unresectable Stage IV Malignant Melanoma

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

Registration date (date on) *(mm/dd/yyyy)* __ __/__ __/__ __ __ __

Patient study ID number *(provided at time of Reg/Random)* ____________________

NCCTG member (participant sponsor) ____

NCCTG treating location ____

NCCTG treating physician ____

Institution patient number (local subject number) _________________________

IRB approval date *(mm/dd/yyyy)* __ __/__ __/__ __ __ __

Person Completing Form:

Last Name: **(print)** _________________________________ First Name: **(print)** ___________________________________

Phone: _____________________ Fax: _______________________ Email: _____________________________________

Patient initials *(last, first, middle)* ____ ____ ____

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

Addendum 2 dated May 15, 2009, IRB approved?
____Yes. If Yes, Addendum 2 approval date *(mm/dd/yyyy)* __ __/__ __/__ __ __ __
____ No. If No, End form, Addendum 2 approval required.

Addendum 5 dated August 14, 2009, IRB approved?
____Yes. If Yes, Addendum 5 approval date *(mm/dd/yyyy)* __ __/__ __/__ __ __ __
____ No. If No, End form, Addendum 5 approval required.

Patient study ID number ________________________

<u>Eligibility Check</u> - Answer questions below (yes/no). All requirements must be confirmed. All dates are to be *mm/dd/yyyy*.

Inclusion Criteria

Inclusion Criteria	Yes	No	NA
Histologic proof of stage IV malignant melanoma not amenable to surgery. Note: Prior adjuvant chemotherapy and/or immunotherapy is allowed.	____	____	
Measurable disease with at least one lesion whose longest diameter can be measured as ≥20 mm by CT or MRI scans or ≥10 mm by spiral CT. Note: Disease that is measurable by physical examination only is not eligible.	____	____	
Life expectancy of ≥4 months.	____	____	
≥18 years of age. Age = ________.	____	____	
ECOG performance score (PS) of 0 or 1.	____	____	
The following laboratory values obtained ≤14 days prior to registration/randomization. Earliest laboratory test date __ __/__ __/__ __ __ __; latest laboratory test date __ __/__ __/__ __ __ __. NOTE: These dates pertain to the following labs only.	____	____	
• ANC ≥1500/mL. ANC = _______.	____	____	
• PLT ≥100,000. PLT = ________.	____	____	
• Hgb ≥9 g/dL (patients may be transfused to meet this requirement.) Hgb = ______.	____	____	
• Creatinine ≤1.5 x institutional upper limit of normal (ULN). Creatinine = _______; ULN = _______.	____	____	
• Total bili ≤1.5 mg/dL (exception: Patients with documented Gilbert's syndrome are allowed to participate despite elevated bilirubin.) **Does patient have documented Gilbert's syndrome?** (This question may be answered yes or no.) ____ Yes, patient with Gilbert's syndrome → Bili = ________. ____ No, not a patient with Gilbert's syndrome → Bili (≤1.5) = ______.	____	____	
• AST ≤2.5 x ULN. AST = ______; ULN = _______.	____	____	
• Alk phos ≤2.5 x ULN. Alk phos = ______; ULN = _______.	____	____	
• Proteinuria at screening as demonstrated by one of the following: o Urine protein:creatinine (UPC) ratio <1.0 at screening OR o Urine dipstick for proteinuria <2+ (patients discovered to have ≥2+ proteinuria on dipstick urinalysis at baseline should undergo a 24-hour urine collection and must demonstrate ≤1g of protein in 24 hours to be eligible).	____	____	
Negative serum pregnancy test done ≤7 days prior to registration/randomization, for women of childbearing potential only. Not a woman of childbearing potential *(check NA)* vs. negative pregnancy test date __ __/__ __/__ __ __ __	____	____	____
Ability to understand and the willingness to sign a written informed consent document.	____	____	
Willingness to return to an NCCTG institution for follow-up.	____	____	
Patient willing to provide mandatory blood samples for research purposes (see Sections 6.13 and 14.0).	____	____	

All responses in above section must be "Yes" unless specified as "NA."

Exclusion Criteria

Exclusion Criteria	Yes	No	NA
Prior treatment with agents disrupting VEGF activity (i.e. Avastin®, VEGF-trap, anti-VEGFR Mab.)	____	____	
Brain metastases per MRI or CT.	____	____	
Other investigational agents ≤4 weeks prior to registration/randomization.	____	____	
Major surgical procedure, open biopsy, or significant traumatic injury ≤4 weeks prior to registration/randomization. • Fine needle aspirations or core biopsies ≤7 days prior to registration/randomization. • Planned/or anticipated major surgical procedure during the course of the study.	____	____	

Patient study ID number ________________________

Exclusion Criteria—*continued*

	Yes No
Other medical conditions including but not limited to: • Active infection requiring parenteral antibiotics • Poorly controlled high blood pressure (≥150 mm Hg systolic and/or 100 mmHg diastolic) despite treatment. • New York Heart Association class II-IV congestive heart failure. • Serious cardiac arrhythmia requiring medication. • Myocardial infarction or unstable angina ≤6 months prior to registration/randomization. • Clinically significant peripheral vascular disease. • Deep venous thrombosis or pulmonary embolus ≤1 year of registration/randomization and/or ongoing need for full-dose oral or parenteral anticoagulation. • Ongoing anti-platelet treatment other than low-dose aspirin (i.e., aspirin 81 mg p.o. daily). • Active bleeding or pathological conditions that carry high risk of bleeding (e.g., known esophageal varices, etc.). • Serious, non-healing wound (including wounds healing by secondary intention), ulcer or bone fracture. • History of abdominal fistula, gastrointestinal perforation or intra-abdominal abscess ≤6 months prior to registration/randomization. • History of CNS disease (e.g., primary brain tumor, vascular abnormalities, etc.), clinically significant stroke or TIA ≤6 months prior to registration/randomization, seizures not controlled with standard medical therapy. • Radiographically documented invasion of adjacent organs (duodenum, stomach, etc.) or tumor invading major blood vessels. • History of hypertensive crisis or hypertensive encephalopathy.	____ ____
Any of the following as this regimen may be harmful to a developing fetus or nursing child: • Pregnant women • Nursing women • Women of childbearing potential or their sexual partners who are unwilling to employ adequate contraception	____ ____
Existence of peripheral neuropathy ≥grade 2.	____ ____
History of other malignancy ≤5 years with the exception of basal cell or squamous cell carcinoma of the skin, treated with local resection only, or carcinoma in situ of the cervix.	____ ____
Prior chemotherapy in the metastatic setting.	____ ____
Prior treatment with sunitinib malate or sorafenib.	____ ____
Prior treatment with any taxane-based chemotherapy.	____ ____
≤4 weeks since last day of adjuvant radiation therapy prior to registration or ≤2 weeks since last day of palliative radiation therapy. NOTE: Patients who have had >25% of their functional bone marrow irradiated are not eligible for this trial. Last day of adjuvant radiation therapy __ __/__ __/__ __ __ __. (*Leave blank if no prior adjuvant radiation therapy.)* Last day of palliative radiation therapy __ __/__ __/__ __ __ __. (*Leave blank if no prior palliative radiation therapy.)*	____ ____
Active or recent history of hemoptysis (≥ ½ teaspoon of bright red blood per episode) ≤30 days prior to registration.	____ ____
Known hypersensitivity to any of the components of Avastin®.	____ ____
Known to be HIV positive.	____ ____
Current or known history of hepatitis.	____ ____

All responses in above section must be "No."

Registration Check - Answer questions below (yes/no). All requirements must be confirmed. All dates are to be *mm/dd/yyyy*.

	Yes No NA
Consent form signed and dated. Date of consent __ __/__ __/__ __ __ __.	____ ____
Authorization for use and disclosure of protected health information signed and dated. **Non-USA institution only** *(check NA)* vs. Date of authorization __ __/__ __/__ __ __ __.	____ ____ ____
A mandatory translational research component is part of this study, the patient will be automatically registered onto this component (Section 14.0).	____ ____

Patient study ID number ________________________

Registration Check – *(continued)*

	Yes No
Treatment on this protocol must commence at the accruing membership under the supervision of an NCCTG member physician.	____ ____
Treatment cannot begin prior to registration and must begin ≤7 days after registration.	____ ____
Pretreatment tests/procedures must be completed ≤14 days prior to registration (see Section 4.0). Earliest pretreatment test date __ __/__ __/__ __ __ __; latest pretreatment test date __ __/__ __/__ __ __ __. NOTE: The earliest pretreatment test date must be less than or equal to the earliest laboratory test date **and** the latest pretreatment test date must be greater than or equal to the latest laboratory test date.	____ ____
Exception to the above dates: • Brain MRI (or CT if MRI cannot be performed) must be completed ≤28 days prior to registration. Brain MRI (or CT) date __ __/__ __/__ __ __ __	
All required baseline symptoms must be documented and graded.	____ ____
Study drug availability checked.	____ ____
Kit availability checked.	____ ____

All responses in above section must be "Yes" unless specified as "NA."

At the time of registration/randomization, the following will also be recorded:

▪ Patient has given permission to store and use blood sample(s) for future research to learn about, prevent, or treat cancer.	____ ____
▪ Patient has given permission to store and use blood sample(s) for future research to learn, prevent, or treat other health problems.	____ ____
▪ Patient has given NCCTG permission to give blood sample(s) to outside researchers.	____ ____
Patient has agreed to be enrolled on N0392.	____ ____

All responses in above section may be answered "Yes" or "No."

Stratification Factors

ECOG Performance Status (PS) *(check one):*
____ 0
____ 1

Location of metastatic disease *(check one)*:
____ M1a (skin or subcutaneous tissue or lymph node only
____ M1b (lung)
____ M1c (other visceral sites)

Assigned Treatment

_NA_A) Temozolomide + Bevacizumab (*Arm A closed to accrual as of 8/21/2009*)
_____B) Bevacizumab + ABI-007 + CBDCA

Person registering Signature ______________________________ Registration Office specialist initials _______

Physician Signature _____________________________________ Date (*mm/dd/yyyy*) __ __/__ __/__ __ __ __

PLACE LABEL HERE

Protocol Number: N0775

Patient ID: ______________________ Patient Initials: ___________
L F M

Institution Number: ____

Institution: ____

NORTH CENTRAL CANCER TREATMENT GROUP

ON-STUDY 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)

Description of Primary Disease

MedDRA code: 10053571 *[Melanoma]*

Cell type: *(check one)* 1 ☐ Spindle cell 2 ☐ Desmoplastic 3 ☐ Malignant melanoma
4 ☐ Acral lentiginous 5 ☐ Other, specify ____________________

Date of Initial Pathologic Diagnosis: *(mm/dd/yyyy)* __ __/__ __/__ __ __ __

Date of Most Extensive Primary Surgery: *(mm/dd/yyyy)* __ __/__ __/__ __ __ __
(if required, use last re-excision date)

Most Extensive Surgery this patient had *(check one)*
1 ☐ Wide local excision of primary only
2 ☐ Wide local excision of primary plus sentinel lymph node biopsy
3 ☐ Wide local excision of primary plus lymph node dissection
4 ☐ Biopsy only
5 ☐ Other, specify______________________

Primary Site *(check one)*
1 ☐ Head
2 ☐ Neck
3 ☐ Upper extremity
4 ☐ Lower extremity
5 ☐ Trunk
6 ☐ Ocular → *(go to Regional Recurrence)*
7 ☐ Subungual
8 ☐ Mucosal
9 ☐ Anogenital *(non-mucosal)*
10 ☐ Unknown → *(go to Number of Lymph Nodes Examined)*
11 ☐ Other, specify ____________________

Breslow Thickness *(mm)*: ___ ___ . ___ ___

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

Ulceration? 1 ☐ Yes 2 ☐ No 3 ☐ Unknown

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

Number of Positive Sentinel Nodes ___ ___

Number of Lymph Nodes Examined ___ ___
(if not done, enter 0; if done, enter number of sentinel and non-sentinel nodes examined)

Number of Positive Lymph Nodes ___ ___
(including sentinel lymph node if done)

Regional Recurrence? 1 ☐ Yes 2 ☐ No 3 ☐ Not applicable *(primary unknown)*
↓
Date of First Regional Recurrence *(mm/dd/yyyy)* __ __/__ __/__ __ __ __

Metastatic Disease? *(Including metastatic disease of unknown primary)* 1 ☐ Yes 2 ☐ No ⟶ Continue with Prior Treatment
↓
Date of First Metastasis *(mm/dd/yyyy)* __ __/__ __/__ __ __ __

Number of metastatic sites: ________

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 _______________

PLACE LABEL HERE

Protocol Number: N0775

Patient ID: ______________________ Patient Initials: ____________
L F M

Institution Number: ____

Institution: ____

NORTH CENTRAL CANCER TREATMENT GROUP

ON-STUDY 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)

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

Melanoma: Prior Treatment

Prior Radiation Therapy? 1 ☐ Yes 2 ☐ No *(Go to Prior Vaccine Therapy)*

Radiation Therapy Sites *(check all that apply)*	Date Prior RT Ended *(mm/dd/yyyy)*		Date Prior RT Ended *(mm/dd/yyyy)*
☐ Brain	__ __/__ __/__ __ __ __	☐ Lymph nodes *(soft tissue)*	__ __/__ __/__ __ __ __
☐ Bone	__ __/__ __/__ __ __ __	☐ Other, specify ________________	__ __/__ __/__ __ __ __
☐ Head and Neck	__ __/__ __/__ __ __ __		

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
Prior Anti-angiogenesis Therapy?	1 ☐ Yes *(If yes, provide treatment details below.)*	2 ☐ No	3 ☐ Unknown

Melanoma: Prior Treatment - Systemic Regimens

Prior Treatment Regimen	Prior Treatment Regimen Start Date *(mm/dd/yyyy)*	Prior Treatment Regimen End Date *(mm/dd/yyyy)*	Prior Treatment Regimen Type *(check one for each regimen)*
____________________	__ __/__ __/__ __ __ __	__ __/__ __/__ __ __ __	1 ☐ Adjuvant 2 ☐ Metastatic
____________________	__ __/__ __/__ __ __ __	__ __/__ __/__ __ __ __	1 ☐ Adjuvant 2 ☐ Metastatic
____________________	__ __/__ __/__ __ __ __	__ __/__ __/__ __ __ __	1 ☐ Adjuvant 2 ☐ Metastatic
____________________	__ __/__ __/__ __ __ __	__ __/__ __/__ __ __ __	1 ☐ Adjuvant 2 ☐ Metastatic
____________________	__ __/__ __/__ __ __ __	__ __/__ __/__ __ __ __	1 ☐ Adjuvant 2 ☐ Metastatic
____________________	__ __/__ __/__ __ __ __	__ __/__ __/__ __ __ __	1 ☐ Adjuvant 2 ☐ Metastatic
____________________	__ __/__ __/__ __ __ __	__ __/__ __/__ __ __ __	1 ☐ Adjuvant 2 ☐ Metastatic

ALC: ___ ___ . ___

aPTT (seconds): ___ ___ ___ .

PT/INR (seconds): ___ ___ ___ .

Fibrinogen (mg/dL): ___ ___ ___ ___

Height (cm): ___ ___ ___ .

PLACE LABEL HERE

Protocol Number: N0775

Patient ID: ________________ Patient Initials: __________
L F M

Institution Number: ______________________

Institution: ______________________

NORTH CENTRAL CANCER TREATMENT GROUP

BASELINE
ADVERSE EVENTS 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)

Required Baseline Adverse Events from Section 10.0 of Protocol		
CTC Adverse Events Term ***(CTCAE v.3.0)***	**MedDRA Code** ***(v.10.0)***	**CTC Adverse Event Grade**
Hypertension	10020772	0 1 2 3 4
Fatigue (asthenia, lethargy, malaise)	10016256	0 1 2 3 4
Neuropathy: sensory	10034620	0 1 2 3 4
Pain - *Selects*		
- Joint	10023222	0 1 2 3 4
- Muscle	10028411	0 1 2 3 4
Hemoglobin	10019483	0 1 2 3 4
Neutrophils/granulocytes (ANC/AGC)	10029366	0 1 2 3 4
Platelets	10035528	0 1 2 3 4
Leukocytes (total WBC)	10048552	0 1 2 3 4
Proteinuria	10037020	0 1 2 3 4
Cardiac ischemia/infarction	10028601	0 1 2 3 4
Wound complication, non-infectious	10048031	0 1 2 3 4

PLACE LABEL HERE

Protocol Number: N0775

Patient ID: ______________ Patient Initials: ________
L F M

Institution Number: ______________

Institution: ______________

NORTH CENTRAL CANCER TREATMENT GROUP

ADVERSE EVENT 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)

Current Cycle Number *(adverse events associated with this cycle)*: ____

Evaluation Date: *(mm/dd/yyyy)* __ __/__ __/__ __ __ __

CTC Adverse Event Term *(CTCAE v.3.0)*	**MedDRA Code *(v. 10.0)*** *(must be completed)*	CTC Adverse Event Grade *(highest grade this cycle)* **INCLUDE GRADE 0's**	CTC AE Attribution Code ***(If Grade > 0)*** 1 = Unrelated 2 = Unlikely 3 = Possible 4 = Probable 5 = Definite	Has an adverse event expedited report been submitted?* *(Enter 1 for Yes or 2 for No)*
Required Adverse Events from Section 10.0 of Protocol				
Allergic reaction/hypersensitivity (including drug fever)	10020751	0 1 2 3 4 5 (death)	1 2 3 4 5	____
Hemoglobin	10019483	0 1 2 3 4 5 (death)	1 2 3 4 5	____
Neutrophils/granulocytes (ANC/AGC)	10029366	0 1 2 3 4 5 (death)	1 2 3 4 5	____
Platelets	10035528	0 1 2 3 4 5 (death)	1 2 3 4 5	____
Leukocytes (total WBC)	10048552	0 1 2 3 4 5 (death)	1 2 3 4 5	____
Hypertension	10020772	0 1 2 3 4 5 (death)	1 2 3 4 5	____
Fatigue (asthenia, lethargy, malaise)	10016256	0 1 2 3 4	1 2 3 4 5	____
Fever (in the absence of neutropenia, where neutropenia is defined as ANC <1.0 x 10^9/L)	10016558	0 1 2 3 4 5 (death)	1 2 3 4 5	____
Nausea	10028813	0 1 2 3 4 5 (death)	1 2 3 4 5	____
Vomiting	10047700	0 1 2 3 4 5 (death)	1 2 3 4 5	____
Hemorrhage, CNS	10022763	0 1 2 3 4 5 (death)	1 2 3 4 5	____
Hemorrhage GI - *Select*				
- Abdomen NOS	10055291	0 1 2 3 4 5 (death)	1 2 3 4 5	____

* See Section 10.0 of the protocol.

PLACE LABEL HERE

Protocol Number: N0775

Patient ID: ______________ Patient Initials: ________ (L F M)

Institution Number: ______________________

Institution: ______________________

NORTH CENTRAL CANCER TREATMENT GROUP

ADVERSE EVENT 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)

Current Cycle Number (*adverse events associated with this cycle*): ____

CTC Adverse Event Term *(CTCAE v.3.0)*	**MedDRA Code** ***(v. 10.0)*** *(must be completed)*	CTC Adverse Event Grade *(highest grade this cycle)* **INCLUDE GRADE 0's**	CTC AE Attribution Code ***(If Grade > 0)*** 1 = Unrelated 2 = Unlikely 3 = Possible 4 = Probable 5 = Definite	Has an adverse event expedited report been submitted?* *(Enter 1 for Yes or 2 for No)*
Required Adverse Events from Section 10.0 of Protocol				
Hemorrhage pulmonary/upper respiratory - *Select*				
- Bronchopulmonary NOS	10065746	0 1 2 3 4 5 (death)	1 2 3 4 5	____
Febrile neutropenia (fever of unknown origin without clinically or microbiologically documented infection) (ANC <1.0 x 10^9/L, fever ≥ 38.5° C)	10016288	0 3 4 5 (death)	1 2 3 4 5	____
Proteinuria	10037020	0 1 2 3 4 5 (death)	1 2 3 4 5	____
Leukoencephalopathy (radiographic findings)	10024382	0 1 2 3	1 2 3 4 5	____
Neuropathy: sensory	10034620	0 1 2 3 4 5 (death)	1 2 3 4 5	____
Pain - *Selects*				
- Joint	10023222	0 1 2 3 4	1 2 3 4 5	____
- Muscle	10028411	0 1 2 3 4	1 2 3 4 5	
Thrombosis/thrombus/embolism	10043607	0 2 3 4 5 (death)	1 2 3 4 5	____
Cardiac ischemia/infarction	10028601	0 1 2 3 4 5 (death)	1 2 3 4 5	____
Wound complication, non-infectious	10048031	0 1 2 3 4 5 (death)	1 2 3 4 5	____

* See Section 10.0 of the protocol.

PLACE LABEL HERE

Protocol Number: N0775

Patient ID: ______________________ Patient Initials: __________
L F M

Institution Number: ______________________________________

Institution: ____

NORTH CENTRAL CANCER TREATMENT GROUP

ADVERSE EVENT 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)

Current Cycle Number *(adverse events associated with this cycle)*: ____

Were *(other)* adverse events assessed during this report period?

1 ☐ Yes, and reportable adverse events occurred

3 ☐ Yes, but no reportable adverse events occurred *(Stop here)*

2 ☐ No *(Stop here)*

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 CTC Adverse Event Terms not listed *(CTCAE v.3.0)*	**MedDRA Code *(v. 10.0)*** *(must be completed)*	CTC Adverse Event Grade *(highest grade this cycle)*	CTC AE Attribution Code ***(If Grade > 0)*** 1 = Unrelated 2 = Unlikely 3 = Possible 4 = Probable 5 = Definite	Has an adverse event expedited report been submitted?* *(Enter 1 for Yes or 2 for No)*
	☐☐☐☐☐☐☐☐	2 3 4 5 (death)	1 2 3 4 5	____
	☐☐☐☐☐☐☐☐	2 3 4 5 (death)	1 2 3 4 5	____
	☐☐☐☐☐☐☐☐	2 3 4 5 (death)	1 2 3 4 5	____
	☐☐☐☐☐☐☐☐	2 3 4 5 (death)	1 2 3 4 5	____
	☐☐☐☐☐☐☐☐	2 3 4 5 (death)	1 2 3 4 5	____
	☐☐☐☐☐☐☐☐	2 3 4 5 (death)	1 2 3 4 5	____
	☐☐☐☐☐☐☐☐	2 3 4 5 (death)	1 2 3 4 5	____
	☐☐☐☐☐☐☐☐	2 3 4 5 (death)	1 2 3 4 5	____
	☐☐☐☐☐☐☐☐	2 3 4 5 (death)	1 2 3 4 5	____
	☐☐☐☐☐☐☐☐	2 3 4 5 (death)	1 2 3 4 5	____
	☐☐☐☐☐☐☐☐	2 3 4 5 (death)	1 2 3 4 5	____
	☐☐☐☐☐☐☐☐	2 3 4 5 (death)	1 2 3 4 5	____

* See Section 10.0 of the protocol.
** Both hematologic and nonhematologic Adverse Events must be graded on this form as applicable.

PLACE LABEL HERE

Protocol Number: N0775

Patient ID: ______________________ Patient Initials: ____________
L F M

Institution Number: ____

Institution: ____

NORTH CENTRAL CANCER TREATMENT GROUP

PRETREATMENT
RECIST MEASUREMENT 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)

INSTRUCTIONS

1. *Record the target lesions (per Section 11 of the protocol).*
2. *Measure target lesions in cm. using longest diameter (one dimension only).*
3. *Record measurements at pretreatment.*
4. *Maintain same type of assessment throughout study.*
5. *Record presence or absence of non-target lesions at baseline, thereafter record the status of non-target lesions at each required evaluation.*

Assessment Date ***(mm/dd/yyyy)*** __ __/__ __/__ __ __ __
(Assessment date is the date reflecting type of assessment, not the physician interpretation date.)

Target Lesion Site(s)	Type of Assessment					Measurement
	PET/CT*	Spiral CT	Conventional CT	MRI	CXR	*(cm)*
1	15 ☐	13 ☐	2 ☐	3 ☐	5 ☐	
2	15 ☐	13 ☐	2 ☐	3 ☐	5 ☐	
3	15 ☐	13 ☐	2 ☐	3 ☐	5 ☐	
4	15 ☐	13 ☐	2 ☐	3 ☐	5 ☐	
5	15 ☐	13 ☐	2 ☐	3 ☐	5 ☐	
6	15 ☐	13 ☐	2 ☐	3 ☐	5 ☐	
7	15 ☐	13 ☐	2 ☐	3 ☐	5 ☐	
8	15 ☐	13 ☐	2 ☐	3 ☐	5 ☐	
9	15 ☐	13 ☐	2 ☐	3 ☐	5 ☐	
10	15 ☐	13 ☐	2 ☐	3 ☐	5 ☐	
					Sum of all Lesions	

Non-Target Lesions *(check one)*	☐ Present	2 ☐ Absent

*PET/CT - Only CT portion of scan can be used for measurement.

PLACE LABEL HERE

Protocol Number: N0775

Patient ID: ______________ Patient Initials: ________ L F M

Institution Number: ______________________

Institution: ______________________

NORTH CENTRAL CANCER TREATMENT GROUP

ACTIVE MONITORING
RECIST MEASUREMENT 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)

Current Cycle Number: _______

INSTRUCTIONS

1. *Record the target lesions in the same order as recorded at pretreatment (refer to Section 11 of the protocol).*
2. *Measure target lesions in cm. using longest diameter (one dimension only).*
3. *Record measurements at scheduled evaluations and progression (refer to protocol Section 4).*
4. *Maintain same type of assessment throughout study.*
5. *Record presence or absence of non-target lesions at baseline, thereafter record the status of non-target lesions at each required evaluation.*
6. *Overall objective status is determined by combining status of target lesions, non-target lesions and new lesions (refer to protocol Section 11).*

Assessment Date *(mm/dd/yyyy)* __ __/__ __/__ __ __ __
(*Assessment date is the date reflecting type of assessment, not the physician interpretation date. If tumor measurements are not required this cycle per Section 4.0, Assessment Date is the date the patient was evaluated.)*

Overall Objective Status *(check one)* **Note: If PD is selected for overall response status, and Yes is selected for "Was the appearance of any new lesions documented" go to Non-Target Lesions.**	19 ☐ N/A *(not applicable this cycle)* ⟶ End Form 1 ☐ CR* 2 ☐ PR* 5 ☐ SD 6 ☐ PD* *(Complete End of Active Treatment and Event Monitoring Forms.)* • Was the appearance of any new lesions documented? 1 ☐Yes 2 ☐No • Symptomatic Deterioration? 1☐ Yes 2☐ No

Target Lesion Site(s) Measurement (cm)
1.
2.
3.
4.
5.
6.
7.
8.
9.
10.
Sum of all Lesions:

Non-Target Lesions	**Change:** *(check one)* 1 ☐ CR 2 ☐ NonCR/NonPD 3 ☐ PD 5 ☐ Not Done 9 ☐ Not Applicable

*Submit documentation to verify CR, PR, PD.

PLACE LABEL HERE

Protocol Number: N0775

Patient ID: ________________________ Patient Initials: ____________
L F M

Institution Number: ____

Institution: ____

NORTH CENTRAL CANCER TREATMENT GROUP

BASELINE
BLOOD SPECIMEN SUBMISSION 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)

INSTRUCTIONS:
Complete this form ***for all patients*** *and enter into the remote data entry system within 14 days of study entry.*
See Section 14 of the protocol for specimen requirements and shipment.

Was a research blood specimen collected? *(check one)*

1 ☐ Yes. If Yes: Date of collection: *(mm/dd/yyyy)* __ __/__ __/__ __ __ __

Date Specimen Shipped: *(mm/dd/yyyy)* __ __/__ __/__ __ __ __

2 ☐ No. If No, reason: ____

PLACE LABEL HERE

Protocol Number: N0775____________________

Patient ID: ________________________ Patient Initials: ____________
L F M

Institution Number: ____

Institution: ____

NORTH CENTRAL CANCER TREATMENT GROUP

ACTIVE MONITORING
BLOOD SPECIMEN SUBMISSION 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)

Current Cycle Number: ____

INSTRUCTIONS:
C*omplete this form* ***for all patients*** *and enter into the remote data entry system within 7 days of specimen collection.*
See Section 14 of the protocol for specimen requirements and shipment.

Was a research blood specimen collected? *(check one)*

1 ☐ Yes. If Yes: Date of collection: *(mm/dd/yyyy)* __ __/__ __/__ __ __ __

Date Specimen Shipped: *(mm/dd/yyyy)* __ __/__ __/__ __ __ __

2 ☐ No. If No, reason: ____

PLACE LABEL HERE

Protocol Number: N0775

Patient ID: ______________________ Patient Initials: ____________
L F M

Institution Number: ____

Institution: ____

NORTH CENTRAL CANCER TREATMENT GROUP

RESEARCH TISSUE SUBMISSION 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)

INSTRUCTIONS:

- *Complete this form* ***for all patients*** *and enter into the remote data entry system on the same day the specimen is submitted.*
- *See Section 17 of the protocol for specimen requirements and shipment.*
- *Include a copy of this form with tissue submission (see Section 17).*

Patient's Consent given for *(tissue)* specimen use for this research study? *(check one)*

1☐ Yes. If Yes, complete rest of form.

2☐ No. If No, end form.

Patient's Consent given for *(tissue)* specimen use in future research to learn about, prevent, or treat cancer? *(check one)*

1☐ Yes. 2☐ No. If No, reason: ____

Patient's Consent given for *(tissue)* specimen use in future research to learn about, prevent, or treat other health problems (for example: diabetes, Alzheimer's disease, or heart disease)? *(check one)*

1☐ Yes. 2☐ No. If No, reason: ____

Patient's Consent given for NCCTG to give *(tissue)* specimen to outside researchers? *(check one)*

1☐ Yes. 2☐ No. If No, reason: ____

Was sample obtained? *(check one)*

1☐ Yes. If Yes: Date of collection: *(mm/dd/yyyy)* __ __/__ __/__ __ __ __

Date Specimen Shipped: *(mm/dd/yyyy)* __ __/__ __/__ __ __ __

2☐ No. If No, reason: ____

(Complete boxes below for submission with this specimen. Not entered into the remote data entry system).

Number of slides sent: ___ ___

Accession number(s) (on the slides sent):

_______________ _______________

_______________ _______________

_______________ _______________

_______________ _______________

Number of blocks sent: ___ ___

Accession number(s) (on the blocks sent):

_______________ _______________

_______________ _______________

_______________ _______________

_______________ _______________

Institution Contact Information: (Please Print)

Contact Person at Institution *(CRA/Nurse):*

____

Institution Name: ____________________________

Street Address: ____________________________

____

City: ____________________________

State: ____________________________

Zip Code: ____________________________

Phone Number: ____________________________

Fax Number: ____________________________

E-mail Address: ____________________________

PLACE LABEL HERE

Protocol Number: N0775

Patient ID: ______________________ Patient Initials: ____________
L F M

Institution Number: ____

Institution: ____

NORTH CENTRAL CANCER TREATMENT GROUP

TMZ & AVASTN
REGIMEN A
EVALUATION/TREATMENT 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)

Use one form per cycle, one column per agent.

Current Cycle Number: ____

ALC: ______

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

ECOG Performance Status: *(check one)* [0] [1] [2] [3] [4]
(used for this cycle)

BSA(m^2): *(used for this cycle)* ___ . ___ ___ ___

Was this cycle of treatment held *(delayed)*? *(check one)*
1 ☐ Yes, planned 2 ☐ No 3 ☐ Yes, unplanned

If Yes, planned or unplanned, Primary reason treatment held *(delayed)*: *(check one)*

35 ☐ Hematologic
146 ☐ Hypertension
129 ☐ Hemorrhage/Bleeding
148 ☐ Proteinuria Grade 3
171 ☐ Congestive heart failure
38 ☐ Other nonhematologic adverse event
99 ☐ Other (not per protocol) __________

Agent	Temozolomide (TMZ)	Bevacizumab (AVASTN)
Agent Start Date this cycle *(mm/dd/yyyy)*	__ __/__ __/__ __ __ __	__ __/__ __/__ __ __ __
Dose Level day one this cycle *If agent not given this cycle, enter '0' for dose level.*	mg/m^2	mg/kg
Total Dose this cycle *If agent not given this cycle, enter '0' for dose level.*	mg	mg
Was **DOSE LEVEL** adjusted this cycle? (i.e. mg/m^2)	1 ☐ Yes 2 ☐ No	1 ☐ Yes 2 ☐ No
If Yes, PRIMARY REASON for Dose Adjustment per Section 8.0. Not BSA changes. *(If Yes, check one Primary Reason.)*	35 ☐ Hematologic 38 ☐ Other nonhematologic adverse event 99 ☐ Other (not per protocol) __________________	99 ☐ Other (not per protocol) __________________

Were growth factors administered this cycle: *(check one)* 1 ☐ Yes 2 ☐ No

If Yes, *check one:* 1 ☐ G-CSF 2 ☐ GM-CSF

Is this Cycle 2: *(check one)* 1 ☐ Yes 2 ☐ No *(End Form)*

If Yes: **aPTT** (seconds): ___ ___ ___ .

PT/INR (seconds): ___ ___ ___ .

Fibrinogen (mg/dL): ___ ___ ___ ___

PLACE LABEL HERE

Protocol Number: N0775

Patient ID: ______________________ Patient Initials: ___________
L F M

Institution Number: ____

Institution: ____

NORTH CENTRAL CANCER TREATMENT GROUP

AVASTN & ABI-007 & CBDCA
REGIMEN B
EVALUATION/TREATMENT 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)

Use one form per cycle, one column per agent.

Current Cycle Number: ____

ALC: ____

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

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

BSA(m^2): *(used for this cycle)* ___ . ___ ___ ___

Was this cycle of treatment held *(delayed)*? *(check one)*
1 ☐ Yes, planned 2 ☐ No 3 ☐ Yes, unplanned

If Yes, planned or unplanned, Primary reason treatment held *(delayed)*: *(check one)*

35 ☐ Hematologic
136 ☐ AST or alkaline phosphatase
51 ☐ Neuropathy
146 ☐ Hypertension
171 ☐ Congestive heart failure
129 ☐ Hemorrhage/bleeding
148 ☐ Proteinuria Grade 3
38 ☐ Other nonhematologic adverse event
99 ☐ Other (not per protocol) ___________________

Agent	Bevacizumab (AVASTN)	Paclitaxel (ABI-007)	Carboplatin (CBDCA)
Agent Start Date this cycle *(mm/dd/yyyy)*	__ __/__ __/__ __ __ __	__ __/__ __/__ __ __ __	__ __/__ __/__ __ __ __
Dose Level day one this cycle *If agent not given this cycle, enter '0' for dose level.*	mg/kg	mg/m^2	AUC = ___
Total Dose this cycle *If agent not given this cycle, enter '0' for dose level.*	mg	mg	
Was **DOSE LEVEL** adjusted this cycle? (i.e. mg/m^2)	1 ☐ Yes 2 ☐ No	1 ☐ Yes 2 ☐ No	1 ☐ Yes 2 ☐ No
If Yes, PRIMARY REASON for Dose Adjustment per Section 8.0. Not BSA changes. *(If Yes, check one Primary Reason.)*	99 ☐ Other (not per protocol) ___________________	136 ☐ AST or alkaline phosphatase 51 ☐ Neuropathy 35 ☐ Hematologic 38 ☐ Other nonhematologic adverse event 99 ☐ Other (not per protocol) ___________________	35 ☐ Hematologic 51 ☐ Neuropathy 38 ☐ Other nonhematologic adverse event 99 ☐ Other (not per protocol) ___________________

Were growth factors administered this cycle: *(check one)* 1 ☐ Yes 2 ☐ No

If Yes, *check one:* 1 ☐ G-CSF 2 ☐ GM-CSF

Is this Cycle 2: *(check one)* 1 ☐ Yes 2 ☐ No *(End Form)*

If Yes: **aPTT** (seconds): ___ ___ ___ .

PT/INR (seconds): ___ ___ ___ .

Fibrinogen (mg/dL): ___ ___ ___ ___

PLACE LABEL HERE

Protocol Number: N0775________________

Patient ID: ______________________ Patient Initials: ___________
L F M

Institution Number: ____________________________________

Institution: ____

NORTH CENTRAL CANCER TREATMENT GROUP

END OF ACTIVE TREATMENT/CANCEL NOTIFICATION FORM
Submit Once Per Patient

ALL ITEMS MUST BE COMPLETED

Are data amended? *(check one)* ☐ **Yes** ☐ **No**
(if data are amended, please circle in red when using paper form)

Last Date (any modality of) protocol therapy was given: *(mm/dd/yyyy)* __ __/__ __/__ __ __ __
(date of last treatment dose on this study or date decision made not to initiate protocol treatment)

Off Treatment Date: *(mm/dd/yyyy)* __ __/__ __/__ __ __ __
(date decision was made to end active treatment or not to initiate protocol treatment)

This patient will now go to: *(check one)*

(See Schema and Section 13.0 of the protocol)

1 ☐ Observation *(follow test schedule and enter cycle data)*
2 ☐ Event Monitoring *(follow Event Monitoring schedule)*
9 ☐ Off Study *(cancels only)*

Reason Treatment Ended *(check one)*	COMMENTS
1 ☐ Treatment Completed Per Protocol Criteria	
2 ☐ Patient Withdrawal/Refusal **After** Beginning Protocol Therapy	Specify:
24 ☐ Patient Withdrawal/Refusal **Prior To** Beginning Protocol Therapy *(cancel)*	Specify:
3 ☐ Adverse Event/Side Effects/ Complications	Specify:
4 ☐ Disease Progression, Relapse During Active Treatment*	Complete Event Monitoring Form
5 ☐ Alternative Therapy	Specify:
6 ☐ Patient Off-Treatment For Other Complicating Disease	Specify:
7 ☐ Death On Study	Complete Event Monitoring Form
8 ☐ Other	Specify:

* Submit documentation to verify progression. See Section 11.0 and Section 18.0 of protocol.

PLACE LABEL HERE

Protocol Number: N0775

Patient ID: ______________________ Patient Initials: ____________
L F M

Institution Number: ____

Institution: ____

NORTH CENTRAL CANCER TREATMENT GROUP

EVALUATION/OBSERVATION 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)

Use one form per cycle.

Current Cycle Number: ____

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

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

Observation*

Day 1 of this observation cycle: *(mm/dd/yyyy)* __ __/__ __/__ __ __ __

End of observation? *(check one)* 1☐ Yes 2☐ No

*When observation ends amend the last existing Evaluation/Observation Form by checking "Yes" for the End of observation question above.

PLACE LABEL HERE

Protocol Number: N0775

Patient ID: ________________ Patient Initials: __________ L F M

Institution Number: ______________________________

Institution: ______________________________

NORTH CENTRAL CANCER TREATMENT GROUP

EVENT MONITORING 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)

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

1☐ Yes. If Yes, complete rest of form.

2☐ No. If No, date of last attempt to contact patient: *(mm/dd/yyyy)* __ __/__ __/__ __ __ __ *(End form)*

Vital Status

1☐ Alive Date of last contact or date of death: *(mm/dd/yyyy)* __ __/__ __/__ __ __ __

2☐ Dead

Primary Cause of Death: *(check one)* 1☐ Due to this disease 2☐ Due to other cause, specify __________ 4☐ Due to protocol treatment *(adverse event related to treatment)*

Disease Follow-up Status

Has the patient had a documented clinical assessment for this cancer (*since* ***submission of the last event monitoring form)?****

2☐ No. If No, Go to Notice of New Primary.

1☐ Yes. If Yes, Cancer Follow-up Status Date: *(mm/dd/yyyy)* __ __/__ __/__ __ __ __

Notice of First Relapse/Progression in the Event Monitoring Phase

Has the patient developed a first relapse or progression **that has not been previously reported** ***(in event monitoring phase)?***

2☐ No 1☐ Yes. If Yes, Date of Relapse/Progression:** *(mm/dd/yyyy)* __ __/__ __/__ __ __ __

Site(s) of Relapse/Progression: *(check all that apply)*
- ☐ Lung
- ☐ Liver
- ☐ Distant lymph nodes
- ☐ Distant soft tissue/skin metastasis
- ☐ Bone
- ☐ Brain
- ☐ Other CNS __________
- ☐ Other visceral, specify __________
- ☐ Other non-visceral, specify __________
- ☐ Unknown

Method (s) of Diagnosis: *(check all that apply)*
- ☐ Radiologic
- ☐ Histologic
- ☐ Patient contact
- ☐ Other, specify __________________

Notice of New Primary

Has a new primary cancer or MDS *(myelodyplastic syndrome)* been diagnosed **that has not been previously reported***?*

2☐ No 3☐ Unknown 1☐ Yes. If Yes, New Primary Cancer Date: *(mm/dd/yyyy)* __ __/__ __/__ __ __ __

Site of New Primary: ______________________________

Late Adverse Event ***(post completion of active monitoring)***

Has the patient experienced (prior to treatment for progression or relapse or a second primary, and prior to non-protocol treatment) any severe (grade $\geq$3) long term toxicity that has not been previously reported:
- Adverse events at least possibly attributed to treatment on this study.
- Death within 30 days of treatment.
- Death any time at least **possibly** treatment related.

2☐ No 3☐ Unknown/Not evaluated 1☐ Yes. If Yes, Submit page 2 of the Event Monitoring Form for Late Adverse Event Reporting.

*If this is the first event monitoring form check yes, enter cancer follow-up status date and complete the rest of the form.

**Submit documentation to verify PD.

PLACE LABEL HERE

Protocol Number: N0775

Patient ID: ______________ Patient Initials: ______ L F M

Institution Number: ______________

Institution: ______________

NORTH CENTRAL CANCER TREATMENT GROUP

EVENT MONITORING FORM
(LATE ADVERSE EVENT REPORTING)

ALL ITEMS MUST BE COMPLETED

Are data amended? ***(check one)*** ☐ **Yes** ☐ **No**
(if data are amended, please circle in red when using paper form)

The CTC AE v.3.0 will be used to evaluate the following adverse events:

CTC Adverse Event Term	**MedDRA Code** ***(v. 10.0)*** *(must be completed)*	CTC Adverse Event Grade *(Highest Grade)*	CTC AE Attribution Code 1 = Unrelated 2 = Unlikely 3 = Possible 4 = Probable 5 = Definite	Late Adverse Event Onset Date *(mm/dd/yyyy)*
	☐☐☐☐☐☐☐☐	3 4 5 (death)	1 2 3 4 5	__ __/__ __/__ __ __ __
	☐☐☐☐☐☐☐☐	3 4 5 (death)	1 2 3 4 5	__ __/__ __/__ __ __ __
	☐☐☐☐☐☐☐☐	3 4 5 (death)	1 2 3 4 5	__ __/__ __/__ __ __ __
	☐☐☐☐☐☐☐☐	3 4 5 (death)	1 2 3 4 5	__ __/__ __/__ __ __ __
	☐☐☐☐☐☐☐☐	3 4 5 (death)	1 2 3 4 5	__ __/__ __/__ __ __ __
	☐☐☐☐☐☐☐☐	3 4 5 (death)	1 2 3 4 5	__ __/__ __/__ __ __ __
	☐☐☐☐☐☐☐☐	3 4 5 (death)	1 2 3 4 5	__ __/__ __/__ __ __ __
	☐☐☐☐☐☐☐☐	3 4 5 (death)	1 2 3 4 5	__ __/__ __/__ __ __ __
	☐☐☐☐☐☐☐☐	3 4 5 (death)	1 2 3 4 5	__ __/__ __/__ __ __ __
	☐☐☐☐☐☐☐☐	3 4 5 (death)	1 2 3 4 5	__ __/__ __/__ __ __ __
	☐☐☐☐☐☐☐☐	3 4 5 (death)	1 2 3 4 5	__ __/__ __/__ __ __ __
	☐☐☐☐☐☐☐☐	3 4 5 (death)	1 2 3 4 5	__ __/__ __/__ __ __ __
	☐☐☐☐☐☐☐☐	3 4 5 (death)	1 2 3 4 5	__ __/__ __/__ __ __ __
	☐☐☐☐☐☐☐☐	3 4 5 (death)	1 2 3 4 5	__ __/__ __/__ __ __ __
	☐☐☐☐☐☐☐☐	3 4 5 (death)	1 2 3 4 5	__ __/__ __/__ __ __ __
	☐☐☐☐☐☐☐☐	3 4 5 (death)	1 2 3 4 5	__ __/__ __/__ __ __ __
	☐☐☐☐☐☐☐☐	3 4 5 (death)	1 2 3 4 5	__ __/__ __/__ __ __ __

PLACE LABEL HERE

Protocol Number: N0775

Patient ID: ______________________ Patient Initials: ____________
L F M

Institution Number: ____

Institution: ____

NORTH CENTRAL CANCER TREATMENT GROUP

NOTIFICATION FORM
Grade 4 or 5 Non-AER Reportable Events/Hospitalization

ALL ITEMS MUST BE COMPLETED

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.***
- ***Verify reporting requirements listed within the study protocol, prior to entering into the remote data entry system.***
- ***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: (_______) ________-_____________

Current Cycle Number: _____ Assigned Treatment Arm: _____

Event ≥ Grade 4: *(check one)* 1☐ Yes 2☐ No

Date of First Occurrence of Adverse Event *(mm/dd/yyyy)*	CTC Adverse Event Term ***(only one event per line)***	CTC Adverse Event Grade	In your opinion, is this related to the study medication?*
__ __/__ __/__ __ __ __		4 5	4☐ Yes: Unlikely 1☐ Yes: Possible, probable, or definite 2☐ No 3☐ Unknown
__ __/__ __/__ __ __ __		4 5	4☐ Yes: Unlikely 1☐ Yes: Possible, probable, or definite 2☐ No 3☐ Unknown
__ __/__ __/__ __ __ __		4 5	4☐ Yes: Unlikely 1☐ Yes: Possible, probable, or definite 2☐ No 3☐ Unknown
__ __/__ __/__ __ __ __		4 5	4☐ Yes: Unlikely 1☐ Yes: Possible, probable, or definite 2☐ No 3☐ Unknown
__ __/__ __/__ __ __ __		4 5	4☐ Yes: Unlikely 1☐ Yes: Possible, probable, or definite 2☐ No 3☐ Unknown

*Answer YES if attribution is unlikely, possible, probable or definite; answer NO if unrelated; answer UNKNOWN if you are not sure. Verify if expedited reporting (e.g. ADEERS) is required (see protocol), based on relationship to study treatment.

Hospitalization: *(check one)* 1☐ Yes 2☐ No

If Yes: Hospital Admission Date: *(mm/dd/yyyy)* __ __/__ __/__ __ __ __

Reason(s) for Hospitalization:

1☐ Adverse Event, specify type and grade: ____

2☐ Prophylactic, specify: ____

3☐ Other reason, specify ____

2/6/2008