



NCCTG

NORTH CENTRAL CANCER TREATMENT GROUP

Operations Office

DATE: October 21, 2011

TO: NCCTG Primary Clinical Research Associates

FROM: Sanna McKinzie
Research Protocol Specialist

RE: N0574, Phase III Randomized Trial of the Role of Whole Brain Radiation Therapy in Addition to Radiosurgery in the Management of Patients with One to Three Cerebral Metastases.

Attached are updated forms for this protocol. Edits are as follows:

CRF Title	Brief Description of Edit
Adverse Event Form	<ul style="list-style-type: none">Added "CTCAE v3.0" to CTC Adverse Event Term on both pages.
Baseline Adverse Events Form	<ul style="list-style-type: none">Added "CTCAE v3.0" to CTC Adverse Event Term

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

Enclosure

North Central Cancer Treatment Group

N0574: Phase III Randomized Trial of the Role of Whole Brain Radiation Therapy in Addition to Radiosurgery in the Management of Patients with One to Three Cerebral Metastases

Addendum 5 – October 21, 2011

Summary

- In compliance with the NCI/CTEP mandate (dated May 28, 2010), expedited adverse event reporting requirements were converted from CTCAE v3.0 to CTCAE v4.0 (affected sections 10.1 and 10.11) while routine data collection via Case Report Forms (which includes the Notification Form: Grade 4 or 5 Non-AER Reportable Events/Hospitalization Form) will remain using CTCAE v3.0 (clarifications added to sections 10.23, 10.3, and 10.31). Effective October 1, 2011, expedited reporting via ADEERS must use CTCAE v4.0 while the remainder of the data collection for legacy trials will continue to use CTCAE v3.0.
- Administrative update.

A replacement protocol is provided. Please replace the current copy with the one attached. Please keep this addendum with your protocol. Note: for sites participating through NCCTG, replacement pages are provided. Please incorporate into the protocol and keep this addendum with your protocol.

Title page Updated to reflect the addition of Addendum 5 and a revised NCI version date.

NCCTG Address and Contact Information

Page 3: ~~Patricia A. Aggen~~ has been removed as the NCCTG Research Base Protocol Specialist.

Section 10.0 Adverse Event (AE) Reporting and Monitoring

Page 24: Section 10.1 and Section 10.11 have been revised as follows to update the required AE reporting from CTCAE v3.0 to CTCAE v4.0:

~~This study will utilize the Common Terminology Criteria for Adverse Events (CTCAE) v3.0 for adverse event monitoring and reporting. The CTCAE v3.0 can be accessed from the CTEP home page <http://ctep.cancer.gov>.~~ **CTCAE term (AE description) and grade: The descriptions and grading scales found in the revised NCI Common Terminology Criteria for Adverse Events (CTCAE) version 3.0 will be utilized until September 30, 2011. CTCAE version 4.0 will be utilized for expedited adverse event reporting only, beginning October 1, 2011. (<http://ctep.cancer.gov>).** All appropriate treatment areas should have access to a copy of the CTCAE v3.0. **A copy of the CTCAE version 4.0 can be downloaded from the CTEP web site (<http://ctep.cancer.gov>).**

10.11 Adverse event monitoring and reporting is a routine part of every clinical trial...

Expedited adverse event reporting requires submission of an Adverse Event Expedited Reporting System (AdEERS)...

Effective with Addendum 8, and beginning July 1, 2011, expedited AdEERS reporting for this protocol has been updated by the NCI/CTEP to use CTCAE v4.0. Therefore:

- 1) Events reporting expedited reporting through AdEERS must be reported through the AdEERS system in CTCAE v4.0.**
- 2) The events reported via AdEERS must ALSO be reported through routine reporting (i.e., Case Report Forms) using CTCAE v3.0.**
- 3) Routine data collection via Case Report Forms, including the “Notification Form: Grade 4 or 5 Non-AER Reportable Events/Hospitalization Form,” will remain using CTCAE v3.0 for this study.**

Page 24:

The second column for Secondary AML/MDS in Section 10.23 has been revised for clarification as follows:

Reporting for this event required during and after completion of study treatment, via AdEERS ~~using CTCAE v3.0: Report Myelodysplasia as “Blood/Bone Marrow—Myelodysplasia” and Leukemias as “Blood/Bone Marrow—Other (Specify, —)”~~.

Beginning October 1, 2011, AdEERS will only accept CTCAE v4.0 for this study. Report these events using “Neoplasms benign, malignant and unspecified (incl. cysts and polyps)” and including the appropriate adverse event:

- Leukemia secondary to oncology chemotherapy OR**
- Myelodysplastic syndrome OR**
- Treatment related secondary malignancy**

The second column for “Other Grade 4 or 5 Events...” section in Section 10.23 has been revised for clarification as follows:

Complete a Notification Form: Grade 4 or 5 Non-AER Reportable Events/Hospitalization Form within 5 working days, **using CTCAE v3.0, of the date the clinical research associate (CRA) is aware of the event(s) necessitating the form.**

Page 25:

Section 10.3 and Section 10.31 have been revised for clarification. In Section 10.3, the first column header in the table has added CTCAE v3.0 and Section 10.31 has been revised as follows:

Submit to the NCCTG Research Base via the Nadir/AE Log the following Aes **using CTCAE v3.0** experienced by a patient and not specified in Section 10.3:

North Central Cancer Treatment Group

N0574: Phase III Randomized Trial of the Role of Whole Brain Radiation Therapy in Addition to Radiosurgery in the Management of Patients with One to Three Cerebral Metastases

Update 2 – October 21, 2011

Summary

Administrative/editorial changes.

A replacement protocol is provided. Please replace the current copy with the one attached. Please keep this update with your protocol. Note: for sites participating through NCCTG, replacement pages are provided. Please incorporate into the protocol and keep this update with your protocol.

Title page Updated to reflect Update 2 and revised NCI version date.

Appendix II Adverse Event (AE) Reporting

Page 6: With Addendum 5, the CTCAE was converted from v3.0 to v4.0. All appropriate protocol sections were updated accordingly with the exception of Appendix II. Therefore, the first sentence on page 6 has now been updated as follows:
This study will utilize the CTCAE version ~~3.0~~ **4.0** for toxicity and Adverse Event (AE) reporting.

North Central Cancer Treatment Group

Phase III Randomized Trial of the Role of Whole Brain Radiation Therapy in Addition to Radiosurgery in Patients with One to Three Cerebral Metastases

Study Chairs

NCCTG: Paul Brown, M.D. (Research Base)*
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Elana Farace, Ph.D. (Neuropsychology)

Statistician: Karla V. Ballman, Ph.D.

ACOSOG: Anthony L. Asher, M.D.
 Fred Barker, M.D.

DCTD Supplied Investigational Agents: N/A

*Investigator having NCI responsibility for this protocol

Document History	(Effective Date)	Document History	(Effective Date)
Activation	July 28, 2006	Update 1	March 25, 2011
Addendum 1	July 6, 2007	Addendum 5	October 21, 2011
Addendum 2	November 30, 2007	Update 2	October 21, 2011
Addendum 3	October 24, 2008		
Addendum 4	March 25, 2011		

<u>Study Participants</u>	<u>Date Activated</u>
NCCTG	July 28, 2006
CTSUs sites (Non-NCCTG members): Patient enrollments from institutions that are not aligned with NCCTG will be conducted via the NCI Cancer Trials Support Unit (CTSUs) and all data from these institutions should be sent to NCCTG Operations Office unless otherwise specified in the CTSUs logistical appendix.	August 8, 2006

NCI Version Date: October 12, 2011

Add 4

**North Central Cancer Treatment Group (NCCTG)
ADDRESS AND CONTACT INFORMATION**

	Questions:	Contact:
Add 4	Patient eligibility, test schedule, treatment delays/interruptions/adjustments, dose modifications, adverse events, forms completion	Butch Kvittem NCCTG <i>Research Base</i> Quality Assurance Specialist Phone: 507/284-3559 Fax: 507/266-7240 E-mail: kvittem@mayo.edu
Add 1,3,4,5 Update 1	Protocol Document, Regulatory Issues	Sanna McKinzie NCCTG <i>Research Base</i> Research Protocol Specialist Phone: (507) 538-6646 Fax: (507) 284-5280 E-mail: mckinzie.sanna@mayo.edu
Add 2	Neurocognitive Testing	Elana Farace, Ph.D. Associate Professor of Neurosurgery and Public Health Sciences Phone: 717-531-7386 Fax: 717-531-0748 Email: efarace@hmc.psu.edu
Add 1,2,3 Update 1	Drug administration, infusion pumps, nursing guidelines	TJ Scheffler Hanson NCCTG <i>Research Base</i> Nurse Phone: 507-284-2459 Email: scheffler.temperance@mayo.edu
Add 1		Wanda DeKrey, R.N., OCN NCCTG Member Nurse Phone: 701/780-6520 Email: wdekrey@altru.org
	Forms completion and submission	Carlene Dillavou NCCTG Member Clinical Research Associate Phone: 515-244-7586 Email: cdillavou@iora.org
	Radiation Quality Control	Kathryn Scherger NCCTG <i>Research Base</i> Radiation Quality Control Coordinator Phone: (507) 266-0006 Fax: (507) 266-7240 E-mail: scherger.kathryn@mayo.edu
	Adverse Events	Pat McNamara NCCTG <i>Research Base</i> AdEERS Coordinator Phone: 507/266-3028 Fax: 507/284-9628 E-mail: mcnamara.patricia@mayo.edu

9.0 Ancillary Treatment

9.1 Concomitant Medications

Patients may be currently receiving hormonal agents, steroids, and/or anticonvulsants.

10.0 Adverse Event (AE) Reporting and Monitoring

10.1 CTCAE term (AE description) and grade: The descriptions and grading scales found in the revised NCI Common Terminology Criteria for Adverse Events (CTCAE) version 3.0 will be utilized until September 30, 2011. CTCAE version 4.0 will be utilized for expedited adverse event reporting only, beginning October 1, 2011. All appropriate treatment areas should have access to a copy of the CTCAE v3.0. A copy of the CTCAE version 4.0 can be downloaded from the CTEP web site (<http://ctep.cancer.gov>).

10.11 Adverse event monitoring and reporting is a routine part of every clinical trial. First, identify and grade the severity of the event using the CTCAE. Next, determine whether the event is expected or unexpected (see Section 10.12) and if the adverse event is related to the medical treatment or procedure (see Section 10.13). With this information, determine whether an adverse event should be reported as an expedited report (see Section 10.2). Important: All AEs reported via expedited mechanisms must also be reported via the routine data reporting mechanisms defined by the protocol (see Sections 10.3 and 18.0).

Expedited adverse event reporting requires submission of an Adverse Event Expedited Reporting System (AdEERS) report(s). Other expedited reporting requirements and systems may also apply. Expedited reports are to be completed within the timeframes and via the mechanisms specified in Sections 10.2 and 10.3. All expedited AE reports must also be sent to the local Institutional Review Board (IRB) according to local IRB's policies and procedures.

Effective with Addendum 5, and beginning October 1, 2011, expedited AdEERS reporting for this protocol has been updated by the NCI/CTEP to use CTCAE v4.0. Therefore:

- 1) Events reporting expedited reporting through AdEERS must be reported through the AdEERS system in CTCAE v4.0.
- 2) The events reported via AdEERS must ALSO be reported through routine reporting (i.e., Case Report Forms) using CTCAE v3.0.
- 3) Routine data collection via Case Report Forms, including the "Notification Form: Grade 4 or 5 Non-AER Reportable Events/Hospitalization Form," will remain using CTCAE v3.0 for this study.

10.12 Expected vs. Unexpected

- The determination of whether an AE is expected is based on information/data in available sources, including the protocol (including the model consent form).
- Unexpected AEs are those not listed in the available sources, including the protocol (including the model consent form).

10.13 Assessment of Attribution

When assessing whether an adverse event is related to a medical treatment or procedure, the following attribution categories are utilized:

Definite - The adverse event *is clearly related* to the agent(s).

Probable - The adverse event *is likely related* to the agent(s).

Possible - The adverse event *may be related* to the agent(s).

Unlikely - The adverse event *is doubtfully related* to the agent(s).

Unrelated - The adverse event *is clearly NOT related* to the agent(s).

Add 5

Add 5

10.2 Expedited Adverse Event Reporting Requirements

10.21 Standard Expedited Reporting for Commercial Agents

	Grade 4 or 5 Unexpected with Attribution of Possible, Probable, or Definite	Increased Incidence of an Expected AE ¹
Submit a full expedited commercial report via AdeERS within 7 working days ²	X	X

Add 4

1. Any increased incidence of a known AE (as reported in the package insert or the literature), including adverse events resulting from a drug overdose.
2. In the rare event when Internet connectivity is disrupted, a 24-hour notification is to be made to NCI by telephone at: 301-897-7497. An electronic report **MUST** be submitted immediately upon re-establishment of internet connection. Please note that all paper AdeERS forms have been removed from the CTEP website and will **NO LONGER** be accepted.

Add 4

10.22 Additional Instructions or Exceptions

- **SECONDARY MALIGNANCIES** (defined as “cancer caused by treatment for a previous malignancy”, e.g., treatment with radiation or chemotherapy) are to be reported through AdeERS.
- Secondary malignancies are not considered metastasis of the initial neoplasm. Secondary malignancy is unrelated to the first cancer that was treated, and may occur months or even years after initial treatment.
- Second Primary malignancy (malignancy **not** due to prior treatment) should not be reported through AdeERS.

Add 4

10.23 Other Required Expedited Reporting

Add 5

Add 5

EVENT TYPE	REPORTING PROCEDURE
Secondary AML/MDS	Beginning October 1, 2011, AdeERS will only accept CTCAE v4.0 for this study. Report these events using “Neoplasms benign, malignant and unspecified (incl. cysts and polyps)” and including the appropriate adverse event: - Leukemia secondary to oncology chemotherapy OR - Myelodysplastic syndrome OR - Treatment related secondary malignancy
Other Grade 4 or 5 Events and/or Any Hospitalizations During Treatment Not Otherwise Warranting an Expedited Report	NCCTG Institutions Only: Complete a Notification Form: Grade 4 or 5 Non-AER Reportable Events/Hospitalization Form within 5 working days, using CTCAE v3.0, of the date the clinical research associate (CRA) is aware of the event(s) necessitating the form. If an AdeERS report has been submitted, this form does not need to be submitted. Fax or mail to the NCCTG SAE Coordinator, NCCTG Operations Office, 200 First Street SW, Rochester, MN 55905, Fax (507)284-9628. You must use CTCAE v3.0 for data submission with this form. The events reported on this form must also appear on the Case Report Forms (i.e., routine data) for this study.

Adverse Event (AE) Reporting

Assessing and submitting expedited reports

Update 2

This study will utilize the CTCAE version 4.0 for toxicity and Adverse Event (AE) reporting. A link to the CTCAE guidelines is available on the CTSU registered member Web site. CTSU investigators should assess adverse events according to the instructions and tables in section 10.0 of the protocol. All reporting should be conducted within the time frames specified in section 10.0 of the protocol.

Events must be reported electronically using the CTEP AdEERS application. A link to the AdEERS application can be found on both the CTSU member homepage and the N0574 Web page on the CTSU member site.

Please do not copy the CTSU on expedited serious adverse event reports.

CTSU sites must comply with the expectations of their local Institutional Review Board (IRB) regarding submission of documentation of adverse events. Local IRBs must be informed of all reportable serious adverse events.

Secondary AML/MDS/ALL reporting:

CTSU investigators will submit the NCI Secondary AML/MDS/ALL Report Form and supporting documentation to the CTSU. Once received, the CTSU will send this information to NCCTG where it will be forwarded on to the NCI.

Drug Procurement:

Not applicable.

REGULATORY AND MONITORING

Study Audit

To assure compliance with Federal regulatory requirements [CFR 21 parts 50, 54, 56, 312, 314 and HHS 45 CFR 46] and National Cancer Institute (NCI)/ Cancer Therapy Evaluation Program (CTEP) Clinical Trials Monitoring Branch (CTMB) guidelines for the conduct of clinical trials and study data validity, all protocols approved by NCI/CTEP that have patient enrollment through the CTSU are subject to audit.

FORMS PACKET COVER SHEET

N0574, “A Phase III Randomized Trial of the Role of Whole Brain Radiation Therapy in Addition to Radiosurgery in the Management of Patients with One to Three Cerebral Metastases”

- Contents:
- Forms completion instructions (05/08/2006)
 - Pre-Registration Eligibility checklist (10/24/2008)
 - Randomization Eligibility checklist (4/17/2009)
 - Pre-registration screening failure form (06/20/2006)
 - On-study form (01/15/2007)
 - ✓ Baseline adverse events form (09/22/2011)
 - Evaluation/treatment form (08/14/2007)
 - Evaluation/observation form (08/21/2007)
 - End of active treatment/Cancel notification form (06/20/2006)
 - Pretreatment measurement form (06/19/2006)
 - Active monitoring measurement form (06/19/2006)
 - ✓ Adverse event form (09/22/2011)
 - Functional independence form (07/24/2008)
 - Patient FACT-Br booklet compliance form (06/19/2006)
 - Event monitoring form (02/12/2008)
 - Arm B radiation therapy reporting form (06/15/2007)
 - Radiosurgery reporting form (08/28/2007)
 - Notification form [Grade 4 or 5 Non-AER Reportable Events] (06/20/2006)
 - Neurocognitive testing booklet compliance form (06/19/2006)
 - Booklet Order Form (6/12/2007)
 - Neurocognitive testing verification form (11/8/2006)

✓ designates revised/new forms

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

NCCTG Protocol Number: N0574

**BASELINE
ADVERSE EVENTS FORM**

NCCTG Patient ID: _____ Patient Initials: _____

L F M

Institution Number: _____

ALL ITEMS MUST BE COMPLETED

Institution: _____

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

BASELINE ADVERSE EVENTS

Required Baseline Adverse Events from Section 10.0 of Protocol		
CTC Adverse Event Term (CTCAE v3.0)	MedDRA Code (v. 9.0)	CTC Adverse Event Grade
Hair loss/alopecia (scalp or body)	1 0 0 0 1 7 6 0	0 1 2
Rash: dermatitis associated with radiation - Radiation	1 0 0 6 1 1 0 3	0 1 2 3 4
Nausea	1 0 0 2 8 8 1 3	0 1 2 3 4
Vomiting	1 0 0 4 7 7 0 0	0 1 2 3 4
Cognitive disturbance	1 0 0 0 9 8 4 5	0 1 2 3 4
Neuropathy: motor	1 0 0 3 4 5 8 0	0 1 2 3 4
CNS necrosis/cystic progression	1 0 0 6 5 7 8 4	0 1 2 3 4
Retinopathy	1 0 0 3 8 9 2 3	0 1 2 3 4
Hearing: patients without baseline audiogram and not enrolled in a monitoring program	1 0 0 1 9 2 4 6	0 2 3 4
Otitis, external ear (non-infectious)	1 0 0 6 5 8 3 7	0 1 2 3 4

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

NCCTG Protocol Number: N0574

NCCTG Patient ID: _____ Patient Initials: _____
L F M

Institution Number: _____

Institution: _____

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 treatment cycle) : _____

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

CTC Adverse Event Term (CTCAE v3.0)	MedDRA Code (v. 9.0) <i>(must be completed)</i>	CTC Adverse Event Grade <i>(highest grade this cycle)</i> INCLUDE GRADE 0's	CTC AE Attribution Code <i>(If Grade > 0)</i> 1 = Unrelated 2 = Unlikely 3 = Possible 4 = Probable 5 = Definite	Has an adverse event expedited report been submitted?* <i>(Enter 1 for Yes or 2 for No)</i>
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Required Adverse Events from Section 10.0 of Protocol

Hair loss/alopecia (scalp or body)	1 0 0 0 1 7 6 0	0 1 2	1 2 3 4 5	—
Rash: dermatitis associated with radiation - Radiation	1 0 0 6 1 1 0 3	0 1 2 3 4 5 (death)	1 2 3 4 5	—
Nausea	1 0 0 2 8 8 1 3	0 1 2 3 4 5 (death)	1 2 3 4 5	—
Vomiting	1 0 0 4 7 7 0 0	0 1 2 3 4 5 (death)	1 2 3 4 5	—
Cognitive disturbance	1 0 0 0 9 8 4 5	0 1 2 3 4 5 (death)	1 2 3 4 5	—
Neuropathy: motor	1 0 0 3 4 5 8 0	0 1 2 3 4 5 (death)	1 2 3 4 5	—
CNS necrosis/cystic progression	1 0 0 6 5 7 8 4	0 1 2 3 4 5 (death)	1 2 3 4 5	—
Retinopathy	1 0 0 3 8 9 2 3	0 1 2 3 4	1 2 3 4 5	—
Hearing: patients without baseline audiogram and not enrolled in a monitoring program	1 0 0 1 9 2 4 6	0 2 3 4	1 2 3 4 5	—
Otitis, external ear (non-infectious)	1 0 0 6 5 8 3 7	0 1 2 3 4 5	1 2 3 4 5	—

* See Section 10.0 of the protocol.

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

NCCTG Protocol Number: N0574

ADVERSE EVENT FORM

NCCTG Patient ID: _____ Patient Initials: _____

ALL ITEMS MUST BE COMPLETED

Institution Number: _____ L F M

Institution: _____

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 treatment cycle): _____

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

- 1 Yes, and reportable adverse events occurred
- 2 No (Stop here)
- 3 Yes, but no reportable adverse events occurred (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 Term not listed (CTCAE v3.0)	MedDRA Code (v. 9.0) (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)
	<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	_____
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** See Section 10.0 of the protocol.