

FORMS PACKET

N057K, Phase I/II Evaluation of Everolimus (RAD001), Radiation and Temozolomide (TMZ) Followed by Adjuvant Temozolomide and Everolimus in Newly Diagnosed Glioblastoma

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- Pre-registration eligibility checklist (3/4/2011)
 - Eligibility checklist (3/4/2011)
 - * Forms completion instructions
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 - On-study form (3/26/08)
 - Baseline adverse events form (7/21/2010)
 - Radiation therapy reporting form (11/13/2007)
 - Pathology reporting form (11/13/2007)
 - Pathology submission form (11/13/2007)
 - Concurrent steroid and anticonvulsant treatment form (baseline) (3/3/2008)
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✓ 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
Pre-Registration Eligibility Checklist

03/04/2011
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N057K: Phase I/II Evaluation of Everolimus (RAD001), Radiation and Temozolomide (TMZ) Followed by Adjuvant Temozolomide and Everolimus in Newly Diagnosed Glioblastoma

Phase II patients only (Mayo Clinic Rochester ONLY): 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: Prior study number _____; prior patient study ID number _____

Registration date (date on) (mm/dd/yyyy) __/__/____
Patient study ID number (provided at time of Reg/Random) _____
NCCTG member (participant sponsor) _____
NCCTG treating location (chemo) _____ (RT) _____
NCCTG treating physician (chemo) _____ (RT) _____
Institution patient number (local subject number) _____
IRB approval date (chemo) (mm/dd/yyyy) __/__/____ IRB approval date (RT) (mm/dd/yyyy) __/__/____

Patient initials (last, first, middle) _____ (For Mayo Rochester patients, include first four letters of last name.)	Race (check all that apply)
Gender (check one) <input type="checkbox"/> Male <input type="checkbox"/> Female <input type="checkbox"/> Unknown	<input type="checkbox"/> White
Date of birth (mm/dd/yyyy) __/__/____	<input type="checkbox"/> Black or African American
Zip code _____	<input type="checkbox"/> Native Hawaiian or Other Pacific Islander
Country of Residence _____	<input type="checkbox"/> Asian
Method of payment (check one)	<input type="checkbox"/> American Indian or Alaska Native
<input type="checkbox"/> PI (Private Insurance)	<input type="checkbox"/> Not reported: Patient refused or not available
<input type="checkbox"/> MR (Medicare)	<input type="checkbox"/> Unknown: Patient unsure
<input type="checkbox"/> MRP (Medicare and Private Insurance)	Ethnicity (check one)
<input type="checkbox"/> MD (Medicaid)	<input type="checkbox"/> Not Hispanic or Latino
<input type="checkbox"/> MM (Medicaid and Medicare)	<input type="checkbox"/> Hispanic or Latino
<input type="checkbox"/> MVA (Military or Veterans Sponsored, Not Otherwise Specified (NOS))	<input type="checkbox"/> Not reported: Refused or data not available
<input type="checkbox"/> MS (Military Sponsored [including CHAMPUS & TRCARE])	<input type="checkbox"/> Unknown: Unsure of their ethnicity
<input type="checkbox"/> MV (Veterans Sponsored)	
<input type="checkbox"/> SP (Self pay [no insurance])	
<input type="checkbox"/> NP (No means of payment [no insurance])	
<input type="checkbox"/> OTH (Other)	
<input type="checkbox"/> UNK (Unknown)	

Is your site using IMRT for this study? Yes No

If Yes, is your site NCCTG certified? Yes No (If No, End Form. NCCTG IMRT certification by the Radiological Physics Center (RPC) required.)

NCCTG Pre-Registration Eligibility Checklist N057K

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Patient study ID number _____

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

Inclusion Criteria

Yes No NA

Central pathology review. This review is mandatory prior to registration to confirm eligibility. It should be initiated as soon after surgery as possible.	_____	_____	_____
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All responses in above section must be “Yes.”

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 (<i>check NA</i>) vs. Date of authorization ____/____/____.	_____	_____	_____
The site has reviewed and understands the process listed in Section 17.2 and must account for sufficient time to complete pre-registration and registration steps.	_____	_____	_____

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

Assigned Treatment

_____ Pre-registration allowed

Person registering _____ Registration Office specialist _____
Signature initials

Physician _____
Signature M D Y

Registration Eligibility Checklist

03/04/2011

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N057K: Phase I/II Evaluation of Everolimus (RAD001), Radiation and Temozolomide (TMZ) Followed by Adjuvant Temozolomide and Everolimus in Newly Diagnosed Glioblastoma

Phase II patients (Mayo Clinic Rochester ONLY): 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: Prior study number _____; prior patient study ID number _____

Registration date (date on) (mm/dd/yyyy) ___/___/_____
Patient study ID number (provided at time of Reg/Random) _____
NCCTG member (participant sponsor) _____
NCCTG treating location (chemo) _____ (RT) _____
NCCTG treating physician (chemo) _____ (RT) _____
Institution patient number (local subject number) _____
IRB approval date (chemo) (mm/dd/yyyy) ___/___/_____ IRB approval date (RT) (mm/dd/yyyy) ___/___/_____

Patient initials (last, first, middle) _____ (For Mayo Rochester patients, include first four letters of last name.)	Race (check all that apply)
Gender (check one) <input type="checkbox"/> Male <input type="checkbox"/> Female <input type="checkbox"/> Unknown	<input type="checkbox"/> White
Date of birth (mm/dd/yyyy) ___/___/_____	<input type="checkbox"/> Black or African American
Zip code _____	<input type="checkbox"/> Native Hawaiian or Other Pacific Islander
Country of Residence _____	<input type="checkbox"/> Asian
Method of payment (check one)	<input type="checkbox"/> American Indian or Alaska Native
<input type="checkbox"/> PI (Private Insurance)	<input type="checkbox"/> Not reported: Patient refused or not available
<input type="checkbox"/> MR (Medicare)	<input type="checkbox"/> Unknown: Patient unsure
<input type="checkbox"/> MRP (Medicare and Private Insurance)	
<input type="checkbox"/> MD (Medicaid)	Ethnicity (check one)
<input type="checkbox"/> MM (Medicaid and Medicare)	<input type="checkbox"/> Not Hispanic or Latino
<input type="checkbox"/> MVA (Military or Veterans Sponsored, Not Otherwise Specified (NOS))	<input type="checkbox"/> Hispanic or Latino
<input type="checkbox"/> MS (Military Sponsored [including CHAMPUS & TRCARE])	<input type="checkbox"/> Not reported: Refused or data not available
<input type="checkbox"/> MV (Veterans Sponsored)	<input type="checkbox"/> Unknown: Unsure of their ethnicity
<input type="checkbox"/> SP (Self pay [no insurance])	
<input type="checkbox"/> NP (No means of payment [no insurance])	
<input type="checkbox"/> OTH (Other)	
<input type="checkbox"/> UNK (Unknown)	

Patient study ID number _____

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

Inclusion Criteria

Yes No NA

Histologically confirmed GBM (grade 4 astrocytoma). Gliosarcomas and other grade 4 astrocytoma variants (e.g. giant cell) may be included. Grade 4 oligodendrogliomas or oligoastrocytomas are specifically excluded.	____	____	____
≥1 week and ≤6 weeks following surgical resection or biopsy.	____	____	____
(For Phase I patients only) Measurable disease ≥1 cm ³ . Not Phase I patient (<i>check NA</i>).	____	____	____
≥18 years of age. Because no dosing or adverse event data are currently available on the use of everolimus in patients <18 years of age, children are excluded from this study. Age = _____.	____	____	____
ECOG Performance Status (PS) of 0, 1 or 2. PS = _____.	____	____	____
The following laboratory values obtained ≤14 days prior to registration. Earliest laboratory test date ___/___/____; latest laboratory test date ___/___/____. NOTE: These dates pertain to the following labs only.	____	____	____
• ANC ≥1500/μL ANC = _____	____	____	____
• Hemoglobin ≥9.0 g/dL Hemoglobin = _____	____	____	____
• PLT ≥100,000/μL PLT = _____	____	____	____
• Total bilirubin ≤2.5 x institutional upper limit of normal (ULN) Total bilirubin = _____; ULN = _____	____	____	____
• Serum total cholesterol <350 mg/dL Serum total cholesterol = _____	____	____	____
• Serum total triglycerides <400 mg/dL Serum total triglycerides = _____	____	____	____
• AST(SGOT) ≤2.5 x ULN AST(SGOT) = _____; ULN = _____	____	____	____
• Creatinine ≤1.5 x ULN Creatinine = _____; ULN = _____	____	____	____
Negative pregnancy test done ≤7 days prior to registration, for women of childbearing potential only. Not a woman of childbearing potential or male (<i>check NA</i>) vs. negative pregnancy test date ___/___/____	____	____	____
Ability to understand, and willingness to sign, a written informed consent.	____	____	____
Willingness to undergo 2 mandatory research PET or PET/CT scans. (Sections 4.2 and 6.36) PHASE I: All MCR and MCF patients PHASE II: MCR patients with measurable disease of ≥1 cm ³ . <i>Not PHASE I patient or PHASE II MCR patient with measurable disease of ≥1 cm³ (check NA).</i>	____	____	____
Willingness to provide mandatory translational research components. • Two mandatory research blood draws (Sections 6.33, 14.11) PHASE I: All MCR and MCF patients PHASE II: MCR patients only who are at MTD and undergo FLT PET • Mandatory FFPE tumor tissue blocks/slides (6.33, 17.3). PHASE I and II: All patients	____	____	____
Willingness to abstain from eating grapefruit or drinking grapefruit juice for the duration of the study.	____	____	____
Willing to follow a diet low in fat and cholesterol while taking everolimus.	____	____	____
Willingness and ability to comply with antibiotic prophylaxis with either trimethoprim/sulfamethoxazole (daily or 3 x per week), oral dapsone (daily) combined with daily levofloxacin, or monthly pentamidine (inhaled or IV) combined with daily levofloxacin.	____	____	____
Willing to have imaging scans submitted for central review. (Mandatory for patients enrolled post-Addendum 10).	____	____	____

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

Exclusion Criteria

Yes No NA

Prior chemotherapy for any brain tumor. Prior temozolomide or mTOR inhibitor therapies. Any prior cranial radiotherapy.	____	____	____
Planned immunization with attenuated live vaccines ≤7 days prior to registration and during study period. Note: Close contact with those who have received attenuated live vaccines should be avoided during treatment with everolimus. Examples of live vaccines include intranasal influenza, measles, mumps, rubella, oral polio, BCG, yellow fever, varicella and TY21a typhoid vaccines.	____	____	____

Patient study ID number _____

Current or prior treatment for this cancer with any other investigational agents.	_____
Currently on enzyme inducing anti-convulsants (EIACs) or other strong inducers of CYP3A4. Note: For the purpose of this study, these drugs will be defined as carbamazepine, phenytoin, phenobarbital/primidone, rifabutin, rifampin or St. John's wort.	_____
Any of the following because everolimus has potential teratogenic or abortifacient effects based on the potential that mTOR expression is important for normal organ development: <ul style="list-style-type: none"> • Pregnant women • Nursing women • Men or women of childbearing potential who are unwilling to employ adequate contraception for duration of the study and for 60 days following completion of study therapy. 	_____
Other active cancers requiring therapy to control disease, or prior cancer diagnoses, which pose a greater than 30% risk of death within the next 2 years.	_____
Major surgery (excluding neurosurgical biopsy or resection of brain tumor or treatment of immediate post neurosurgical complication, eg intracranial hematoma) or significant traumatic injury occurring ≤21 days prior to registration.	_____
Gastrointestinal tract disease resulting in an inability to take oral medication or a requirement for IV alimentation, prior surgical procedures affecting absorption, or active uncontrolled peptic ulcer disease.	_____
Uncontrolled intercurrent illness including, but not limited to the following: <ul style="list-style-type: none"> • ongoing or active infection • symptomatic congestive heart failure • unstable angina pectoris • cardiac arrhythmia • psychiatric illness/social situations that would limit compliance with study requirements • severely impaired lung function • uncontrolled diabetes as defined by fasting serum glucose >2 x ULN • any active (acute or chronic) or uncontrolled infection/ disorders. • liver disease such as cirrhosis, chronic active hepatitis, chronic persistent hepatitis or history of hepatitis B or C. 	_____
Known to be HIV-positive. Note: The mucosal adverse events of ionizing radiation in HIV-positive patients are significantly greater than in patients without HIV. Therefore, HIV-positive patients will be excluded.	_____
Any history of allergy or intolerance to Dacarbazine (DTIC).	_____
Patients who require therapeutic dose of warfarin (see Section 9.4). Note: Low molecular weight heparin is allowed. Patients who can be converted to low molecular weight heparin may enroll on the trial once they have discontinued warfarin.	_____
PHASE I (MCR and MCF ONLY): Uncontrolled diabetes that will interfere with the performance of the FDG-PET/CT or FDG-PET scans. <i>Not PHASE I (check NA).</i>	_____
Severe allergy to sulfa medications and inability to tolerate levofloxacin with dapson or pentamidine (inhaled or IV).	_____
Positive hepatitis B antigen (HBsAg) or hepatitis C serology (HCV) tests.	_____

All responses in above section must be “No” unless specified as “NA.”

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

Yes No NA

The Registration Office will automatically register patients separately to the mandatory blood (see Section 3.29a and 14.2): <ul style="list-style-type: none"> • Phase I - MCR and MCF only. <i>Not a Phase I MCR and MCF patient (check NA).</i> • Phase II – MCR only. <i>Not a Phase II MCR patient (check NA).</i> 	_____
The Registration Office will automatically register patients separately to the translational component of this study for mandatory tissue (see sections 3.29b and 17.3): <ul style="list-style-type: none"> • All patients – Phase I and II. 	_____

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Patient study ID number
Registration Check – (continued)

	Yes	No	NA
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. Note: Treatment may not start ≤6 days following a stereotactic biopsy or ≤13 days following an open craniotomy.	___	___	___
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.	___	___	___
All required baseline symptoms must be documented and graded.	___	___	___
Study drug availability checked.	___	___	___
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.”

The Registration Office will register patients separately to the optional translational research component of this study. The following will be recorded:	___	___	___
<ul style="list-style-type: none"> • Patient has given permission to give tissue samples for the optional research testing. (<i>Applies to Phase I & II, MCR patients only – frozen surgical tissue from initial resection</i>). <i>Not a Phase I or II MCR patient (check NA)</i>. 	___	___	___
<ul style="list-style-type: none"> • Patient has given permission to give future tissue samples (if available) at recurrence for the optional research testing. (<i>Applies to all patients</i>). 	___	___	___
At the time of registration/randomization, the following will also be recorded:	___	___	___
<ul style="list-style-type: none"> • Patient has given permission to collect and keep blood sample(s) for use in future research to learn about, prevent, or treat cancer. 	___	___	___
<ul style="list-style-type: none"> • Patient has given permission to collect and keep blood sample(s) for use in future research to learn about, prevent, or treat other health problems (for example: diabetes, Alzheimer’s disease, or heart disease). 	___	___	___
<ul style="list-style-type: none"> • Patient has given permission to keep tissue sample(s) for use in future research to learn about, prevent, or treat cancer. 	___	___	___
<ul style="list-style-type: none"> • Patient has given permission to keep tissue sample(s) for use in future research to learn about, prevent, or treat other health problems (for example: diabetes, Alzheimer’s disease, or heart disease). 	___	___	___
<ul style="list-style-type: none"> • PHASE I (MCR and MCF Only) and PHASE II (MCR Only): Patient has given permission to store MRI and PET scan discs for future research. <i>Not PHASE I or PHASE II (MCR Only) (check NA)</i> 	___	___	___
<ul style="list-style-type: none"> • PHASE II (NCCTG EXCEPT MCR): Patient has given permission to store MRI scan discs for future research. <i>Not PHASE II or PHASE II (MCR Only) (check NA)</i>. 	___	___	___
<ul style="list-style-type: none"> • Patient has given NCCTG permission to give sample(s) to outside researchers. 	___	___	___
Patient will be registered to NCCTG 94-72-52.	___	___	___

All responses in above section may be “Yes” or “No” or “NA”.

Grouping Factor

Phase
 I
 II

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Patient study ID number _____

Descriptive Factors

Dose Level (to be assigned by the Randomization Center)

- 3
- 2
- 1
- 0
- 1
- 2

Registering Site (for Phase 2 only)

- MCR
- non-MCR

Assigned Treatment

A) Everolimus + RT + Temozolomide

Person registering _____

Signature

Registration Office specialist _____

initials

Physician _____

Signature

____ - ____ - ____
M D Y

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

Protocol Number: N057K

Patient ID: _____ Patient Initials: _____

L F M

Institution Number: _____

Institution: _____

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: 10018337 (*Glioblastoma Multiforme*)

Disease History

Date Onset First Symptoms: (mm/dd/yyyy) ___/___/_____

Date of Operative Procedure: (mm/dd/yyyy) ___/___/_____

Maximum Diameter of Tumor on Pre-Operative Scan (cm)

____ . ____ Contrast Enhancement

____ . ____ T2 Abnormality on MRI or Low Attenuation on CT

Extent of Resection (check one)

- 1 Biopsy only
- 2 Subtotal resection
- 3 Gross total resection

Location of Primary Neoplasm (check all that apply)

- | | |
|--------------------------|--------------------------|
| L | R |
| <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"/> |
| <input type="checkbox"/> | <input type="checkbox"/> |

- | | |
|--------------------------|--------------------------|
| L | R |
| <input type="checkbox"/> | <input type="checkbox"/> |
| <input type="checkbox"/> | <input type="checkbox"/> |
| <input type="checkbox"/> | <input type="checkbox"/> |
| <input type="checkbox"/> | <input type="checkbox"/> |

- | | |
|--------------------------|--------------------------|
| L | R |
| <input type="checkbox"/> | <input type="checkbox"/> |
| <input type="checkbox"/> | <input type="checkbox"/> |
| <input type="checkbox"/> | <input type="checkbox"/> |
| <input type="checkbox"/> | <input type="checkbox"/> |

Side Of Primary Tumor (check one)

- 1 Right 2 Left 3 Midline 4 Bilateral

Family History of Brain Tumor? (check one) 1 Yes 2 No

- If yes, (check all that apply):
- Father
 - Mother
 - Brother or sister
 - Child
 - Other (list: _____)

Corticosteroid Therapy at Study Entry? (check one) 1 Yes 2 No

Height (cm): ____ . ____ . ____ .

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

Protocol Number: N057K

Patient ID: _____ Patient Initials: _____
L F M

Institution Number: _____

Institution: _____

**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 v3.0)	MedDRA Code (v. 10.0)	CTC Adverse Event Grade
Baseline number of stools per day: _____		
Neutrophils/granulocytes (ANC/AGC)	10029366	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4
Platelets	10035528	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4
Nausea	10028813	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4
Cholesterol, serum-high (hypercholesteremia)	10040190	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4
Triglyceride, serum-high (hypertriglyceridemia)	10040424	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4
Cough	10011224	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3
Dyspnea (shortness of breath)	10013963	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4

PLACE LABEL HERE

Protocol Number: N057K

Patient ID: _____ Patient Initials: _____

L F M

Institution Number: _____

Institution: _____

NORTH CENTRAL CANCER TREATMENT GROUP

RADIATION THERAPY REPORTING FORM

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

BRAIN

Date Start Radiotherapy
m m d d y y y y

Date End Radiotherapy
m m d d y y y y

Please Enclose a Copy of:

1. Preoperative and postoperative scans.
2. Prescription, dosimetry calculations, and daily treatment record.
3. Isodose plots.
4. Simulator port films.
5. Port films.

TECHNIQUE

Modality	Field	Field Size	Treatment Distance
Primary: <input type="checkbox"/>	_____	<input type="text"/> <input type="text"/> . <input type="text"/> <input type="text"/> cm X <input type="text"/> <input type="text"/> . <input type="text"/> <input type="text"/> cm	<input type="text"/> <input type="text"/> <input type="text"/> cm <input type="checkbox"/> 1=SSD
1-Cobalt	_____	<input type="text"/> <input type="text"/> . <input type="text"/> <input type="text"/> cm X <input type="text"/> <input type="text"/> . <input type="text"/> <input type="text"/> cm	<input type="text"/> <input type="text"/> <input type="text"/> cm <input type="checkbox"/> 2=SAD
2-Linear Accel. _____ MV	_____	<input type="text"/> <input type="text"/> . <input type="text"/> <input type="text"/> cm X <input type="text"/> <input type="text"/> . <input type="text"/> <input type="text"/> cm	<input type="text"/> <input type="text"/> <input type="text"/> cm <input type="checkbox"/>
3-Other _____ MV	_____	<input type="text"/> <input type="text"/> . <input type="text"/> <input type="text"/> cm X <input type="text"/> <input type="text"/> . <input type="text"/> <input type="text"/> cm	<input type="text"/> <input type="text"/> <input type="text"/> cm <input type="checkbox"/>
Modality	Field	Field Size	Treatment Distance
Boost: <input type="checkbox"/>	_____	<input type="text"/> <input type="text"/> . <input type="text"/> <input type="text"/> cm X <input type="text"/> <input type="text"/> . <input type="text"/> <input type="text"/> cm	<input type="text"/> <input type="text"/> <input type="text"/> cm <input type="checkbox"/> 1=SSD
1-Cobalt _____ MV	_____	<input type="text"/> <input type="text"/> . <input type="text"/> <input type="text"/> cm X <input type="text"/> <input type="text"/> . <input type="text"/> <input type="text"/> cm	<input type="text"/> <input type="text"/> <input type="text"/> cm <input type="checkbox"/> 2=SAD
2-Linear Accel. _____ MV	_____	<input type="text"/> <input type="text"/> . <input type="text"/> <input type="text"/> cm X <input type="text"/> <input type="text"/> . <input type="text"/> <input type="text"/> cm	<input type="text"/> <input type="text"/> <input type="text"/> cm <input type="checkbox"/>
3-Other _____ MV	_____	<input type="text"/> <input type="text"/> . <input type="text"/> <input type="text"/> cm X <input type="text"/> <input type="text"/> . <input type="text"/> <input type="text"/> cm	<input type="text"/> <input type="text"/> <input type="text"/> cm <input type="checkbox"/>

Treatment Areas, Dose and Time

Site	Tumor Dose (cGy)	# of Fractions	Elapsed Days
Initial Volume	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>
Boost Volume	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>

Unscheduled Interruptions? 1 = Yes, 2 = No. If yes, enter number of days and reasons below:

Days	Reasons
<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>

- | | |
|-----------------------|---------------------------|
| 1 = Social | 4 = Machine down |
| 2 = Local reaction | 5 = Other, specify: _____ |
| 3 = Systemic reaction | 6 = Unknown |

Radiation Oncologist's Comments:

Radiation Oncologist's Signature

Date

I. Data Manager	PLACE LABEL HERE	NORTH CENTRAL CANCER TREATMENT GROUP	
	Protocol Number: <u>N057K</u> Patient ID: _____ Patient Initials: _____ L F M Institution Number: _____ Institution: _____	PATHOLOGY REPORTING FORM	
		BRAIN TUMOR	
		Primary Pathologist: _____	No. of slides sent: _____
		Clinic/Hospital: _____	Date sent: _____
		Reviewer: _____	Slide No. _____ Sequence No. _____
	THIS REPORT IS FOR: (check one) 1 <input type="checkbox"/> Primary 2 <input type="checkbox"/> Recurrent		
	1. DATE OF OPERATIVE PROCEDURE		
	-- / -- / -- (mm/dd/yyyy)		

II. Information obtained from pathology report	2. RADIATION EFFECTS (If prior radiation) <input type="checkbox"/> 1. Yes <input type="checkbox"/> 2. No
	3. MICROSCOPIC FEATURE OF PRIMARY NEOPLASM (0=Absent, 1=Present, 9=Uncertain) <input type="checkbox"/> Nuclear abnormalities (atypia, pleomorphism) <input type="checkbox"/> Mitoses <input type="checkbox"/> Endothelial proliferation <input type="checkbox"/> Necrosis
	4. HISTOLOGIC SUBTYPE (For mixed tumors, specify by prevalence) (number all that apply): <input type="checkbox"/> Oligodendroglioma <input type="checkbox"/> Astrocytoma, fibrillary <input type="checkbox"/> Astrocytoma, NOS (describe in comments) <input type="checkbox"/> Astrocytoma, pilocytic <input type="checkbox"/> Astrocytoma, gemistocytic <input type="checkbox"/> Gliosarcoma <input type="checkbox"/> Astrocytoma, microcystic (cerebellar type) <input type="checkbox"/> Astrocytoma, giant cell <input type="checkbox"/> Astrocytoma, protoplasmic <input type="checkbox"/> Astrocytoma, small cell (undifferentiated)
	5. HISTOLOGIC GRADE OF PRIMARY NEOPLASM (Degree of differentiation) (check one) 1 <input type="checkbox"/> Grade I 2 <input type="checkbox"/> Grade II 3 <input type="checkbox"/> Grade III 4 <input type="checkbox"/> Grade IV
	COMMENTS: _____ <div style="text-align: center;"> FOR PATIENTS WITH REBIOPSY AFTER RADIATION <i>(Please complete the following items after rebiopsy)</i> </div>
	6. MICROSCOPIC FEATURES OF RADIATION EFFECT (0=Absent, 1=Present, 9=Uncertain) Vascular Changes: Tissue Changes: <input type="checkbox"/> Proliferation <input type="checkbox"/> Atrophy/Gliosis <input type="checkbox"/> Other (specify) _____ <input type="checkbox"/> Necrosis, thrombosis, sclerosis <input type="checkbox"/> Necrosis
	COMMENTS: _____

III. Signatures	_____ Reviewer _____ Date <input type="checkbox"/> 1. Agree with diagnosis <input type="checkbox"/> 2. Minor disagreement <input type="checkbox"/> 3. Substantial disagreement Comments: _____	_____ Research Base Advisor _____ Date <input type="checkbox"/> 1. Agree with diagnosis <input type="checkbox"/> 2. Minor disagreement <input type="checkbox"/> 3. Substantial disagreement Comments: _____	_____ Committee Chairman _____ Date <input type="checkbox"/> 1. Agree with diagnosis <input type="checkbox"/> 2. Minor disagreement <input type="checkbox"/> 3. Substantial disagreement Comments: _____
	Block/Slide number(s) to be used for research/banking: _____		

PLACE LABEL HERE

Protocol Number: N057K

Patient ID: _____ Patient Initials: _____

L F M

Institution Number: _____

Institution: _____

NORTH CENTRAL CANCER TREATMENT GROUP

PATHOLOGY SUBMISSION FORM

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

**** 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: Dr. Caterina Giannini and/or associates, Mayo Clinic Rochester - Rochester, MN

Number of slides sent: ___

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

_____	_____
_____	_____
_____	_____
_____	_____
_____	_____

Number of blocks sent: ___

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

_____	_____
_____	_____
_____	_____
_____	_____
_____	_____

COMMENTS:

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

**NORTH CENTRAL CANCER TREATMENT GROUP
CONCURRENT STEROID AND ANTICONVULSANT
TREATMENT FORM
(BASELINE)**

Protocol Number: N057K
 Patient ID: _____ Patient Initials: _____
 L F M
 Institution Number: _____
 Institution: _____

ALL ITEMS MUST BE COMPLETED

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

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

Concomitant Treatment	Total Daily Dose
Corticosteroids 2 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes ↓	
Decadron/Dexamethasone 2 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes →	
Other corticosteroid 2 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes → (specify) _____	
Anticonvulsants 2 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes ↓	
Neurontin 2 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes →	
Phenytoin/Dilantin 2 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes →	
Carbamazepine/Tegretol 2 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes →	
Valproic acid/Depakene 2 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes →	
Phenobarbital 2 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes →	

Concomitant Treatment	Total Daily Dose
Keppra 2 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes →	
Other anticonvulsant 2 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes → (specify) _____	
Antiemetics 2 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes ↓	
Compazine 2 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes →	
Granisetron 2 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes →	
Ondansetron 2 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes →	
Ativan 2 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes →	
Other antiemetic 2 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes → (specify) _____	

PLACE LABEL HERE

Protocol Number: N057K

Patient ID: _____ Patient Initials: _____
L F M

Institution Number: _____

Institution: _____

**NORTH CENTRAL CANCER TREATMENT GROUP
CONCURRENT STEROID AND ANTICONVULSANT
TREATMENT FORM**

(ACTIVE MONITORING PHASE)

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: ____

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

Concomitant Treatment	Total Daily Dose
Corticosteroids 2 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes ↓	
Decadron/Dexamethasone 2 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes →	
Other corticosteroid 2 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes → (specify) _____	
Anticonvulsants 2 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes ↓	
Neurontin 2 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes →	
Phenytoin/Dilantin 2 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes →	
Carbamazepine/Tegretol 2 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes →	
Valproic acid/Depakene 2 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes →	
Phenobarbital 2 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes →	

Concomitant Treatment	Total Daily Dose
Keppra 2 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes →	
Other anticonvulsant 2 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes → (specify) _____	
Antiemetics 2 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes ↓	
Compazine 2 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes →	
Granisetron 2 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes →	
Ondansetron 2 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes →	
Ativan 2 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes →	
Other antiemetic 2 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes → (specify) _____	

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

**CONCURRENT TREATMENT FORM
(BASELINE)**

ALL ITEMS MUST BE COMPLETED

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

Protocol Number: N057K

Patient ID: _____ Patient Initials: _____
L F M

Institution Number: _____

Institution: _____

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

Concomitant medications? (check one)

1 Yes 2 No (Stop here)

If Yes, enter all medications (including prescription, over-the-counter, and alternative medications).

Concomitant Treatment	Dose and Schedule

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

**CONCURRENT TREATMENT FORM
(ACTIVE MONITORING PHASE)**

ALL ITEMS MUST BE COMPLETED

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

Protocol Number: N057K

Patient ID: _____ Patient Initials: _____

L F M

Institution Number: _____

Institution: _____

Current Cycle Number: ____

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

Has there been any change in medications since the previous visit?

1 Yes 2 No (*Stop here*)

If yes, enter all medications (*including prescription, over-the-counter, and alternative medications*)

Concomitant Treatment	Dose and Schedule

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

Protocol Number: N057K

Patient ID: _____ Patient Initials: _____

L F M

Institution Number: _____

Institution: _____

**BASELINE
OPTIONAL 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 7 days of specimen collection. See Section 14 of the protocol for specimen requirements and shipment.

Did this patient provide written consent to give blood specimen(s) for research? (check one)

- 1 Yes. If Yes, complete rest of form.
- 2 No. If No, end form.

Was a research blood specimen collected? (check one)

- 1 Yes. If Yes: Date of collection: (mm/dd/yyyy) ___/___/_____
Date Specimen Shipped: (mm/dd/yyyy) ___/___/_____
(Not applicable for Mayo Rochester)
- 2 No. If No, reason: _____

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

**RECURRENT
TISSUE 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)

Protocol Number: N057K

Patient ID: _____ Patient Initials: _____
L F M

Institution Number: _____

Institution: _____

Current Cycle Number: ____ or Event Monitoring

INSTRUCTIONS:

- Complete this form **for all patients** and enter into the remote data entry system within 60 days of specimen collection
- 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 Initial Consent given for recurrent tissue specimen use for research on the patient's cancer? (check one)

1 Yes. If Yes, complete rest of form

2 No. If No, end form

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: (check one) 1 No biopsy/surgery performed: (check all that apply)

Brain mets Other disease recurrence

Bone mets Patient deceased

Liver mets

2 Fine needle aspirate only

3 Facility will not release block

4 Block depleted/insufficient tissue

5 Other reason, specify _____

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: N057K

Patient ID: _____ Patient Initials: _____

L F M

Institution Number: _____

Institution: _____

**NORTH CENTRAL CANCER TREATMENT GROUP
PHASE I MCR AND MCF
CYCLE 1
ACTIVE MONITORING
MANDATORY 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: 1

Time point: (check one) 1 Day 2 2 Day 8

INSTRUCTIONS:

Complete 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) ___/___/_____

Time of collection: (military) _____

Date Specimen Shipped: (mm/dd/yyyy) ___/___/_____

(Not applicable for Mayo Rochester)

2 No. If No, reason: _____

PLACE LABEL HERE

Protocol Number: N057K

Patient ID: _____ Patient Initials: _____

L F M

Institution Number: _____

Institution: _____

**NORTH CENTRAL CANCER TREATMENT GROUP
PHASE II MCR ONLY
PATIENTS AT MTD AND UNDERGO FLT PET
ACTIVE MONITORING
MANDATORY 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: 1

Time point: (check one) 1 Day 2 2 Day 8

INSTRUCTIONS:

Complete 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) __ __ / __ __ / __ __ __ __

Time of collection: (military) __ __ __ __

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

(Not applicable for Mayo Rochester)

2 No. If No, reason: _____

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

Protocol Number: N057K

**PRETREATMENT
MEASUREMENT FORM**

Patient ID: _____ Patient Initials: _____

L F M

Institution Number: _____

Institution: _____

ALL ITEMS MUST BE COMPLETED

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

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

Primary Indicator Lesion Site Type of Assessment: (check one)

- 2 CT
- 4 MRI

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

Protocol Number: N057K

**ACTIVE MONITORING
MEASUREMENT FORM**

Patient ID: _____ Patient Initials: _____

L F M

Institution Number: _____

Institution: _____

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: ____

Date (mm/dd/yyyy)	____/____/____	
Primary Indicator Lesion Site	Type of Assessment (check one)	
	CT 2 <input type="checkbox"/>	MRI 4 <input type="checkbox"/>
CT/MRI Scan Score ① (check one)	0 <input type="checkbox"/> NED 1 <input type="checkbox"/> CR 2 <input type="checkbox"/> PR 3 <input type="checkbox"/> REGR	5 <input type="checkbox"/> SD 6 <input type="checkbox"/> PD 7 <input type="checkbox"/> NOT DONE
Neuro Exam Score ② (check one)	1 <input type="checkbox"/> B 2 <input type="checkbox"/> S 3 <input type="checkbox"/> W	7 <input type="checkbox"/> NOT DONE
Objective Status ③ (check one)	0 <input type="checkbox"/> NED 1 <input type="checkbox"/> CR 2 <input type="checkbox"/> PR 3 <input type="checkbox"/> REGR	5 <input type="checkbox"/> SD 6 <input type="checkbox"/> PD 8 <input type="checkbox"/> UNKN

① CT/MRI SCAN SCORE (compared to pretreatment exam)

NED = no evidence of disease
 CR = complete disappearance of all tumor
 PR = ≥50% reduction of L x W of 1^o lesions; no new lesion
 REGR = Unequivocal decrease in size of contrast enhancement or in mass effect and no new lesion
 SD = failure to qualify for CR, PR, ReGR or Prog
 PD = ≥25% increase in L x W of any lesions or appearance of new lesion

② NEURO EXAM SCORE (compared to pretreatment exam)

B = Better: must be stable or decreasing dose of steroids
 S = Same: failure to qualify for B or W
 W = Worse: includes patients requiring increasing steroid doses to remain stable

③ OBJECTIVE STATUS CODE

(objective status has value shown in table below)

NEURO STATUS	SCAN STATUS					
	NED	CR	PR	REGR	SD	PD
Better						UNKN*
Same	NED	CR	PR	REGR	SD	PD
Worse	UNKN*					

* Set the Objective Status equal to unknown. Treat one more cycle and at the next visit evaluate according to the table below:

NEURO STATUS	SCAN STATUS					
	NED	CR	PR	REGR	SD	PD
Better						PD
Same	NED	CR	PR	REGR	SD	
Worse						

PLACE LABEL HERE

Protocol Number: N057K

Patient ID: _____ Patient Initials: _____

L F M

Institution Number: _____

Institution: _____

NORTH CENTRAL CANCER TREATMENT GROUP

CYCLES 1 and 3

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: _____

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(m²): (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

154 Metabolic Laboratory

38 Other Nonhematologic adverse event

60 GI

140 Pulmonary

99 Other (not per protocol) _____

Agent	Everolimus (RAD001)	Temozolomide (TMZ)
Agent Start Date this cycle (mm/dd/yyyy)	____/____/____	____/____/____
Dose Level day one this cycle (i.e. mg/m ²)		
Total Dose (mg) this cycle		
Was DOSE LEVEL adjusted this cycle? (i.e. mg/m ²)	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No ↓	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No ↓
PRIMARY REASON for Dose Adjustment per Section 8.0. Not BSA changes. (If Yes, check one Primary Reason.)	35 <input type="checkbox"/> Hematologic 60 <input type="checkbox"/> GI 154 <input type="checkbox"/> Metabolic Laboratory 140 <input type="checkbox"/> Pulmonary 38 <input type="checkbox"/> Other Non hematologic adverse event 99 <input type="checkbox"/> Other (not per protocol) _____	35 <input type="checkbox"/> Hematologic 60 <input type="checkbox"/> GI 154 <input type="checkbox"/> Metabolic Laboratory 38 <input type="checkbox"/> Other Non hematologic adverse event 99 <input type="checkbox"/> Other (not per protocol) _____
Did this patient have dose limiting toxicity this cycle as defined in Section 7.114? (If Yes, check all that apply.)	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No <input type="checkbox"/> ≥ grade 3 diarrhea <input type="checkbox"/> ≥ grade 3 skin rash/desquamation <input type="checkbox"/> ≥ grade 4 neutropenia or leukopenia <input type="checkbox"/> ≥ grade 4 thrombocytopenia <input type="checkbox"/> ≥ grade 4 hypercholesterolemia, hyperglycemia and triglyceridemia <input type="checkbox"/> ≥ grade 3 (other) nonhematologic adverse event, except hypercholesterolemia, hyperglycemia and triglyceridemia <input type="checkbox"/> ≥ grade 4 radiation dermatitis <input type="checkbox"/> Failure to administer >75% or interruption of radiation for more than 5 days due to toxicity <input type="checkbox"/> Severe acute CNS deterioration which cannot be controlled with corticosteroid administration	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No <input type="checkbox"/> ≥ grade 3 diarrhea <input type="checkbox"/> ≥ grade 3 skin rash/desquamation <input type="checkbox"/> ≥ grade 4 neutropenia or leukopenia <input type="checkbox"/> ≥ grade 4 thrombocytopenia <input type="checkbox"/> ≥ grade 4 hypercholesterolemia, hyperglycemia and triglyceridemia <input type="checkbox"/> ≥ grade 3 (other) nonhematologic adverse event, except hypercholesterolemia, hyperglycemia and triglyceridemia <input type="checkbox"/> ≥ grade 4 radiation dermatitis <input type="checkbox"/> Failure to administer >75% or interruption of radiation for more than 5 days due to toxicity <input type="checkbox"/> Severe acute CNS deterioration which cannot be controlled with corticosteroid administration

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

CYCLE 2

FOR

EVALUATION FORM 4-6 WEEK REST PERIOD

ALL ITEMS MUST BE COMPLETED

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

Protocol Number: N057K

Patient ID: _____ Patient Initials: _____
L F M

Institution Number: _____

Institution: _____

Current Cycle Number: 2

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)

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

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

CYCLES 4 through 8

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)

Protocol Number: N057K
 Patient ID: _____ Patient Initials: _____
 L F M
 Institution Number: _____
 Institution: _____

Use one form per cycle, one column per agent.

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)

BSA(m²): *(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 154 Metabolic Laboratory 38 Other Nonhematologic adverse event
 60 GI 140 Pulmonary 99 Other (not per protocol) _____

Agent	Everolimus (RAD001)	Temozolomide (TMZ)
Agent Start Date this cycle (mm/dd/yyyy)	___/___/___	___/___/___
Dose Level day one this cycle (i.e. mg/m ²)		
Total Dose (mg) this cycle		
Was DOSE LEVEL adjusted this cycle? (i.e. mg/m ²)	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No ↓	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No ↓
PRIMARY REASON for Dose Adjustment per Section 8.0. Not BSA changes. <i>(If Yes, check one Primary Reason.)</i>	35 <input type="checkbox"/> Hematologic 60 <input type="checkbox"/> GI 154 <input type="checkbox"/> Metabolic Laboratory 140 <input type="checkbox"/> Pulmonary 38 <input type="checkbox"/> Nonhematologic adverse event 99 <input type="checkbox"/> Other <i>(not per protocol)</i> _____	35 <input type="checkbox"/> Hematologic 60 <input type="checkbox"/> GI 154 <input type="checkbox"/> Metabolic Laboratory 38 <input type="checkbox"/> Nonhematologic adverse event 99 <input type="checkbox"/> Other <i>(not per protocol)</i> _____

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

Protocol Number: N057K

CYCLES ≥ 9

Patient ID: _____ Patient Initials: _____

EVALUATION/TREATMENT FORM

L F M

ALL ITEMS MUST BE COMPLETED

Institution Number: _____

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

Institution: _____

Use one form per cycle, one column per agent.

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)

BSA(m²): *(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

154 Metabolic Laboratory

38 Other Nonhematologic adverse event

60 GI

140 Pulmonary

99 Other (not per protocol) _____

Agent	Everolimus (RAD001)
Agent Start Date this cycle (mm/dd/yyyy)	___/___/___
Dose Level day one this cycle (i.e. mg/m ²)	
Total Dose (mg) this cycle	
Was DOSE LEVEL adjusted this cycle? (i.e. mg/m ²)	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No ↓
PRIMARY REASON for Dose Adjustment per Section 8.0. Not BSA changes. (If Yes, check one Primary Reason.)	35 <input type="checkbox"/> Hematologic 60 <input type="checkbox"/> GI 154 <input type="checkbox"/> Metabolic Laboratory 140 <input type="checkbox"/> Pulmonary 38 <input type="checkbox"/> Nonhematologic adverse event 99 <input type="checkbox"/> Other (not per protocol) _____

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

Protocol Number: N057K

NADIR/ADVERSE EVENT FORM

Patient ID: _____ Patient Initials: _____

ALL ITEMS MUST BE COMPLETED

Pg. 1 of 2

L F M

Institution Number: _____

Are data amended? (check one) Yes No

(if data are amended, please circle in red when using paper form)

Current Cycle Number (nadir/adverse events associated with this cycle): _____

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

Test	Date of Nadir (Date of lab test) (mm/dd/yyyy)	Nadir Value (The nadir is the lowest value of counts occurring between two treatments. If the only count available is taken the day of retreatment, use that value as the nadir.)	Is this nadir below the LLN? (check one)	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)
ALC K/uL or 10 ⁹ /L	____/____/____	____.____	1 <input type="checkbox"/> Yes → 2 <input type="checkbox"/> No → (Go to Adverse Event)	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	____

CTC Adverse Event Term (CTCAE v3.0)	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

Neutrophils/granulocytes (ANC/AGC)	10029366	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	____
Platelets	10035528	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	____
Rash/desquamation	10037853	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	____
Diarrhea	10012727	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <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	____
Nausea	10028813	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <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	____
Cholesterol, serum-high (hypercholesteremia)	10040190	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <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	____
Triglyceride, serum-high (hypertriglyceridemia)	10040424	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <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	____
Cough	10011224	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	____
Dyspnea (shortness of breath)	10013963	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <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	____

* See Section 10.0 of the protocol.

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

Protocol Number: N057K

NADIR/ADVERSE EVENT FORM

Patient ID: _____ Patient Initials: _____

ALL ITEMS MUST BE COMPLETED

Pg. 2 of 2

Institution Number: _____

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 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 v3.0)	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)
	<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	_____
	<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	_____
	<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	_____
	<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	_____
	<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	_____
	<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	_____
	<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	_____
	<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	_____
	<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	_____
	<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	_____
	<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	_____

* See Section 10.0 of the protocol.

** Both hematologic (except for the nadirs listed on page 1) and nonhematologic Adverse Events must be graded on this form as applicable.

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

Protocol Number: N057K

END OF ACTIVE TREATMENT/CANCEL NOTIFICATION FORM

Patient ID: _____ Patient Initials: _____

Submit Once Per Patient

Institution Number: _____ L F M

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)

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)

- 2 Event Monitoring (follow Event Monitoring schedule)
- 9 Off Study (cancels only)

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

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

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

Protocol Number: N057K

Patient ID: _____ Patient Initials: _____

L F M

Institution Number: _____

Institution: _____

EVENT MONITORING FORM

ALL ITEMS MUST BE COMPLETED

Pg. 1 of 2

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:
 - Local
 - Distant
 - Other, Specify _____
- Method (s) of Diagnosis:
 - Clinical exam
 - Pathologic
 - Radiographic
 - Other, specify _____

Notice of Subsequent Surgery or Biopsy

- Has the patient had subsequent surgery or biopsy for this cancer **that has not been previously reported?**
- 2 No 1 Yes. If Yes, date of surgery or biopsy: (mm/dd/yyyy) ___/___/_____
- Institution where surgery or biopsy was performed: _____

Notice of First Subsequent Treatment

- Has the patient received subsequent treatment for this cancer **that has not been previously reported?**
- 2 No 3 Unknown 1 Yes. If Yes, Start date of subsequent treatment: (mm/dd/yyyy) ___/___/_____
- Specify subsequent treatment: _____

Notice of New Primary

- Has a new primary cancer or MDS (myelodysplastic 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 ≥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

*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. 10/26/2009

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

**EVENT MONITORING FORM
(LATE ADVERSE EVENT REPORTING)**

ALL ITEMS MUST BE COMPLETED

Pg. 2 of 2

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

Protocol Number: N057K

Patient ID: _____ Patient Initials: _____

L F M

Institution Number: _____

Institution: _____

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)
	<input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> (death)	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	___/___/_____
	<input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> (death)	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	___/___/_____
	<input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> (death)	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	___/___/_____
	<input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> (death)	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	___/___/_____
	<input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> (death)	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	___/___/_____
	<input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> (death)	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	___/___/_____
	<input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> (death)	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	___/___/_____
	<input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> (death)	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	___/___/_____
	<input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> (death)	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	___/___/_____
	<input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> (death)	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	___/___/_____
	<input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> (death)	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	___/___/_____
	<input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> (death)	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	___/___/_____
	<input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> (death)	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	___/___/_____
	<input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> (death)	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	___/___/_____
	<input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> (death)	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	___/___/_____
	<input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> (death)	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	___/___/_____
	<input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> (death)	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	___/___/_____
	<input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> (death)	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	___/___/_____
	<input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> (death)	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	___/___/_____

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

Protocol Number: N057K

Patient ID: _____ Patient Initials: _____

L F M

Institution Number: _____

Institution: _____

**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?*
___/___/_____		<input type="checkbox"/> 4 <input type="checkbox"/> 5	4 <input type="checkbox"/> Yes: Unlikely 1 <input type="checkbox"/> Yes: Possible, probable, or definite 2 <input type="checkbox"/> No 3 <input type="checkbox"/> Unknown
___/___/_____		<input type="checkbox"/> 4 <input type="checkbox"/> 5	4 <input type="checkbox"/> Yes: Unlikely 1 <input type="checkbox"/> Yes: Possible, probable, or definite 2 <input type="checkbox"/> No 3 <input type="checkbox"/> Unknown
___/___/_____		<input type="checkbox"/> 4 <input type="checkbox"/> 5	4 <input type="checkbox"/> Yes: Unlikely 1 <input type="checkbox"/> Yes: Possible, probable, or definite 2 <input type="checkbox"/> No 3 <input type="checkbox"/> Unknown
___/___/_____		<input type="checkbox"/> 4 <input type="checkbox"/> 5	4 <input type="checkbox"/> Yes: Unlikely 1 <input type="checkbox"/> Yes: Possible, probable, or definite 2 <input type="checkbox"/> No 3 <input type="checkbox"/> Unknown
___/___/_____		<input type="checkbox"/> 4 <input type="checkbox"/> 5	4 <input type="checkbox"/> Yes: Unlikely 1 <input type="checkbox"/> Yes: Possible, probable, or definite 2 <input type="checkbox"/> No 3 <input type="checkbox"/> 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 _____

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

Protocol Number: N057K

**CYCLE 1 - WEEKLY
HEMATOLOGY
LABORATORY FORM**

Patient ID: _____ Patient Initials: _____

L F M

Institution Number: _____

Institution: _____

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: 1

	Tests	Test Result
Hematology	Week	_____
	Date of Collection (<i>mm/dd/yyyy</i>)	____/____/____
	TESTS	UNITS
	Platelets	K/uL or 10 ⁹ /L
	WBC	K/uL or 10 ⁹ /L
	Neutrophils	K/uL or 10 ⁹ /L
	Lymphocytes	K/uL or 10 ⁹ /L
	Monocytes	K/uL or 10 ⁹ /L

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

Protocol Number: N057K

**CYCLES \geq 3
HEMATOLOGY
LABORATORY FORM**

Patient ID: _____ Patient Initials: _____
L F M

Institution Number: _____

Institution: _____

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: _____

Prior to the start of each cycle.

	Tests	Test Result	
	Date of Collection (mm/dd/yyyy)	___/___/____	
Hematology	TESTS	UNITS	
	Platelets	K/uL or 10 ⁹ /L	_____.
	WBC	K/uL or 10 ⁹ /L	_____.
	Neutrophils	K/uL or 10 ⁹ /L	_____.
	Lymphocytes	K/uL or 10 ⁹ /L	_____.
	Monocytes	K/uL or 10 ⁹ /L	_____.

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

FOLSTEIN MINI MENTAL STATE

Appendix IV

Protocol # N057K

Patient ID # _____ Initials: _____

L F M

Local ID # _____ Institution _____

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

Age _____

Sex _____

____/5 What is the: (year) (season) (date) (day) (month)?

____/5 Where are we: (state) (county) (town) (building) (floor) ?

____/3 Learn: "apple, table, penny." ____ # of trials.

____/5 Subtract serial 7's: (100, 93, 86, 79, 72); or, spell "WORLD" backwards.

____/3 Recall: "apple, table penny."

____/2 Name: "pencil" and "watch."

____/1 Repeat: "no ifs, ands or buts."

____/3 "Take this paper in your right hand, fold it in half, and put it on the floor."

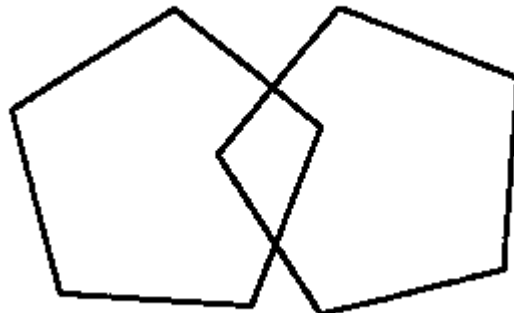
____/1 Read and obey: "Close your eyes."

____/1 Write a sentence on the back of this card.

____/1 Copy the design on the back of this card.

____/30 Total (abnormal if <24; if <8th grade, then <21 is considered abnormal.)

Close your eyes.





NCCTG

NORTH CENTRAL CANCER TREATMENT GROUP

N057K REIMBURSEMENT REQUEST

(form may be completed by member institution or their affiliate and sent to below address or email)

Today's Date: _____ NCCTG Patient ID (one patient per form): _____

NCCTG Member Institution Information (payment is made payable and sent to NCCTG member*):

Name of institution: _____

Attention to: _____

Address of institution: _____

Institutional TAX ID #: _____

Enrolling Institution Information:

Name of institution: _____

Contact CRA: _____

Phone: _____ Email: _____

Item(s) to be reimbursed	Maximum number of times per patient	Maximum amount allowed	Date obtained or completed	Amount requested
Hepatitis B surface antigen (HBsAg)/ Hepatitis C antibody screen (HCV)	1	\$159.78		\$
				\$
				\$
Total amount requested:				\$

Submit to: NCCTG Operations Office, PL4
Attn: CRO Finance Coordinator
200 First Street SW
Rochester, MN 55905

OR

CROFinance@mayo.edu

Questions: Send email to CROFinance@mayo.edu

*Due to contractual obligations, payments may only be made to the NCCTG member site. No direct payment will be made to a member's affiliate from the NCCTG Operations Office.