



NCCTG

NORTH CENTRAL CANCER TREATMENT GROUP

Date: December 9, 2011

To: Primary Clinical Research Associates

From: Sanna McKinzie
Research Protocol Specialist III

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

Attached is an updated form for N057K. Edits are as follows:

CRF Title	Brief Description of Edit
CD Submission/Electronic Submission Form (All Patients) MRI or CT	Added time point for submission of this form during Event Monitoring

If you have any questions, please feel free to contact me.

Enclosure

FORMS PACKET

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

- Contents:
- Pre-registration eligibility checklist (3/4/2011)
 - Eligibility checklist (3/4/2011)
 - * Forms completion instructions
 - Preregistration screening failure form (11/13/2007)
 - 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)
 - Concurrent steroid and anticonvulsant treatment form (active monitoring phase) (3/3/2008)
 - Concurrent treatment form (baseline) (11/13/2007)
 - Concurrent treatment form (active monitoring phase) (11/13/2007)
 - Baseline tissue specimen submission form (10/15/2008)
 - Baseline optional blood specimen submission form (10/15/2008)
 - Recurrent tissue specimen submission form (7/28/2009)
 - (Phase I MCR and MCF only)** Cycle 1 active monitoring mandatory blood specimen submission form (10/15/2008)
 - (Phase II MCR only)** Patients at MTD and undergo FLT-PET active monitoring mandatory blood specimen submission form (10/15/2008)
 - Pretreatment measurement form (11/13/2007)
 - Active monitoring measurement form (11/13/2007)
 - Cycles 1 and 3 Evaluation/treatment form (11/13/2007)
 - Cycle 2 Evaluation form 4-6 week rest period (11/26/2007)
 - Cycles 4 through 8 Evaluation/treatment form (11/13/2007)
 - Cycles ≥ 9 Evaluation/treatment form (11/13/2007)
 - Nadir/adverse event form (7/21/2010)
 - End of active treatment/cancel notification form (11/13/2007)
 - Event monitoring form (10/26/2009)
 - Notification form – Grade 4 or 5 Non-AER Reportable events/hospitalization (3/27/2008)
 - ✓ CD submission / electronic submission form (all patients) (11/21/2011)
 - CD submission/electronic submission form (MCR & MCF only) (12/13/2010)
 - Cycle 1 weekly hematology laboratory form (12/17/2007)
 - Cycle ≥ 3 hematology laboratory form (12/17/2007)
 - Folstein mini mental state form (12/23/2008)
 - NCCTG research blood requisition form (3/11/2010)
 - NCCTG N057K reimbursement request form (9/9/2010)

✓ 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.

