OMB#0925-0624 Expiration Date: 12/31/2013

Public reporting burden for this collection of information is estimated to average 10 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0624). Do not return the completed form to this address.

### **Filling out PDF Forms**

This PDF form contains "roll-over or double-click" help functionality.

This form allows you to enter data directly onto the screen. After completing the form, you are able to print the document so that you can fax/mail the document.

To fill out a form:

- 1. Select the hand tool.
- 2. Position the pointer inside a field, and click to type text.
- 3. After entering text or selecting a check box, do one of the following:
  - Press tab to accept the form field change and go to the next form field.
  - Press Shift+Tab to accept the form field change and go to the previous form field.
  - Press Enter (Windows) or Return (Mac OS) to accept the form field change and deselect the current form field.
- 4. Once completed, print the form.

Attachment\_1I\_rtog0834

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## \*STY-RT0G-0834\*

#### RTOG-0834 CTSU DATA TRANSMITTAL FORM

#### For Post-Enrollment Data Submissions

- Use this form for post-enrollment data submissions; do not use this form to submit site registration/patient enrollment documents
- Record only one patient and protocol per transmittal form
- Ensure Patient ID and Protocol ID are recorded on each page of each item included
- Ensure pages are in proper sequence (2-sided forms must be copied by site before faxing)

<ul> <li>Do not fax more than 50 pages in one submission</li> <li>Changes to data initiated by the site must be reported on the Data Correction Form</li> </ul>				
Submit updated data with a new CTSU Data Transmittal Form and new date				
	<b># Pages Fax</b> uding Transn	Patient ID#:           mittal)         (EORTC Sequential IDENT. No.)		
Site Name:(Institution)		NCI CTEP Code:		
Site Address:	INST. No:			
Transmittal Completed By:		Phone #:		
Email address:				
The item(s) listed below should be <u>faxed</u> to CTSU at 1-301-545-0406. Call 1-888-823-5923 if experiencing difficulty faxing.  Do not mail forms to CTSU. Do not fax or mail forms to the EORTC Data Center				
Item(s) Attached	Number of pages	Visit		
☐ Query Form ( <b>Query</b> )				
☐ Data Correction Form ( <b>DCF</b> )				
☐ Local Pathology / Genetic Testing (Form 2)		☐ Before Randomization		
☐ On Study Form (Form 5)		☐ Before 1 <sup>st</sup> treatment administration ( <b>Send this with other baseline forms</b> )		
☐ Hematology Form (Form 6)		Baseline, All Arms:  Within 4 weeks before randomization		
		During Radiotherapy, Arms 2 & 4:  ☐ Week 1, 2, 3, 4, and 5 for TMZ administration		
		End of Radiotherapy, Arms 2 & 4:  Week 6		
		After the end of Radiotherapy, All Arms:  4 weeks after the end of Radiotherapy		
		Adjuvant TMZ, Arms 3 & 4:  Additional Assessments		
☐ Biochemistry Form (Form 7)		Baseline, All Arms:  Within 4 weeks before randomization		
		During Radiotherapy, Arms 2 & 4:  ☐ Week 4		
		End of Radiotherapy, Arms 2 & 4:  Week 6		
		After the end of Radiotherapy, All Arms:  4 weeks after the end of Radiotherapy		
		Adjuvant TMZ, Arms 3 & 4:  Additional Assessments		

**Contact Information:** Westat, CTSU Data Operations Center, 1-888-823-5923 Form Version: May 26, 2010

Attachment\_1I\_rtog0834

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Item(s) Attached	Number of pages	Visit
☐ Adverse Event Form (Form 8)		Baseline, All Arms:  Within 4 weeks before randomization
		During Radiotherapy, All Arms:  Week 1, 2, 3, 4 and 5
		End of Radiotherapy:  ☐ Week 6
		After the end of Radiotherapy, All Arms:  4 weeks after the end of Radiotherapy  AND thereafter for every 3 months until disease progression  At disease progression
		Adjuvant TMZ, Arms 3 & 4:  Additional Assessments
☐ EORTC QLQ-C30 ☐ EORTC QLQ-BN20		<ul> <li>Within 4 weeks before randomization</li> <li>4 Weeks after Radiotherapy</li> <li>Thereafter every 3 months until disease progression or death</li> <li>At disease progression</li> <li>Follow up</li> </ul>
<ul> <li>Neurocognitive Function Forms: *</li> <li>Hopkins Verbal Learning Test-Revised (Hopkins VL): Forms 1 - 6</li> <li>Trail Making Test Part A (TM Part A)</li> <li>Trail Making Test Part B (TM Part B)</li> <li>Controlled Oral Word Association (COWA): Forms 1 and 2</li> <li>TMT Data Summary Form</li> <li>Form CS</li> <li>Form QP</li> </ul>		* For patients participating in this component  Baseline Thereafter for yearly intervals until tumor progression or death
☐ Radiotherapy Form (Form 9)		☐ At the end of Radiotherapy
□ Patient Evaluation During RT Form (Form 10)		<ul><li>☐ Week 4 during Radiotherapy</li><li>☐ Week 6 during Radiotherapy</li></ul>
☐ Concomitant Temozolomide Form (Form 11)		☐ Arms 2 & 4 only: at the end of concomitant chemotherapy
Adjuvant Temozolomide Form (Form 12)		Arms 3 & 4 only: After each cycle of Adjuvant Chemotherapy Cycle:
☐ Disease Assessment Form (Form 13)		☐ 4 Weeks after end of Radiotherapy ☐ Thereafter every 3 months until disease progression ☐ At disease progression
☐ End of Treatment Form (Form 14)		<ul> <li>☐ End of Protocol Treatment (or in case patient is not randomized)</li> <li>Arms 3 &amp; 4 only</li> <li>☐ At disease progression</li> </ul>
☐ Follow Up Form ( <b>Form 15</b> )		☐ Due every 3 months after disease progression and until patient's death

For CTSU use only: Short Name shown in (brackets)

**Contact Information:** Westat, CTSU Data Operations Center, 1-888-823-5923 Form Version: May 26, 2010