OMB#0925-0753
Expiration Date: 07/31/2021



## 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.

OMB# 0925-0753
Expiration Date 07/31/2021

**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)
- Do not fax more than 50 pages in one submission
- **Changes to data initiated by the site must be reported on the Data Correction Form**
- Submit updated data with a new CTSU Data Transmittal Form and new date

**Date: __ __-__ __ -__ __ __ __** *(dd-mm-yyyy)*

**Total # Pages Faxed: _____** *(Including Transmittal)*

**Patient ID#: __ __ __ __** *(EORTC Sequential IDENT. No.)*

**Site Name: _____** *(Institution)*

**NCI CTEP Code: __ __ __ __ __** *(Internal ID)*

**Site Address: _____**

**INST. No: __ __ __ __**

**Transmittal Completed By: _____**

**Phone #: _____**

**Email address: _____**

**The item(s) listed below should be faxed 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 (**Query**) | | |
| ☐ Data Correction Form (**DCF**) | | |
| ☐ Local Pathology / Genetic Testing (**Form 2**) | | ☐ Before Randomization |
| ☐ On Study Form (**Form 5**) | | ☐ Before 1st treatment administration (***Send this with other baseline forms)*** |
| ☐ Hematology Form (**Form 6**) | | Baseline, All Arms:<br>☐ Within 4 weeks before randomization<br>During Radiotherapy, Arms 2 & 4:<br>☐ Week 1, 2, 3, 4, and 5 for TMZ administration<br>End of Radiotherapy, Arms 2 & 4:<br>☐ Week 6<br>After the end of Radiotherapy, All Arms:<br>☐ 4 weeks after the end of Radiotherapy<br>Adjuvant TMZ, Arms 3 & 4:<br>☐ Additional Assessments |
| ☐ Biochemistry Form (**Form 7**) | | Baseline, All Arms:<br>☐ Within 4 weeks before randomization<br>During Radiotherapy, Arms 2 & 4:<br>☐ Week 4<br>End of Radiotherapy, Arms 2 & 4:<br>☐ Week 6<br>After the end of Radiotherapy, All Arms:<br>☐ 4 weeks after the end of Radiotherapy<br>Adjuvant TMZ, Arms 3 & 4:<br>☐ Additional Assessments |

OMB# 0925-xxxx
Expiration Date xx/xx/xxxx

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

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