SF Radiation Therapy Oncology Group
Phase II Rectal IMRT / Chemotherapy
Post-op Treatment Summary Form

RTOG Study 0822 Case #

PLACE LABEL HERE

Institution Institution No.

Participant's Initials Participant's I.D. No.

AMENDED DATA ☐ YES

INSTRUCTIONS: Submit this form per section 12.0 of the Protocol.
Date fields are mm/dd/yyyy.

SUMMARY OF SYSTEMIC TREATMENT

1 **HEIGHT** ___ ___ ___ . ___ **(CM)**(1)

2 **WEIGHT** ___ ___ ___ . ___ **(KG)**(2)

3 **BSA** ___ . ___ ___ **(M2)**(3)

CYCLES

4 ___ **(CODE 1 ENTRY ONLY)**(4)
- 1 Cycles 1-3
- 2 Cycles 4-6
- 3 Cycles 7-9

5 **TOTAL NUMBER OF CYCLES ADMINISTERED DURING THIS REPORT PERIOD?**_____(5)

CHEMOTHERAPY		**OXALIPLATIN**	**5FU BOLUS**	**5FU INFUSION**	**LEUCOVORIN**
6	**START DATE**	___-___-___(6)	___-___-___(11)	___-___-___(16)	___-___-___(21)
7	**COMPLETION DATE**	___-___-___(7)	___-___-___(12)	___-___-___(17)	___-___-___(22)
8	**TOTAL DOSE**	_____**mg**(8)	_____**mg**(13)	_____**mg**(18)	_____**mg**(23)
9	**TREATMENT MODIFICATION (If yes, specify in comments)** 1 Yes, per protocol (Describe in comments) 2 Yes, not per protocol (Describe in comments) 3 No	(9)	(14)	(19)	(24)
10	**TREATMENT TERMINATION (Use codetable from below)**	(10)	(15)	(20)	(25)

REASON FOR TERMINATION
- 0 N/A Plan to countinue to next cycle
- 1 Post-op treatment completed per protocol criteria
- 2 Disease progression, relapse during active treatment
- 3 Adverse events/side effects/complications
- 4 Death on study
- 5 Patient withdrawal or refusal after beginning protocol therapy
- 6 Patient withdrawal or refusal prior to beginning protocol therapy
- 7 Alternative therapy, specify_____(26)
- 8 Other complicating disease, specify _____(27)
- 98 Other, specify _____(28)

TREATMENT RELATED COMMENTS_____

_____

_____

_____

_____

_____(29-30)

SF AMENDED DATA ☐ YES

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11 ☐ **ANY TREATMENT RELATED ADVERSE EVENTS?**(31)

1 No
2 Yes
9 Unknown

Adverse Events: Use the CTCAE version 3.0 (**MedDRA 9.0**) to code all events.
Score most severe grade observed during report period (grade 1-5).
Adverse Events of grade 3 or higher require start date.
Assign attribution to protocol treatment for each AE and indicate if an SAE was reported.
[*If SAE reported, AE grade, start date, and attributions must match on ADEERS report and CRF]
All "other" adverse events must be specified.

A. Attribution to Protocol Treatment
1 Unrelated
2 Unlikely
3 Possible
4 Probable
5 Definite

B. SAE Report Submitted
1 No
2 Yes
9 Unknown

Adverse Event Code	Adverse Event Shortname (specify if "other")	Grade	Start Date	A	B*
(301)	(302)	(303)	(304)	(305)	(306)
(307)	(308)	(309)	(310)	(311)	(312)
(313)	(314)	(315)	(316)	(317)	(318)
(319)	(320)	(321)	(322)	(323)	(324)
(325)	(326)	(327)	(328)	(329)	(330)
(331)	(332)	(333)	(334)	(335)	(336)
(337)	(338)	(339)	(340)	(341)	(342)
(343)	(344)	(345)	(346)	(347)	(348)
(349)	(350)	(351)	(352)	(353)	(354)
(355)	(356)	(357)	(358)	(359)	(360)
(361)	(362)	(363)	(364)	(365)	(366)
(367)	(368)	(369)	(370)	(371)	(372)
(373)	(374)	(375)	(376)	(377)	(378)
(379)	(380)	(381)	(382)	(383)	(384)
(385)	(386)	(387)	(388)	(389)	(390)
(391)	(392)	(393)	(394)	(395)	(396)
(397)	(398)	(399)	(400)	(401)	(402)
(403)	(404)	(405)	(406)	(407)	(408)
(409)	(410)	(411)	(412)	(413)	(414)

SF

AMENDED DATA ☐ YES

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12 INSTRUCTIONS: Record **normal ranges**.
Record laboratory values.
See protocol Appendix II for lab Timepoints.
Grade lab abnormalities on page 2.

	Normal Range	Pre-Rx						
Date (mm/dd) Year:	/	/	/	/	/	/	/	/
Treatment Week								
Hgb (gms/dl)								
Hct (%)								
WBC (x1000) mm^3								
Platelets (x1000) mm^3								
Neutrophils/gran (%)								
ANC mm^3								
Sodium (mEq/L)								
Potassium (mEq/L)								
Chloride (mEq/L)								
BUN (mg/dl)								
Creatinine (mg/dl)								
Calc. Creatinine Clearance								
Bilirubin (total) (mg/dl)								
Alk PO4 (ImU/ml)								
LDH (U/L)								
SGOT (IU/L)								
SGPT (IU/L)								
Total Protein (g/dl)								
Albumin (g/dl)								
Uric Acid (mg/dl)								
Calcium (mg/dl)								
Glucose (mg/dl)								
Mg (mEq/L)								
U/A								
Other specify _____								
Other specify _____								
Other specify _____								
Other specify _____								
Other specify _____								

Comments_____

_____

_____(1273-1274)

The reported case report **form** information has been reviewed and confirmed by the principal Investigator.

Person completing form_____(1275) **Form completion date, original** ____-____-_____(1276)