I1 Radiation Therapy Oncology Group Phase III Sandostatin Initial Evaluation Form

RTOG Study 0315 Case #

PLACE LABEL HERE

Institution Institution No.

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

If this is a revised or corrected form, indicate by checking box. ☐

INSTRUCTIONS: Submit this form at time of patient's entry on study. Use -1 for unknown or not applicable unless otherwise specified in the codetable.

1 **DATE OF BIRTH** _____-_____-_____

2 ☐ **ZUBROD PERFORMANCE SCORE**

3 ☐ **GENDER**
1 Male
2 Female

4 ☐ **PRIMARY SITE**
1 Anal
2 Rectal

5 ☐ **IS THERE EVIDENCE OF METASTASIS BEYOND PELVIC REGIONAL NODES?**
1 No
2 Yes

6 ☐ **PAST MEDICAL HISTORY / INTERCURRENT DISEASE**
1 No (skip to Q7)
2 Yes (complete all)

☐ **HEPATIC (LFT'S >3X ULN)**

☐ **UNCONTROLLED DIABETES**

(FBS >250 MG/DL)

☐ **ENTERITIS**

☐ **INFLAMMATORY BOWEL DISEASE**

☐ **MALABSORPTION SYNDROME**

☐ **HIV**

☐ **CHOLECYSTITIS OR GALLSTONES**

If yes, did the patient have a

☐ **CHOLECYSTECTOMY**

☐ **PRIOR MALIGNANCY**

If yes, specify site_____

☐ **DOES PATIENT HAVE A COLOSTOMY?**

7 ☐ **DISEASE RELATED SIGNS/SYMPTOMS AT STUDY ENTRY**
1 No (skip to Q8)
2 Yes (complete all)

☐ **DIARRHEA** (If yes provide grade using CTCAE Version 3.0)

Grade_____

☐ **INCONTINENT OF STOOL**

8 ☐ **PRIOR TREATMENT**
1 No (skip to Q9)
2 Yes (complete all)

☐ **PELVIC RADIATION**

☐ **RADIATION FOR ABDOMINAL CANCER**

☐ **ANY INVESTIGATIONAL DRUG WITHIN 30 DAYS OF STUDY RANDOMIZATION**

☐ **GLUCOCORTICOID THERAPY, INSULIN SENSITIZERS, OR EXOGENOUS GROWTH HORMONE THERAPY WITHIN 6 MONTHS OF STUDY RANDOMIZATION**

☐ **SANDOSTATIN, FOR CANCER-THERAPY RELATED DIARRHEA**

9 ☐ **WILL PATIENT BE RECEIVING CHEMOTHERAPY AS SPECIFIED IN SECTION 7.2?**
1 No
2 Yes

10 ☐ **WILL PATIENT BE RECEIVING RADIATION THERAPY AS SPECIFIED IN SECTION 6.1?**
1 No
2 Yes

I1

REVISION ☐

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11 PRE TREATMENT EVALUATION

0 Not done
1 Normal, specify value
2 Abnormal, elevated specify value and lab range
3 Abnormal, < normal specify value and lab range

☐ WBC ☐☐☐.☐

☐ HGB ☐☐☐.☐

☐ PLATELETS ☐☐☐☐

☐ SGOT ☐☐☐.☐

☐ SGPT ☐☐☐.☐

☐ LDH ☐☐☐☐.☐

☐ T. BILI ☐☐.☐

☐ NA ☐☐☐☐.☐

☐ K ☐☐☐.☐

☐ CHLORIDE ☐☐☐☐.☐

☐ BUN ☐☐☐.☐

☐ CREATININE ☐☐☐.☐

☐ GLUCOSE ☐☐☐☐.☐

12 ☐ **DID THE PATIENT RECEIVE SANDOSTATIN TEST DOSE AS SPECIFIED IN SECTION 7.1.2?**

1 No
2 Yes

13 ☐ **DID THE PATIENT EXHIBIT SIGNS/ SYMPTOMS OF INTOLERANCE AS SPECIFIED IN SECTION 7.1.2?**

1 No
2 Yes, specify_____

14 ☐ **PRIMARY TUMOR**

0 T0
1 T1
2 T2
3 T3
4 T4
5 TIS
9 TX

15 ☐ **NODAL STATUS**

0 N0
1 N1
2 N2
3 N3
4 NX

16 ☐ **DISTANT METASTASIS**

0 M0
1 M1
2 MX

COMMENTS:_____

_____

_____

Signature of person completing this form_____ **Date** _____-_____-_____