I1

Radiation Therapy Oncology Group
Phase III Prostate
Initial Evaluation Form

RTOG Study **9601** Case #

Intergroup Study R9601 Case #

Intergroup Name SWOG

Institution	Institution No.
Patient's Name	Patient's I.D. No.

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.

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

1 ☐☐ **PATIENT'S AGE**

2 GENERAL HEALTH HISTORY

A ☐☐☐ KARNOFSKY PERFORMANCE STATUS AT ENTRY TO STUDY

B ☐☐☐.☐ WEIGHT *(kg = lb/2.2)*

C HAS PATIENT HAD ANOTHER MALIGNANCY (other than study site)

☐
1 No
2 Yes (complete all items in Q3)
9 Unknown

_____
SITE

___/_____ DATE ERADICATED *(mm/yyyy)* If not NED from second malignancy, leave date blank.

D ☐ INTERCURRENT DISEASE
1 No, skip to 3
2 Yes, complete all
9 Unknown

☐ CARDIOVASCULAR

☐ DIABETES

☐ HYPERTENSION

☐ OTHER, Specify_____

3 PRIOR TREATMENT FOR CANCER (prior to entry on study) (If No, skip to Q4.)

☐
1 No
2 Yes (complete section)
9 Unknown

☐ PRIOR SURGERY FOR PROSTATE CANCER (excluding diagnostic biopsy and lymph node sampling)

___/___/_____ DATE OF SURGERY
mm/dd/yyyy

_____
SPECIFY TYPE OF SURGERY

☐ PRIOR RADIOTHERAPY

___/___/_____ DATE COMPLETED
mm/dd/yyyy

_____
DETAILS

☐ PRIOR HORMONES (non-protocol only)

___/___/___ DATE OF LAST TREATMENT
mm/dd/yyyy

_____
TYPE / REASON

☐ ORCHIECTOMY

___/___/_____DATE, IF DONE
mm/dd/yyyy

4 ☐ **PRIOR CHEMOTHERAPY(FOR ANY REASON)**
1=No, 2=Yes

___/___/_____DATE OF LAST TREATMENT
mm/dd/yyyy

_____
SPECIFY AGENTS USED

5 HAS PATIENT STARTED PROTOCOL HORMONES?

☐
1 No (skip to Q6)
2 Yes (complete A & B)

	A: DOSE TO DATE	B: START DATE
ZOLADEX	_____	___/___/___
LUPRON	_____	___/___/___
FLUTAMIDE	_____	___/___/___
CASODEX	_____	___/___/___

6 URINARY INCONTINENCE

A HAS THE PATIENT EXPERIENCED URINARY INCONTINENCE (LEAKING, DRIBBLING, ETC.) WITHIN THE 3 MONTHS PRIOR TO STUDY ENTRY?

☐
1 No(Skip to 7)
2 Yes (if yes, complete B)
9 Unknown

B IF YES, DOES INCONTINENCE INTERFERE WITH DAILY ACTIVITIES

☐
1 No
2 Yes
9 Unknown

7 SEXUAL CAPABILITY

0 Not sexually active
1 No (impotent)
2 Yes, assisted (implants, drugs, etc.)
3 Yes, unassisted
9 Unknown

ERECTION	EJACULATION	
☐	☐	AT STUDY ENTRY
☐	☐	WITHIN PAST YEAR

8 HISTOPATHOLOGIC INFORMATION

A ___/___/_____ DATE MALIGNANCY CONFIRMED
mm/dd/yyyy

B METHOD OF CONFIRMATION

☐
1 Needle biopsy
2 T.U.R.
3 Prostatectomy
4 Other, specify_____
9 Unknown

C HISTOLOGIC TYPE

☐
1 Adenocarcinoma
2 Other, specify_____
9 Unknown

D ☐ DIFFERENTIATION (Grade 1 to 4, 9=unknown)

E ☐ PRIMARY GLEASON PATTERN OF MALIGNANCY (Gleason classification 1-5, 9=unknown)

F ☐ SECONDARY GLEASON PATTERN OF MALIGNANCY (Gleason classification 1-5, 9=unknown)

G ☐☐ COMBINED GLEASON SCORE (Unknown=99)

H ☐ WAS A LYMPH NODE SAMPLING DONE

1 No (Skip to Q 9)
2 Yes (Complete I & J)
9 Unknown

I METHOD OF LYMPH NODE SAMPLING

☐
0 Not applicable
1 Laparotomy (pelvic lymphadenectomy)
2 Laparoscopy
3 Percutaneous biopsy
4 Other, specify_____

J ___/___/_____ DATE PELVIC NODE SAMPLING
mm/dd/yyyy

9 LABORATORY VALUES AT TIME OF ENTRY (See protocol for requirements)

1 Not done
2 Normal (specify value)
3 Abnormal, elevated (specify value and lab range *)
4 Abnormal, < normal (specify value and lab range *)
9 Unknown

PROSTATIC SPECIFIC ANTIGEN (PSA) (See protocol for requirements) Report pre-surgical, post-surgical, study entry, and (if applicable) pre-hormone PSA VALUE.

DATE mm/dd/yyyy	PSA VALUE	METHOD OF ASSAY	UNITS	TIME POINTS

METHOD OF ASSAY
1 Hybritech
2 Yang
3 Abbott
4 Other
9 Unknown

TIME POINTS
1 Pre-surgical
2 Post-surgical
3 Pre-hormones
4 Study entry

UNITS
1 n/mg
2 ng/ml
3 ngm
4 u/l
5 mg/l
6 ng/dl
7 mcg/l
8 ug/l

9 LABORATORY VALUES AT TIME OF ENTRY (See protocol for requirements) ***Continued***

1 Not done
2 Normal (specify value)
3 Abnormal, elevated (specify value and lab range *)
4 Abnormal, < normal (specify value and lab range *)
9 Unknown

☐ ALKALINE PHOSPHATASE

☐☐☐.☐ ☐ SPECIFY
1 u/ml
2 u/l

*_____

☐ SERUM TESTOSTERONE

☐☐☐.☐ ☐ SPECIFY
1 ng/dl
2 ng/ml
3 nmol/l
4 units/NOS

*_____

☐ HEMOGLOBIN ☐☐.☐ (G%)

*_____

☐ WBC ☐☐.☐ (mm^3/1000)

*_____

☐ PLATELETS ☐☐☐☐ (mm^3/1000)

*_____

☐ LIVER FUNCTION LABS (SGOT, SGPT, Bilirubin)

*_____

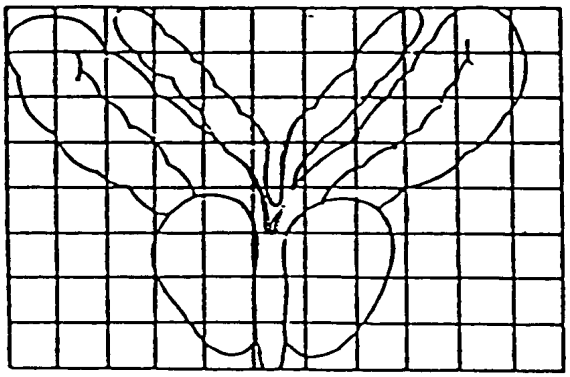
☐ CHEMISTRY (Serum creatinine)

*_____

10 DISEASE EVALUATION (Based on physical exam at study entry (Post prostatectomy))

A ☐ PALPABLE TUMOR *(Please indicate on diagram)*

1 No
2 Yes, one lobe
3 Yes, both lobes
4 Yes, NOS
9 Unknown



B ☐☐.☐ LARGEST DIMENSION *(cm)*

C ☐☐.☐ PERPENDICULAR DIMENSION *(cm)*

D ☐ DIMENSIONS REPORTED ARE:

0 N/A
1 Tumor dimensions
2 Prostate dimensions *(Only if gland diffusely involved with tumor)*
9 Unknown

11 ☐ **TUMOR BEYOND CAPSULE AS DETERMINED BY CLINICAL EXAMINATION**

1 No
2 Yes
9 Unknown

TUMOR BEYOND CAPSULE

SITE	ASSESS-MENT	METHODS OF ASSESSMENT	
		METHOD 1	METHOD 2
12 LOCAL EXTENSION (Based on prostatectomy / lymphadenectomy information where applicable)			
SEMINAL VESICLES			
PERIPROSTATIC SOFT TISSUE			
B LADDER			
OTHER EXTENSION Specify _____			
13 OTHER SITES (Based on prostatectomy / lymphadenectomy information & post-prostatectomy abdominal/pelvic CT)			
A PELVIC NODES			
EXTERNAL ILIAC			
HYPOGASTRIC / OBTURATOR			
SACRAL			
OTHER PELVIC NODES, Specify _____			
B OTHER NODES			
COMMON ILIAC NODES			
PARA-AORTIC NODES			
14 DISTANT METASTASES			
BONE			
LUNG			
OTHER, specify _____			

ASSESSMENT
1 Normal
2 Positive
3 Equivocal
4 Not evaluated
9 Unknown

METHOD OF ASSESSMENT
0 Not applicable
1 Physical examination
2 Pathologic
3 CT Scan
4 MRI
5 Ultrasound
6 Nuclear scan
7 Cytoscopy or proctoscopy
8 CXR
9 Unknown
10 Other, specify_____

15 TNM *(See protocol)*

A ☐☐ CODED CLINICAL T CLASSIFICATION
(Prior to prostatectomy)
Use Code table from 15B

B ☐☐ CODED PATHOLOGIC T CLASSIFICATION
0 T0
1 T1, NOS
2 T1a
3 T1b
4 T1c
5 T2, NOS
6 T2a
7 T2b
~~8 T2c~~
10 T3, NOS
11 T3a
12 T3b
~~13 T3c~~
14 T4, NOS
~~15 T4a~~
~~16 T4b~~
9 TX

C ☐ RADIOGRAPHIC N CLASSIFICATION
(Post-prostatectomy CT information)
Use Code table from 15D

D ☐ PATHOLOGIC N CLASSIFICATION
(Prostatectomy/lymphadenectomy information)
0 N0
1 N1
2 N2
3 N3
9 NX

E ☐ METASTASES
0 M0
1 M1
2 M1a
3 M1b
4 M1c
9 MX

16 **STUDY SPECIFIC PATHOLOGY/SURGERY INFORMATION**

A ☐ IF PATIENT HAD A RADICAL PERINEAL PROSTATECTOMY, WHAT WAS THE TYPE OF NERVE CONSERVATION?
0 N/A
1 None
2 Bilateral
3 Right side only
4 Left side only
5 Unilateral, side unknown
9 Unknown

B ☐ WERE INKED MARGINS POSITIVE?
1 No (skip to D)
2 Yes (complete C)
9 Unknown

C ☐ SITE OF POSITIVE INKED MARGINS

0 None
1 Prostatic apex
2 Distal prostatic urethra
3 Bladder neck
4 Anterior
5 Posterior
6 Right lateral
7 Left lateral
8 Multiple locations, specify_____

D ☐ WAS THERE TUMOR PRESENT WITHIN 2mm OF INKED MARGIN?

1 No
2 Yes

E ☐☐ # OF LYMPH NODES DISSECTED

F ☐ WERE ANY OF THE DISSECTED NODES POSITIVE?

1 No
2 Yes (Specify number *)

* ☐☐

COMMENTS_____

_____

_____

_____ _____

Signature **Date**