

Case #:

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Form I 1

Staging - Labs/Imaging

1. Last pre-treatment Prostate-Specific Antigen (PSA) level _____ ng/ml (999. = unknown)

2. Computed Tomography (CT) scan _____
1 = No
2 = Yes
9 = Unknown

3. Magnetic Resonance Imaging (MRI) _____
1 = No
2 = Yes
9 = Unknown

4. Bone scan _____
1 = No
2 = Yes
9 = Unknown

5. ProstaScint scan _____
1 = No
2 = Yes
9 = Unknown

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Pathology

6. Method of diagnosis _____
1 = Ultrasound (US) - guided needle biopsy
2 = Transurethral Resection of the prostate (TURP)
8 = Other
9 = Unknown

Prostate Biopsy:

7. Total # of cores taken: _____ (88 = not reported; 99 = unknown)
8. Total # of positive cores: _____ (88 = not reported; 99 = unknown)
9. Maximum percent of cancer tissue in the core with the highest Gleason score _____ %
(888 = not reported; 999 = unknown)

Gleason Score:

10. Gleason Grade (GG) - primary _____ (8 = not reported; 9 = unknown)
11. Gleason Grade (GG) - secondary _____ (8 = not reported; 9 = unknown)
12. Gleason Score (GS) _____ (88 = not reported; 99 = unknown)
(Combined primary and secondary grade)

If no Gleason Score:

13. Histological differentiation _____
1 = Well-differentiated (Grade 1)
2 = Moderately well-differentiated (Grade 2)
3 = Poorly-to-very poorly differentiated (Grades 3-4)
9 = Unknown

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Stage/Extent of Disease

14. Digital Rectal Exam (DRE) done by radiation oncologist _____
 1 = No
 2 = Yes
 9 = Unknown
15. T-Classification _____
 1 = TX = Primary tumor cannot be assessed
 2 = T0 = No evidence of primary tumor
 3 = T1 = Clinically in-apparent tumor neither palpable nor visible by imaging
 4 = T1a = Tumor incidental - histological finding in 5% or less of tissue resected
 5 = T1b = Tumor incidental - histological finding in more than 5% or less of tissue resected
 6 = T1c = Tumor identified by needle biopsy (e.g. because of elevated PSA)
 7 = T2 = Tumor confined within prostate
 8 = T2a = Tumor involves one- half of one lobe or less
 9 = T2b = Tumor involves more than one-half of one lobe but not both lobes
 10 = T2c = Tumor involved both lobes
 11 = T3 = Tumor extends through prostate capsule
 12 = T3a = Extra-capsular extension (unilateral or bilateral)
 13 = T3b = Tumor invades seminal vesicle(s)
 14 = T4 = Tumor is fixed or invades other adjacent structures other than seminal vesicles:
 (e.g. Bladder neck, external sphincter, rectum, levator muscles and/or pelvic walls)
 99 = Unknown
16. Was nodal biopsy done? _____
 1 = No
 2 = Yes, Fine-needle aspiration (FNA)
 3 = Yes, lymph node dissection
 4 = Yes, both FNA & lymph node dissection
 9 = Unknown
17. Number positive nodes _____ (99 = unknown)
18. N Classification _____
 0 = NX = Regional lymph nodes were not assessed
 1 = N0 = No regional lymph node metastasis
 2 = N1 = Metastasis in regional lymph node(s)
 9 = Unknown

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Treatment Summary

19. Investigational protocol _____

1 = No

2 = Yes, National Cancer Institute (NCI) Clinical Trials Cooperative Group (*specify below*)

3 = Yes, Institutional Review Board (IRB)-approved institutional clinical trial

4 = Yes, IRB-approved Pharmaceutical Research and Manufacturers of America (PHARMA) clinical trial

5 = Yes, IRB-approved device clinical trial

8 = Other

9 = Unknown

If question #19 is Yes, NCI Clinical Trials Cooperative Group, (code 2):

20. Protocol group & number are (*e.g., Radiation Therapy Oncology Group [RTOG] 9709*)
_____ (*9999 = Unknown*)

Treatment:

23. Orchiectomy _____

1 = No

2 = Yes

9 = Unknown

24. History of Transurethral resection (TURP) of the prostate _____

1 = No

2 = Yes

9 = Unknown

25. Endocrine manipulation _____

1 = No

2 = Yes

9 = Unknown

If yes,

26. Diethylstilbestrol (DES) _____

1 = No

2 = Yes

9 = Unknown

27. Luteinizing hormone-releasing hormone (LHRH) agonist _____

1 = No

2 = Yes

9 = Unknown

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28. Androgen blocker _____

- 1 = No
- 2 = Yes, short term (< 6 months)
- 3 = Yes, long term (> = to 6 months)
- 9 = Unknown

30. Other hormonal manipulation _____

- 1 = No
- 2 = Yes
- 9 = Unknown

31. Planned duration of hormonal therapy (months): _____

(Longest duration of any endocrine therapy)

(777. = On-going; 778. = Short-term; 888. = Duration cannot be determined; 999. = Unknown)

32. Chemotherapy _____

- 1 = No
- 2 = Yes
- 9 = Unknown

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External Beam RT

34. Any external beam Radiation Therapy (RT)? _____
1 = No
2 = Yes, at other facility
3 = Yes, at this facility
4 = Yes, at both other and this facility
9 = Unknown
35. If yes, at other facility (code 2 or 4), name of facility _____
36. Other facility's data available _____
1 = No
2 = Yes
9 = Unknown
37. CT used in external beam treatment planning _____
1 = No
2 = Yes
9 = Unknown
38. MRI used in external beam treatment planning _____
1 = No
2 = Yes
9 = Unknown
39. Equipment _____
1 = Linear accelerator
2 = TomoTherapy
3 = Proton
4 = Cyberknife
8 = Other
9 = Unknown
40. Energy _____ megavolts (MV) (*record maximum energy*)
(99=unknown)

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41. Was Intensity-Modulated Radiation Therapy (IMRT) used? _____

- 1 = No
- 2 = Yes
- 9 = Unknown

42. Was some form of immobilization used? _____

- 1 = No
- 2 = Yes, external
- 3 = Yes, internal
- 4 = Yes, external and internal
- 9 = Unknown

43. Daily target localization _____

- 1 = Fiducial markers with imaging
- 2 = Electronic portal imaging (for bony anatomy landmarks)
- 3 = Film portal imaging (for bony anatomy landmarks)
- 4 = Calypso
- 5 = CT imaging
- 6 = TomoTherapy
- 7 = Transabdominal Ultrasound
- 8 = None of the above
- 9 = Unknown

44. Dose volume histogram (DVH) information recorded for target and normal tissue structures? _____

- 1 = No
- 2 = Yes
- 9 = Unknown

If yes, for which structure was a DVH generated and found in chart?

45. Prostate _____

- 1 = No
- 2 = Yes

46. Rectum _____

- 1 = No
- 2 = Yes

47. Bladder _____

- 1 = No
- 2 = Yes

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External Beam RT Details

Technique 0 = Not applicable 1 = 2-dimensional (2D) 2 = 3-dimensional (3D) 3 = IMRT 8 = Other 9 = Unknown				
Region	Technique	Dose/Fx centi-Gray (cGy) (999=unknown)	# of Fractions (99= unknown)	Total Dose (cGy) (9999= unknown)
Prostate & seminal vesicles & nodes	_____ 48	_____ 49	_____ 50	_____ 51
Prostate & nodes	_____ 52	_____ 53	_____ 54	_____ 55
Prostate & seminal vesicles	_____ 56	_____ 57	_____ 58	_____ 59
Prostate alone	_____ 60	_____ 61	_____ 62	_____ 63
Nodes alone	_____ 64	_____ 65	_____ 66	_____ 67
Other/ Unknown If Other, specify _____ 68	_____ 69	_____ 70	_____ 71	_____ 72

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Brachytherapy

73. Brachytherapy (Interstitial implant) _____

- 1 = No
- 2 = Yes
- 9 = Unknown

If yes,

74. Where was Brachytherapy done? _____

- 2 = At other facility
- 3 = At this facility
- 4 = At both other and this facility
- 9 = Unknown

75. If other facility, (code 2), name of other facility _____

76. Other facility's data available _____

- 1 = No
- 2 = Yes
- 9 = Unknown

77. Prostate volume at time of implant: _____ cubic centimeters (cc) (999. = *unknown*)

78. Imaging used for brachytherapy treatment planning _____

- 1 = No
- 2 = Yes
- 9 = Unknown

79. If yes: _____

- 1 = Transrectal ultrasound (TRUS)
- 2 = CT
- 3 = MRI
- 8 = Other
- 9 = Unknown

80. Imaging used for implant procedure _____

- 1 = No
- 2 = Yes
- 9 = Unknown

81. If yes: _____

- 1 = TRUS
- 2 = Fluoroscopy
- 3 = Both, TRUS and Fluoroscopy
- 4 = CT (Computerized tomography)
- 5 = MRI
- 8 = Other
- 9 = Unknown

82. If other, specify _____

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Brachytherapy Operating Room (OR)

83. Location of procedure room _____
1 = Operating room inside hospital
2 = Freestanding surgical center
8 = Other
9 = Unknown
84. *If other, specify* _____
88. Method of anesthesia _____
1 = General anesthesia
2 = Spinal anesthesia
3 = Local anesthesia
8 = Other
9 = Unknown
89. *If other, specify* _____
90. Cystoscopy performed intraoperatively _____
1 = No
2 = Yes
9 = Unknown
91. Post-implant care _____
1 = Planned outpatient with immediate discharge
2 = Inpatient hospitalization (<24 hours)
3 = Inpatient hospitalization (>=24 hours)
8 = Other
9 = Unknown
92. *If other, specify* _____
93. Foley catheter required >24 hours after brachytherapy procedure _____
1 = No
2 = Yes
9 = Unknown

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Form I 1

Brachytherapy - LDR

94. Low Dose Rate (LDR) _____

- 1 = No
- 2 = Yes
- 9 = Unknown

If No or Unknown, skip to Q107

95. Isotope utilized _____

- 1 = Iodine-125
- 2 = Palladium-103
- 3 = Gold-198
- 4 = Cs-131
- 8 = Other
- 9 = Unknown

96. *If other, specify* _____

97. LDR planning technique _____

- 1 = Preoperative planning onsite
- 2 = Intraoperative planning
- 8 = Other
- 9 = Unknown

98. *If other, specify* _____

99. Source loading _____

- 1 = Loose seeds, preloaded needles
- 2 = Seeds embedded in suture material, preloaded needles
- 3 = Mick applicator
- 4 = Loose seeds and seeds embedded in suture material
- 8 = Other
- 9 = Unknown

100. *If other, specify* _____

101. Number of sources placed _____ (999 = unknown)

102. Activity/source (mCi/source) _____ (9. = unknown)

103. Total activity placed (mCi) _____ (999. = unknown)

104. Sources assayed on site _____

- 1 = No
- 2 = Yes
- 9 = Unknown

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Form I 1

105. Brachytherapy prescription dose to the prostate
(entire gland or periphery): _____ (cGy) (99999 = *unknown*)

106. Post-implant dosimetry _____

1 = None

2 = Orthogonal radiographs

3 = CT

4 = MRI

5 = Ultrasound

8 = Other

9 = Unknown

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Brachytherapy - HDR

107. High Dose Rate (HDR): _____

- 1. No
- 2. Yes
- 9. Unknown

If No or Unknown, skip to next section (Q151)

If yes to HDR:

Application Number*	Isotope Utilized 1 = Ir192 8 = Other 9 = Unknown	# of Fractions (99=unknown)	Dose/Fraction (cGy) (9999= unknown)	Minimum Interval Between Fractions 1 = 0 - <4 hrs 2 = 4 - 6 hrs 3 = > 6 hrs 9 = Unknown	Total Prescription Dose w/ HDR (cGy) (9999= unknown)
1	_____ 108 <i>If other, specify:</i> _____ 109	_____ 110	_____ 111	_____ 112	_____ 113
2	_____ 114 <i>If other, specify:</i> _____ 115	_____ 116	_____ 117	_____ 118	_____ 119
3	_____ 120 <i>If other, specify:</i> _____ 121	_____ 122	_____ 123	_____ 124	_____ 125

* (Needle inserted is one application. Applications separated by 2 weeks)

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GENERAL COMMENTS

Use multiple lines, as needed.

Note: DO NOT include any Personal Health Information (PHI) in these comments.

151. _____

152. _____

153. _____

154. _____

155. _____

156. _____

157. _____

158. _____

159. _____

160. _____

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Form I 1

Adult Comorbidity Evaluation

200. Comorbidities _____

1 = No comorbidities 2 = Yes, one or more 9 = Cannot be determined

Comorbidity	Grade: 0 = None 1 = Grade 1 (mild) 2 = Grade 2 (mod) 3 = Grade 3 (severe) 4 = Present, grade unknown 9 = Unknown
Cardiovascular system comorbidity score (Including myocardial infarction [MI], angina / coronary artery disease [CAD], congestive heart failure [CHF], arrhythmias, hypertension [HTN], venous and peripheral arterial disease)	201. _____
Respiratory system comorbidity score (Including pulmonary insufficiency, and restrictive lung disease or chronic obstructive pulmonary disease [COPD])	202. _____
Gastrointestinal system comorbidity score (Including hepatic disease, stomach/intestine, and pancreatic disease)	203. _____
Renal system comorbidity score (End stage renal disease)	204. _____
Endocrine system comorbidity score (Including Insulin dependent diabetes mellitus, and adult onset diabetes mellitus)	205. _____
Neurological system comorbidity score (Including stroke, dementia, paralysis, and neuromuscular disorders)	206. _____
Psychiatric comorbidity score (Including major depression, bipolar disorder, and schizophrenia)	207. _____
Rheumatologic comorbidity score (Including rheumatoid arthritis, systemic lupus, connective tissue disorder, and polymyositis)	208. _____
Immunological system comorbidity score (human immunodeficiency virus [HIV], and acquired immunodeficiency syndrome [AIDS])	209. _____
Malignancy comorbidity score (Solid tumors including melanoma, leukemia, myeloma, and lymphoma)	210. _____
Substance Abuse comorbidity score (Including alcohol abuse, illicit drug abuse)	211. _____
Body weight comorbidity score (Obesity, body mass index [BMI] >= 38)	212. _____

213. Was treatment contra-indicated or changed due to comorbidities?

No Yes Unknown

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Form I 1

Sequence of Events (SOE)

All dates will be blanked out before data are transmitted to the database. Only Elapsed days and Duration will be retained.

Events	mm/dd/yyyy	Elapsed days*	Duration (days)
<u>Staging- Labs/Imaging:</u>			
Last pre-treatment PSA performed:	222. ___ / ___ / ___	223. _____	
<u>Pathology:</u>			
Original diagnosis:	224. ___ / ___ / ___	225. _____	
<u>Treatment Summary:</u>			
Start of first Systemic** therapy:	226. ___ / ___ / ___	227. _____	
Start of External Beam therapy:	228. ___ / ___ / ___	229. _____	
Completion of External Beam therapy:	230. ___ / ___ / ___	231. _____	232. _____ (231-229)
<u>Brachytherapy – LDR:</u>			
Placement of sources:	238. ___ / ___ / ___	239. _____	
Post-implant dosimetry:	240. ___ / ___ / ___	241. _____	
<u>Brachytherapy – HDR:</u>			
First HDR fraction:	242. ___ / ___ / ___	243. _____	
Last HDR fraction:	244. ___ / ___ / ___	245. _____	246. _____ (245-243)

* Elapsed time (in days) for an event is the date of that event minus the reference date.

** The earlier of hormonal therapy or chemotherapy.

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SOE COMMENTS:

Use multiple lines, as needed.

Note: DO NOT include any Personal Health Information (PHI) in these comments.

250. _____

251. _____

252. _____

253. _____

254. _____

255. _____

256. _____

257. _____

258. _____

259. _____