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TITLE: SUPPORT OF THE CENTER FOR PROSTATE DISEASE RESEARCH AT
WALTER REED ARMY INSTITUTE OF RESEARCH

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13. ABSTRACT (Maximum 200 words) The Center For Prostate Disease Research (CPDR), a cooperative clinical and basic science research initiative focusing on prostate cancer and disease, began operations 14 September 1992 and this report summarizes the second year of operation. The CPDR is a research collaboration between the Uniformed Services University of the Health Sciences (USUHS), Walter Reed Army Medical Center (WRAMC) Urology Program, and the Armed Forces Institute of Pathology (AFIP) Genito-urinary Pathology Department. Regarding clinical research, a comprehensive prostate cancer patient database has been established with prospective data gathering on all patients from WRAMC. A retrospective database of all patients treated at WRAMC since 1980 is also underway. A serum and tissue bank for all prostate cancer patients at WRAMC has also been established. Regarding basic research, a fully equipped molecular biology laboratory has been established at USUHS for the exclusive study of the molecular genetics and cellular markers in prostate cancer and disease. The full collaborative cooperation between clinicians, clinical researchers, and basic scientists within CPDR has already been productive. The group has reported a commonly mutated region in the Androgen Receptor (AR) gene in advanced prostate cancer. Work is ongoing to determine the clinical significance of this genetic alteration. The CPDR group is excited and enthusiastic to continue with the clinical and basic research study of prostate cancer and disease within the DoD health care system and university.			
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FOREWORD

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JWM For the protection of human subjects, the investigator(s) adhered to policies of applicable Federal Law 45 CFR 46.

JM In conducting research utilizing recombinant DNA technology, the investigator(s) adhered to current guidelines promulgated by the National Institutes of Health.

JWM In the conduct of research utilizing recombinant DNA, the investigator(s) adhered to the NIH Guidelines for Research Involving Recombinant DNA Molecules.

 In the conduct of research involving hazardous organisms, the investigator(s) adhered to the CDC-NIH Guide for Biosafety in Microbiological and Biomedical Laboratories.

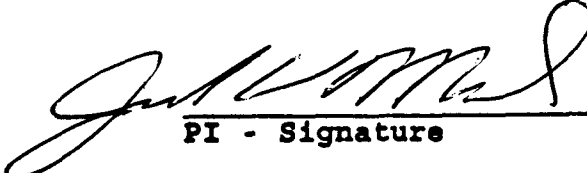
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PROGRESS REPORT

PRINCIPAL INVESTIGATOR: JUDD W. MOUL, MD, LTC, MC, USA

DEPARTMENT OF: SURGERY, UROLOGY

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INTRODUCTION/SUMMARY STATEMENT

This progress report covers the second year of existence of the Center for Prostate Disease Research (CPDR), a collaborative research program of the Uniformed Services University of the Health Sciences (USUHS), the Walter Reed Army Medical Center (WRAMC) the and Institute of Research (WRAIR), and the Armed Forces Institute of Pathology (AFIP). The Center is involved in the study of the molecular biology of prostate disease through laboratory activities at USUHS and the clinical study of prostate patients and pathology of the prostate at WRAMC and AFIP. The main goal of CPDR is to integrate both basic and clinical study of prostate cancer to bring basic science advances to the clinical benefit of prostate cancer patients.

The CPDR laboratory is housed in rooms A-3009 & A-3018 and contains approximately 1,500 sq. ft. of space within the Department of Surgery at USUHS and is a fully-equipped molecular biology laboratory. Five full-time researchers and several part-time research students are utilizing this facility. The CPDR laboratory is also being utilized for training of Urology residents from Walter Reed in the field of molecular biology of prostate cancer. There is formal

invitation for the National Naval Medical Center, Bethesda, MD, to participate in these efforts. CPDR clinical activities are based at the Urology Service, Department of Surgery at WRAMC. A 150 sq. ft. office houses two full-time employees and a number of part-time researchers. A clinical database of all prostate cancer patients treated at WRAMC is underway which is integrated with pathologic and molecular studies.

BODY

a) Personnel

NAME	FUNDING SOURCE	START DATE	STOP DATE	FT/PT	JOB DESCRIPTION
Judd W. Moul, LTC, MC	Military	09/14/92	NA	FT	Director, CPDR
David G. McLeod, COL, MC	Military	09/14/92	NA	FT	Chief of Urology, WRAMC
F.K. Mostofi, MD	AFIP	09/14/92	NA	PT	Pathologist
Isabell A. Sesterhenn, MD	AFIP	09/14/92	NA	PT	Pathologist
Stephen A. Sihelnik, LTC, MC	Military	09/14/92	NA	PT	Clinical Researcher
Shiv K. Srivastava, PhD	HJF	05/01/93	NA	FT	Director, CPDR Laboratory
Jaya Gaddipatti, PhD	HJF	10/01/93	NA	FT	Molecular Biologist
Dorothy Tong	HJF	05/01/94	NA	FT	Molecular Biologist
Juli Harris, BA	HJF	10/01/93	NA	FT	Clinical DBase Coordinator
Rene Mooneyhan, BA	HJF	06/20/94	NA	FT	Clinical DBase Researcher
Shirley L. Craig	HJF	05/09/94	NA	FT	Administrative Assistant
Denise Young	HJF	01/15/94	NA	PT	Pathology Technician
Roger Connelly, MS	HJF	09/19/94	NA	PT	Biostatistician
Paul H. Maher, BS	HJF	11/16/92	05/01/94	FT	Database Researcher
Michelle L. Dixon	HJF	05/10/93	03/24/94	FT	Secretary
Magda Szuszkiewicz	HJF	92-94 summers		PT	Research Assistant (Student)
Sravant Lavu	HJF	01/01/93	NA	PT	Research Assistant (Student)
Howard Heidenberg, MAJ, MC	Military	07/01/93	NA	FT	Urology Research Resident
Michael Finger, MAJ, MC	Military	07/01/93	NA	FT	Urology Research Resident
Thomas Douglas, CPT, MC	Military	07/01/94	NA	FT	Urology Research Resident
John Bauer, MAJ, MC	Military	07/01/94	NA	FT	Urology Research Resident
Lucille Washington, BS	USUHS	11/13/89	06/01/94	FT	Research Biologist

b) Programs/Projects

1. Prostate Cancer Clinical Database

A major CPDR initiative is to collect demographic, medical, pathologic, and outcomes data on all prostate cancer patients treated at WRAMC and to expand this collection to other DoD health care facilities. The project has a retrospective component (collecting data on all patients treated at WRAMC

since 1980), and a prospective component focusing on complete data collection of all patients seen since 1 January 1994. This project has been approved by the Department of Clinical Investigation (DCI) at WRAMC and copies of data collection forms are attached as Addendum 1. The forms have been used both for patient care progress notes and for CPDR data collection. Hard copy research files have been established for over 2000 patients and are housed in the CPDR office at WRAMC. Double data entry with quality assurance and security precautions are utilized to enter data into a relational database with database support assistance from DCI at WRAMC. WRAMC is the alpha-site for this clinical data collection and the system will be exported to other DoD facilities for similar data collection.

2. Prospective Prostate Cancer Tissue Collection Project

In collaboration with the AFIP, all radical prostatectomies performed for prostate cancer at WRAMC are processed for CPDR research per a WRAMC DCI-approved protocol. AFIP pathology personnel come into the operating room and immediately collect fresh prostate cancer tissue and snap-freeze it for future molecular study. A strict protocol is followed for whole-mounting of the specimens for pathologic research studies. Multicentricity and volume of the tumor are determined, and tissue sections are processed for various immunohistochemical studies. As of the end of this report period, over 100 prospective specimens have been collected and cataloged. These tissues serve as the basis for CPDR laboratory studies at USUHS. Recently CPDR began collecting a portion of prostate tumor from each case for short-term cell culture and gene-therapy studies.

3. CPDR Molecular Biology Laboratory

The ongoing initiative at USUHS is involved in the study of oncogenes, tumor suppressor genes, and other molecular markers and factors in prostate cancer and benign prostate diseases. The following is a listing of ongoing projects:

- a. P53 tumor suppressor gene - a survey of tumor suppressor gene p53 mutations in various stages of prostate cancer utilizing immunohistochemistry and gene sequencing has been completed and has been submitted for publication (Heidenberg, et al. - see below) Our studies have shown the involvement of p53 gene alterations in a high fraction of hormone refractory prostate cancer.
- b. Androgen Receptor (AR) mutations in prostate cancer - this project has been the main laboratory focus over this reporting period, and the group has examined in excess of 100 prostate cancer specimen for mutations in the AR gene. A major finding has been frequent detection of a specific AR mutation in a significant percentage of advanced prostate cancer cases (Gaddipatti, et al., - see below). Work is ongoing to determine the frequency and significance of these mutations in early, as well as metastatic prostate cancer.
- c. Gene therapy of Prostate Cancer: In vivo experiments with p53 adenovirus transfection. In collaboration with Dr. Prem Seth (Medicine Branch NIH), we have developed adenovirus vectors containing the tumor suppressor gene p53. We have obtained very exciting results in demonstrating that adenovirus p53 vectors have dramatic inhibitory effects on the growth of metastatic prostate cancer cell lines. Further studies are in progress to follow up these observations in animal models and to design strategies for clinical trials. For this research, the CPDR has received a Research Award from the Association for the Cure of Cancer of the Prostate (CaP Cure). We have also initiated projects to develop the adenovirus vector containing normal AR gene to see if we can correct defects of mutated AR using this approach.

d. Development of primary cell culture from prostate tumor specimens: We have established protocols for growing normal and prostate tumor derived cultures of epithelial cells. This work is extremely important for studies which require a pure population of tumor cells. This study also has utility for future testing of antitumor agents as there are very few prostate cancer cell lines available.

4. Translational and clinical prostate cancer projects - there are a number of other research projects involving collaborations with outside researchers/institutions or research involving the CPDR database and laboratory personnel:

- a. RT-PCR of PSA gene to assess occult micrometastasis in prostate cancer. A VA research grant was written with the University of Washington, Seattle, and the Seattle VA Hospital to fund this project. The grant was approved for \$65,000 for two years during this reporting period and work will commence during FY 1995.
- b. Neural Network artificial intelligence computer programs to assess prostate cancer using clinical variables from the CPDR database. Collaboration with Kaman Sciences Corporation is ongoing to predict outcomes of CaP patients based on pre-treatment clinical and pathologic variables.
- c. Cathepsin-D and EGFR expression in prostate cancer as prognostic markers. Collaboration with Medical College of Virginia and University of North Carolina. (One publication in press, [see Maygarden, et al.], and a final report-second publication in progress)
- d. Racial variation in diagnostic, treatment, and outcome variables in patients with prostate

cancer: Comparison of radical prostatectomy between black and white patients, PSA variation between black and white prostate cancer patients.

- e. Clinical review of PSA-detected prostate cancers (stage T1C) in patients undergoing radical prostatectomy.
- f. Clinical trials with Eastern Cooperative Oncology Group (ECOG) at WRAMC.

CONCLUSIONS

The Center for Prostate Disease Research (CPDR) program project has made significant progress in the second year of operations. Our mission to advance knowledge of prostate cancer and disease and to integrate clinical and basic scientists and projects is continuing and expanding. The main advances during this reporting period have been the growth of the CPDR clinical database, the studies of p53 gene and androgen receptor gene alterations in prostate cancer, development of gene therapy experiments, and the general growth and solidification of our program as a national resource for the study for prostate disease.

A. REFERENCES CPDR publications during reporting period :

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Trotter J, Greenstein F, Hom R, McLeod DG, Moul JW, Reich P, and Smith B:GNRH agonists for the treatment of advanced prostate cancer:managed care implications. Med Interface 7(7)Supplement; 14-32, 1994.

Heidenberg HB, Moul JW, Mostofi FK, and McLeod DG: Clinically detected carcinoma of the prostate treated by radical prostatectomy in a 29 year old man. J Urol 152:966-967, 1994.

Maygarden SJ, Novotny DB, Moul JW, Bae VL, and Ware JL:Evaluation of cathepsin D and epidermal growth factor receptor in prostate carcinoma. Mod Path (In Press)

Heidenberg HB, Sesterhenn IA, Gaddipati P, Weghorst CM, Buzard GS, Moul JW, and Srivastava S:Alterations of the tumor suppressor gene p53 in a high fraction of treatment resistant prostate cancer. J Urol (submitted)

Schenkman NS, Giangeruso E, and Moul JW:Autologous blood transfusion for radical prostatectomy:the use of whole blood vs. packed cells. Urol (submitted)

Zhao L, Chung LWK, Symmans WF, Moul JW, Hall MC, Ye M, Zhau HE:Comparison of the histopathologic grades of prostate cancers in American, Chinese, and Japanese patients. Int J Cancer (submitted)

McLeod DG:Prostate Cancer: Past, Present and Future. In Dawson and Vogelzang, Wiley-Liss, NY. Prostate Cancer, 1-18, 1994

Moul JW, Gaddipati J, Srivastava SK:Molecular biology of prostate cancer:Oncogenes and tumor suppressor genes. In:NA Dawson and Vogelzang, JN (Eds.) Current Clinical Oncology:Prostate Cancer, Wiley-Liss, New York, 1994.

McLeod DG, Moul JW:Controversies in the treatment of prostate cancer with maximal androgen deprivation. In: PJ Walther (Ed.), Controversies and Advances in Urologic Oncology, Surgical Oncology Clinics of North America, WB Saunders, Philadelphia, 1995 (in press)

Moul JW:Oncogenes and tumor suppressor genes in prostate cancer. In:TA Stamey (Ed), 1995 Monographs in Urology, Medical Directions Pub Co, Montverde, FL, 1995 (in press)

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Moul JW: Neoadjuvant hormonal therapy in clinically localized prostate cancer. In" SN Rous (Ed), 1996 Urology Annual, Norton, New York, 1996 (in press)

McLeod DG, O'Brien ME: Hormonal management of metastatic prostate cancer and quality of life issues. In: NI Vogelzang, PT Scardino, WU Shipley, DS Coffey (Eds) Comprehensive Textbook of Genitourinary Oncology, Williams and Wilkins, Baltimore, MD, 1995 (in press)

B. PUBLISHED ABSTRACTS CPDR during reporting period:

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McLeod DG, Maher PD, Schenkman NS, and Moul JW: Comparison of radical prostatectomy in white and black patients in an equal-access health care system. J Urol, 151:304!(#305), 1994.

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Gaddipati J, McLeod D, Heidenberg H, Sesterhenn I, Finger M, Moul J, Srivastava S: Frequent detection of codon 877 mutation in the androgen receptor gene in advanced prostate cancers. The Molecular Basis of Cancer Meeting, June 16-18, 1994, Frederick, MD. Abst #65.

Heidenberg H, Sesterhenn I, Gaddipati J, Weghorst C, Buzard G, Moul J, Srivastava S: Alteration of the tumor suppressor gene p53 in a high fraction of treatment resistant prostate cancer. The Molecular Basis of Cancer Meeting. June 16-June 18, 1994. Frederick, MD. Abst #86

ADDENDUM

WALTER REED ARMY MEDICAL CENTER
 Personal Data - Privacy Act of 1974 (PL 93-579)
 Urology Clinic-WRAMC

DIVISION: WALTER REED AMC
 Automated Version of SF 600
 BBLA

REGISTRATION

Patient Rank: 1 Officer 2 Enlisted	Marital Status: 1 Single 2 Married 3 Divorced 4 Widowed 5 Unk	Height: _____ ft. _____ in.
Ethnic Origin: 1 African-American 2 Caucasian 3 Asian 4 Hispanic 5 Other: _____		Weight: _____ lbs.

PATIENT MEDICAL HISTORY:

Family History of CAP? 0 No 1 Yes 2 Unk	# of 1st degree affected: _____ (Father, Brother, Son)	# of 2nd degree affected: _____ (Grandfather, Uncle, Cousin)
Alcohol Use: 1 <input type="checkbox"/> 0-1 drinks per day 2 <input type="checkbox"/> more than 1 drink per day	Treated BPH: 0 No 1 Yes 2 Unk	COPD: 0 No 1 Yes 2 Unk
Tobacco Use: 0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes	Treatment of BPH (Check all that apply):	CAD: 0 No 1 Yes 2 Unk
Cigs: 0 Current 1 Past 2 Never 3 Unk	1 <input type="checkbox"/> Alpha Block	HTN: 0 No 1 Yes 2 Unk
Pipe: 0 Current 1 Past 2 Never 3 Unk	2 <input type="checkbox"/> 5 Alpha Reductase	CVA: 0 No 1 Yes 2 Unk
Cigars: 0 Current 1 Past 2 Never 3 Unk	3 <input type="checkbox"/> Surgery	Renal Insuf.: 0 No 1 Yes 2 Unk
Pre-tx Potency: 0 No 1 Yes 2 Unk	4 <input type="checkbox"/> Other: _____	Diabetes: 0 No 1 Yes 2 Unk
	Vasectomy: 0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> Unk	Other Cancer: 0 No 1 Yes 2 Unk
	Age: <input type="checkbox"/> <30 <input type="checkbox"/> 30-34 <input type="checkbox"/> 35-39 <input type="checkbox"/> >40	Specify: _____
	1 2 3 4	

SYMPTOMS:

None:	0 No	1 Yes	2 Unk
Prostatism:	0 No	1 Yes	2 Unk
Perineal Pain:	0 No	1 Yes	2 Unk
SX of Metastasis:	0 No	1 Yes	2 Unk
Hematospermia:	0 No	1 Yes	2 Unk
Gross Hematuria:	0 No	1 Yes	2 Unk

REASON FOR BIOPSY:

ABNDRE:	0 No	1 Yes	2 Unk
Elev. PSA:	0 No	1 Yes	2 Unk
PSA Velocity:	0 No	1 Yes	2 Unk
Other:	0 No	1 Yes	2 Unk
Specify:	_____		

BIOPSY RESULTS:

Diagnosis Date: D _____ M _____ Y _____

Number of Biopsies: _____ **Number of Pos Biopsies:** _____

Location of Pos Biopsy (Worst grade, worst gleason sum): **Specific Location (if known):**

LEFT SIDE: 0 Neg 1 Pos 2 Not Done **L. Apex L. Mid L. Base L. SV**

Grade: W M P **Gleason Sum:** _____ **R. Apex R. Mid R. Base R. SV**

RIGHT SIDE: 0 Neg 1 Pos 2 Not Done

Grade: W M P **Gleason Sum:** _____

UNKNOWN SIDE: 0 Neg 1 Pos 2 Not Appl.

Grade: W M P **Gleason Sum:** _____

BIOPSY VARIATIONS:

1 TRUS-Findings:	0 Neg	1 Pos	2 Unk
Vol:	_____ cc's		
2 Digitally-Directed Transrectal			
3 TURP			
4 Other/Specify:	_____		

PRE-BIOPSY PSA: _____ **D** _____ **M** _____ **Y** _____

SOAP NOTE:

PX Name: _____ **Prefix/SSN:** _____ **Physician's Signature:** _____

STAGING

PRETREATMENT LAB VALUES (Check all that apply or enter value if known)

Creatinine: _____ D _____ M _____ Y _____ Alk Phosphatase: _____ D _____ M _____ Y _____

Testosterone: _____ D _____ M _____ Y _____ Pre-Tx PSA: _____ D _____ M _____ Y _____

Pre-Tx PAP: _____ D _____ M _____ Y _____

RADIOLOGY (Circle)					
Bone Scan:	0 Neg	1 Pos	2 ND	3 Pending	
MRI-Pelvis:	0 Neg	1 Pos	2 ND	3 Pending	
MRI-Transrectal:	0 Neg	1 Pos	2 ND	3 Pending	
CT Scan ABD:	0 Neg	1 Pos	2 ND	3 Pending	
CT Scan Pelvis:	0 Neg	1 Pos	2 ND	3 Pending	
CXR:	0 Neg	1 Pos	2 ND	3 Pending	
IVP:	0 Neg	1 Pos	2 ND	3 Pending	
CYSTO:	0 Neg	1 Pos	2 ND	3 Pending	

FINAL CLINICAL STAGE (PRE-TREATMENT)	
1 A1	6 C1
2 A2	7 C2
3 B0	8 C3
4 B1	9 D0
5 B2	10 D1
	11 D2

FINAL TNM STAGE (PRE-TREATMENT)			
1 T1a	7 T3a	1 NX	1 MX
2 T1b	8 T3b	2 N0	2 M0
3 T1c	9 T3c	3 N1	3 M1
4 T2a	10 T4a	4 N2	
5 T2b	11 T4b	5 N3	
6 T2c			

PRIMARY TREATMENT:

1 Prostatectomy 2 Hormonal 3 Radiation 4 Watch Wait 5 Decision Pending

SOAP NOTE:

Patient's Name: _____ Last Four: _____ Physician: _____

RADICAL PROSTATECTOMY

Date of Prostatectomy: Day _____ Month _____ Year _____

Operation Time: Hours _____ Minutes _____

Lymphadenectomy: 1 Open 2 Laparoscopic

Type: 1 Retropubic 2 Perineal

Nerve Sparing: 1 Unilateral 2 Bilateral 3 Not Done

HCT: Pre-Op _____ Day _____ Month _____ Year _____

Post-Op (first value on post op day 1) _____

Autologous Blood Collected: 0 No 1 Yes 2 Unk

of Units _____

Estimated Blood Loss (during surgery): _____ cc's

Transfusion Units (intraoperative): ATOL _____ Non ATOL _____

Was Preoperative Hormone Manipulation Used? 0 No 1 Yes 2 Unk

Type (Circle): Flutamide Proscar

Lupron Zoladex

Other: _____

Duration (weeks): _____

RADIATION TREATMENT SUMMARY
WALTER REED ARMY MEDICAL CENTER

Date: _____

Last Name: _____		First Name: _____		MI: _____	SSN: _____
Date of Birth: D _____	M _____	Y _____	Diagnosis: _____	Histology: _____	
Gleason Sum: _____		Stage: T _____ N _____ M _____			
1 <input type="checkbox"/> From Biopsy		Pre-treatment Lab Values: PSA _____ PAP _____			
2 <input type="checkbox"/> From Surgery					

	Start Date: D _____ M _____ Y _____	Elapsed Days _____	# of Fractions: _____
	(include start and stop date)		
	Completion Date: D _____ M _____ Y _____		Fraction Size: _____ cGy

Field Arrangement: 1 <input type="checkbox"/> 4 Field 2 <input type="checkbox"/> Arc 3 <input type="checkbox"/> Other	Energy: 1 <input type="checkbox"/> 6 MV 2 <input type="checkbox"/> 15 MV 3 <input type="checkbox"/> Mixed	Dose: Pelvis: _____ cGy Prostate + SV: _____ cGy Prostate: _____ cGy	Field Size: AP-PA: _____ X _____ R/L Lat: _____ X _____
---	---	--	--

SYMPTOMS	
Rectal SX: 1 <input type="checkbox"/> Diarrhea 3 <input type="checkbox"/> Other 2 <input type="checkbox"/> Proctitis	Management:
G-U SX: 1 <input type="checkbox"/> Frequency 3 <input type="checkbox"/> Dysuria 2 <input type="checkbox"/> Hematuria 4 <input type="checkbox"/> Other	Management:
Skin SX: 0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes	Management:
Breaks in Treatment: 0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes	Describe:

FOLLOW UP		
PSA at Completion of RT: _____	Date: D _____ M _____ Y _____	F/U Clinic 4 Weeks: _____

Physician Signature: _____

RADIATION THERAPY FOLLOW-UP
WALTER REED ARMY MEDICAL CENTER

Date: _____

Name: _____ SSN: _____ Surgery: 0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes Date: D _____ M _____ Y _____ Radiation Dose: _____ Completion Date: D _____ M _____ Y _____ Hormone Therapy: 0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes Date Therapy Began: D _____ M _____ Y _____ Orchiectomy: 0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes Date: D _____ M _____ Y _____ Hormone Failure: 0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes	Original Stage: T _____ N _____ M _____ PSA: Pre-treatment: _____ Immediate Post Treatment: _____ Current: _____
---	---

Weight Loss: 0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes	Fatigue: 0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes	Night Sweats: 0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes	Febrile Episodes: 0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes
Bone Pain: 0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes Site: _____			

GI SYMPTOMS Diarrhea: 0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes Frequency: 1 <input type="checkbox"/> Daily 3 <input type="checkbox"/> Monthly 2 <input type="checkbox"/> Weekly 4 <input type="checkbox"/> Less BRBPR: 0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes Frequency: 1 <input type="checkbox"/> Daily 3 <input type="checkbox"/> Monthly 2 <input type="checkbox"/> Weekly 4 <input type="checkbox"/> Less Incontinence: 0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes Frequency: 1 <input type="checkbox"/> Daily 3 <input type="checkbox"/> Monthly 2 <input type="checkbox"/> Weekly 4 <input type="checkbox"/> Less	Constipation: 0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes Frequency: 1 <input type="checkbox"/> Daily 3 <input type="checkbox"/> Monthly 2 <input type="checkbox"/> Weekly 4 <input type="checkbox"/> Less Melena: 0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes Frequency: 1 <input type="checkbox"/> Daily 3 <input type="checkbox"/> Monthly 2 <input type="checkbox"/> Weekly 4 <input type="checkbox"/> Less Pain: 0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes Frequency: 1 <input type="checkbox"/> Daily 3 <input type="checkbox"/> Monthly 2 <input type="checkbox"/> Weekly 4 <input type="checkbox"/> Less
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URINARY SYMPTOMS Hematuria: 0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes Frequency: 1 <input type="checkbox"/> Daily 3 <input type="checkbox"/> Monthly 2 <input type="checkbox"/> Weekly 4 <input type="checkbox"/> Less Dysuria: 0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes Frequency: 1 <input type="checkbox"/> Daily 3 <input type="checkbox"/> Monthly 2 <input type="checkbox"/> Weekly 4 <input type="checkbox"/> Less Nocturia: 0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes Frequency (Episodes Per Night): _____	Urinary Frequency: 0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes Frequency: 1 <input type="checkbox"/> Daily 3 <input type="checkbox"/> Monthly 2 <input type="checkbox"/> Weekly 4 <input type="checkbox"/> Less Decreased Erectile Function: 0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes Frequency: 1 <input type="checkbox"/> Daily 3 <input type="checkbox"/> Monthly 2 <input type="checkbox"/> Weekly 4 <input type="checkbox"/> Less Incontinence: 0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes Pads/Day: 1 <input type="checkbox"/> < One 2 <input type="checkbox"/> One 3 <input type="checkbox"/> > One
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Vital Signs: Temp: _____ Pulse: _____ Respirations: _____ Blood Pressure: _____	Rectal: Tone: _____ Fissure: _____ Hemorrhoids: _____ Prostate: _____	G-U: Phallus: _____ Scrotum: _____
HEENT: _____ Lymphadenopathy: _____ Abdomen: _____		

QUALITY OF LIFE DISPOSITION
1. Disease Status: 1 <input type="checkbox"/> NED 2 <input type="checkbox"/> PSA Failure 3 <input type="checkbox"/> Clinical Failure Specify: _____ 2. Studies Ordered: _____ 3. Other Orders: _____ 4. Return Appt.: <input type="checkbox"/> No <input type="checkbox"/> Yes D _____ M _____ Y _____

Physician's Signature: _____

HORMONAL THERAPY

GONADOTROPIN	No	Yes	Date Started	D	M	Y
Total:	0	1	2			
Subcapsular:	0	1	2			
Testicular Prostheses:	0	1	2			

LRH-RH	No	Yes	Date Started	D	M	Y	Date Terminated	D	M	Y
Type (Circle):	Lupron	Zoladex	Other:	_____						

ANTIANDROGEN	No	Yes	Date Started	D	M	Y
Type (Circle):	Flutamide	Other:	_____			

SOAP NOTE:

PROSTATE CANCER FOLLOW-UP

Follow-up Date: D _____ M _____ Y _____		Protocol: 0 No 1 Yes _____	
New Address: N Y Specify: _____		New Phone: N Y Specify: _____	
RECURRENT: 0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes Date of Recurrence: D _____ M _____ Y _____			
Type of Recurrence: Increased PSA: 0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes Pos Bone Scan: 0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes Increased PAP: 0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes Local Recur.: 0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes Visceral Mets: 0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes		Diagnosis of Recurrence (NO ENTRY IF NOT DONE): Bone Scan: 0 <input type="checkbox"/> Neg 1 <input type="checkbox"/> Pos 2 <input type="checkbox"/> Pending MRI: 0 <input type="checkbox"/> Neg 1 <input type="checkbox"/> Pos 2 <input type="checkbox"/> Pending CT: 0 <input type="checkbox"/> Neg 1 <input type="checkbox"/> Pos 2 <input type="checkbox"/> Pending Tissue Bx: 0 <input type="checkbox"/> Neg 1 <input type="checkbox"/> Pos 2 <input type="checkbox"/> Pending TRUS: 0 <input type="checkbox"/> Neg 1 <input type="checkbox"/> Pos 2 <input type="checkbox"/> Pending	
TREATMENT / COURSE RECURRENCE (Circle all that apply)			
Hormonal		TURP Radiation Chemo Watchful Wait Other: _____	
CONTINENCE/POTENCY: 0 <input type="checkbox"/> New Data 1 <input type="checkbox"/> No Change			
Continence: 0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes If no, number of pads/day: _____ If yes, month/year continent: M _____ Y _____		Potency: 0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes If no, circle Tx: 1 VET 2 ICI 3 Penile Pros 4 Other: _____ If yes, month/year potent: M _____ Y _____	
LABS / TESTS (check all that apply or enter value if known)			
PSA: _____ D _____ M _____ Y _____		PAP: _____ D _____ M _____ Y _____	
CR: _____ D _____ M _____ Y _____		ALK PHOS: _____ D _____ M _____ Y _____	
HCT: _____ D _____ M _____ Y _____		TESTOS: _____ D _____ M _____ Y _____	
COMPLICATIONS OF PRIMARY TREATMENT: 0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes			
If Prostatectomy: DVT/PE: 0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> Unk MI/Cardiac: 0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> Unk Rectal Injury: 0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> Unk Reoperation: 0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> Unk Specify: _____ Other: 0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes _____		If Hormonal: Hot Flashes: 0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> Unk Diarrhea: 0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> Unk Surgical: 0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> Unk Gynecomastia: 0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> Unk Antiandrogen Stopped: 0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> Unk Other: 0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes _____	

SOAP NOTE:

Current Clinical Stage: _____ Disease Status (Circle): 1 NED 2 Alive w/CAP 3 Alive/Unk

Patient's Name: _____ Last Four: _____ Physician's Signature: _____