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Table of Contents

List of Abbreviations iv

1. Protocol Summary 1

1. Study Objectives 2
1.1. Objectives 2
1.2 Hypotheses / Research Questions 2

2. Background and Significance 3

3. Study Design and Methods 3

3.1 Overall Design 3

3.2 Patient Questionnaires – Refer to Appendix A. 3

4. Study Enrollment 4

4.1 Study Population 4

4.2 Inclusion Criteria 4

4.3 Exclusion Criteria 4

4.4 Recruitment and Retention 4

6. Study Procedures 5

6.1 Schedule of Trial Events 5

7. Data Reporting / Regulatory Considerations 5

7.1 Institutional Review Board/Ethics Committee Approval 6
7.2. Ethical Conduct of the Study 6
7.3 Informed Consent 6
7.4 Compliance with Trial Registration and Results Posting Requirements 7
7.5 Record Retention 7

8. Statistical Considerations 7

APPENDIX A 9

Baseline Survey 9

First Follow Up Survey 17

Second Follow Up Survey 28

Confidentiality Statement

This document is confidential and is to be distributed for review only to investigators, potential investigators, consultants, study staff, and applicable independent ethics committees or institutional review boards. The contents of this document shall not be disclosed to others without written authorization from WCM.

_____

Institution Name

_____	_____	_____
Principal Investigator's Name	**Principal Investigator's Signature**	**Date**

List of Abbreviations

AE	Adverse Event
AS	Active surveillance
BMI	Body Mass Index
CER	Comparative Effectiveness Research
CFR	Code of Federal Regulations
CI	Confidence interval
CRF	Case Report Form
CTSC	Clinical Translational Science Center
FDA	Food and Drug Administration
GCP	Good Clinical Practice
HIPAA	Health Insurance Portability and Accountability Act of 1996
HRQOL	Health Related Quality of Life
ICF	Informed Consent Form
IMRT	Intensity Modulated Radiation Therapy
IRB	Institutional Review Board
NCCN	National Comprehensive Cancer Network
NYS	New York State
PCORI	Patient-Centered Outcomes Research Institute
PC-CONCEPT	Prostate Cancer Comparative Outcomes of New Conceptual Paradigms for Treatment
PGA	Partial Gland Ablation
PHI	Protected Health Information
PI	Principal Investigator
PSA	Prostate-specific antigen
REDCap	Research Electronic Data Capture
RP	Radical Prostatectomy
SAC	Study Advisory Committee
SBRT	Stereotactic Body Radiation Therapy
SCa	Southern California
SEER	Surveillance Epidemiology and End Results
WCM	Weill Cornell Medicine

1. Protocol Summary

Full Title:	Prostate Cancer Comparative Outcomes of New Conceptual Paradigms for Treatment
Short Title:	PC CONCEPT
Principal Investigators:	Jim C. Hu, MD MPH; Ronald C. Chen, MD MPH
Study Description:	This study will use a population-based cohort design to study men with newly diagnosed low- and intermediate-risk prostate cancer at high-volume centers in Southern California (SCa) and New York State (NYS). Complications of contemporary treatments for prostate cancer and quality of life outcomes, such as general health, urinary, sexual, and bowel function, cancer anxiety, and treatment regret will be compared and tracked over the course of this study.
Sample Size:	N= 3,657
Enrollment:	This study will enroll 2,378 subjects and screen up to 3,657 subjects.
Study Population:	Subjects will have pathologically-confirmed clinically localized prostate adenocarcinoma with National Comprehensive Cancer Network (NCCN) low (T1-T2a, Gleason 6, Grade Group 1, PSA <10 ng/mL) or intermediate risk (T2b-T2c or, Gleason 7, Grade Group 2 or 3 or PSA 10-20 ng/mL) at one of the selected hospitals in SCa and NYS. Subjects must also have a diagnosis date during the 18-month recruitment window.
Enrollment Period:	18 months
Study Design:	Prospective, observational
Description of Sites	Patient enrollment at 15 sites within SCa and NYS, identified through National Cancer Institute-sponsored Surveillance Epidemiology and End Results (SEER)
Study Duration:	01Oct2020 - 30Nov2023
Participant Duration:	12 months
Primary Objectives:	To measure the self-reported, overall and disease specific health related quality of life (HRQOL) prior to treatment, at 8 months, and 12 months following active surveillance (AS), SBRT, IMRT, PGA, and RP.

	To define and compare the rate of adverse events following stereotactic body radiation therapy (SBRT), partial gland ablation (PGA), intensity modulated radiation therapy (IMRT) and radical prostatectomy (RP) among men recently diagnosed with low and intermediate risk prostate cancer.
Primary Endpoints:	Change from Baseline in Patient-Reported Quality of Life as Measured on EQ-5D-5L at 8 Months & 12 Months following Treatment
	Change from Baseline in Patient-Reported Urinary, Sexual, and Bowel Function as Measured on EPIC-26 at 8 Months & 12 Months following Treatment
	Change from Baseline in Ejaculatory Function as Measured on MSHQ-EjD at 8 Months & 12 Months following Treatment
	Change from Baseline in Patient-Reported Anxiety as Measured on MAX-PC at 8 Months & 12 Months following Treatment
	Assessment of Treatment Regret as Measured on Clark's Prostate Cancer Health Worry at 8 Months & 12 Months following Treatment
	Assessment of Adverse Events at 8 Months & 12 Months following Treatment by CTCAE v5.0
	Assessment of Cancer Recurrence at 8 Months & 12 Months following Treatment by Patient Medical Records

1. Study Objectives

To compare complications of contemporary treatments for prostate cancer and quality of life outcomes in men with newly diagnosed low- and intermediate-risk prostate cancer through a prospective, population-based cohort study design.

1.1. Objectives

To measure the self-reported, overall and disease specific health related quality of life (HRQOL) prior to treatment, at 8 months, and 12 months following active surveillance (AS), SBRT, IMRT, PGA, and RP.

To define and compare the rate of adverse events following stereotactic body radiation therapy (SBRT), partial gland ablation (PGA), intensity modulated radiation therapy (IMRT) and radical prostatectomy (RP) among men recently diagnosed with low and intermediate risk prostate cancer.

1.2 Hypotheses / Research Questions

PGA is associated with less reduction of urinary and sexual function compared to before treatment than both RP and IMRT. SBRT is associated with less reduction of urinary and sexual

function before treatment compared to RP and IMRT. SBRT will be associated with less reduction in bowel function compared to IMRT. PGA is associated with better overall quality of life at 12 months compared to AS.

PGA and SBRT are associated with fewer adverse events compared to RP and IMRT.

2. Background and Significance

Prostate cancer remains the most commonly diagnosed, solid organ tumor and the second most common cause of cancer death in U.S. men. Technological advances have enabled new treatment options, such as stereotactic body radiation therapy (SBRT) and partial gland ablation (PGA). Although heavily marketed as more convenient with fewer side effects, there is an absence of high-level, comparative effective research (CER) to discern relative outcomes to traditional therapies such as active surveillance (AS), radical prostatectomy (RP) and intensity modulated radiation therapy (IMRT).

We will conduct a pragmatic, population-based cohort study of men with newly diagnosed low and intermediate risk prostate cancer in Southern California (SCa) and New York State (NYS) Surveillance Epidemiology and End Results (SEER) regions to bridge the evidence gap concerning adverse events and patient reported outcomes. Our proposed study will inform multiple stakeholders, who contributed to our study design. This includes prostate cancer survivors, payers, medical device manufacturers, professional organizations, community and academic prostate cancer experts and the Food and Drug Administration (FDA).

3. Study Design and Methods

3.1 Overall Design

We will conduct rapid case ascertainment (within 3 weeks of diagnosis or sooner) at hospitals within these National Cancer Institute-sponsored Surveillance Epidemiology and End Results (SEER) Regions where PGA and SBRT are more likely to be offered. Cases will be identified through the SEER registries' rapid case ascertainment system, and patients will be enrolled to the cohort study directly by the investigator team (not through the individual hospitals). At the time of rapid case ascertainment, the type of treatment a man receives is not yet known; therefore, we will enroll all patients diagnosed with low and intermediate-risk prostate cancer.

3.2 Patient Questionnaires – Refer to Appendix A.

A. Administration

- **Timing and Frequency** – Baseline questionnaires will be sent to eligible participants for study enrollment. Follow-up questionnaires at 8 months and 12 months will be sent to enrolled participants to ascertain treatment choice and obtain patient-reported outcomes following treatment.

- **Survey method**
  Eligible participants will be mailed a survey packet consisting of a paper copy of the survey, an introductory letter and information sheet, and a postage paid return envelope. In the letter the participant will be informed that, if he wishes, he may also complete the survey online and will be given a code and link to the online survey. All materials will be provided in Spanish and English to those participants with Spanish surnames. Interviewers contacting the men are bilingual.

  A modified Dillman method will be used to increase response. This includes follow-up with telephone, mail, and offers of completion of the survey online or by telephone.

Specifically, if no response is received after 2 weeks, the study staff will telephone the participant to determine if he has any questions or concerns and to encourage him to complete the survey. At least 5 calls will be made on different days, times of the day (including evenings), and on weekends to reach the person. Additional follow-up efforts will include sending reminder postcards, re-mailing of the survey packet, sending a reminder letter with the link to the online survey, or offering to do the interview over the telephone.

- **Person Identifiers**
  Patient identifiers obtained at the time of rapid case ascertainment will be used to link to the completed registry abstract. The registry variables to be linked to the cases will include: patient demographic data (age, date of birth, race, socio-economic status, quintile of census block of residence, marital status, birthplace), tumor data (PSA, stage, histology, grade, clinical and pathologic Gleason score, extension), treatment data (surgical code, radiation (type), dates of treatments, chemotherapy, and hormone therapy, PGA and AS).

B. Study Instruments – Refer to **Appendix A.**

4. Study Enrollment

4.1 Study Population

Subjects with a diagnosis of prostate cancer who meet the inclusion and exclusion criteria will be eligible for participation in this study.

4.2 Inclusion Criteria

To be included in the study, the participant will: (1) have pathologically-confirmed clinically localized prostate adenocarcinoma with Grade Group 1-2 (Gleason score 6 & 7)[72] at one of the selected hospitals in SCa and NYS; (2) have a diagnosis date during the 18 month recruitment window; (3) speak either English or Spanish and; 4) agree to participate by completing the baseline questionnaire.

4.3 Exclusion Criteria

Patients will be **excluded** if they: 1) have clinically metastatic disease or high-risk PCa (T3a-T4, Gleason Grade Group 4 or 5 or PSA >20 ng/mL; (2) do not speak English or Spanish; or (3) are unwilling or unable (low literacy, too ill, etc.) to give informed consent; or (4) are diagnosed with prostate cancer incidentally at the time of radical cysto-prostatectomy to treat bladder cancer.

4.4 Recruitment and Retention

We will conduct rapid case ascertainment (within usually 4 weeks of diagnosis or sooner) at hospitals within these SEER Regions where PGA and SBRT are more likely to be offered in order to maximize the sample size of men receiving these new treatments.

The SCa and NYS SEER registries are mandated by their respective states to routinely collect and report information on all cancers diagnosed in their catchment areas, including sociodemographic information and tumor characteristics, such as final pathologic stage and histologic grade. Active and passive follow-up is also conducted to ascertain vital status and underlying cause of death.

The Study Advisory Committee (SAC) is comprised of patient partners Fans for the Cure and Us TOO, a senior FDA officer, and a representative from Centers for Medicare and Medicaid Services. Patient partners will participate actively in research decision-making through monthly SAC meetings. Patient partners will co-lead to troubleshoot challenges that may arise in subject recruitment, review preliminary outcomes, troubleshoot research obstacles and participate in dissemination of study findings. Patient partners will resolve potentially confusing and/or missing survey responses.

6. Study Procedures

6.1 Schedule of Trial Events

Data elements	Baseline	8 months	12 months
Patient reported			
Income	X		
Education	X		
Family history of prostate cancer	X		
Employment status	X	X	X
Charlson co-morbidity	X	X	X
Height	X	X	X
Weight	X	X	X
Medications	X	X	X
Treatment (confirm PGA and SBRT)			
Cancer recurrence		X	X
Secondary treatment(s)		X	X
Adverse events		X	X
Patient reported outcomes	X	X	X
Registry reported			
Age	X		
Race	X		
Marital status	X		
Insurance type	X		
Poverty level based on census tract	X		
PSA	X		
Biopsy pathology	X		
Clinical stage	X		
Treatment	X		

7. Data Reporting / Regulatory Considerations

The SCa and NYS SEER research teams will independently contact participants, collect data and enter survey results in a unified study database maintained at USC. A Study ID will be created for each case and survey and registry data will be linked to it, and no personal identifiers (or registry IDs) will be included in the analytic dataset. Only staff directly involved with the study at each site will have access to the tracking systems. In addition, a central database will be maintained at Weill Cornell to assess the overall progress of the project. Each site will maintain a local password-protected and secure linkage database containing participant protected health information and identifiers and the linkage to the Study ID number. This database will only be accessible to researchers at the local site where the participant is followed. Participants will return their questionnaires to the local investigators. Accordingly, local study staff will go over each completed questionnaire and check all coding (although the questionnaire will be designed to be self-coded when possible).

7.1 Institutional Review Board/Ethics Committee Approval

As required by local regulations, the Investigator will ensure all legal aspects are covered, and approval of the appropriate regulatory bodies obtained, before study initiation.

Before initiation of the study at each study center, the protocol, the ICF, other written material given to the patients, and any other relevant study documentation will be submitted to the appropriate Ethics Committee. Written approval of the study and all relevant study information must be obtained before the study center can be initiated. Any necessary extensions or renewals of IEC/IRB approval must be obtained for changes to the study, such as amendments to the protocol, the ICF, or other study documentation. The written approval of the IEC/IRB together with the approved ICF must be filed in the study files.

The Investigator will report promptly to the IEC/IRB any new information that may adversely affect the safety of the subjects or the conduct of the study. The Investigator will submit written summaries of the study status to the IEC/IRB as required. On completion of the study, the IEC/IRB will be notified that the study has ended.

All agreed protocol amendments will be clearly recorded on a protocol amendment form and will be signed and dated by the original protocol approving signatories. All protocol amendments will be submitted to the relevant institutional IEC/IRB for approval before implementation, as required by local regulations. The only exception will be when the amendment is necessary to eliminate an immediate hazard to the trial participants. In this case, the necessary action will be taken first, with the relevant protocol amendment following shortly thereafter.

Once protocol amendments or consent form modifications are implemented at the lead site, Weill Cornell Medicine, updated documents will be provided to participating sites. Weill Cornell Medicine must approve all consent form changes prior to local IRB submission.

Relevant study documentation will be submitted to the regulatory authorities of the participating countries, according to local/national requirements, for review and approval before the beginning of the study. On completion of the study, the regulatory authorities will be notified that the study has ended.

7.2. Ethical Conduct of the Study

The Investigators and all parties involved should conduct this study in adherence to the ethical principles based on the Declaration of Helsinki, GCP, ICH guidelines and the applicable national and local laws and regulatory requirements.

This study will be conducted under a protocol reviewed and approved by the applicable ethics committees and investigations will be undertaken by scientifically and medically qualified persons, where the benefits of the study are in proportion to the risks.

7.3 Informed Consent

The investigator or qualified designee must obtain documented consent according to ICH-GCP and local regulations, as applicable, from each potential subject or each subject's legally authorized representative prior to participating in the research study. Subjects who agree to participate will sign the approved informed consent form and will be provided a copy of the signed document.

The initial ICF, any subsequent revised written ICF and any written information provided to the subject must approved by IRB prior to use. The ICF will adhere to IRB/IEC requirements,

applicable laws and regulations.

7.4 Compliance with Trial Registration and Results Posting Requirements

Under the terms of the Food and Drug Administration Modernization Act (FDAMA) and the Food and Drug Administration Amendments Act (FDAAA), the Sponsor-Investigator of the trial is solely responsible for determining whether the trial and its results are subject to the requirements for submission to **http://www.clinicaltrials.gov**. Information posted will allow subjects to identify potentially appropriate trials for their disease conditions and pursue participation by calling a central contact number for further information on appropriate trial locations and trial site contact information.

7.5 Record Retention

Essential documents are those documents that individually and collectively permit evaluation of the study and quality of the data produced. After completion of the study, all documents and data relating to the study will be kept in an orderly manner by the Investigator in a secure study file. All subject medical records and other source documentation will be kept for the maximum time permitted by the hospital, institution, or medical practice.

8. Statistical Considerations

The data structure for the patient reported outcomes is longitudinal, and data could be missing at certain time points (e.g. a patient provides data at 8 but not 12 months). We will use a general estimating equations approach using a Gaussian link-function and auto-regressive correlation. The covariates will adjust for adverse events (prostate cancer aggressiveness [low or intermediate risk], age [continuous], race [white, black, other], comorbidity score [Charlson Index]) plus baseline disease-specific HRQOL score; treatment group will be entered as four separate variables (e.g. PGA 1 or 0; RP 1 or 0; SBRT 1 or 0; IMRT 1 or 0) with AS as the reference group.

Because differences between groups will vary by time (e.g. large decreases in urinary function in the surgery group at month 8, smaller by month 12), we will include a time by treatment interaction term. This model provides adjusted differences from AS over time for each treatment, along with a 95% CI and a p-value. From these estimates, it is straightforward to conduct pairwise comparisons (e.g. sexual function between PGA and surgery). As a sensitivity analysis, we will use propensity scores as the covariate as described above, again excluding patients at the extremes of the propensity distribution.

Adverse events will be treated as binary variables, defined as present or absent, with the severity being characterized by the associated categorical response. Mild AEs (grade 1) will be excluded because it typically resolves without intervention. However, inclusion of mild AEs will be considered in sensitivity analysis. Type and severity of AEs will be described separately by treatment.

The analysis will be by binomial logistic regression. The covariates will be age (continuous), BMI (using restricted cubic splines with knots at 30 and 35), comorbidity score (Charlson index), clinical stage (T1c or T2a, T2b, T2c, T3/4), NCCN risk group and pretreatment PSA (CI-5). Treatment group will be entered as 3 separate variables (i.e. PGA 1 or 0; SBRT 1 or 0; IMRT 1 or 0) with surgery as the reference group.

We will also conduct a sensitivity analysis using propensity methods – where propensity for treatment is derived from a multinomial logistic regression with the same covariates as above – and excluding any patient with >95% or <15% chance of receiving any of the treatments.

For adverse events, we expect a rate of 10% in the IMRT and RP arms. The main HRQOL endpoint of interest is EPIC-26 sexual function. The estimated number of patients we will evaluate is as follows: AS 300; PGA: 280; SBRT: 288; IMRT: 316; RP: 333. This is based on the incidence of low and intermediate prostate cancer in the SCa and NYS SEER registries.

APPENDIX A.

Baseline Survey

1. Today's date: __ __ / __ __ / 2 0 __ __
   M M D D Y Y Y Y

2. What is your birth date: __ __ / __ __ / 19__ __
   M M D D Y Y Y Y

3. When were you first diagnosed with prostate cancer: __ __ / __ __ / 2 0 __ __
   M M. D D Y Y Y Y

4. In general, you would say your health is:
   - ☐ Excellent
   - ☐ Very good
   - ☐ Good
   - ☐ Fair
   - ☐ Poor
   - ☐ Very poor

5. What is your most recent PSA result? __ __ . __ __ ☐ Don't know

6. What date was this PSA test done? __ __ / __ __ / 2 0 __ __ ☐ Don't know
   M M D D Y Y Y Y

7. This next question is about your plans for treatment for prostate cancer or treatment you have already received.

   For each of the following types of treatment, please indicate if you have chosen it, started to receive it, are considering it, or are not considering it at this time. ***Check one box on each row that best reflects your decision at this time for each type of treatment.***

Type of Treatment	**I have chosen this plan and have started or completed it**	**I have chosen this plan but have not yet received it**	**I am considering this option but have not made a decision yet**	**I am not considering this option at this time**
a. Active Surveillance (My doctor will monitor how I am doing without directly treating the cancer)	☐ Date started: __ __ / __ __ / __ __ M M D D Y Y	☐	☐	☐
Type of Treatment (Cont.)	**I have chosen this plan and have started or**	**I have chosen this plan but**	**I am considering this option but**	**I am not considering this option**

	completed it	have not yet received it	have not made a decision yet	
b. **Prostate surgery** (**radical prostatectomy**), which would remove the whole prostate.	☐ Date of surgery: __ __ / __ __ / __ __ M M D D Y Y	☐	☐	☐
c. **HIFU / High Intensity Focused Ultrasound** (ultrasound waves cross tissue to destroy the **part** of the prostate that had cancer)	☐ Date started: __ __ / __ __ / __ __ M M D D Y Y	☐	☐	☐
d. **Cryotherapy** (freezing the **part** of the prostate that had cancer)	☐ Date started: __ __ / __ __ / __ __ M M D D Y Y	☐	☐	☐
e. **Laser therapy**	☐ Date started: __ __ / __ __ / __ __ M M D D Y Y	☐	☐	☐
f. **Radio Frequency Ablation**	☐ Date started: __ __ / __ __ / __ __ M M D D Y Y	☐	☐	☐
g. **Photodynamic therapy**	☐ Date started: __ __ / __ __ / __ __ M M D D Y Y	☐	☐	☐
h. **External Beam Radiation Therapy or IMRT** (radiation treatment requiring more than 2 weeks of treatment)	☐ Date started: __ __ / __ __ / __ __ M M D D Y Y	☐	☐	☐
i. **Stereotactic Body Radiation Therapy (SBRT)** (radiation treatment requiring less than 2 weeks of treatment)	☐ Date started: __ __ / __ __ / __ __ M M D D Y Y	☐	☐	☐

j. Brachytherapy (radioactive seeds) This involves having radioactive seeds placed within the prostate	☐ Date started: __ __ / __ __ / __ __ M M D D Y Y	☐	☐	☐
k. Proton Beam Therapy	☐ Date started: __ __ / __ __ / __ __ M M D D Y Y	☐	☐	☐
l. Any other type of radiation therapy? Describe:_____ _____	☐ Date started: __ __ / __ __ / __ __ M M D D Y Y	☐	☐	☐
m. Hormonal treatments to lower testosterone (e.g. Lupron, Zoladex, Firmagon, Eligard, Vantas, etc)	☐ Date started: __ __ / __ __ / __ __ M M D D Y Y	☐	☐	☐
n. Surgical removal of testicles (Orchiectomy)	☐ Date of surgery: __ __ / __ __ / __ __ M M D D Y Y	☐	☐	☐
o. Chemotherapy (docetaxel, cabazitaxel, other)	☐ Date started: __ __ / __ __ / __ __ M M D D Y Y	☐	☐	☐

Health Before Treatment

For the next set of questions, please refer to the time just BEFORE you were diagnosed.

Urinary Issues

8. **During the 4 weeks before your diagnosis**, how often have you leaked urine (pee)? *(Choose one)*

☐ More than once a day
☐ About once a day
☐ More than once a week
☐ About once a week
☐ Rarely or never

9. Which of the following best describes your urinary control (ability to hold pee) **during the 4 weeks before your diagnosis**? *(Choose one)*

☐ No urinary control whatsoever
☐ Frequent dribbling
☐ Occasional dribbling
☐ Total control

10. How many pads or adult diapers per day did you usually use to control leakage (pee) **during the 4 weeks before your diagnosis**? *(Choose one)*

☐ None
☐ 1 pad per day
☐ 2 pads per day
☐ 3 or more pads per day

11. How big a problem, if any, has each of the following been for you **during the 4 weeks before your diagnosis**? *(Choose one for each item)*

		No problem	Very small problem	Small problem	Moderate problem	Big problem
a.	Dripping or leaking urine (pee)	☐	☐	☐	☐	☐
b.	Pain or burning on urination (when peeing)	☐	☐	☐	☐	☐
c.	Bleeding with urination (pee)	☐	☐	☐	☐	☐
d.	Weak urine stream (pee) or incomplete emptying	☐	☐	☐	☐	☐
e.	Need to urinate (pee) frequently during the day	☐	☐	☐	☐	☐

12. Overall, how big a problem has your urinary function (ability to pee) been for you **during the 4 weeks before your diagnosis**? *(Choose one)*

☐ No problem
☐ Very small problem
☐ Small problem
☐ Moderate problem

☐ Big problem

Bowel Issues

13. How big a problem, if any, has each of the following been for you **during the 4 weeks before your diagnosis**? *(Choose one response on each line)*

		No problem	Very small problem	Small problem	Moderate problem	Big problem
a.	Urgency to have a bowel movement (poop)	☐	☐	☐	☐	☐
b.	Increased frequency of bowel movements (poop)	☐	☐	☐	☐	☐
c.	Losing control of your stools (poop)	☐	☐	☐	☐	☐
d.	Bloody stools (blood with poop)	☐	☐	☐	☐	☐
e.	Abdominal/pelvic/rectal pain	☐	☐	☐	☐	☐

14. Overall, how big a problem have your bowel habits (ability to poop) been for you **during the 4 weeks before your diagnosis**? *(Choose one)*

☐ No problem
☐ Very small problem
☐ Small problem
☐ Moderate problem
☐ Big problem

Sexual Issues

15. How would you rate each of the following **during the 4 weeks before your diagnosis**? *(Choose one response on each line)*

		Very poor to none	Poor	Fair	Good	Very good
a.	Your ability to have an erection (hard on)?	☐	☐	☐	☐	☐
b.	Your ability to reach orgasm (climax)?	☐	☐	☐	☐	☐

16. How would you describe the usual QUALITY of your erections (hard on) **during the 4 weeks before your diagnosis**? *(Choose one)*

☐ None at all
☐ Not firm enough for any sexual activity

☐ Firm enough for masturbation and foreplay only
☐ Firm enough for intercourse

17. How would you describe the FREQUENCY of your erections (hard on) **during the 4 weeks before your diagnosis**? *(Choose one)*

☐ I NEVER had an erection when I wanted one
☐ I had an erection LESS THAN HALF the time I wanted one
☐ I had an erection ABOUT HALF the time I wanted one
☐ I had an erection MORE THAN HALF the time I wanted one
☐ I had an erection WHENEVER I wanted one

18. Overall, how would you rate your ability to function sexually **during the 4 weeks before your diagnosis**? *(Choose one)*

☐ Very poor
☐ Poor
☐ Fair
☐ Good
☐ Very good

19. Overall, how big a problem has your sexual function, or lack of sexual function, been for you **during the 4 weeks before your diagnosis**? *(Choose one)*

☐ No problem
☐ Very small problem
☐ Small problem
☐ Moderate problem
☐ Big problem

20. How big a problem **during the 4 weeks before your diagnosis** was each of the following for you? *(Choose one response on each line)*

	No problem	Very small problem	Small problem	Moderate problem	Big problem
a. Feeling depressed	☐	☐	☐	☐	☐
b. Lack of energy	☐	☐	☐	☐	☐
c. Change in body weight	☐	☐	☐	☐	☐

Demographic Questions

21. What is your ethnicity?

☐ Hispanic or Latino
☐ Not Hispanic or Latino

22. What is your race? *(Choose all that apply)*

- ☐ White or Caucasian
- ☐ Black or African-American
- ☐ Asian
- ☐ Native Hawaiian or Other Pacific Islander
- ☐ Native American or Alaska Native

23. What is your current marital status?
- ☐ Single or never married
- ☐ Married or domestic partnership
- ☐ Divorced
- ☐ Widowed
- ☐ Separated

24. What is your current employment status?
- ☐ Working full time
- ☐ Working part time
- ☐ Retired
- ☐ Unemployed or looking for work
- ☐ On disability

25. What is the HIGHEST level of education you have completed?
- ☐ Grade school or less
- ☐ Some high school
- ☐ High school graduate or GED
- ☐ Vocational school
- ☐ Some college
- ☐ Associates degree
- ☐ College graduate (Bachelor's degree)
- ☐ Some graduate education
- ☐ Graduate degree

26. What is the total income of your household?
- ☐ Less than $10,000
- ☐ $10,001 to $20,000
- ☐ $20,001 to $40,000
- ☐ $40,001 to $70,000
- ☐ $70,001 to $90,000
- ☐ More than $90,000

27. What kind of health insurance or health care coverage do you currently have? *(Check all that apply)*

☐ Private insurance (please select type below):

- ☐ Insurance provided through my current or former employer or union (including Kaiser/HMO/PPO)
- ☐ Insurance provided by another family member (e.g., spouse) through their current or former employer or union (including Kaiser/HMO/PPO)
- ☐ Insurance purchased directly from an insurance company (by you or another family member)
- ☐ Insurance purchased from an exchange (sometimes called Obamacare or the Affordable Care Act)

☐ Public or government insurance (please select type below):

- ☐ Medicaid or other state provided insurance
- ☐ Medicare/government insurance for age 65 years and older
- ☐ Medicare Advantage
- ☐ MediGAP

☐ VA (including those who have ever used or enrolled for VA health care)

☐ I do not have any medical insurance

First Follow Up Survey

1. Today's date: __ __ / __ __ / 2 0 __ __
   M M D D Y Y

2. How tall are you? _____ *(feet, inches)*

3. What is your weight? _____(pounds)

4. Do you have any history of any of the following (check box if Yes)?:

☐ Heart attack

☐ Congestive heart failure

☐ Peripheral vascular disease

☐ Cerebrovascular disease

☐ Hypertension

☐ Chronic pulmonary disease

☐ Rheumatologic disease

☐ Peptic ulcer disease

Liver disease:
- ¨ Mild liver disease
- ¨ Moderate or severe liver disease

Diabetes:
- ¨ Diabetes without chronic complications
- ¨ Diabetes with chronic complications

☐ Hemiplegia or paraplegia

☐ Renal disease

☐ Any other malignancy besides prostate cancer, including leukemia and lymphoma

☐ Metastatic (non-prostate) solid tumor

5. What was your last PSA value? (approximate value): _____. _____**ng/ml**

☐ Don't know

6. When was the date of your last PSA? (approximate date): _____/ _____

Month Year

☐ Don't know

7. **PSA**: How true has each of the following statements been for you during the past **4 weeks**?

Choose one response on each line

	Not at all	A little bit	Somewhat	Quite a bit	Very much
a. I keep close track of my PSA	☐	☐	☐	☐	☐
b. Knowing my PSA level is comforting to me	☐	☐	☐	☐	☐
c. I live in fear that my PSA will rise	☑	☐	☐	☐	☐

8. Since your initial treatment for prostate cancer, did your doctor ever tell you that your prostate cancer came back (recurred) or progressed (got worse)?
   ☐ Yes
   ☐ No

9. Since you were diagnosed with prostate cancer, has a doctor ever told you that your prostate cancer had spread to other areas of your body?
   ☐ Yes
   ☐ No

10. These next questions are about the treatments for prostate cancer **that you have received.**
For each of the following types of treatment, please check the one(s) you have received and indicate the date you received it (or started it)

Type of Treatment	I have received this treatment	Date received or started
a. Active Surveillance (My doctor will monitor how I am doing without directly treating the cancer)	☐	__ __ / __ __ / __ __ M M D D Y Y
b. Prostate surgery (**radical prostatectomy**), which would remove the whole prostate.	☐	__ __ / __ __ / __ __ M M D D Y Y
c. HIFU / High Intensity Focused Ultrasound (ultrasound waves cross tissue to destroy the **part** of the prostate that had cancer)	☐	__ __ / __ __ / __ __ M M D D Y Y
d. Cryotherapy (freezing the **part** of the prostate that had cancer)	☐	__ __ / __ __ / __ __ M M D D Y Y
e. Laser therapy	☐	__ __ / __ __ / __ __ M M D D Y Y
f. Radio Frequency Ablation	☐	__ __ / __ __ / __ __ M M D D Y Y

Type of Treatment	I have received this treatment	Date received or started
g. Photodynamic therapy	☐	__ __ / __ __ / __ __ M M D D Y Y
h. External Beam Radiation Therapy or IMRT (radiation treatment requiring more than 2 weeks of treatment)	☐	__ __ / __ __ / __ __ M M D D Y Y
i. Stereotactic Body Radiation Therapy (SBRT) (radiation treatment requiring less than 2 weeks of treatment)	☐	__ __ / __ __ / __ __ M M D D Y Y
j. Brachytherapy (radioactive seeds) This involves having radioactive seeds placed within the prostate	☐	__ __ / __ __ / __ __ M M D D Y Y
k. Proton Beam Therapy	☐	__ __ / __ __ / __ __ M M D D Y Y
l. Any other type of radiation therapy? Describe:_____	☐	__ __ / __ __ / __ __ M M D D Y Y
m. Hormonal treatments to lower testosterone (e.g. Lupron, Zoladex, Firmagon, Eligard, Vantas, etc)	☐	__ __ / __ __ / __ __ M M D D Y Y
n. Surgical removal of testicles (Orchiectomy)	☐	__ __ / __ __ / __ __ M M D D Y Y
o. Chemotherapy (docetaxel, cabazitaxel, other)	☐	__ __ / __ __ / __ __ M M D D Y Y

If you have only received active surveillance or have not had any treatment yet for your prostate cancer, please skip to Question 16.

11. As individuals go through treatment for cancer, they sometimes experience different symptoms and side effects. For each symptom below, please select the one response that best describes your experiences in the 7 days after your initial treatment choice (surgery, radiation, partial gland ablation).

1) Symptom: Abdominal pain

a. In the 7 days after your initial treatment, how **often** did you have **pain in the abdomen (belly area)**?

☐	☐	☐	☐	☐
Never	Rarely	Occasionally	Frequently	Almost constantly

b. In the 7 days after your initial treatment, what was the **severity** of your **pain in the abdomen (belly area)** at its **worst**?

☐	☐	☐	☐	☐
None	Mild	Moderate	Severe	Very severe

c. In the 7 days after your initial treatment, how much did **pain in the abdomen (belly area) interfere** with your usual or daily activities?

☐	☐	☐	☐	☐
Not at all	A little bit	Somewhat	Quite a bit	Very much

2) Symptom: Swelling

a. In the 7 days after your initial treatment, how **often** did you have **arm or leg swelling**?

☐	☐	☐	☐	☐
Never	Rarely	Occasionally	Frequently	Almost constantly

b. In the 7 days after your initial treatment, what was the **severity** of your **arm or leg swelling** at its **worst**?

☐	☐	☐	☐	☐
None	Mild	Moderate	Severe	Very severe

c. In the 7 days after your initial treatment, how much did **arm or leg swelling interfere** with your usual or daily activities?

☐	☐	☐	☐	☐
Not at all	A little bit	Somewhat	Quite a bit	Very much

3) Symptom: General pain

a. In the 7 days after your initial treatment, how **often** did you have **pain**?

☐	☐	☐	☐	☐
Never	Rarely	Occasionally	Frequently	Almost constantly

b. In the 7 days after your initial treatment, what was the **severity** of your **pain** at its **worst**?

☐	☐	☐	☐	☐
None	Mild	Moderate	Severe	Very severe

c. In the 7 days after your initial treatment, how much did **pain interfere** with your usual or daily activities?

☐	☐	☐	☐	☐
Not at all	A little bit	Somewhat	Quite a bit	Very much

4) Symptom: Fatigue

a. In the 7 days after your initial treatment, what was the **severity** of your **fatigue, tiredness, or lack of energy** at its **worst**?

☐	☐	☐	☐	☐
None	Mild	Moderate	Severe	Very severe

b. In the 7 days after your initial treatment, how much did **fatigue, tiredness, or lack of energy interfere** with your usual or daily activities?

☐	☐	☐	☐	☐
Not at all	A little bit	Somewhat	Quite a bit	Very much

12. Have you been hospitalized for complications from your prostate cancer treatment or for any other problems after receiving prostate cancer treatment?
    ☐ Yes:
    a. What was the reason for the hospitalization?
    _____

    b. How many days did you spend in the hospital? ___ ___

    ☐ No

13. Did you perform Kegel exercises after your prostate cancer treatment?
    ☐ Yes--How often do you (did you) do Kegel exercises?
        ☐ Once a week or less
        ☐ Twice a week
        ☐ More often than twice a week
    ☐ No
    ☐ I don't know

14. Did your doctor advise you to do Kegel exercises after your prostate cancer treatment?
    ☐ Yes--What resources were given to you to help you do Kegel exercises? Check all that apply.
        ☐ Verbal explanation
        ☐ Handout
        ☐ Visit with a Nurse Counselor
        ☐ Referral to Physical Therapy
        ☐ None
        ☐ I don't know
        ☐ Other: _____

    ☐ No
    ☐ I don't know

15. Did you experience any (other) complication or unexpected outcome within 3 months after your prostate cancer treatment?

    ☐ Yes: If yes, please describe: _____

    ☐ No

<u>Current Health</u>

16. In general, would you say your health is:

    ☐ Excellent
    ☐ Very good
    ☐ Good
    ☐ Fair
    ☐ Poor
    ☐ Very poor

For the next set of questions, please think about your experience during the past 4 weeks.
Urinary Issues

17. **In the past 4 weeks** how often did you leak urine (pee)? *(Choose one)*

☐ More than once a day
☐ About once a day
☐ More than once a week
☐ About once a week
☐ Rarely or never

18. Which of the following best describes your urinary control (ability to hold pee) **during the past 4 weeks**? *(Choose one)*

☐ No urinary control whatsoever
☐ Frequent dribbling
☐ Occasional dribbling
☐ Total control

19. How many pads or adult diapers did you usually use per day to control urine (pee) leakage **during the past 4 weeks**? *(Choose one)*

☐ None
☐ 1 pad per day
☐ 2 pads per day
☐ 3 or more pads per day

20. How big a problem, if any, was each of the following **during the past 4 weeks**? *(Choose one for each item)*

		No problem	Very small problem	Small problem	Moderate problem	Big problem
a.	Dripping or leaking urine (pee)	☐	☐	☐	☐	☐
b.	Pain or burning on urination (when peeing)	☐	☐	☐	☐	☐
c.	Bleeding with urination (when peeing)	☐	☐	☐	☐	☐
d.	Weak urine stream (pee) or incomplete emptying	☐	☐	☐	☐	☐
e.	Need to urinate (pee) frequently during the day	☐	☐	☐	☐	☐

21. Overall, how big a problem was your urinary function (ability to pee) for you **during the past 4 weeks**? *(Choose one)*

☐ No problem
☐ Very small problem
☐ Small problem
☐ Moderate problem
☐ Big problem

Bowel Issues

22. How big a problem, if any, was each of the following **during the past 4 weeks**? *(Choose one response on each line)*

		No problem	Very small problem	Small problem	Moderate problem	Big problem
a.	Urgency to have a bowel movement (poop)	☐	☐	☐	☐	☐
b.	Increased frequency of bowel movements (poop)	☐	☐	☐	☐	☐
c.	Losing control of your stools (poop)	☐	☐	☐	☐	☐
d.	Bloody stools (blood with poop)	☐	☐	☐	☐	☐
e.	Abdominal/pelvic/rectal pain	☐	☐	☐	☐	☐

23. Overall, how big a problem were your bowel habits (ability to poop) **during the past 4 weeks**? *(Choose one)*

☐ No problem
☐ Very small problem
☐ Small problem
☐ Moderate problem
☐ Big problem

Sexual Issues

24. Do you currently use any of the following to help with problems with sexual function? (Choose one response on each line)

		Yes	No
a.	Vacuum suction device	☐	☐
b.	Penile injections (shots)	☐	☐
c.	Pills, such as Viagra, Cialis, Levitra, Staxyn, Stendra	☐	☐
d.	Urethral pellets or suppositories (Muse)	☐	☐
e.	Penile prosthesis (surgical implant)	☐	☐
f.	Other (please specify): _____	☐	☐

25. How would you rate each of the following **during the past 4 weeks**?
(Choose one response on each line)

		Very poor to none	Poor	Fair	Good	Very good
a.	Your ability to have an erection (getting hard for sex)?	☐	☐	☐	☐	☐
b.	Your ability to reach orgasm (climax)?	☐	☐	☐	☐	☐

26. How would you describe the usual QUALITY of your erections (getting hard for sex) **during the past 4 weeks**?
(Choose one)

☐ None at all
☐ Not firm enough for any sexual activity
☐ Firm enough for masturbation and foreplay only
☐ Firm enough for intercourse

27. How would you describe the FREQUENCY of your erections (getting hard for sex) **during the past 4 weeks**?
(Choose one)

☐ I NEVER had an erection when I wanted one
☐ I had an erection LESS THAN HALF the time I wanted one
☐ I had an erection ABOUT HALF the time I wanted one
☐ I had an erection MORE THAN HALF the time I wanted one
☐ I had an erection WHENEVER I wanted one

28. Overall, how would you rate your ability to function sexually **during the past 4 weeks**? *(Choose one)*

☐ Very poor
☐ Poor
☐ Fair
☐ Good
☐ Very good

29. Overall, how big a problem was your sexual function, or lack of sexual function, for you **during the past 4 weeks**? *(Choose one)*

☐ No problem
☐ Very small problem
☐ Small problem
☐ Moderate problem
☐ Big problem

30. How often have you been able to ejaculate or "cum" when having sexual activity?

☐ All the time
☐ Most of the time
☐ About half the time
☐ Less than half the time
☐ None of the time / could not ejaculate

31. How would you rate the strength or force of your ejaculation?

☐ As strong as it always was
☐ A little less strong than it used to be
☐ Somewhat less strong than it used to be
☐ Much less strong than it used to be
☐ Very much less strong than it used to be
☐ Could not ejaculate

32. How would you rate the amount or volume of semen or fluid when you ejaculate?

☐ As much as it always was
☐ A little less than it used to be
☐ Somewhat less than it used to be
☐ Much less than it used to be
☐ Very much less than it used to be
☐ Could not ejaculate

33. If you have had any ejaculation difficulties or have been unable to ejaculate, have you been bothered by this?

☐ No problem with ejaculation
☐ Not at all bothered
☐ A little bothered
☐ Moderately bothered
☐ Very bothered
☐ Extremely bothered

34. How big a problem **during the past 4 weeks** was each of the following for you? *(Choose one response on each line)*

	No problem	Very small problem	Small problem	Moderate problem	Big problem
a. Feeling depressed	☐	☐	☐	☐	☐
b. Lack of energy	☐	☐	☐	☐	☐
c. Change in body weight	☐	☐	☐	☐	☐

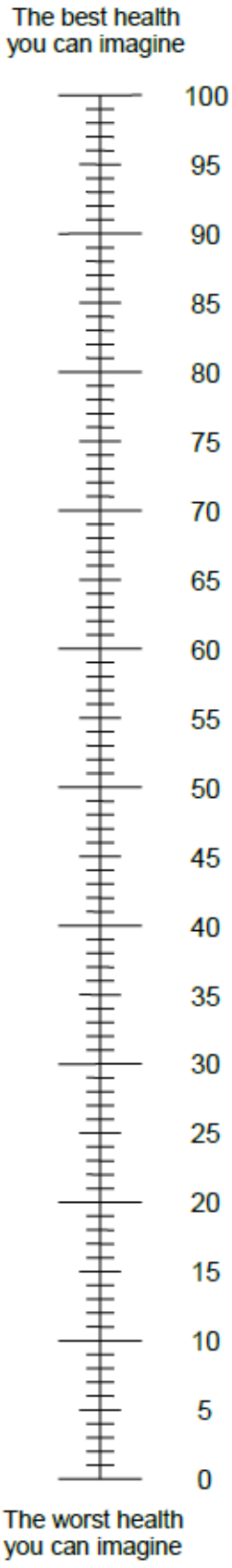
For the next set of questions, indicate which best describes your health <u>TODAY</u>.

35. Mark an **X** on the scale to indicate how your health is **<u>today</u>**.

    This scale is numbered from 0 to 100.

    100 means the <u>best</u> health you can imagine.

    0 means the <u>worst</u> health you can imagine.



    Please write the number you marked on the scale in the box:

36. Mobility:
    - ☐ I have no problems walking
    - ☐ I have slight problems walking
    - ☐ I have moderate problems walking
    - ☐ I have severe problems walking
    - ☐ I am unable to walk

37. Self-care:
    - ☐ I have no problems washing or dressing myself
    - ☐ I have slight problems washing or dressing myself
    - ☐ I have moderate problems washing or dressing myself
    - ☐ I have severe problems washing or dressing myself
    - ☐ I am unable to wash or dress myself

38. Usual activities
    (e.g. work, study, housework, family or leisure activities):
    - ☐ I have no problems doing my usual activities
    - ☐ I have slight problems doing my usual activities
    - ☐ I have moderate problems doing my usual activities
    - ☐ I have severe problems doing my usual activities
    - ☐ I am unable to do my usual activities

39. Pain / Discomfort:
    - ☐ I have no pain or discomfort
    - ☐ I have slight pain or discomfort
    - ☐ I have moderate pain or discomfort
    - ☐ I have severe pain or discomfort
    - ☐ I have extreme pain or discomfort

40. Anxiety / Depression
    - ☐ I am not anxious or depressed
    - ☐ I am slightly anxious or depressed
    - ☐ I am moderately anxious or depressed
    - ☐ I am severely anxious or depressed
    - ☐ I am extremely anxious or depressed

Views Surrounding Impact of Prostate Cancer and Treatment Decision

41. **During the past four weeks**, how much of the time have you wished that you could change your mind about the kind of treatment you chose for your prostate cancer?
    - ☐ All of the time
    - ☐ Most of the time
    - ☐ A good bit of the time
    - ☐ Some of the time
    - ☐ A little bit of the time
    - ☐ None of the time

42. How true or false has the following statement been for you **during the past four weeks**:
    I feel that I would be better off if I had chosen the other treatment for prostate cancer.
    - ☐ Definitely true
    - ☐ Mostly true
    - ☐ Neither true nor false
    - ☐ Mostly false
    - ☐ Definitely false

43. How true or false has the following statement been for you **during the past four weeks**:
    It bothers me that other men with prostate cancer get treatment that is very different from what I have received.
    - ☐ Definitely true
    - ☐ Mostly true
    - ☐ Neither true nor false
    - ☐ Mostly false
    - ☐ Definitely false

44. Listed below are a number of statements concerning a person's beliefs about their own health. **During the past week**, please indicate how much you agree or disagree with each statement.

		Strongly agree	Agree	Disagree	Strongly Disagree
a.	Because cancer is unpredictable, I feel I cannot plan for the future.	☐	☐	☐	☐
b.	My fear of having my cancer getting worse gets in the way of enjoying life.	☐	☐	☐	☐
c.	I am afraid of my cancer getting worse.	☐	☐	☐	☐
d.	I am more nervous since I was diagnosed with prostate cancer.	☐	☐	☐	☐

45. **Outlook:** How true is each of the following statements for you? (*Choose one response on each line)*

		Not at all	A little bit	Somewhat	Quite a bit	Very much
a.	I feel that my cancer has given me a better outlook on life.	☐	☐	☐	☐	☐
b.	I feel that coping with cancer has made me a stronger person.	☐	☐	☐	☐	☐

46. Are there any other issues or concerns about your prostate cancer or your treatment that you would like to mention?

_____

_____

Thank you very much for completing this survey. Please return in one of the enclosed postage paid envelopes or mail to address on front of survey.

Please also review and complete the HIPAA form if you agree to provide authorization for us to review your medical records regarding your prostate cancer and treatment.

Second Follow Up Survey

General Questions

1. Today's date: __ __ / __ __ / 2 0 __ __
   M M D D Y Y Y Y

2. What was your last PSA value? (approximate value): _____. _____**ng/ml**

   ☐ Don't know

3. When was the date of your last PSA? (approximate date): _____/ _____
   Month Year

   ☐ Don't know

4. **PSA:** How true has each of the following statements been for you during the **past 4 weeks**?
   Choose one response on each line.

	Not at all	A little bit	Somewhat	Quite a bit	Very much
a. I keep close track of my PSA	☐	☐	☐	☐	☐
b. Knowing my PSA level is comforting to me	☐	☐	☐	☐	☐
c. I live in fear that my PSA will rise	☐	☐	☐	☐	☐

5. Since your initial treatment for prostate cancer, did your doctor ever tell you that your prostate cancer came back (recurred) or progressed (got worse)?
   ☐ Yes
   ☐ No

6. Since you were diagnosed with prostate cancer, has a doctor ever told you that your prostate cancer had spread to other areas of your body?
   ☐ Yes
   ☐ No

7. These next questions are about the treatments for prostate cancer **that you have received up to the present time (even if you have told us about them before).**
   For each of the following types of treatment, please check the one(s) you have received and indicate the date you received it (or started it):

Type of Treatment	I have received this treatment	Date received or started
Active Surveillance (My doctor will monitor how I am doing without directly treating the cancer)	☐	__ __ / __ __ / __ ___ M M D D Y Y
Prostate surgery (**radical prostatectomy**), which would remove the whole prostate.	☐	__ __ / __ __ / __ ___ M M D D Y Y

HIFU / High Intensity Focused Ultrasound (ultrasound waves cross tissue to destroy the **part** of the prostate that had cancer)	☐	__ __ / __ __ / __ ___ M M D D Y Y
Cryotherapy (freezing the **part** of the prostate that had cancer)	☐	__ __ / __ __ / __ ___ M M D D Y Y
Laser therapy	☐	__ __ / __ __ / __ ___ M M D D Y Y
Radio Frequency Ablation	☐	__ __ / __ __ / __ ___ M M D D Y Y
Photodynamic therapy	☐	__ __ / __ __ / __ ___ M M D D Y Y
External Beam Radiation Therapy or IMRT (radiation treatment requiring more than 2 weeks of treatment)	☐	__ __ / __ __ / __ ___ M M D D Y Y
Stereotactic Body Radiation Therapy (SBRT) (radiation treatment requiring less than 2 weeks of treatment)	☐	__ __ / __ __ / __ ___ M M D D Y Y
Brachytherapy (radioactive seeds) This involves having radioactive seeds placed within the prostate	☐	__ __ / __ __ / __ ___ M M D D Y Y
Proton Beam Therapy	☐	__ __ / __ __ / __ ___ M M D D Y Y
Any other type of radiation therapy? Describe:_____	☐	__ __ / __ __ / __ ___ M M D D Y Y
Hormonal treatments to lower testosterone (e.g. Lupron, Zoladex, Firmagon, Eligard, Vantas, etc)	☐	__ __ / __ __ / __ ___ M M D D Y Y
Surgical removal of testicles (Orchiectomy)	☐	__ __ / __ __ / __ ___ M M D D Y Y
Chemotherapy (docetaxel, cabazitaxel, other)	☐	__ __ / __ __ / __ ___ M M D D Y Y

8. How did you make your treatment decision?
   - ☐ I made the decision alone
   - ☐ I made the decision together with a family member or friend
   - ☐ I made the decision together with my doctor, nurse, or health practitioner
   - ☐ I made the decision together with a family member or friend and my doctor, nurse, or health practitioner
   - ☐ My doctor, nurse, or health practitioner made the decision
   - ☐ I don't know or remember how the decision was made

9. What were the most important factors you considered in making your treatment decision? *(Check all that apply)*
   - ☐ Best chance for cure of my cancer
   - ☐ Minimize side effects related to sexual function
   - ☐ Minimize side effects related to urinary function
   - ☐ Minimize side effects related to bowel function
   - ☐ Minimize financial cost
   - ☐ Amount of time and travel required to receive treatments
   - ☐ Length of recovery time
   - ☐ Amount of time away from work
   - ☐ Burden on family members
   - ☐ Reduction of worry and concern about cancer

10. Have you been hospitalized for complications from your prostate cancer treatment or for any other problems after receiving prostate cancer treatment?
    - ☐ Yes
      - a. What was the reason for the hospitalization?
        _____
      - b. How many days did you spend in the hospital? ___ ___
    - ☐ No

11. Did you experience any (other) complication or unexpected outcome within 3 months after your prostate cancer treatment?

    ☐ Yes: If yes, please describe: _____

    ☐ No

Current Health

12. In general, would you say your health is:
    - ☐ Excellent
    - ☐ Very good
    - ☐ Good
    - ☐ Fair
    - ☐ Poor
    - ☐ Very poor

For the next set of questions, indicate which best describes your health <u>TODAY</u>.

13. Mobility:
    - ☐ I have no problems walking
    - ☐ I have slight problems walking
    - ☐ I have moderate problems walking
    - ☐ I have severe problems walking
    - ☐ I am unable to walk

14. Self-care:
    - ☐ I have no problems washing or dressing myself
    - ☐ I have slight problems washing or dressing myself
    - ☐ I have moderate problems washing or dressing myself
    - ☐ I have severe problems washing or dressing myself
    - ☐ I am unable to wash or dress myself

15. Usual activities
    (e.g. work, study, housework, family or leisure activities):
    - ☐ I have no problems doing my usual activities
    - ☐ I have slight problems doing my usual activities
    - ☐ I have moderate problems doing my usual activities
    - ☐ I have severe problems doing my usual activities
    - ☐ I am unable to do my usual activities

16. Pain / Discomfort:
    - ☐ I have no pain or discomfort
    - ☐ I have slight pain or discomfort
    - ☐ I have moderate pain or discomfort
    - ☐ I have severe pain or discomfort
    - ☐ I have extreme pain or discomfort

17. Anxiety / Depression
    - ☐ I am not anxious or depressed
    - ☐ I am slightly anxious or depressed
    - ☐ I am moderately anxious or depressed
    - ☐ I am severely anxious or depressed
    - ☐ I am extremely anxious or depressed

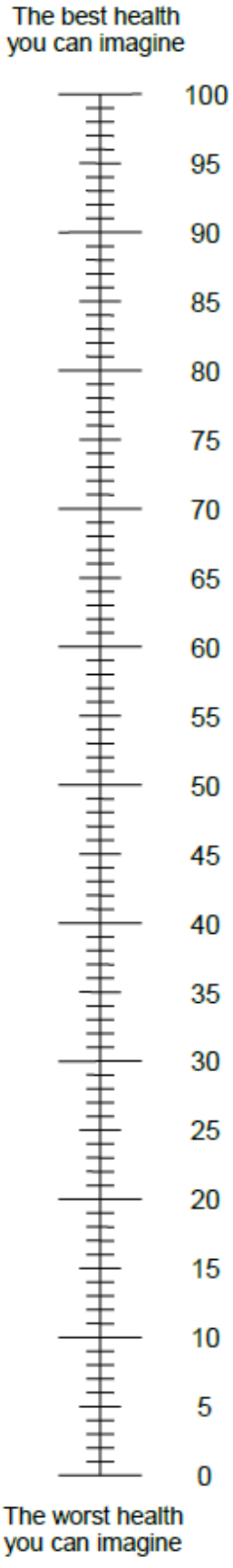
18. Mark an **X** on the scale to indicate how your health is **today**.

    This scale is numbered from 0 to 100.

    100 means the <u>best</u> health you can imagine.

    0 means the <u>worst</u> health you can imagine.

    Please write the number you marked on the scale in the box.



For the next set of questions, please think about your experience during the past 4 weeks.

Urinary Issues

19. **In the past 4 weeks** how often did you leak urine (pee)? *(Choose one)*

☐ More than once a day
☐ About once a day
☐ More than once a week
☐ About once a week
☐ Rarely or never

20. Which of the following best describes your urinary control (ability to hold pee) **during the past 4 weeks**? *(Choose one)*

☐ No urinary control whatsoever
☐ Frequent dribbling
☐ Occasional dribbling
☐ Total control

21. How many pads or adult diapers did you usually use per day to control urine (pee) leakage **during the past 4 weeks**? *(Choose one)*

☐ None
☐ 1 pad per day
☐ 2 pads per day
☐ 3 or more pads per day

22. How big a problem, if any, was each of the following **during the past 4 weeks**? *(Choose one for each item)*

		No problem	Very small problem	Small problem	Moderate problem	Big problem
a.	Dripping or leaking urine (pee)	☐	☐	☐	☐	☐
b.	Pain or burning on urination (when peeing)	☐	☐	☐	☐	☐
c.	Bleeding with urination (when peeing)	☐	☐	☐	☐	☐
d.	Weak urine stream (pee) or incomplete emptying	☐	☐	☐	☐	☐
e.	Need to urinate (pee) frequently during the day	☐	☐	☐	☐	☐

23. Overall, how big a problem was your urinary function (ability to pee) for you **during the past 4 weeks**? *(Choose one)*

☐ No problem
☐ Very small problem
☐ Small problem
☐ Moderate problem
☐ Big problem

Bowel Issues

24. How big a problem, if any, was each of the following **during the past 4 weeks**? *(Choose one response on each line)*

		No problem	Very small problem	Small problem	Moderate problem	Big problem
a.	Urgency to have a bowel movement (poop)	☐	☐	☐	☐	☐
b.	Increased frequency of bowel movements (poop)	☐	☐	☐	☐	☐

c.	Losing control of your stools (poop)	☐	☐	☐	☐	☐
d.	Bloody stools (blood with poop)	☐	☐	☐	☐	☐
e.	Abdominal/pelvic/rectal pain	☐	☐	☐	☐	☐

25. Overall, how big a problem were your bowel habits (ability to poop) **during the past 4 weeks**? *(Choose one)*

☐ No problem
☐ Very small problem
☐ Small problem
☐ Moderate problem
☐ Big problem

Sexual Issues

26. Do you currently use any of the following to help with problems with sexual function? (Choose one response on each line)

		Yes	No
a.	Vacuum suction device	☐	☐
b.	Penile injections (shots)	☐	☐
c.	Urethral pellets or suppositories (Muse)	☐	☐
d.	Penile prosthesis (surgical implant)	☐	☐
e.	Other (please specify): _____	☐	☐

27. How would you rate each of the following **during the past 4 weeks**?
(Choose one response on each line)

		Very poor to none	Poor	Fair	Good	Very good
a.	Your ability to have an erection (getting hard for sex)?	☐	☐	☐	☐	☐
b.	Your ability to reach orgasm (climax)?	☐	☐	☐	☐	☐

28. How would you describe the usual QUALITY of your erections (getting hard for sex) **during the past 4 weeks**?
(Choose one)
☐ None at all
☐ Not firm enough for any sexual activity
☐ Firm enough for masturbation and foreplay only
☐ Firm enough for intercourse

29. How would you describe the FREQUENCY of your erections (getting hard for sex) **during the past 4 weeks**?
(Choose one)

☐ I NEVER had an erection when I wanted one
☐ I had an erection LESS THAN HALF the time I wanted one
☐ I had an erection ABOUT HALF the time I wanted one
☐ I had an erection MORE THAN HALF the time I wanted one
☐ I had an erection WHENEVER I wanted one

30. Overall, how would you rate your ability to function sexually **during the past 4 weeks**? *(Choose one)*
☐ Very poor
☐ Poor
☐ Fair
☐ Good
☐ Very good

31. Overall, how big a problem was your sexual function, or lack of sexual function, for you **during the past 4 weeks**? *(Choose one)*
☐ No problem
☐ Very small problem
☐ Small problem
☐ Moderate problem
☐ Big problem

32. How often have you been able to ejaculate or "cum" when having sexual activity?
☐ All the time
☐ Most of the time
☐ About half the time
☐ Less than half the time
☐ None of the time / could not ejaculate

33. How would you rate the strength or force of your ejaculation?
☐ As strong as it always was
☐ A little less strong than it used to be
☐ Somewhat less strong than it used to be
☐ Much less strong than it used to be
☐ Very much less strong than it used to be
☐ Could not ejaculate

34. How would you rate the amount or volume of semen or fluid when you ejaculate?
☐ As much as it always was
☐ A little less than it used to be
☐ Somewhat less than it used to be
☐ Much less than it used to be
☐ Very much less than it used to be
☐ Could not ejaculate

35. If you have had any ejaculation difficulties or have been unable to ejaculate, have you been bothered by this?

☐ No problem with ejaculation
☐ Not at all bothered
☐ A little bothered
☐ Moderately bothered
☐ Very bothered
☐ Extremely bothered

36. How big a problem **during the past 4 weeks** was each of the following for you? *(Choose one response on each line)*

	No problem	Very small problem	Small problem	Moderate problem	Big problem
a. Feeling depressed	☐	☐	☐	☐	☐
b. Lack of energy	☐	☐	☐	☐	☐
c. Change in body weight	☐	☐	☐	☐	☐

Views Surrounding Impact of Prostate Cancer and Treatment Decision

37. **During the past four weeks**, how much of the time have you wished that you could change your mind about the kind of treatment you chose for your prostate cancer?
☐ All of the time
☐ Most of the time
☐ A good bit of the time
☐ Some of the time
☐ A little bit of the time
☐ None of the time

38. How true or false has the following statement been for you **during the past four weeks**:
I feel that I would be better off if I had chosen the other treatment for prostate cancer.
☐ Definitely true
☐ Mostly true
☐ Neither true nor false
☐ Mostly false
☐ Definitely false

39. How true or false has the following statement been for you **during the past four weeks**:
It bothers me that other men with prostate cancer get treatment that is very different from what I have received.
☐ Definitely true
☐ Mostly true
☐ Neither true nor false
☐ Mostly false
☐ Definitely false

Concerns Surrounding Impact of Prostate Cancer
Below is a list of comments made by men about prostate cancer and prostate specific antigen (PSA) tests.

40. Please indicate how frequently these comments were true for you **during the past week**. *(Choose one for each item)*

		Not at all	Rarely	Sometimes	Often
a.	Any reference to prostate cancer brought up strong feelings in me.	☐	☐	☐	☐
b.	Even though it's a good idea, I found that getting a PSA test scared me.	☐	☐	☐	☐
c.	Whenever I heard about a friend or public figure with prostate cancer, I got more anxious about my having prostate cancer	☐	☐	☐	☐
d.	When I thought about having a PSA test, I got more anxious about my having prostate cancer.	☐	☐	☐	☐
e.	Other things kept making me think about prostate cancer.	☐	☐	☐	☐
f.	I felt kind of numb when I thought about prostate cancer.	☐	☐	☐	☐
g.	I thought about prostate cancer even though I didn't mean to.	☐	☐	☐	☐

h.	I had a lot of feelings about prostate cancer, but I didn't want to deal with them.	☐	☐	☐	☐
i.	I had more trouble falling asleep because I couldn't get thoughts of prostate cancer out of my mind.	☐	☐	☐	☐
j.	I was afraid that the results from my PSA test would show that my disease was getting worse.	☐	☐	☐	☐
k.	Just hearing the words "prostate cancer" scared me.	☐	☐	☐	☐

41. Please indicate how frequently these situations have **EVER** been true for you.

		Not at all	Rarely	Sometimes	Often
a.	I have been so anxious about my PSA test that I have thought about delaying it.	☐	☐	☐	☐
b.	I have been so worried about my PSA test result that I have thought about asking my doctor to repeat it.	☐	☐	☐	☐
c.	I have been so concerned about my PSA test result that I have thought about having the test repeated at another lab to make sure they were accurate.	☐	☐	☐	☐

42. Listed below are a number of statements concerning a person's beliefs about their own health. **During the past week**, please indicate how much you agree or disagree with each statement.

		Strongly agree	Agree	Disagree	Strongly Disagree
a.	Because cancer is unpredictable, I feel I cannot plan for the future.	☐	☐	☐	☐
b.	My fear of having my cancer getting worse gets in the way of enjoying life.	☐	☐	☐	☐
c.	I am afraid of my cancer getting worse.	☐	☐	☐	☐
d.	I am more nervous since I was diagnosed with prostate cancer.	☐	☐	☐	☐