HARVARD T.H. CHAN SCHOOL OF PUBLIC HEALTH

Health Professionals Follow-Up Study

Dear Colleague,

Thank you for your longstanding participation in the Health Professionals Follow-Up Study. As you know, we are studying the determinants of long-term survival from prostate cancer. Through this study, we are gaining valuable insight about how diet and other factors can improve prognosis. **Please note that we have all of your original diagnosis information. The purpose of this mailing, as we do every couple of years, is to obtain new follow-up information regarding your prostate cancer. Even if nothing has changed, that information is still important to our study.**

We would greatly appreciate it if you could complete the enclosed questionnaire regarding your prostate cancer and return it to us in the envelope provided. We realize this is a lengthy questionnaire; please fill out whatever you can. Your participation is completely voluntary, and if you do not wish to participate in this study on prostate cancer survival, you will still be a valuable member of the Health Professionals Follow-Up Study. By participating, you will be making a key contribution to our understanding of prostate cancer, which may ultimately lead to strategies geared at prevention or cure. Please do not hesitate to call me or Dr. Lorelei Mucci at 617-432-1732 if you have any questions about the study.

Sincerely Yours,

Walter C. Willett, M.D.
Principal Investigator

Lorelei Mucci, ScD.
Co-Principal Investigator

PLEASE USE AN ORDINARY NO. 2 PENCIL TO ANSWER ALL QUESTIONS.

Fill in the appropriate response circles completely, or write the requested information in the boxes provided. The form is designed to be read by optical-scanning equipment, so it is important that you make NO STRAY MARKS and keep any write-in responses within the spaces provided. Should you need to change a response, erase the incorrect mark completely. If you have comments, please write them on a separate piece of paper.

Please fill in the circles completely; do not mark this way: ✓ ✗ ◒

4c. Mark all of the treatments you have had SINCE JANUARY 2016 and provide the dates as best as you can (if you cannot remember the month, include just the year).

Treatment/medication since January 2016 only	Start date or procedure date	End date or...	...Currently doing/taking?
Procedures	month/year	month/year	
1. ● Radical prostatectomy	01/201[illegible]	N/A	
→ If radical prostatectomy, which type?		N/A	
○ laparoscopic		N/A	
● robotic		N/A	
○ open / retropubic	N/A	N/A	
○ open / perineal	N/A	N/A	
○ don't know type	N/A	N/A	
2. ● Radiation to the pe[illegible]s (exter[illegible]am, proton beam, cyber[illegible]e, etc)	02/2016		●
3. ○ Brachytherapy/seeds		N/A	○
4. ○ Orchiectomy		N/A	○
5. ○ Cryosurgery/cryoablation		N/A	○
6. ○ High intensity focused ultrasound (HIFU)		N/A	○

EXAMPLE

The research team has great respect for your continued study participation, and therefore would like to remind you of several important points, as is standard practice in research. We do so in recognition of the fact that consent is an ongoing process rather than a one-time agreement. Please do not hesitate to contact us if you have any questions regarding this information.

a. You are participating in a research study that focuses on what happens to men after a cancer diagnosis. Participation involves the completion of this questionnaire.
b. Your participation is voluntary. Refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled.
c. There is a small risk of breach of confidentiality; however we have taken many steps to minimize this risk, and in the 32 years of the study have never had a breach.
d. Samples are sometimes shared with entities outside of Harvard as part of research collaborations; in such cases we use a separate ID number to ensure confidentiality.
e. You will not receive monetary compensation for participating.
f. There are no direct benefits to you from study participation.
g. If you wish to speak with someone not directly involved in this research study about your rights as a research participant, please contact the Harvard School of Public Health's Office for Human Research Administration at 617-432-2143 (local calls) or 866-606-0573 (long distance calls), or at: ohra@hsph.harvard.edu.
h. If you have any questions regarding the study itself, please call the study Research Assistant at 617-384-8664.

THANK YOU FOR PREVIOUSLY PROVIDING VALUABLE INFORMATION RELATED TO YOUR PROSTATE CANCER.
PLEASE NOTE THAT WE HAVE ALL OF YOUR ORIGINAL DIAGNOSIS INFORMATION.
WE NOW SEEK TO UPDATE YOUR INFORMATION.

1. Have you had a recurrence or progression of your prostate cancer since January 2016, indicated by a rise in PSA?

- ○ No – what is your highest PSA value since Jan 2016? _____ Continue to question 2
- ○ Yes – please complete question 1b:

1b. When did your PSA rise occur? _____ / _____ (Month / Year) **What was your highest PSA value ever?** _____

2. Have you ever been diagnosed with prostate cancer metastases to lymph nodes, bone, or other organs?

- ○ No – continue to question 3
- ○ Yes – found *at* diagnosis (continue to question 3)
- ○ Yes – found *after* diagnosis (please complete the box below)

2a. At which site(s) were you diagnosed with metastases? Please mark all that apply.

- ○ Lymph nodes ..... Date diagnosed: _____ / _____ (Month / Year)
- ○ Bone ..... Date diagnosed: _____ / _____ (Month / Year)
- ○ Other organs, specify: _____ Date diagnosed: _____ / _____ (Month / Year)

2b. How were your metastases verified? Please mark all that apply.

- ○ Imaging (bone scan, CT, MRI)
- ○ Metastatic biopsy
- ○ Other, specify: _____

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3. Have you ever been told by your physician that you have castration-resistant prostate cancer?

- ○ Yes
  If yes, what date? _____ / _____ (Month / Year)
- ○ No

4. Please read the *entire* list on the following page of medications and treatments for prostate cancer and prostate cancer symptoms.

4a. Have you had any treatment or medications for your prostate cancer since January 2016?

- ○ No – continue to question 4b
- ○ Yes – continue to question 4c

4b. Have you ever had any treatment for your prostate cancer?

- ○ Yes
- ○ No
- ○ Active surveillance / watchful waiting only

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4c. Mark all of the treatments you have had SINCE JANUARY 2016 and provide the dates as best as you can (if you cannot remember the month, include just the year).

Treatment/medication since January 2016 only	Start date or procedure date	End date or...	...Currently doing/taking?
Procedures	month/year	month/year	
1. ◯ Radical prostatectomy		N/A	
→ If radical prostatectomy, which type?	N/A	N/A	
◯ laparoscopic	N/A	N/A	
◯ robotic	N/A	N/A	
◯ open / retropubic	N/A	N/A	
◯ open / perineal	N/A	N/A	
◯ don't know type	N/A	N/A	
2. ◯ Radiation to the pelvis (external beam, proton beam, cyberknife, etc.)			◯
3. ◯ Brachytherapy/seeds		N/A	◯
4. ◯ Orchiectomy		N/A	◯
5. ◯ Cryosurgery/cryoablation		N/A	◯
6. ◯ High intensity focused ultrasound (HIFU)		N/A	◯
Oral medications	month/year	month/year	
7. ◯ Casodex (bicalutamide), Eulexin (flutamide)			◯
8. ◯ Estrogens and DES			◯
9. ◯ Nilandron (nilutamide)			◯
10. ◯ Zytiga (abiraterone)			◯
11. ◯ Xtandi (enzalutamide)			◯
12. ◯ Lynparza (olaparib)			◯
13. ◯ Erleada (apalutamide)			◯
Injections/implants/infusions	month/year	month/year	
14. ◯ Lupron/Eligard/Viadur (leuprolide)			◯
15. ◯ Zoladex (goserelin)			◯
16. ◯ Trelstar (triptorelin)			◯
17. ◯ Plenaxis (abarelix)			◯
18. ◯ Firmagon (degarelix)			◯
19. ◯ Vantas (histrelin)			◯
20. ◯ Zometa (zoledronic acid)			◯
21. ◯ Xgeva (denosumab)			◯
22. ◯ Jevtana (cabazitaxel)			◯
23. ◯ Taxotere (docetaxel)			◯
24. ◯ Provenge (sipuleucel-T)			◯
25. ◯ Xofigo (Radium-223)			◯
26. ◯ OTHER, specify: ______________			◯
Prostate symptom control	month/year	month/year	
27. ◯ Proscar (finasteride)			◯
28. ◯ Avodart (dutasteride)			◯
29. ◯ Flomax (tamsulosin)			◯

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Treatment Code: 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31 32

Start month/year: 1 2 3 4 5 6 7 8 9 10 11 12 Before 2016 2016 2017 2018 2019

End month/year: 1 2 3 4 5 6 7 8 9 10 11 12 2016 2017 2018 2019

Treatment Code: 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31 32

Start month/year: 1 2 3 4 5 6 7 8 9 10 11 12 Before 2016 2016 2017 2018 2019

End month/year: 1 2 3 4 5 6 7 8 9 10 11 12 2016 2017 2018 2019

Treatment Code: 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31 32

Start month/year: 1 2 3 4 5 6 7 8 9 10 11 12 Before 2016 2016 2017 2018 2019

End month/year: 1 2 3 4 5 6 7 8 9 10 11 12 2016 2017 2018 2019

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Please answer the following questions by darkening the appropriate circle. All questions are about your health and symptoms in the LAST MONTH. Select one answer for each question.

5. Overall, how much of a problem has your urinary function been for you?

○ No problem ○ Very small problem ○ Small problem ○ Moderate problem ○ Big problem

6. Which of the following best describes your urinary control?

○ Total control ○ Occasional dribbling ○ Frequent dribbling ○ No urinary control

7. How many pads or adult diapers per day have you been using for urinary leakage?

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

8. How large a problem, if any, has each of the following been for you?

	No problem	Very small problem	Small problem	Moderate problem	Big problem
a. Pain or burning with urination	○	○	○	○	○
b. Need to urinate frequently	○	○	○	○	○
c. Weak urine stream/incomplete bladder emptying	○	○	○	○	○
d. Urinary dripping or leakage	○	○	○	○	○

9. How large a problem, if any, has each of the following been for you?

	No problem	Very small problem	Small problem	Moderate problem	Big problem
a. Rectal pain or urgency of bowel movements	○	○	○	○	○
b. Increased frequency of your bowel movements	○	○	○	○	○
c. Overall problems with your bowel habits	○	○	○	○	○

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10. How large a problem, if any, has each of the following been for you in the past 4 weeks?

	No problem	Very small problem	Small problem	Moderate problem	Big problem
a. Hot flashes or breast tenderness/enlargement	○	○	○	○	○
b. Feeling depressed	○	○	○	○	○
c. Lack of energy	○	○	○	○	○

11. During the past month have you had any pain?

○ None ○ Mild ○ Moderate ○ Severe

12. During the past month have you had any bone pain?

○ None ○ Mild ○ Moderate ○ Severe

13. During the past month, how often did you worry?

○ Most of the time ○ Sometimes ○ Rarely ○ Never

14. During the past month, how often did you feel tense?

○ Most of the time ○ Sometimes ○ Rarely ○ Never

15. How would you rate your ability to reach orgasm (climax)?

○ Very good ○ Good ○ Fair ○ Poor ○ Very poor to none

16. How would you describe the usual quality of your erections?

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

17. Overall, how large a problem has your sexual function or lack of sexual function been for you?

○ No problem ○ Very small problem ○ Small problem ○ Moderate problem ○ Big problem

18. Which erectile dysfunction medications have you used since January 2016?

NAME OF MEDICATION/TREATMENT	STARTED COURSE BEFORE 2016	2016	2017	2018	2019	CURRENTLY TAKING
○ None						
○ Viagra, Levitra, Cialis	○	○	○	○	○	○
○ Intraurethral/penile injectable medications; Vacuum devices; penile prosthesis	○	○	○	○	○	○
○ Testosterone replacement therapy	○	○	○	○	○	○

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The next questions ask you about your sleep habits. Please choose one of the answers for each of the following questions. Pick the answer that best describes how often you experienced the situation in the past 4 weeks?

	No, not in the past 4 weeks	Yes, less than once a week	Yes, 1 or 2 times a week	Yes, 3 or 4 times a week	Yes, 5 or more times a week
19. Do you have trouble falling asleep?	○	○	○	○	○
20. Did you wake up several times at night?	○	○	○	○	○
21. Did you wake up earlier than you planned to? *(If no, skip to question 23)*	○	○	○	○	○
22. Did you have trouble getting back to sleep after you woke up too early?	○	○	○	○	○

23. Overall, how would you describe your typical night's sleep during the past 4 weeks?

○ Very sound or restful ○ Sound and restful ○ Average quality ○ Restless ○ Very restless

24. To what extent do you consider your sleep pattern to interfere with your daily functioning (e.g., daytime fatigue, mood, ability to function at work/daily chores, concentration, memory, mood, etc.) currently?

○ Not interfering ○ Mild ○ Moderate ○ Severe ○ Very interfering

25. Since 2016, have you been told by a doctor or other health professional that you have obstructive sleep apnea?

○ Yes ○ No (if no, continue to question 27)

26. Are you currently receiving treatment for sleep apnea (e.g., CPAP machine, dental device, throat/uvula surgery)?

○ Yes ○ No

27. Do you have difficulty climbing a flight of stairs or walking eight blocks due to physical impairment?

○ Yes ○ No

28. What is your usual walking pace outdoors?

○ Unable to walk eight blocks

○ Easy, casual (less than 2 mph) ○ Normal, average (2–2.9 mph) ○ Brisk pace (3–3.9 mph) ○ Very brisk/striding (4 mph or faster)

29. How many flights of stairs (not steps) do you climb daily? (Do not include time spent on stair or exercise machines.)

○ No flights ○ 1–2 flights ○ 3–4 flights ○ 5–9 flights ○ 10–14 flights ○ 15 or more flights

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30. DURING THE PAST YEAR, what was your average time PER WEEK spent at each of the following recreational activities?

	Zero	1–4 Min.	5–19 Min.	20–59 Min.	One Hour	1–1.5 Hrs.	2–3 Hrs.	4–6 Hrs.	7–10 Hrs.	11+ Hrs.
Walking for exercise or walking for transportation or errands	○	○	○	○	○	○	○	○	○	○
Jogging (slower than 10 minutes/mile)	○	○	○	○	○	○	○	○	○	○
Running (10 minutes/mile or faster)	○	○	○	○	○	○	○	○	○	○
Bicycling: **stationary exercise bike** Intensity: ○ Low ○ Medium ○ High	○	○	○	○	○	○	○	○	○	○
Bicycling: **outside, separated from traffic (e.g., bike path)** Intensity: ○ Low ○ Medium ○ High	○	○	○	○	○	○	○	○	○	○
Bicycling: **outside on road** Intensity: ○ Low ○ Medium ○ High	○	○	○	○	○	○	○	○	○	○
Tennis, squash, or racquetball Racquet sport intensity: ○ Low ○ Medium ○ High	○	○	○	○	○	○	○	○	○	○
Lap swimming Swimming intensity: ○ Low ○ Medium ○ High	○	○	○	○	○	○	○	○	○	○
Other aerobic exercise (aerobic dance, ski or stair machine, etc.)	○	○	○	○	○	○	○	○	○	○
Lower intensity exercise (yoga, stretching, toning)	○	○	○	○	○	○	○	○	○	○
Other vigorous activities (e.g., lawn mowing)	○	○	○	○	○	○	○	○	○	○
Weight training or resistance exercises (including free weights or resistance machines) — Arm Weights	○	○	○	○	○	○	○	○	○	○
Weight training or resistance exercises (including free weights or resistance machines) — Leg Weights	○	○	○	○	○	○	○	○	○	○

31. DURING THE PAST YEAR, on average, how many HOURS PER WEEK did you spend:

	Zero	One Hour	2–5 Hrs.	6–10 Hrs.	11–20 Hrs.	21–40 Hrs.	41–60 Hrs.	61–90 Hrs.	Over 90 Hrs.
Standing or walking around at work or away from home?	○	○	○	○	○	○	○	○	○
Standing or walking around at home?	○	○	○	○	○	○	○	○	○
Sitting at work or away from home or while driving?	○	○	○	○	○	○	○	○	○
Sitting at home while watching TV/DVD/movies?	○	○	○	○	○	○	○	○	○
Other sitting at home (e.g., reading, meal times, at desk)?	○	○	○	○	○	○	○	○	○

32. Do you own any of the following animals? (Mark all that apply)

○ Dog ○ Cat ○ Rabbit ○ Parrot ○ Other bird ○ Reptile ○ Horse ○ Farm animals ○ Other animal

Thank you for your participation!

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