



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 617-998-1067 if you have any questions about the study.

Sincerely Yours,

Walter Willett

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 2018 and provide the dates as best as you can (if you cannot remember the month, include just the year).

Treatment/medication since January 2018 only	Start date or procedure date	End date or...	...Currently doing/taking?
Procedures	month/year	month/year	
1. <input checked="" type="radio"/> Radical prostatectomy	01/2018	N/A	
<input type="checkbox"/> If radical prostatectomy, which type?		N/A	
<input type="checkbox"/> laparoscopic		N/A	
<input checked="" type="radio"/> robotic		N/A	
<input type="checkbox"/> open / retropubic		N/A	
<input type="checkbox"/> open / perineal		N/A	
<input type="checkbox"/> don't know type		N/A	
2. <input checked="" type="radio"/> Radiation to the pelvis (external beam, proton beam, cyberknife, etc.)	02/2018		<input checked="" type="radio"/>
3. <input type="checkbox"/> Brachytherapy/seeds		N/A	<input type="radio"/>
4. <input type="checkbox"/> Orchiectomy		N/A	<input type="radio"/>
5. <input type="checkbox"/> Cryosurgery/cryoablation		N/A	<input type="radio"/>
6. <input type="checkbox"/> High intensity focused ultrasound (HIFU)		N/A	<input type="radio"/>

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 34 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 TH Chan 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. Since January 2018, have you had a recurrence or progression of your prostate cancer indicated by a rise in PSA?

- No - what is your highest PSA value since Jan 2018? Continue to question 2
Yes - please complete question 1b:

1b. When did your PSA rise occur? What was your highest PSA value during this rise?

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)

FOR OFFICE USE ONLY

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

- Lymph nodes Date diagnosed:
Bone Date diagnosed:
Other organs, specify: Date diagnosed:

Grid for marking metastasis sites and dates, including columns for 'Before 2018', '2018', '2019', '2020', and '2021'.

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

- Imaging (bone scan, CT, MRI, PSMA scan, PET)
Metastatic biopsy
Other, specify:

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

- Yes
If yes, what date?
No

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

4a. Since January 2018, have you had any treatment or medications for your prostate cancer?

- 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

Grid for marking treatment types and dates, including columns for '2020', '2021', and '2022'.

PLEASE TURN PAGE OVER

4c. Mark all of the treatments you have had SINCE JANUARY 2018 and provide the dates as best as you can (if you cannot remember the month, include just the year).

Treatment/medication since January 2018 only	Start date or procedure date	End date or...	...Currently doing/taking?	FOR OFFICE USE ONLY Treatment Code:
				1 2 3 4 5 6 7 8 9 T 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31 32 33 34 35
Procedures	month/year	month/year		
1. <input type="radio"/> Radical prostatectomy		N/A		
➔ If radical prostatectomy, which type?	N/A	N/A		Start month/year:
<input type="radio"/> laparoscopic	N/A	N/A		1 2 3 4 Before 2018 M
<input type="radio"/> robotic	N/A	N/A		5 6 7 8 2018 2019 Y
<input type="radio"/> open / retropubic	N/A	N/A		9 10 11 12 2020 2021
<input type="radio"/> open / perineal	N/A	N/A		End month/year:
<input type="radio"/> don't know type	N/A	N/A		1 2 3 4 2018 2019 M
2. <input type="radio"/> Radiation to the pelvis (external beam, proton beam, cyberknife, etc.)			<input type="radio"/>	5 6 7 8 2020 2021 Y
3. <input type="radio"/> Brachytherapy/seeds		N/A	<input type="radio"/>	9 10 11 12
4. <input type="radio"/> Orchiectomy		N/A	<input type="radio"/>	Treatment Code:
5. <input type="radio"/> Cryosurgery/cryoablation		N/A	<input type="radio"/>	1 2 3 4 5 6 7 8 9 T
6. <input type="radio"/> High intensity focused ultrasound (HIFU)		N/A	<input type="radio"/>	10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31 32 33 34 35
Oral medications	month/year	month/year		Start month/year:
7. <input type="radio"/> Casodex (bicalutamide), Eulexin (flutamide)			<input type="radio"/>	1 2 3 4 Before 2018 M
8. <input type="radio"/> Estrogens and DES			<input type="radio"/>	5 6 7 8 2018 2019 Y
9. <input type="radio"/> Nilandron (nilutamide)			<input type="radio"/>	9 10 11 12 2020 2021
10. <input type="radio"/> Zytiga (abiraterone)			<input type="radio"/>	End month/year:
11. <input type="radio"/> Xtandi (enzalutamide)			<input type="radio"/>	1 2 3 4 2018 2019 M
12. <input type="radio"/> Lynparza (olaparib)			<input type="radio"/>	5 6 7 8 2020 2021 Y
13. <input type="radio"/> Erleada (apalutamide)			<input type="radio"/>	9 10 11 12
14. <input type="radio"/> Nubeqa (darolutamide)			<input type="radio"/>	Treatment Code:
15. <input type="radio"/> Rubraca (rucaparib)			<input type="radio"/>	1 2 3 4 5 6 7 8 9 T
16. <input type="radio"/> Zejula (niraparib)			<input type="radio"/>	10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31 32 33 34 35
17. <input type="radio"/> Talzenna (talazoparib)			<input type="radio"/>	Start month/year:
Injections/implants/infusions	month/year	month/year		1 2 3 4 Before 2018 M
18. <input type="radio"/> Lupron/Eligard/Viadur (leuprolide)			<input type="radio"/>	5 6 7 8 2018 2019 Y
19. <input type="radio"/> Zoladex (goserelin)			<input type="radio"/>	9 10 11 12 2020 2021
20. <input type="radio"/> Trelstar (triptorelin)			<input type="radio"/>	End month/year:
21. <input type="radio"/> Plenaxis (abarelix)			<input type="radio"/>	1 2 3 4 2018 2019 M
22. <input type="radio"/> Firmagon (degarelix)			<input type="radio"/>	5 6 7 8 2020 2021 Y
23. <input type="radio"/> Vantas (histrelin)			<input type="radio"/>	9 10 11 12
24. <input type="radio"/> Zometa (zoledronic acid)			<input type="radio"/>	Treatment Code:
25. <input type="radio"/> Xgeva (denosumab)			<input type="radio"/>	1 2 3 4 5 6 7 8 9 T
26. <input type="radio"/> Jevtana (cabazitaxel)			<input type="radio"/>	10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31 32 33 34 35
27. <input type="radio"/> Taxotere (docetaxel)			<input type="radio"/>	Start month/year:
28. <input type="radio"/> Provenge (sipuleucel-T)			<input type="radio"/>	1 2 3 4 Before 2018 M
29. <input type="radio"/> Xofigo (Radium-223)			<input type="radio"/>	5 6 7 8 2018 2019 Y
30. <input type="radio"/> ¹⁷⁷ Lu-PSMA-617			<input type="radio"/>	9 10 11 12 2020 2021
31. <input type="radio"/> Keytruda (pembrolizumab)			<input type="radio"/>	End month/year:
32. <input type="radio"/> OTHER, specify: _____			<input type="radio"/>	1 2 3 4 2018 2019 M
				5 6 7 8 2020 2021 Y
				9 10 11 12
Prostate symptom control	month/year	month/year		Treatment Code:
33. <input type="radio"/> Proscar (finasteride)			<input type="radio"/>	1 2 3 4 5 6 7 8 9 T
34. <input type="radio"/> Avodart (dutasteride)			<input type="radio"/>	10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31 32 33 34 35
35. <input type="radio"/> Flomax (tamsulosin)			<input type="radio"/>	Start month/year:

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. During the LAST MONTH, 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	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
b. Need to urinate frequently	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
c. Weak urine stream/incomplete bladder emptying	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
d. Urinary dripping or leakage	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

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	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
b. Increased frequency of your bowel movements	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
c. Overall problems with your bowel habits	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

1	1	1	1	1	1	1	1
2	2	2	2	2	2	2	2
4	4	4	4	4	4	4	4
8	8	8	8	8	8	8	8
P	P	P	P	P	P	P	P

10. How large a problem, if any, has each of the following been for you during the LAST MONTH?

	No problem	Very small problem	Small problem	Moderate problem	Big problem
a. Hot flashes or breast tenderness/enlargement	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
b. Lack of energy	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

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

- Very good
 Good
 Fair
 Poor
 Very poor to none

12. 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

13. 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

14. Since January 2018, which erectile dysfunction medications have you used?

NAME OF MEDICATION/TREATMENT	STARTED COURSE BEFORE 2018	2018	2019	2020	2021	CURRENTLY TAKING					
<input type="radio"/> None											
<input type="radio"/> Viagra, Levitra, Cialis (sildenafil)							<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<input type="radio"/> Intraurethral/penile injectable medications; Vacuum devices; penile prosthesis							<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<input type="radio"/> Testosterone replacement therapy							<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

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

- Dog
 Cat
 Rabbit
 Parrot
 Other bird
 Reptile
 Horse
 Farm animals
 Other animal
- No animals

We are interested in some things about you and your health. Please answer all of the questions yourself by filling in the number that best applies to you. There are no "right" or "wrong" answers. The information that you provide will remain strictly confidential.

	Not at All	A Little	Quite a Bit	Very Much	
16. Do you have any trouble doing strenuous activities like carrying heavy shopping bag or a suitcase?	1	2	3	4	16
17. Do you have any trouble taking a long walk?	1	2	3	4	17
18. Do you have any trouble taking a short walk outside the house?	1	2	3	4	18
19. Do you need to stay in bed or a chair during the day?	1	2	3	4	19
20. Do you need help with eating, dressing, washing yourself or using the toilet?	1	2	3	4	20

During the <u>past week</u> :	Not at All	A Little	Quite a Bit	Very Much	
21. Were you limited in doing either your work or other daily activities?	1	2	3	4	21
22. Were you limited in pursuing your hobbies or other leisure activities?	1	2	3	4	22
23. Were you short of breath?	1	2	3	4	23
24. Have you had pain?	1	2	3	4	24
25. Have you had bone pain?	1	2	3	4	25
26. Did you need rest?	1	2	3	4	26
27. Have you had trouble sleeping?	1	2	3	4	27
28. Have you felt weak?	1	2	3	4	28
29. Have you lacked appetite?	1	2	3	4	29
30. Have you felt nauseated?	1	2	3	4	30
31. Have you vomited?	1	2	3	4	31
32. Have you been constipated?	1	2	3	4	32
33. Have you had diarrhea?	1	2	3	4	33
34. Were you tired?	1	2	3	4	34
35. Did pain interfere with your daily activities?	1	2	3	4	35
36. Have you had difficulty in concentrating on things, like reading a newspaper or watching television?	1	2	3	4	36
37. Did you feel tense?	1	2	3	4	37
38. Did you worry?	1	2	3	4	38
39. Did you feel irritable?	1	2	3	4	39
40. Did you feel depressed?	1	2	3	4	40

