HARVARD 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. Please also sign and date the consent form below and provide us with the name and address of your current physician whom you see for follow-up/treatment of your prostate cancer.

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. Edward Giovannucci at 617-384-8663 if you have any questions about the study.

Sincerely Yours,

Walter Willett

Walter Willett, MD, DrPH
Professor of Nutrition and Epidemiology
Harvard School of Public Health

Please Complete Below and Return with Questionnaire

PLEASE SEE BACK FOR HIPAA AUTHORIZATION INFORMATION

I hereby grant permission to my physician (named below - please give the name and address) to answer questions regarding my prostate cancer diagnosis and continued treatment and release this information to Walter C. Willett, MD, Professor of Nutrition and Epidemiology, Harvard School of Public Health, 677 Huntington Ave, Boston, MA 02115. I also grant permission for Walter C. Willett, MD to review my medical records. All information will be kept strictly confidential.

SIGNED: _____ DATE: _____

PRINT NAME: _____ BIRTH DATE: _____

PHYSICIAN'S NAME: _____

PHYSICIAN'S ADDRESS: _____

CITY: _____ STATE: _____ ZIP: _____

Version 12/14/11

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.

Details Regarding Your Participation:

Your prompt reply is helpful and greatly appreciated. As always, your answers will be kept strictly confidential and will be combined with other participants' responses for medical statistical purposes. Also, the samples of blood, toenails, tissue or urine that many of you have provided are sometimes analyzed for markers in laboratories outside of Harvard; in such cases we use a separate ID number to ensure confidentiality. If findings from these samples could be useful clinically, they could provide the basis for commercially available tests. However, under no circumstances would members of our researcher team personally profit from these samples. You may withdraw your sample at any time to the extent the data derived from them have not yet been aggregated.

This release will be valid until the hospital or doctor has fully responded to Harvard's request for medical records. You understand that once the hospital or doctor shares your health information with the researchers, it may no longer be protected by the HIPAA Privacy Rule and there is the potential for your protected health information to be redisclosed by Harvard. The researchers have taken many measures to protect the confidentiality of your health information. One of which is that the researchers have obtained a Certificate of Confidentiality from the Department of Health and Human Services, which gives heightened protection against the researcher being compelled to disclose your confidential information.

You may refuse to sign this release for any reason. You may withdraw this release at any time and for any reason. Refusing to sign or withdrawing your release will not affect the care you receive from the Hospital or doctor in any way. If you wish to withdraw this release, you must contact the Office of Human Research Administration at 617-432-2143 (local calls) or 866-606-0573 (long distance calls). The hospital or doctor may rely on this release in the meantime. You may withdraw your authorization to the extent that data have not yet been aggregated.

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 how to decrease the risk of prostate cancer in men. Participation involves the completion of questionnaires.

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.

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 coordinator, Lauren McLaughlin, at 617-384-8663.

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. Please mark all the prostate cancer treatments you have received since January 2010 only.

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- ○ **I have had no treatment since January 2010**
- ○ **Radical prostatectomy since January 2010** ..... Month / Year
  - ○ Minimally invasive: laparoscopic
  - ○ Minimally invasive: robotic
  - ○ Open: retropubic (incision beneath the navel)
  - ○ Open: perineal (incision beneath the scrotum)
  - ○ Do not know the type of operation
- ○ **External beam radiation to the pelvis since January 2010** .... Month / Year *(date completed)*
- ○ **Brachytherapy** (e.g., seeds) **since January 2010** ..... Month / Year
- ○ **Orchiectomy** (testicle removal) **since January 2010** ..... Month / Year
- ○ **Cryosurgery/cryoablation since January 2010** ..... Month / Year
- ○ **High intensity focused ultrasound since January 2010** ..... Month / Year

Which prostate cancer oral medications have you received since January 2010? (Mark all years that apply)

NAME OF MEDICATION	STARTED COURSE BEFORE 2010	2010	2011	2012	2013	CURRENTLY TAKING
○ **Casodex** (bicalutamide)	○	○	○	○	○	○
○ **Eulexin** (flutamide)	○	○	○	○	○	○
○ **Estrogens and DES**	○	○	○	○	○	○
○ **Nilandron** (nilutamide)	○	○	○	○	○	○
○ **Zytiga** (abiraterone)	○	○	○	○	○	○

Which prostate cancer injections/implants/infusions have you received since January 2010? (Mark all years that apply)

NAME OF MEDICATION	STARTED COURSE BEFORE 2010	2010	2011	2012	2013	CURRENTLY TAKING
○ **Lupron/Eligard/Viadur** (leuprolide)	○	○	○	○	○	○
○ **Zoladex** (goserelin)	○	○	○	○	○	○

MORE TREATMENTS ON NEXT PAGE

Which prostate cancer injections/implants/infusions have you received since January 2010? *(Continued–Mark all years that apply)*

NAME OF MEDICATION	STARTED COURSE BEFORE 2010	2010	2011	2012	2013	CURRENTLY TAKING
Trelstar (triptorelin)	○	○	○	○	○	○ Y
Abarelix (plenaxis)	○	○	○	○	○	○ Y
Firmagon (degarelix)	○	○	○	○	○	○ Y
Vantas (histrelin)	○	○	○	○	○	○ Y
Zometa (zoledronic acid)	○	○	○	○	○	○ Y
Xgeva (denosumab)	○	○	○	○	○	○ Y
Jevtana (cabazitaxel)	○	○	○	○	○	○ Y
Taxotere (docetaxel)	○	○	○	○	○	○ Y
Provenge (sipuleucil-T)	○	○	○	○	○	○ Y

Which erectile dysfunction medications have you ever used?

NAME OF MEDICATION/TREATMENT	MEDICATION/TREATMENT USE (MARK ALL THAT APPLY)			DURATION OF USE				
	PAST: before prostate cancer diagnosis	PAST: after prostate cancer diagnosis	CURRENT	<1 YR	1–5 YRS	6–10 YRS	>10 YRS	
Viagra, Levitra, Cialis, other-related	○	○	○	○	○	○	○	○ U ○ D
Intraurethral/penile injectable medications	○	○	○	○	○	○	○	○ U ○ D
Vacuum devices	○	○	○	○	○	○	○	○ U ○ D
Penile prosthesis	○	○	○	○	○	○	○	○ U ○ D
Testosterone replacement therapy	○	○	○	○	○	○	○	○ U ○ D
Yohimbine	○	○	○	○	○	○	○	○ U ○ D

If you have received any other prostate cancer treatment since January 2010 that is not listed on pages 1-2 of this questionnaire, please specify in box below:

Treatment(s): _____ **Date(s):** _____

_____ _____

_____ _____

_____ _____

2. Did you have treatment for your prostate cancer within one year after your original diagnosis? ○ 2

○ No
○ Yes

1 1 1 1 1 1 1 1
2 2 2 2 2 2 2 2
4 4 4 4 4 4 4 4
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3. Other Medications - Have you ever used any of the following medications/treatments?

NAME OF MEDICATION/TREATMENT	MEDICATION/TREATMENT USE (MARK ALL THAT APPLY)			DURATION OF USE			
	PAST: before prostate cancer diagnosis	PAST: after prostate cancer diagnosis	CURRENT	<1 YR	1–5 YRS	6–10 YRS	>10 YRS
○ **Proscar** (finasteride)	○	○	○	○	○	○	○
○ **Avodart** (dutasteride)	○	○	○	○	○	○	○
○ **Insulin**	○	○	○	○	○	○	○
○ **Glucophage** (metformin)	○	○	○	○	○	○	○
○ **Avandia/Actos** (glitazones)	○	○	○	○	○	○	○
○ **DiaBeta/Micronase/Glucotrol/Amaryl** (sulfonylureas)	○	○	○	○	○	○	○
○ **Other diabetes medication,** specify: _____	○	○	○	○	○	○	○

4. Please list your PSA levels and dates of tests since January 2010 only:

○ I have not had a PSA test since January 2010

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a.) PSA level (ng/ml): _____ Test date: ____ / ____ (Month / Year)

b.) PSA level (ng/ml): _____ Test date: ____ / ____ (Month / Year)

c.) PSA level (ng/ml): _____ Test date: ____ / ____ (Month / Year)

d.) PSA level (ng/ml): _____ Test date: ____ / ____ (Month / Year)

5. Have you ever had recurrence or progression of your prostate cancer, indicated by a rise in PSA?

○ No – continue to question 6
○ Yes – please complete the box below:

5a. When did your prostate cancer recur or progress, relative to your treatment? Please mark all that apply. If your prostate cancer has recurred more than once, please indicate the earliest recurrence.

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○ My prostate cancer recurred (came back) after I received treatment

If so, what was your lowest post-treatment PSA level?

PSA level (ng/ml): _____ Test date: ____ / ____ (Month / Year)

○ My prostate cancer progressed (got worse) before I received any treatment

○ My prostate cancer progressed, but I have never received any treatment

5b. What was your first PSA level that indicated recurrence or progression?

PSA level (ng/ml): _____ Test date: ____ / ____ (Month / Year)

PLEASE TURN PAGE OVER →

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

- ○ No – continue to question 7
- ○ Yes – please complete the box below:

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6a. Where 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)

6b. What prompted a metastasis work-up? Please mark all that apply.

- ○ Pain
- ○ PSA rise
- ○ Other, specify: _____

6c. How were your metastases verified? Please mark all that apply.

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

URINARY AND BOWEL FUNCTION

This section is about your urinary and bowel habits. Please consider your function over THE LAST 4 WEEKS ONLY.

7. Over the PAST 4 WEEKS, how often have you leaked urine? (Please select only one)

- ○ Rarely or never
- ○ About once a week
- ○ More than once a week
- ○ About once a day
- ○ More than once a day

8. Which of the following best describes your urinary control DURING THE LAST 4 WEEKS? (Please select only one)

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

9. How many pads or adult diapers per day did you usually use to control leakage DURING THE LAST 4 WEEKS? (Please select only one)

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

10. How big a problem, if any, has each of the following been for you DURING THE LAST 4 WEEKS?

	No problem	Very small problem	Small problem	Moderate problem	Big problem
a. Dripping or leaking urine	○	○	○	○	○
b. Pain or burning on urination	○	○	○	○	○
c. Bleeding with urination	○	○	○	○	○
d. Weak urine stream or incomplete emptying	○	○	○	○	○
e. Need to urinate frequently	○	○	○	○	○

11. Overall, how big a problem has your urinary function been for you DURING THE LAST 4 WEEKS? (Please select only one)

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

12. How big a problem, if any, has each of the following been for you DURING THE LAST 4 WEEKS?

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

13. Overall, how big a problem have your bowel habits been for you DURING THE LAST 4 WEEKS? (Please select only one)

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

SEXUAL FUNCTION

This section is about your sexual function and satisfaction. Many of the questions are very personal, but they will help us understand the important issues that you face every day. Remember, your answers to this questionnaire will be kept confidential and will be used only for research purposes.

Please consider your function over THE LAST 4 WEEKS ONLY. Please answer even if you are using medications or devices, or are not currently sexually active.

14. How would you rate each of the following DURING THE LAST 4 WEEKS?

	Very good	Good	Fair	Poor	Very poor to none	Not applicable
a. Your ability to have an erection?	○	○	○	○	○	○
b. Your ability to reach orgasm (climax)?	○	○	○	○	○	○

PLEASE TURN PAGE OVER →

15. **How would you describe the usual QUALITY of your erections DURING THE LAST 4 WEEKS? (Please select only one)**

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

16. **How would you describe the FREQUENCY of your erections DURING THE LAST 4 WEEKS? (Please select only one)**

- ○ I had an erection WHENEVER I wanted one
- ○ I had an erection MORE THAN HALF the time I wanted one
- ○ I had an erection ABOUT HALF the time I wanted one
- ○ I had an erection LESS THAN HALF the time I wanted one
- ○ I NEVER had an erection when I wanted one during the last 4 weeks
- ○ Not applicable

17. **Overall, how would you rate your ability to function sexually DURING THE LAST 4 WEEKS? (Please select only one)**

- ○ Very good
- ○ Good
- ○ Fair
- ○ Poor
- ○ Very poor

18. **Overall, how big a problem has your sexual function or lack of sexual function been for you DURING THE LAST 4 WEEKS? (Please select only one)**

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

HORMONAL/VITALITY FUNCTION

This section is about your hormonal and vitality function. Please consider your function over THE LAST 4 WEEKS ONLY.

19. **How big a problem, if any, has each of the following been for you DURING THE LAST 4 WEEKS?**

	No problem	Very small problem	Small problem	Moderate problem	Big problem
a. Hot flashes	○	○	○	○	○
b. Breast tenderness/enlargement	○	○	○	○	○
c. Feeling depressed	○	○	○	○	○
d. Lack of energy	○	○	○	○	○
e. Change in body weight	○	○	○	○	○

Thank you for your participation!

Please return to: Walter C. Willett, M.D. • 677 Huntington Ave. • Boston, MA 02115

1 2 3 4 2012
5 6 7 8 2013
9 10 11 12 2014