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 8/20/09

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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.

EXAMPLE 1:

Did a biopsy show local recurrence?

○ Yes
● No

Please fill circle completely, do not mark this way: ✓ ✗ ●

EXAMPLE 2:

Please Specify: Once a month

Keep handwriting within borders of the response box.

HIPAA AUTHORIZATION INFORMATION

Federal regulations require that the following information be provided to you.

This release will be valid until the hospital or doctor has fully responded to Harvard's request for medical records. I understand that once the hospital or doctor shares my health information with the researchers, it may no longer be protected by the HIPAA Privacy Rule and there is the potential for my protected health information to be redisclosed by Harvard. However, although the researchers are not subject to HIPAA, they nevertheless take many measures to protect the confidentiality of my 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 my confidential information.

I may refuse to sign this release for any reason. I may cancel this release at any time and for any reason. If I decide to refuse to sign this release, I will not suffer any penalty. If I withdraw my release later, I will not suffer any penalty. Refusing to sign or withdrawing my release will not affect the care I receive from the hospital or doctor in any way. If I wish to cancel this release, I must write to the Privacy Officer of the hospital or doctor. My decision to cancel will be effective as soon as the Privacy Officer receives my written notice. The hospital or doctor may rely on this release in the meantime. My decision to withdraw will not affect any action they may have taken before my withdrawal goes into effect.

Federal research regulations require us to include the following information:

There are no direct benefits to you from participating in this study.

The risk of breach of confidentiality associated with participation in this study is very small.

Your choice to participate in this study is completely voluntary and you may decline or withdraw at any time without penalty.

You may skip any question you do not wish to answer.

You will not receive monetary compensation for participating.

If you have any questions regarding your rights as a research participant, you are encouraged to call a representative of the Office of Human Research Administration at the Harvard School of Public Health (866-606-0573).

If you have any questions regarding your status in our study or a question pertaining to the questionnaire, please call the study Research Coordinator, Lauren McLaughlin, at 617-384-8663.

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MANY THANKS FOR PREVIOUSLY PROVIDING VALUABLE INFORMATION RELATED TO YOUR PROSTATE CANCER. WE NOW SEEK TO UPDATE YOUR INFORMATION, AND FOCUS ON THE TIME PERIOD SINCE JANUARY 1, 2007 (UNLESS OTHERWISE SPECIFIED).

1. What treatments have you received for your prostate cancer since January 2007? (Please mark all that apply)

- ○ I have never received any treatment for my prostate cancer (Watchful Waiting/Active Surveillance) → *SKIP TO QUESTION # 3*
- ○ I was initially treated but have not received any treatments since January 2007 → *SKIP TO QUESTION # 2*
- ○ **Radical Prostatectomy** → Date: MONTH (1) (2) (3) (4) (5) (6) (7) (8) (9) (10) (11) (12) (a); YEAR 2007 2008 2009 2010 2011
  - ○ Minimally invasive (Laparoscopic and/or Robotic)
  - ○ Open: Retropubic (incision beneath the navel)
  - ○ Open: Perineal (incision beneath the scrotum)
  - ○ Do not know the type of operation
- ○ **External Beam Radiation** → Completion Date: MONTH (1) (2) (3) (4) (5) (6) (7) (8) (9) (10) (11) (12) (b); YEAR 2007 2008 2009 2010 2011
- ○ **Brachytherapy** (Radioactive seed implants) → Date: MONTH (1) (2) (3) (4) (5) (6) (7) (8) (9) (10) (11) (12) (c); YEAR 2007 2008 2009 2010 2011
- ○ **Androgen Deprivation/Hormone Therapy** (d)

PLEASE LIST UP TO 2 DRUGS THAT YOU HAVE TAKEN SINCE JANUARY 2007

DRUG 1:
- ○ Oral medications (anti-androgens) (e.g., bicalutamide (Casodex), flutamide (Eulexin), nilutamide (Nilandron))
- ○ Hormone therapy by injectable drugs (e.g., leuprolide (Lupron), goserelin (Zoladex), triptorelin (Trelstar))

Start Date for Drug 1: MONTH (1) (2) (3) (4) (5) (6) (7) (8) (9) (10) (11) (12); YEAR 2007 2008 2009 2010 2011 OR ○ started drug before Jan. 2007

Stop Date for Drug 1: MONTH (1) (2) (3) (4) (5) (6) (7) (8) (9) (10) (11) (12); YEAR 2007 2008 2009 2010 2011 OR ○ currently taking or using intermittently

DRUG 2:
- ○ Oral medications (anti-androgens) (e.g., bicalutamide (Casodex), flutamide (Eulexin), nilutamide (Nilandron))
- ○ Hormone therapy by injectable drugs (e.g., leuprolide (Lupron), goserelin (Zoladex), triptorelin (Trelstar))

Start Date for Drug 2: MONTH (1) (2) (3) (4) (5) (6) (7) (8) (9) (10) (11) (12); YEAR 2007 2008 2009 2010 2011 OR ○ started drug before Jan. 2007

Stop Date for Drug 2: MONTH (1) (2) (3) (4) (5) (6) (7) (8) (9) (10) (11) (12); YEAR 2007 2008 2009 2010 2011 OR ○ currently taking or using intermittently

○ If additional drugs given, please list information here: _____

- ○ **Chemotherapy** (e)

PLEASE LIST UP TO 2 DRUGS THAT YOU HAVE TAKEN SINCE JANUARY 2007

DRUG 1:
- ○ docetaxel (Taxotere)
- ○ Other drug

Start Date for Drug 1: MONTH (1) (2) (3) (4) (5) (6) (7) (8) (9) (10) (11) (12); YEAR 2007 2008 2009 2010 2011 OR ○ started drug before Jan. 2007

Stop Date for Drug 1: MONTH (1) (2) (3) (4) (5) (6) (7) (8) (9) (10) (11) (12); YEAR 2007 2008 2009 2010 2011 OR ○ currently taking or using intermittently

DRUG 2:
- ○ docetaxel (Taxotere)
- ○ Other drug

Start Date for Drug 2: MONTH (1) (2) (3) (4) (5) (6) (7) (8) (9) (10) (11) (12); YEAR 2007 2008 2009 2010 2011 OR ○ started drug before Jan. 2007

Stop Date for Drug 2: MONTH (1) (2) (3) (4) (5) (6) (7) (8) (9) (10) (11) (12); YEAR 2007 2008 2009 2010 2011 OR ○ currently taking or using intermittently

- ○ **Orchiectomy** → Date: MONTH (1) (2) (3) (4) (5) (6) (7) (8) (9) (10) (11) (12) (f); YEAR 2007 2008 2009 2010 2011
- ○ **Cryosurgery/Cryoablation** → Date: MONTH (1) (2) (3) (4) (5) (6) (7) (8) (9) (10) (11) (12) (g); YEAR 2007 2008 2009 2010 2011
- ○ **High Intensity Focused Ultrasound** → Date: MONTH (1) (2) (3) (4) (5) (6) (7) (8) (9) (10) (11) (12) (h); YEAR 2007 2008 2009 2010 2011
- ○ **Immunotherapy** → Date Started: MONTH (1) (2) (3) (4) (5) (6) (7) (8) (9) (10) (11) (12) (i); YEAR 2007 2008 2009 2010 2011
- ○ Other → Please Specify: _____ → Date Started: MONTH (1) (2) (3) (4) (5) (6) (7) (8) (9) (10) (11) (12) (j); YEAR 2007 2008 2009 2010 2011

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2. **If you had a radical prostatectomy before January 2007, was it . . .**

- ◯ Minimally invasive (Laparoscopic and/or Robotic)
- ◯ Open: Retropubic (incision beneath the navel)
- ◯ Open: Perineal (incision beneath the scrotum)
- ◯ Do not know the type of operation

3. **Please list your most recent PSA levels and dates of tests since January 2007, starting with the most recent PSA.**

◯ I haven't had a PSA test since January 2007.

a) PSA level (ng/ml): _____ → Date of test: MONTH 1 2 3 4 5 6 7 8 9 10 11 12 / YEAR 2007 2008 2009 2010 2011

b) PSA level (ng/ml): _____ → Date of test: MONTH 1 2 3 4 5 6 7 8 9 10 11 12 / YEAR 2007 2008 2009 2010 2011

c) PSA level (ng/ml): _____ → Date of test: MONTH 1 2 3 4 5 6 7 8 9 10 11 12 / YEAR 2007 2008 2009 2010 2011

d) PSA level (ng/ml): _____ → Date of test: MONTH 1 2 3 4 5 6 7 8 9 10 11 12 / YEAR 2007 2008 2009 2010 2011

IF INITIALLY TREATED, PLEASE ANSWER 4a. **OR** IF NOT INITIALLY TREATED, PLEASE SKIP TO 4b.

4a. **If you were initially treated (i.e., within 12 months) after diagnosis: Have you ever had a recurrence of your prostate cancer after your initial treatment? (Please mark all that apply)**

- ◯ No → ***SKIP TO QUESTION # 6***
- ◯ Yes, indicated by rise in PSA → Lowest post-treatment PSA level (ng/ml): _____ ◯ PSA Unknown; Date of test (month/year) M M Y Y Y Y: 0 0 0 / 1 1 1 1 / 2 2 2 2 / 3 3 3 3 / 4 4 4 4 / 5 5 5 5 / 6 6 6 6 / 7 10 7 7 7 / 8 11 8 8 8 / 9 12 9 9 9; ◯ Date Unknown
  - PSA level at 1st rise after initial treatment (ng/ml): _____ ◯ PSA Unknown; Date of test (month/year) M M Y Y Y Y: 0 0 0 / 1 1 1 1 / 2 2 2 2 / 3 3 3 3 / 4 4 4 4 / 5 5 5 5 / 6 6 6 6 / 7 10 7 7 7 / 8 11 8 8 8 / 9 12 9 9 9; ◯ Date Unknown
- ◯ Yes, indicated by clinical evidence of spread locally (to adjacent organs)
  - **Did a biopsy show local recurrence?**
    - ◯ Yes
    - ◯ No
- ◯ Yes, indicated by clinical evidence of distant spread (to distant organs)

4b. **If you were NOT initially treated within 12 months of diagnosis: Has there ever been evidence of progression or recurrence of your prostate cancer? (Please mark all that apply)**

- ◯ No → ***SKIP TO QUESTION # 6***
- ◯ Yes, and never received treatment
- ◯ Yes, progressed before treatment
- ◯ Yes, recurred after treatment → Lowest post-treatment PSA level (ng/ml): _____ ◯ PSA Unknown; Date of test (month/year) M M Y Y Y Y: 0 0 0 / 1 1 1 1 / 2 2 2 2 / 3 3 3 3 / 4 4 4 4 / 5 5 5 5 / 6 6 6 6 / 7 10 7 7 7 / 8 11 8 8 8 / 9 12 9 9 9; ◯ Date Unknown

If you answered YES to 4b, please answer 4c.

4c. **If progression and/or recurrence did occur, was it indicated by: (Please mark all that apply)**

- ◯ Rise in PSA → PSA level at 1st rise (ng/ml): _____ ◯ PSA Unknown; Date of test (month/year) M M Y Y Y Y: 0 0 0 / 1 1 1 1 / 2 2 2 2 / 3 3 3 3 / 4 4 4 4 / 5 5 5 5 / 6 6 6 6 / 7 10 7 7 7 / 8 11 8 8 8 / 9 12 9 9 9; ◯ Date Unknown
- ◯ Clinical evidence of spread locally (to adjacent organs)
  - **Did a biopsy show local recurrence?**
    - ◯ Yes
    - ◯ No
- ◯ Clinical evidence of distant spread (to distant organs)

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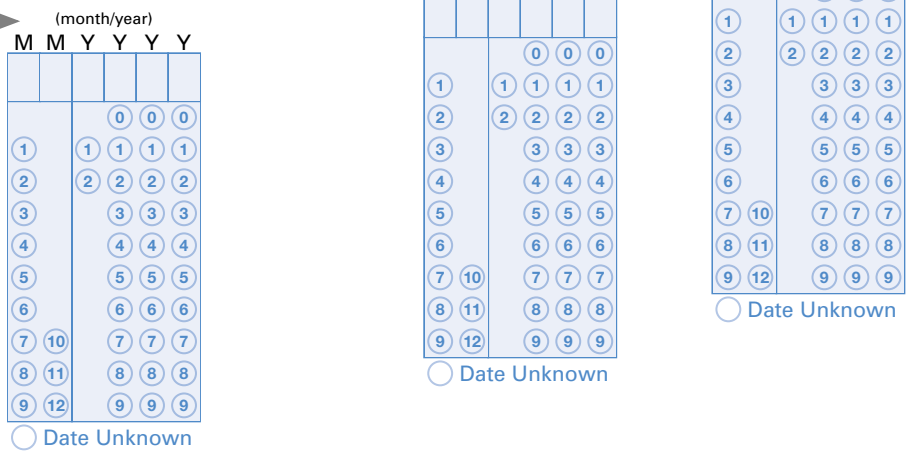
5. **Since your initial diagnosis, has there ever been a diagnosis of metastases to lymph nodes, bone or other organs?**

- ○ No metastases ▶ ***SKIP TO QUESTION # 6***
- ○ Yes, metastases to:
  - ○ lymph nodes → (month/year) M M Y Y Y Y
  - ○ bone → (month/year) M M Y Y Y Y
  - ○ other organs → (month/year) M M Y Y Y Y



- ○ Date Unknown (lymph nodes)
- ○ Date Unknown (bone)
- ○ Date Unknown (other organs)

If metastases, how were they found? (Please mark all that apply)

- ○ Bone scan
- ○ Biopsy
- ○ Pain
- ○ Initiating treatment
- ○ Other: → Please Specify: _____

6. **Have you ever regularly used any of the following medications or treatments?**

Medication/Treatment			Medication/Treatment use: Past: before prostate cancer diagnosis	Medication/Treatment use: Past: after prostate cancer diagnosis	Medication/Treatment use: Current	Duration of use: <1 yr	Duration of use: 1–5 yrs	Duration of use: 6–10 yrs	Duration of use: >10 yrs
Finasteride (Proscar, other)	○ No	○ Yes →	○	○	○	○	○	○	○
Dutasteride (Avodart, other)	○ No	○ Yes →	○	○	○	○	○	○	○
Viagra, Levitra, Cialis, other-related	○ No	○ Yes →	○	○	○	○	○	○	○
Intraurethral/penile injectable medications and/or vacuum devices	○ No	○ Yes →	○	○	○	○	○	○	○
Penile prosthesis	○ No	○ Yes →	○	○	○	○	○	○	○
Testosterone replacement therapy	○ No	○ Yes →	○	○	○	○	○	○	○

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The following questions are designed to measure Quality of Life among prostate cancer patients. You may omit any question for any reason. All information contained within this survey will remain strictly confidential.

7. During the past month, please indicate how frequently you had these urinary symptoms and how large of a problem they were to you:

	% OF TIME EXPERIENCED SYMPTOMS						HOW LARGE A PROBLEM?				
	0%	10%	25%	50%	75%	Almost 100%	None	Very small	Small	Medium	Big
Sensation of incomplete bladder emptying	○	○	○	○	○	○	○	○	○	○	○
Having to urinate again after less than 2 hours	○	○	○	○	○	○	○	○	○	○	○
Stopping and starting several times during urination	○	○	○	○	○	○	○	○	○	○	○
Found it difficult to postpone urinating	○	○	○	○	○	○	○	○	○	○	○
Had to push or strain to begin urination	○	○	○	○	○	○	○	○	○	○	○

8. 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

9. 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

10. 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

11. 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	○	○	○	○	○

12. 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

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13. **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	○	○	○	○	○

14. **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

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

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

16. **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

17. **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

18. **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

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19. **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

20. **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	○	○	○	○	○

21. **What is your overall feeling about the . . .**

	Completely Satisfied	Very Satisfied	Somewhat Satisfied	Mixed/ Uncertain	Somewhat Unsatisfied	Very Unsatisfied	Completely Unsatisfied
a. Effect of health care services in helping you deal with your cancer and maintain your well being?	○	○	○	○	○	○	○
b. Effect of cancer care in preventing cancer progression or recurrence?	○	○	○	○	○	○	○
c. Quality of cancer care you have received?	○	○	○	○	○	○	○
d. Effect of services in helping relieve symptoms or reduce problems?	○	○	○	○	○	○	○
e. In an overall general sense, how satisfied are you with the cancer care you have received?	○	○	○	○	○	○	○

Thank you for your participation!

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

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