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The purpose of this case-control study is to investigate the association between genetic and endocrine markers of estrogen metabolism and prostate cancer progression. Androgens (e.g., testosterone) may be critical in prostate carcinogenesis, but there is accumulating evidence that estrogens facilitate progress during the later stages of prostate cancer formation (1-4). To explore the role of estrogens in human prostate carcinogenesis, we proposed to investigate the association between genetic and endocrine markers of estrogen metabolism and the detection of high-grade prostatic intraepithelial neoplasia (HGPIN) and stage II/III prostate cancer. This study has completed its first full year of funded activity. Specific accomplishments include the development and pilot testing of all data and biospecimen collection procedures. We had a computer-guided interview created specifically for this project. We have hired a Project Coordinator, and have obtained IRB approvals for all protocols. Participant recruitment started in January, and we have successfully recruited the first 10 eligible participants (100%). We anticipate successful project completion, and further details provided below are in parallel with the statement of work.

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(HGPIN) to Prostate Cancer

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Nashville, Tennessee 37232-8300

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DAMD17-02-1-0139  
MOLECULAR MARKERS OF ESTROGEN METABOLISM AND PROGRESSION  
FROM HIGH-GRADE PROSTATIC INTRAEPITHELIAL NEOPLASIA (HGPIN)  
TO PROSTATE CANCER

First Annual Report  
submitted March 14, 2003

This study is beginning its second full year of funded activity. All protocols for the collection of data are finalized and we have begun to recruit participants. Specific accomplishments are described in the following narrative, in parallel with the original Statement of Work.

#### INTRODUCTION

This work is based on a growing body of laboratory evidence that estrogens contribute to the advancement and detection of prostate cancer. Prostate tumor cells express estrogen receptors, and estrogen exposure may sustain tumor growth as androgen levels decrease with advancing age (1). It has further been shown that not all estrogens behave alike. Relative to 2-hydroxyestrone (2HE), 16HE appears bind with higher affinity to the estrogen receptor (5), and the relative balance of estrogen metabolites is determined by several enzyme activities. The CYP3A4 and CYP1B1 P-450s are responsible for converting estradiol to the 16HE or 4 HE metabolites, respectively, at the expense of 2HE production. Both CYP1B1 and CYP3A4 are expressed in prostate tissue, a polymorphism of the *CYP3A4* gene in the 5' transcriptional regulatory element (*CYP3A4-V*) has been significantly associated with later age and advanced stage at CaP detection compared to men with the wild-type gene (6). Similarly, prostate cancer cases may be 3-fold more likely than controls to be homozygous for the *CYP1B1*<sup>Val</sup> allele (7). The goal of this New Investigator Award is to conduct a pilot case-control study investigating the association between molecular markers of estrogen metabolism and diagnosis of prostate cancer (stage II/III) and high-grade prostatic intraepithelial neoplasia (HGPIN), the purported precursor pathologic state to prostate cancer. We will recruit 45 men with HGPIN, 45 prostate cancer cases, and 45 healthy controls free of prostate cancer at biopsy. Genetic polymorphisms in CYP3A4 and CYP1B1 associated with estrogen metabolism will be determined from blood collected from each participant. Data regarding family history of prostate cancer and other risk factors is collected by questionnaire, and habitual dietary intake is measured by in-person interview. We hypothesize that CaP cases will have lower urinary 2HE/16HE and 2HE levels, and higher urinary 16HE, 4HE, E2 and blood E2 levels compared to HGPIN cases or healthy controls.

With the first year of this 3-year award now complete, we have achieved most of the 12-month objectives specified in our statement of work, including the obtainment of IRB approval, development of questionnaires and other data collection tools, and the recruitment of study participants. In the future project years, participant recruitment and data collection will continue,

and our analyses will determine the association between estrogen-related markers and HGPIN.

## **BODY**

Work accomplished during the Year 1 period of this NIA encompasses Statement of Work tasks outlined in Stage 1 (Run-In: Months 1-8)) and Stage 2 (Recruitment and Data Collection: Months 9-26)). Work outlined as Stage 3, Stage 4, or Stage 5 has not been completed.

### Stage 1: Run-In Phase: Months 1-8:

#### 1. Develop all questionnaires, pathology record abstraction forms, and data collection protocols

All forms were developed specifically for this project. Our risk factor questionnaire measures include: demographics; age; sex; race; marital status; education; number of children; medical history and treatment; family health history of prostate cancer; history of other cancers, exercise frequency; and smoking status. (Appendix). Our dietary assessment instrument is the Diet History Questionnaire, recently developed by the NIH and shown to have favorable reliability and validity to other established dietary assessment instruments. We had a computer-assisted program developed to guide the implementation of our dietary assessment instrument. Our Pathology Record Abstraction form records the clinic sites, dates and clinical results of all PSA, endocrine, and digital rectal exam results, ultrasound results, biopsy history and results, pathological diagnosis (HGPIN, cancer), and zone and distribution of the disease. Similarly, we record any cancer diagnosis, as well as stage and Gleason scale of cancer. We have developed Body Measurement protocols (Anthropometrics), including the methods of measuring and recording measurement of participant weight, height, sitting height, waist, and hips. Our Biospecimen Collection form records blood collection status for purposes of DNA extraction or serology, and urine specimens for estrogen metabolite measurement. All samples are aliquoted and stored frozen as necessary to meet our research objectives. Medication use is recorded on the Medication Use form. Subjects are instructed to bring all current medications and supplements to the data collection meeting, and name of the drug, dosage, and use patterns are recorded. The Interview Checklist ensures that all assigned tasks required during the interview are completed, including a review of eligibility, completion of all data collection protocols, and proper consent of participant.

#### 2. Hire a Research Nurse

For this project, Sandra Motley, RN, was hired to serve as Project Manager. Ms. Motley is responsible for the day-to-day administration. She also has been trained to collect body size measurements using standard and systematic protocols, as well as in urine and blood collection, sample preparation, and storage protocols.

#### 3. Pre-test questionnaires and forms

All instrument materials have been thoroughly reviewed and validated, and final versions of all assessment instruments have been produced.

4. Refine questionnaire protocols, as necessary

The Baseline Questionnaire was edited to provide a better organization to the questions. We have improved our assessment of dietary intake by developing portion size guides (Appendix), and the addition of several foods common to the Tennessee population (asparagus, okra, squash). We are conducting a sub-study to determine if completion of the dietary questionnaire at home and with a wife/partner provides substantially different food intake scores compared to our in-person interview protocol. The laptop computer program we had developed for this project initially had several 'glitches', but is now working without errors or failures.

5. Finalize IRB application and consent form, if necessary

IRB approved consent forms have been obtained from Vanderbilt University, the VA, and the US AMRMC (Appendix).

6. Develop the study data management systems, including the combination of Teleform, Microsoft Access, Epi-Info, and SAS

Our data management system continues to develop, as we recognize and incorporate new technologies into our study. We are able to rapidly identify potentially eligible men receiving care at one of the urology cancer centers through newly implemented scheduling and patient monitoring software in the clinic. This will greatly increase our efficiency to recruit urology patients in the future. New data collection protocols have been developed to fully utilize all resources. Dietary assessment data are entered directly into an ACCESS database using a computer-based dietary assessment interview program created specifically for this project. The ACCESS database may be read by SAS, and merged with other databases for the purposes of analysis. Additional data-entry programs for questionnaires and forms will follow this model, using ACCESS with subsequent transfer into SAS.

7. Become trained in all clinic-site office and administrative procedures

The PI and/or Project Manager have received tours of the urology clinic at Vanderbilt and the VA, and understand the operational and administrative procedures of this clinic.

8. Hire and Train Project Director in all clinic based procedures

See #2 above. The position of Project Director and Research Nurse were efficiently combined under Ms. Motley's position in the study.

9. Finalize all biological sample collection and storage procedures to be used in the study

All biological sample collection and storage procedures for urine and blood cells and serum are finalized. After obtaining consent, we obtain a urine and blood sample, body size measurements, and participants complete the diet questionnaire. Urine is aliquoted to 9 cryovials, and stored at -80 C. One tube of blood, 5ml (EDTA) is collected for DNA extraction. Two 5ml tubes of blood (No anticoagulants) are collected, centrifuged, and the supernate aliquoted for steroid hormone measurement.

10. Establish reliability of all laboratory procedures to be used

The genotyping assays for CYP3A4 and CYP1B1 are routine genotyping assays in our group with established reliability. The estrogen metabolite assays have published reliability and validity. Laboratory reliability will be determined at the time the assays are scheduled to run, during Year 2 or Year 3 of the project.

11. Establish screening procedures for men with HGPIN, prostate cancer patients, or controls.

Candidates are identified by collaborators in the urology clinics as potentially eligible for our research study. As part of standard recruitment procedures, we mail an introductory letter and brochure to candidates (Appendix). This is followed by a telephone calls (Appendix for script) intended to answer any questions and evaluate interest in the study. If interested and determined potentially eligible, a meeting is scheduled at the study center. The Project Manager confirms eligibility and obtains informed consent (Appendix for consent form) prior to data collection.

12. Order supplies necessary for biological sample collection

All supplies necessary for biological sample collection have been ordered and received.

13. Create complete manual of operations

We have created a manual of operations to organize and record every procedures and protocol in this study. All items in the Appendix are included in the Manual, as well as a copy of the original grant proposal and correspondence with DOD colleagues.

Stage 2a: Recruitment of 45 men with high grade intraepithelial neoplasia, 45 men with Stage II/III prostate cancer, and 45 men without CaP or HGPIN at biopsy: Months 8-26

Consistent with our time-line for this study, we started study recruitment in January 22, 2003. We have recruited, consented, and collected complete data from 15 participants. An additional 30 candidates are in various states of scheduling and recruitment. At this time, 100% of men approached for recruitment have agreed to participate in our study.

1. Identify 45 men with HGPIN eligible for the study from the urology clinics.

We have identified 3 men with HGPIN.

2. Identify 45 men with prostate cancer.

We have identified 7 men with prostate cancer.

3. Abstract medical records for health history and pathology data, as described in Methods section of this proposal.

We have accessed medical records and abstracted relevant prostate cancer pathology information using our pathology data form.

4. Gain informed consent

All participants are consented in an IRB approved manner.

5. Among those who say they are willing to participate, determine eligibility using the criteria described in the Methods Section of this proposal

Eligibility is determined via telephone interview, and confirmed during the in-person interview.

6. Enroll consecutive eligible men with confirmed HGPIN or stage II/III prostate cancer.

All eligible HGPIN and prostate cancer patients approached for enrollment have enrolled in our study.

7. Ensure that the spot urine samples and blood samples are collected, processed, and stored in a  $-80^{\circ}\text{C}$  freezer at the Vanderbilt University

All urine and blood samples are collected and processed using described protocols, then stored in a  $-80\text{ C}$  freezer at Vanderbilt University.

8. Collect data on lifestyle, demographics, and health (family and personal history), as outlined in proposal

Each participant completes a Background Questionnaire, collecting lifestyle, demographic, and medical data. This questionnaire is mailed to participants prior to the clinical visit, and then reviewed by the Project Manager at that time for completeness. Any blank questions or illogical responses are clarified at that time.

9. Pathology record abstractions will be performed

The Project Manager abstracts relevant medical and pathology information from the pathology report, and records this information on the Pathology Report Form. This data will be key punched into an ACCESS database for analysis.

10. Collect anthropometrics

We measure weight, height, waist, hips, and sitting height for each participant using standardized protocols as described. All body measurements are recorded on our Body Measurement Form, and will be key-punched into an ACCESS data base for analysis.

Stage 3: Data Entry, Verification and Interim Analysis, Months 12-30

- Assure that all data are immediately read into analytic databases
- Flag all outlier and illogical responses
- Verify all outlier and illogical responses, re-contacting participants, if necessary.
- Conduct simple descriptive analyses (e.g., cross-tabulations and univariate statistics)

Stage 4: Laboratory Analyses, Months 24 - 30

- Transfer urine samples to the lab of Dr. Parl for estradiol and estrogen metabolite assays
- Transfer blood sample to lab of Dr. Parl for estradiol assay
- Transfer blood samples to lab of Dr. Cai for CYP1B1 and CYP3A4 genotyping assays
- Confirm quality control procedures, and repeat assays if necessary

Stage 5: Final Data Analysis, Months 30-36:

- Perform exploratory analyses to test for adherence to model assumptions

- Perform any necessary data transformations to meet statistical assumptions
- Test study hypothesis
- Conduct post-hoc analyses of study data
- Prepare manuscripts
- Archive datasets for future analyses and future patient follow-up
- Plan for future studies

There has been no work accomplished within stages 3-5 of the Statement of Work.

### KEY RESEARCH ACCOMPLISHMENTS

- Development of all questionnaires and data collection forms
- IRB approvals
- Key hiring of research nurse
- Training in the collection of all data and measurements
- Preliminary testing of all data collection protocols
- Initiation of participant recruitment, including consent, recruitment, eligibility, data collection, biospecimen collection, and storage protocols.

### REPORTABLE OUTCOMES

No reportable outcomes are available from this work at this time.

### CONCLUSIONS

After experiencing delays with study start up due to issues around Human Subjects agreements and Recruitment protocols, this study is now on track in terms of research deliverables at the end of Year 1.

### REFERENCES

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2. Horvath LG, Henshall SM, Lee C-S, Head DR, Quinn DI, Makela S et al. Frequent loss of estrogen receptor-beta expression in prostate cancer. *Cancer Research* 2001;61:5331-5.
3. Pasquali D, Rossi V, Esposito D, Abbondanza C, Puca GA, Bellastella A et al. Loss of estrogen receptor beta expression in malignant human prostate cells in primary cultures and in prostate cancer tissues. *Journal of Clinical Endocrinology and Metabolism* 2001;86:2051-5.
4. Cavalieri EL, Devanesan P, Bosland MC, Badawi AF, Rogan EG. Catechol estrogen metabolites and conjugates in different regions of the prostate of Noble rats treated with 4-hydroxyestradiol: implications for estrogen-induced initiation of prostate cancer. *Carcinogenesis* 2002;23:329-33.
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6. Rebbeck T, Jaffe JM, Walker AH, Wein AJ, Malkowicz SB. Modification of clinical presentation of prostate tumors by a novel genetic variant in CYP3A4. *Journal of the National Cancer Institute* 1998;90:1225-9.
7. Tangrea JA. Patient participation and compliance in cancer chemoprevention trials: Issues and concerns. *Proceedings of the Society for Experimental Biology and Medicine* 1997;216:260-5.

## Appendices

### Appendix 1: Questionnaires

Diet History Questionnaire  
Background History  
Physical Activity

### Appendix 2: Data Collection Forms

Interview Checklist  
Body Measurement  
Biological Specimen Collection  
Pathology

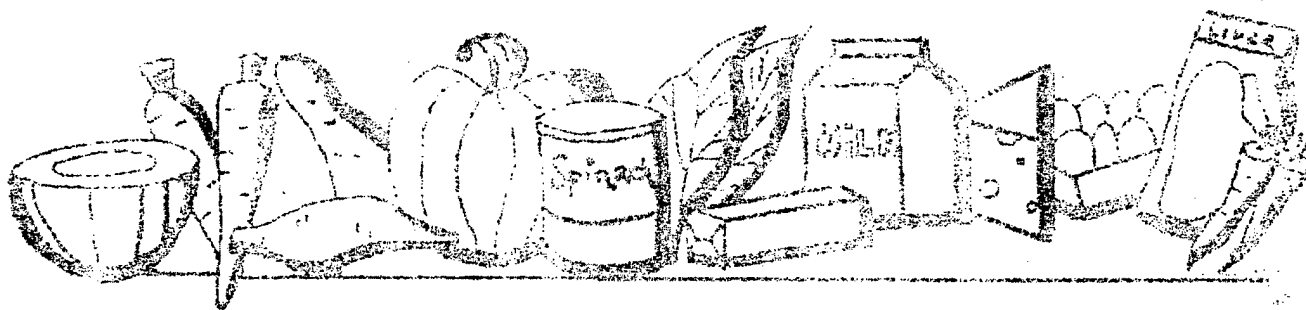
### Appendix 3: Recruitment and Consent

Letter of Introduction  
Brochure  
Phone Script  
Vanderbilt Consent Form  
VA Consent Form  
Thank You Letter

### Appendix 4: Written Protocols

Informed Consent  
Patient ID and Confidentiality  
Adverse Events  
Questionnaires  
Blood Collection  
Urine Collection  
Body Size Measurements

# Diet History Questionnaire



## GENERAL INSTRUCTIONS

- Answer each question as best you can. Estimate if you are not sure. A guess is better than leaving a blank.
- Use only a No. 2 pencil.
- Be certain to completely blacken in each of the answers.
- Erase completely if you make any changes.
- Do not make any stray marks on this form.
- If you blacken NEVER or NO for a question, please follow any arrows or instructions that direct you to the next question.

BAR  
CODE  
LABEL  
HERE

BEFORE TURNING THE PAGE, PLEASE COMPLETE THE FOLLOWING QUESTIONS.

Today's date:

MONTH	DAY	YEAR
<input type="radio"/> JAN		<input type="radio"/> 1998
<input type="radio"/> FEB		<input type="radio"/> 1999
<input type="radio"/> MAR	<input type="radio"/> 0	<input type="radio"/> 2000
<input type="radio"/> APR	<input type="radio"/> 1	<input type="radio"/> 2001
<input type="radio"/> MAY	<input type="radio"/> 2	<input type="radio"/> 2002
<input type="radio"/> JUN	<input type="radio"/> 3	
<input type="radio"/> JUL	<input type="radio"/> 4	
<input type="radio"/> AUG	<input type="radio"/> 5	
<input type="radio"/> SEP	<input type="radio"/> 6	
<input type="radio"/> OCT	<input type="radio"/> 7	
<input type="radio"/> NOV	<input type="radio"/> 8	
<input type="radio"/> DEC	<input type="radio"/> 9	

In what month were you born?

<input type="radio"/> JAN
<input type="radio"/> FEB
<input type="radio"/> MAR
<input type="radio"/> APR
<input type="radio"/> MAY
<input type="radio"/> JUN
<input type="radio"/> JUL
<input type="radio"/> AUG
<input type="radio"/> SEP
<input type="radio"/> OCT
<input type="radio"/> NOV
<input type="radio"/> DEC

In what year were you born?

1	9
<input type="radio"/> 0	<input type="radio"/> 0
<input type="radio"/> 1	<input type="radio"/> 1
<input type="radio"/> 2	<input type="radio"/> 2
<input type="radio"/> 3	<input type="radio"/> 3
<input type="radio"/> 4	<input type="radio"/> 4
<input type="radio"/> 5	<input type="radio"/> 5
<input type="radio"/> 6	<input type="radio"/> 6
<input type="radio"/> 7	<input type="radio"/> 7
<input type="radio"/> 8	<input type="radio"/> 8
<input type="radio"/> 9	<input type="radio"/> 9

Are you male or female?

Male  
 Female

PLEASE DO NOT WRITE IN THIS AREA



SERIAL #

Perf

1. Over the past 12 months, how often did you drink tomato juice or vegetable juice?

NEVER (GO TO QUESTION 2)

- |  |   |
|--|---|
| <input type="radio"/> 1 time per month or less | <input type="radio"/> 1 time per day          |
| <input type="radio"/> 2-3 times per month      | <input type="radio"/> 2-3 times per day       |
| <input type="radio"/> 1-2 times per week       | <input type="radio"/> 4-5 times per day       |
| <input type="radio"/> 3-4 times per week       | <input type="radio"/> 6 or more times per day |
| <input type="radio"/> 5-6 times per week       |   |

1a. Each time you drank tomato juice or vegetable juice, how much did you usually drink?

- Less than  $\frac{3}{4}$  cup (6 ounces)  
  $\frac{3}{4}$  to  $1\frac{1}{4}$  cups (6 to 10 ounces)  
 More than  $1\frac{1}{4}$  cups (10 ounces)

2. Over the past 12 months, how often did you drink orange juice or grapefruit juice?

NEVER (GO TO QUESTION 3)

- |  |   |
|--|---|
| <input type="radio"/> 1 time per month or less | <input type="radio"/> 1 time per day          |
| <input type="radio"/> 2-3 times per month      | <input type="radio"/> 2-3 times per day       |
| <input type="radio"/> 1-2 times per week       | <input type="radio"/> 4-5 times per day       |
| <input type="radio"/> 3-4 times per week       | <input type="radio"/> 6 or more times per day |
| <input type="radio"/> 5-6 times per week       |   |

2a. Each time you drank orange juice or grapefruit juice, how much did you usually drink?

- Less than  $\frac{3}{4}$  cup (6 ounces)  
  $\frac{3}{4}$  to  $1\frac{1}{4}$  cups (6 to 10 ounces)  
 More than  $1\frac{1}{4}$  cups (10 ounces)

3. Over the past 12 months, how often did you drink other 100% fruit juice or 100% fruit juice mixtures (such as apple, grape, pineapple, or others)?

NEVER (GO TO QUESTION 4)

- |  |   |
|--|---|
| <input type="radio"/> 1 time per month or less | <input type="radio"/> 1 time per day          |
| <input type="radio"/> 2-3 times per month      | <input type="radio"/> 2-3 times per day       |
| <input type="radio"/> 1-2 times per week       | <input type="radio"/> 4-5 times per day       |
| <input type="radio"/> 3-4 times per week       | <input type="radio"/> 6 or more times per day |
| <input type="radio"/> 5-6 times per week       |   |

3a. Each time you drank other fruit juice or fruit juice mixtures, how much did you usually drink?

- Less than  $\frac{3}{4}$  cup (6 ounces)  
  $\frac{3}{4}$  to  $1\frac{1}{2}$  cups (6 to 12 ounces)  
 More than  $1\frac{1}{2}$  cups (12 ounces)

Question 4 appears in the next column.

Over the past 12 months...

4. How often did you drink other fruit drinks (such as cranberry cocktail, Hi-C, lemonade, or Kool-Aid, diet or regular)?

NEVER (GO TO QUESTION 5)

- |  |   |
|--|---|
| <input type="radio"/> 1 time per month or less | <input type="radio"/> 1 time per day          |
| <input type="radio"/> 2-3 times per month      | <input type="radio"/> 2-3 times per day       |
| <input type="radio"/> 1-2 times per week       | <input type="radio"/> 4-5 times per day       |
| <input type="radio"/> 3-4 times per week       | <input type="radio"/> 6 or more times per day |
| <input type="radio"/> 5-6 times per week       |   |

4a. Each time you drank fruit drinks, how much did you usually drink?

- Less than 1 cup (8 ounces)  
 1 to 2 cups (8 to 16 ounces)  
 More than 2 cups (16 ounces)

4b. How often were your fruit drinks diet or sugar-free drinks?

- Almost never or never  
 About  $\frac{1}{4}$  of the time  
 About  $\frac{1}{2}$  of the time  
 About  $\frac{3}{4}$  of the time  
 Almost always or always

5. How often did you drink milk as a beverage (NOT in coffee, NOT in cereal)? (Please include chocolate milk and hot chocolate.)

NEVER (GO TO QUESTION 6)

- |  |   |
|--|---|
| <input type="radio"/> 1 time per month or less | <input type="radio"/> 1 time per day          |
| <input type="radio"/> 2-3 times per month      | <input type="radio"/> 2-3 times per day       |
| <input type="radio"/> 1-2 times per week       | <input type="radio"/> 4-5 times per day       |
| <input type="radio"/> 3-4 times per week       | <input type="radio"/> 6 or more times per day |
| <input type="radio"/> 5-6 times per week       |   |

5a. Each time you drank milk as a beverage, how much did you usually drink?

- Less than 1 cup (8 ounces)  
 1 to  $1\frac{1}{2}$  cups (8 to 12 ounces)  
 More than  $1\frac{1}{2}$  cups (12 ounces)

5b. What kind of milk did you usually drink?

- Whole milk  
 2% fat milk  
 1% fat milk  
 Skim, nonfat, or  $\frac{1}{2}$ % fat milk  
 Soy milk  
 Rice milk  
 Other

Question 6 appears on the next page.

Over the past 12 months...

6. How often did you drink meal replacement, energy, or high-protein beverages such as Instant Breakfast, Ensure, Slimfast, Sustacal or others?

- NEVER (GO TO QUESTION 7)
- |  |   |
|--|---|
| <input type="radio"/> 1 time per month or less | <input type="radio"/> 1 time per day          |
| <input type="radio"/> 2-3 times per month      | <input type="radio"/> 2-3 times per day       |
| <input type="radio"/> 1-2 times per week       | <input type="radio"/> 4-5 times per day       |
| <input type="radio"/> 3-4 times per week       | <input type="radio"/> 6 or more times per day |
| <input type="radio"/> 5-6 times per week       |   |

6a. Each time you drank meal replacement beverages, how much did you usually drink?

- Less than 1 cup (8 ounces)  
 1 to 1 1/2 cups (8 to 12 ounces)  
 More than 1 1/2 cups (12 ounces)

7. Over the past 12 months, did you drink soft drinks, soda, or pop?

NO (GO TO QUESTION 8)

YES

7a. How often did you drink soft drinks, soda, or pop **IN THE SUMMER**?

- NEVER
- |  |   |
|--|---|
| <input type="radio"/> 1 time per month or less | <input type="radio"/> 1 time per day          |
| <input type="radio"/> 2-3 times per month      | <input type="radio"/> 2-3 times per day       |
| <input type="radio"/> 1-2 times per week       | <input type="radio"/> 4-5 times per day       |
| <input type="radio"/> 3-4 times per week       | <input type="radio"/> 6 or more times per day |
| <input type="radio"/> 5-6 times per week       |   |

7b. How often did you drink soft drinks, soda, or pop **DURING THE REST OF THE YEAR**?

- NEVER
- |  |   |
|--|---|
| <input type="radio"/> 1 time per month or less | <input type="radio"/> 1 time per day          |
| <input type="radio"/> 2-3 times per month      | <input type="radio"/> 2-3 times per day       |
| <input type="radio"/> 1-2 times per week       | <input type="radio"/> 4-5 times per day       |
| <input type="radio"/> 3-4 times per week       | <input type="radio"/> 6 or more times per day |
| <input type="radio"/> 5-6 times per week       |   |

7c. Each time you drank soft drinks, soda, or pop, how much did you usually drink?

- Less than 12 ounces or less than 1 can or bottle  
 12 to 16 ounces or 1 can or bottle  
 More than 16 ounces or more than 1 can or bottle

Question 8 appears in the next column.

7d. How often were these soft drinks, soda, or pop diet or sugar-free?

- Almost never or never  
 About 1/4 of the time  
 About 1/2 of the time  
 About 3/4 of the time  
 Almost always or always

7e. How often were these soft drinks, soda, or pop caffeine-free?

- Almost never or never  
 About 1/4 of the time  
 About 1/2 of the time  
 About 3/4 of the time  
 Almost always or always

8. Over the past 12 months, did you drink beer?

NO (GO TO QUESTION 9)

YES

8a. How often did you drink beer **IN THE SUMMER**?

- NEVER
- |  |   |
|--|---|
| <input type="radio"/> 1 time per month or less | <input type="radio"/> 1 time per day          |
| <input type="radio"/> 2-3 times per month      | <input type="radio"/> 2-3 times per day       |
| <input type="radio"/> 1-2 times per week       | <input type="radio"/> 4-5 times per day       |
| <input type="radio"/> 3-4 times per week       | <input type="radio"/> 6 or more times per day |
| <input type="radio"/> 5-6 times per week       |   |

8b. How often did you drink beer **DURING THE REST OF THE YEAR**?

- NEVER
- |  |   |
|--|---|
| <input type="radio"/> 1 time per month or less | <input type="radio"/> 1 time per day          |
| <input type="radio"/> 2-3 times per month      | <input type="radio"/> 2-3 times per day       |
| <input type="radio"/> 1-2 times per week       | <input type="radio"/> 4-5 times per day       |
| <input type="radio"/> 3-4 times per week       | <input type="radio"/> 6 or more times per day |
| <input type="radio"/> 5-6 times per week       |   |

8c. Each time you drank beer, how much did you usually drink?

- Less than a 12-ounce can or bottle  
 1 to 3 12-ounce cans or bottles  
 More than 3 12-ounce cans or bottles



Question 9 appears on the next page.

Over the past 12 months...

9. How often did you drink wine or wine coolers?

- NEVER (GO TO QUESTION 10)
- |  |   |
|--|---|
| <input type="radio"/> 1 time per month or less | <input type="radio"/> 1 time per day          |
| <input type="radio"/> 2-3 times per month      | <input type="radio"/> 2-3 times per day       |
| <input type="radio"/> 1-2 times per week       | <input type="radio"/> 4-5 times per day       |
| <input type="radio"/> 3-4 times per week       | <input type="radio"/> 6 or more times per day |
| <input type="radio"/> 5-6 times per week       |   |

9a. Each time you drank wine or wine coolers, how much did you usually drink?

- Less than 5 ounces or less than 1 glass  
 5 to 12 ounces or 1 to 2 glasses  
 More than 12 ounces or more than 2 glasses

10. How often did you drink liquor or mixed drinks?

- NEVER (GO TO QUESTION 11)
- |  |   |
|--|---|
| <input type="radio"/> 1 time per month or less | <input type="radio"/> 1 time per day          |
| <input type="radio"/> 2-3 times per month      | <input type="radio"/> 2-3 times per day       |
| <input type="radio"/> 1-2 times per week       | <input type="radio"/> 4-5 times per day       |
| <input type="radio"/> 3-4 times per week       | <input type="radio"/> 6 or more times per day |
| <input type="radio"/> 5-6 times per week       |   |

10a. Each time you drank liquor or mixed drinks, how much did you usually drink?

- Less than 1 shot of liquor  
 1 to 3 shots of liquor  
 More than 3 shots of liquor

11. Over the past 12 months, did you eat oatmeal, grits, or other cooked cereal?

- NO (GO TO QUESTION 12)  
 YES

11a. How often did you eat oatmeal, grits, or other cooked cereal **IN THE WINTER**?

- NEVER
- |   |   |
|---|---|
| <input type="radio"/> 1-6 times per winter  | <input type="radio"/> 2 times per week        |
| <input type="radio"/> 7-11 times per winter | <input type="radio"/> 3-4 times per week      |
| <input type="radio"/> 1 time per month      | <input type="radio"/> 5-6 times per week      |
| <input type="radio"/> 2-3 times per month   | <input type="radio"/> 1 time per day          |
| <input type="radio"/> 1 time per week       | <input type="radio"/> 2 or more times per day |

Question 12 appears in the next column.

11b. How often did you eat oatmeal, grits, or other cooked cereal **DURING THE REST OF THE YEAR**?

- NEVER
- |   |   |
|---|---|
| <input type="radio"/> 1-6 times per year  | <input type="radio"/> 2 times per week        |
| <input type="radio"/> 7-11 times per year | <input type="radio"/> 3-4 times per week      |
| <input type="radio"/> 1 time per month    | <input type="radio"/> 5-6 times per week      |
| <input type="radio"/> 2-3 times per month | <input type="radio"/> 1 time per day          |
| <input type="radio"/> 1 time per week     | <input type="radio"/> 2 or more times per day |

11c. Each time you ate oatmeal, grits, or other cooked cereal, how much did you usually eat?

- Less than  $\frac{3}{4}$  cup  
  $\frac{3}{4}$  to  $1\frac{1}{4}$  cups  
 More than  $1\frac{1}{4}$  cups

12. How often did you eat cold cereal?

- NEVER (GO TO QUESTION 13)
- |   |   |
|---|---|
| <input type="radio"/> 1-6 times per year  | <input type="radio"/> 2 times per week        |
| <input type="radio"/> 7-11 times per year | <input type="radio"/> 3-4 times per week      |
| <input type="radio"/> 1 time per month    | <input type="radio"/> 5-6 times per week      |
| <input type="radio"/> 2-3 times per month | <input type="radio"/> 1 time per day          |
| <input type="radio"/> 1 time per week     | <input type="radio"/> 2 or more times per day |

12a. Each time you ate cold cereal, how much did you usually eat?

- Less than 1 cup  
 1 to  $2\frac{1}{2}$  cups  
 More than  $2\frac{1}{2}$  cups

12b. How often was the cold cereal you ate Total, Product 19, or Right Start?

- Almost never or never  
 About  $\frac{1}{4}$  of the time  
 About  $\frac{1}{2}$  of the time  
 About  $\frac{3}{4}$  of the time  
 Almost always or always

12c. How often was the cold cereal you ate All Bran, Fiber One, 100% Bran, or Bran Buds?

- Almost never or never  
 About  $\frac{1}{4}$  of the time  
 About  $\frac{1}{2}$  of the time  
 About  $\frac{3}{4}$  of the time  
 Almost always or always

Question 13 appears on the next page.

Over the past 12 months...

12d. How often was the cold cereal you ate some other bran or fiber cereal (such as Cheerios, Shredded Wheat, Raisin Bran, Bran Flakes, Grape-Nuts, Granola, Wheaties, or Healthy Choice)?

- Almost never or never
- About 1/4 of the time
- About 1/2 of the time
- About 3/4 of the time
- Almost always or always

12e. How often was the cold cereal you ate any other type of cold cereal (such as Corn Flakes, Rice Krispies, Frosted Flakes, Special K, Froot Loops, Cap'n Crunch, or others)?

- Almost never or never
- About 1/4 of the time
- About 1/2 of the time
- About 3/4 of the time
- Almost always or always

12f. Was milk added to your cold cereal?

NO (GO TO QUESTION 13)

YES

12g. What kind of milk was usually added?

- Whole milk
- 2% fat milk
- 1% fat milk
- Skim, nonfat, or 1/2% fat milk
- Soy milk
- Rice milk
- Other

12h. Each time milk was added to your cold cereal, how much was usually added?

- Less than 1/2 cup
- 1/2 to 1 cup
- More than 1 cup

13. How often did you eat applesauce?

NEVER (GO TO QUESTION 14)

- 1-6 times per year
- 7-11 times per year
- 1 time per month
- 2-3 times per month
- 1 time per week
- 2 times per week
- 3-4 times per week
- 5-6 times per week
- 1 time per day
- 2 or more times per day

Question 14 appears in the next column

13a. Each time you ate applesauce, how much did you usually eat?

- Less than 1/2 cup
- 1/2 to 1 cup
- More than 1 cup

14. How often did you eat apples?

NEVER (GO TO QUESTION 15)

- 1-6 times per year
- 7-11 times per year
- 1 time per month
- 2-3 times per month
- 1 time per week
- 2 times per week
- 3-4 times per week
- 5-6 times per week
- 1 time per day
- 2 or more times per day

14a. Each time you ate apples, how many did you usually eat?

- Less than 1 apple
- 1 apple
- More than 1 apple

15. How often did you eat pears (fresh, canned, or frozen)?

NEVER (GO TO QUESTION 16)

- 1-6 times per year
- 7-11 times per year
- 1 time per month
- 2-3 times per month
- 1 time per week
- 2 times per week
- 3-4 times per week
- 5-6 times per week
- 1 time per day
- 2 or more times per day

15a. Each time you ate pears, how much did you usually eat?

- Less than 1 pear
- 1 pear
- More than 1 pear

16. How often did you eat bananas?

NEVER (GO TO QUESTION 17)

- 1-6 times per year
- 7-11 times per year
- 1 time per month
- 2-3 times per month
- 1 time per week
- 2 times per week
- 3-4 times per week
- 5-6 times per week
- 1 time per day
- 2 or more times per day

Question 17 appears in the next page

Over the past 12 months...

16a. Each time you ate bananas, how many did you usually eat?

- Less than 1 banana
- 1 banana
- More than 1 banana

17. How often did you eat dried fruit, such as prunes or raisins (not including dried apricots)?

- NEVER (GO TO QUESTION 18)
- 1-6 times per year
- 7-11 times per year
- 1 time per month
- 2-3 times per month
- 1 time per week
- 2 times per week
- 3-4 times per week
- 5-6 times per week
- 1 time per day
- 2 or more times per day

17a. Each time you ate dried fruit, how much did you usually eat (not including dried apricots)?

- Less than 2 tablespoons
- 2 to 5 tablespoons
- More than 5 tablespoons

18. Over the past 12 months, did you eat peaches, nectarines, or plums?

NO (GO TO QUESTION 19)

YES

18a. How often did you eat fresh peaches, nectarines, or plums **WHEN IN SEASON?**

- NEVER
- 1-6 times per season
- 7-11 times per season
- 1 time per month
- 2-3 times per month
- 1 time per week
- 2 times per week
- 3-4 times per week
- 5-6 times per week
- 1 time per day
- 2 or more times per day

18b. How often did you eat peaches, nectarines, or plums (fresh, canned, or frozen) **DURING THE REST OF THE YEAR?**

- NEVER
- 1-6 times per year
- 7-11 times per year
- 1 time per month
- 2-3 times per month
- 1 time per week
- 2 times per week
- 3-4 times per week
- 5-6 times per week
- 1 time per day
- 2 or more times per day

Question 19 appears in the next column.

18c. Each time you ate peaches, nectarines, or plums, how much did you usually eat?

- Less than 1 fruit or less than 1/2 cup
- 1 to 2 fruits or 1/2 to 3/4 cup
- More than 2 fruits or more than 3/4 cup

19. How often did you eat grapes?

- NEVER (GO TO QUESTION 20)
- 1-6 times per year
- 7-11 times per year
- 1 time per month
- 2-3 times per month
- 1 time per week
- 2 times per week
- 3-4 times per week
- 5-6 times per week
- 1 time per day
- 2 or more times per day

19a. Each time you ate grapes, how much did you usually eat?

- Less than 1/2 cup or less than 10 grapes
- 1/2 to 1 cup or 10 to 30 grapes
- More than 1 cup or more than 30 grapes

20. Over the past 12 months, did you eat cantaloupe?

NO (GO TO QUESTION 21)

YES

20a. How often did you eat fresh cantaloupe **WHEN IN SEASON?**

- NEVER
- 1-6 times per season
- 7-11 times per season
- 1 time per month
- 2-3 times per month
- 1 time per week
- 2 times per week
- 3-4 times per week
- 5-6 times per week
- 1 time per day
- 2 or more times per day

20b. How often did you eat fresh or frozen cantaloupe **DURING THE REST OF THE YEAR?**

- NEVER
- 1-6 times per year
- 7-11 times per year
- 1 time per month
- 2-3 times per month
- 1 time per week
- 2 times per week
- 3-4 times per week
- 5-6 times per week
- 1 time per day
- 2 or more times per day

Question 21 appears on the next page.

Over the past 12 months...

20c. Each time you ate cantaloupe, how much did you usually eat?

- Less than 1/4 melon or less than 1/2 cup
- 1/4 melon or 1/2 to 1 cup
- More than 1/4 melon or more than 1 cup

21. Over the past 12 months, did you eat melon, other than cantaloupe (such as watermelon or honeydew)?

NO (GO TO QUESTION 22)

YES

21a. How often did you eat fresh melon, other than cantaloupe, (such as watermelon or honeydew) **WHEN IN SEASON?**

- NEVER
- 1-6 times per season     2 times per week
- 7-11 times per season     3-4 times per week
- 1 time per month     5-6 times per week
- 2-3 times per month     1 time per day
- 1 time per week     2 or more times per day

21b. How often did you eat fresh or frozen melon, other than cantaloupe (such as watermelon or honeydew) **DURING THE REST OF THE YEAR?**

- NEVER
- 1-6 times per year     2 times per week
- 7-11 times per year     3-4 times per week
- 1 time per month     5-6 times per week
- 2-3 times per month     1 time per day
- 1 time per week     2 or more times per day

21c. Each time you ate melon other than cantaloupe, how much did you usually eat?

- Less than 1/2 cup or 1 small wedge
- 1/2 to 2 cups or 1 medium wedge
- More than 2 cups or 1 large wedge



Question 22 appears in the next column.

22. Over the past 12 months, did you eat strawberries?

NO (GO TO QUESTION 23)

YES

22a. How often did you eat fresh strawberries **WHEN IN SEASON?**

- NEVER
- 1-6 times per season     2 times per week
- 7-11 times per season     3-4 times per week
- 1 time per month     5-6 times per week
- 2-3 times per month     1 time per day
- 1 time per week     2 or more times per day

22b. How often did you eat fresh or frozen strawberries **DURING THE REST OF THE YEAR?**

- NEVER
- 1-6 times per year     2 times per week
- 7-11 times per year     3-4 times per week
- 1 time per month     5-6 times per week
- 2-3 times per month     1 time per day
- 1 time per week     2 or more times per day

22c. Each time you ate strawberries, how much did you usually eat?

- Less than 1/4 cup or less than 3 berries
- 1/4 to 3/4 cup or 3 to 8 berries
- More than 3/4 cup or more than 8 berries

23. Over the past 12 months, did you eat oranges, tangerines, or tangelos?

NO (GO TO QUESTION 24)

YES

23a. How often did you eat fresh oranges, tangerines, or tangelos **WHEN IN SEASON?**

- NEVER
- 1-6 times per season     2 times per week
- 7-11 times per season     3-4 times per week
- 1 time per month     5-6 times per week
- 2-3 times per month     1 time per day
- 1 time per week     2 or more times per day

Question 24 appears in the next page.

Over the past 12 months...

23b. How often did you eat oranges, tangerines, or tangelos (fresh or canned) DURING THE REST OF THE YEAR?

- NEVER
- |   |   |
|---|---|
| <input type="radio"/> 1-6 times per year  | <input type="radio"/> 2 times per week        |
| <input type="radio"/> 7-11 times per year | <input type="radio"/> 3-4 times per week      |
| <input type="radio"/> 1 time per month    | <input type="radio"/> 5-6 times per week      |
| <input type="radio"/> 2-3 times per month | <input type="radio"/> 1 time per day          |
| <input type="radio"/> 1 time per week     | <input type="radio"/> 2 or more times per day |

23c. Each time you ate oranges, tangerines, or tangelos, how many did you usually eat?

- Less than 1 fruit  
 1 fruit  
 More than 1 fruit

24. Over the past 12 months, did you eat grapefruit?

NO (GO TO QUESTION 25)

YES

24a. How often did you eat fresh grapefruit WHEN IN SEASON?

- NEVER
- |   |   |
|---|---|
| <input type="radio"/> 1-6 times per season  | <input type="radio"/> 2 times per week        |
| <input type="radio"/> 7-11 times per season | <input type="radio"/> 3-4 times per week      |
| <input type="radio"/> 1 time per month      | <input type="radio"/> 5-6 times per week      |
| <input type="radio"/> 2-3 times per month   | <input type="radio"/> 1 time per day          |
| <input type="radio"/> 1 time per week       | <input type="radio"/> 2 or more times per day |

24b. How often did you eat grapefruit (fresh or canned) DURING THE REST OF THE YEAR?

- NEVER
- |   |   |
|---|---|
| <input type="radio"/> 1-6 times per year  | <input type="radio"/> 2 times per week        |
| <input type="radio"/> 7-11 times per year | <input type="radio"/> 3-4 times per week      |
| <input type="radio"/> 1 time per month    | <input type="radio"/> 5-6 times per week      |
| <input type="radio"/> 2-3 times per month | <input type="radio"/> 1 time per day          |
| <input type="radio"/> 1 time per week     | <input type="radio"/> 2 or more times per day |

24c. Each time you ate grapefruit, how much did you usually eat?

- Less than 1/2 grapefruit  
 1/2 grapefruit  
 More than 1/2 grapefruit

Question 25 appears in the next column.

25. How often did you eat other kinds of fruit?

- NEVER (GO TO QUESTION 26)
- |   |   |
|---|---|
| <input type="radio"/> 1-6 times per year  | <input type="radio"/> 2 times per week        |
| <input type="radio"/> 7-11 times per year | <input type="radio"/> 3-4 times per week      |
| <input type="radio"/> 1 time per month    | <input type="radio"/> 5-6 times per week      |
| <input type="radio"/> 2-3 times per month | <input type="radio"/> 1 time per day          |
| <input type="radio"/> 1 time per week     | <input type="radio"/> 2 or more times per day |

25a. Each time you ate other kinds of fruit, how much did you usually eat?

- Less than 1/4 cup  
 1/4 to 3/4 cup  
 More than 3/4 cup

26. How often did you eat COOKED greens (such as spinach, turnip, collard, mustard, chard, or kale)?

- NEVER (GO TO QUESTION 27)
- |   |   |
|---|---|
| <input type="radio"/> 1-6 times per year  | <input type="radio"/> 2 times per week        |
| <input type="radio"/> 7-11 times per year | <input type="radio"/> 3-4 times per week      |
| <input type="radio"/> 1 time per month    | <input type="radio"/> 5-6 times per week      |
| <input type="radio"/> 2-3 times per month | <input type="radio"/> 1 time per day          |
| <input type="radio"/> 1 time per week     | <input type="radio"/> 2 or more times per day |

26a. Each time you ate COOKED greens, how much did you usually eat?

- Less than 1/2 cup  
 1/2 to 1 cup  
 More than 1 cup

27. How often did you eat RAW greens (such as spinach, turnip, collard, mustard, chard, or kale)?  
(We will ask about lettuce later.)

- NEVER (GO TO QUESTION 28)
- |   |   |
|---|---|
| <input type="radio"/> 1-6 times per year  | <input type="radio"/> 2 times per week        |
| <input type="radio"/> 7-11 times per year | <input type="radio"/> 3-4 times per week      |
| <input type="radio"/> 1 time per month    | <input type="radio"/> 5-6 times per week      |
| <input type="radio"/> 2-3 times per month | <input type="radio"/> 1 time per day          |
| <input type="radio"/> 1 time per week     | <input type="radio"/> 2 or more times per day |

27a. Each time you ate RAW greens, how much did you usually eat?

- Less than 1/2 cup  
 1/2 to 1 cup  
 More than 1 cup

Question 28 appears on the next page.

Over the past 12 months...

28. How often did you eat coleslaw?

- NEVER (GO TO QUESTION 29)
- |   |   |
|---|---|
| <input type="radio"/> 1-6 times per year  | <input type="radio"/> 2 times per week        |
| <input type="radio"/> 7-11 times per year | <input type="radio"/> 3-4 times per week      |
| <input type="radio"/> 1 time per month    | <input type="radio"/> 5-6 times per week      |
| <input type="radio"/> 2-3 times per month | <input type="radio"/> 1 time per day          |
| <input type="radio"/> 1 time per week     | <input type="radio"/> 2 or more times per day |

28a. Each time you ate coleslaw, how much did you usually eat?

- Less than 1/4 cup  
 1/4 to 3/4 cup  
 More than 3/4 cup

29. How often did you eat sauerkraut or cabbage (other than coleslaw)?

- NEVER (GO TO QUESTION 30)
- |   |   |
|---|---|
| <input type="radio"/> 1-6 times per year  | <input type="radio"/> 2 times per week        |
| <input type="radio"/> 7-11 times per year | <input type="radio"/> 3-4 times per week      |
| <input type="radio"/> 1 time per month    | <input type="radio"/> 5-6 times per week      |
| <input type="radio"/> 2-3 times per month | <input type="radio"/> 1 time per day          |
| <input type="radio"/> 1 time per week     | <input type="radio"/> 2 or more times per day |

29a. Each time you ate cabbage or sauerkraut, how much did you usually eat?

- Less than 1/4 cup  
 1/4 to 1 cup  
 More than 1 cup

30. How often did you eat carrots (fresh, canned, or frozen)?

- NEVER (GO TO QUESTION 31)
- |   |   |
|---|---|
| <input type="radio"/> 1-6 times per year  | <input type="radio"/> 2 times per week        |
| <input type="radio"/> 7-11 times per year | <input type="radio"/> 3-4 times per week      |
| <input type="radio"/> 1 time per month    | <input type="radio"/> 5-6 times per week      |
| <input type="radio"/> 2-3 times per month | <input type="radio"/> 1 time per day          |
| <input type="radio"/> 1 time per week     | <input type="radio"/> 2 or more times per day |

30a. Each time you ate carrots, how much did you usually eat?

- Less than 1/4 cup or less than 2 baby carrots  
 1/4 to 1/2 cup or 2 to 5 baby carrots  
 More than 1/2 cup or more than 5 baby carrots

Question 31 appears in the next column.

31. How often did you eat string beans or green beans (fresh, canned, or frozen)?

- NEVER (GO TO QUESTION 32)
- |   |   |
|---|---|
| <input type="radio"/> 1-6 times per year  | <input type="radio"/> 2 times per week        |
| <input type="radio"/> 7-11 times per year | <input type="radio"/> 3-4 times per week      |
| <input type="radio"/> 1 time per month    | <input type="radio"/> 5-6 times per week      |
| <input type="radio"/> 2-3 times per month | <input type="radio"/> 1 time per day          |
| <input type="radio"/> 1 time per week     | <input type="radio"/> 2 or more times per day |

31a. Each time you ate string beans or green beans, how much did you usually eat?

- Less than 1/2 cup  
 1/2 to 1 cup  
 More than 1 cup

32. How often did you eat peas (fresh, canned, or frozen)?

- NEVER (GO TO QUESTION 33)
- |   |   |
|---|---|
| <input type="radio"/> 1-6 times per year  | <input type="radio"/> 2 times per week        |
| <input type="radio"/> 7-11 times per year | <input type="radio"/> 3-4 times per week      |
| <input type="radio"/> 1 time per month    | <input type="radio"/> 5-6 times per week      |
| <input type="radio"/> 2-3 times per month | <input type="radio"/> 1 time per day          |
| <input type="radio"/> 1 time per week     | <input type="radio"/> 2 or more times per day |

32a. Each time you ate peas, how much did you usually eat?

- Less than 1/4 cup  
 1/4 to 3/4 cup  
 More than 3/4 cup

33. Over the past 12 months, did you eat corn?

NO (GO TO QUESTION 34)

YES

33a. How often did you eat fresh corn WHEN IN SEASON?

- NEVER
- |   |   |
|---|---|
| <input type="radio"/> 1-6 times per season  | <input type="radio"/> 2 times per week        |
| <input type="radio"/> 7-11 times per season | <input type="radio"/> 3-4 times per week      |
| <input type="radio"/> 1 time per month      | <input type="radio"/> 5-6 times per week      |
| <input type="radio"/> 2-3 times per month   | <input type="radio"/> 1 time per day          |
| <input type="radio"/> 1 time per week       | <input type="radio"/> 2 or more times per day |

Question 34 appears on the next page.

Over the past 12 months...

33b. How often did you eat corn (fresh, canned, or frozen) DURING THE REST OF THE YEAR?

- NEVER
- 1-6 times per year
- 7-11 times per year
- 1 time per month
- 2-3 times per month
- 1 time per week
- 2 times per week
- 3-4 times per week
- 5-6 times per week
- 1 time per day
- 2 or more times per day

33c. Each time you ate corn, how much did you usually eat?

- Less than 1 ear or less than 1/2 cup
- 1 ear or 1/2 to 1 cup
- More than 1 ear or more than 1 cup

34. Over the past 12 months, how often did you eat broccoli (fresh or frozen)?

- NEVER (GO TO QUESTION 35)
- 1-6 times per year
- 7-11 times per year
- 1 time per month
- 2-3 times per month
- 1 time per week
- 2 times per week
- 3-4 times per week
- 5-6 times per week
- 1 time per day
- 2 or more times per day

34a. Each time you ate broccoli, how much did you usually eat?

- Less than 1/4 cup
- 1/4 to 1 cup
- More than 1 cup

35. How often did you eat cauliflower or Brussels sprouts (fresh or frozen)?

- NEVER (GO TO QUESTION 36)
- 1-6 times per year
- 7-11 times per year
- 1 time per month
- 2-3 times per month
- 1 time per week
- 2 times per week
- 3-4 times per week
- 5-6 times per week
- 1 time per day
- 2 or more times per day

35a. Each time you ate cauliflower or Brussels sprouts, how much did you usually eat?

- Less than 1/4 cup
- 1/4 to 1/2 cup
- More than 1/2 cup

Question 36 appears in the next column

36. How often did you eat mixed vegetables?

- NEVER (GO TO QUESTION 37)
- 1-6 times per year
- 7-11 times per year
- 1 time per month
- 2-3 times per month
- 1 time per week
- 2 times per week
- 3-4 times per week
- 5-6 times per week
- 1 time per day
- 2 or more times per day

36a. Each time you ate mixed vegetables, how much did you usually eat?

- Less than 1/2 cup
- 1/2 to 1 cup
- More than 1 cup

37. How often did you eat onions?

- NEVER (GO TO QUESTION 38)
- 1-6 times per year
- 7-11 times per year
- 1 time per month
- 2-3 times per month
- 1 time per week
- 2 times per week
- 3-4 times per week
- 5-6 times per week
- 1 time per day
- 2 or more times per day

37a. Each time you ate onions, how much did you usually eat?

- Less than 1 slice or less than 1 tablespoon
- 1 slice or 1 to 4 tablespoons
- More than 1 slice or more than 4 tablespoons

38. Now think about all the cooked vegetables you ate in the past 12 months and how they were prepared. How often were your vegetables **COOKED WITH** some sort of fat, including oil spray? (*Please do not include potatoes.*)

- NEVER (GO TO QUESTION 39)
- 1-6 times per year
- 7-11 times per year
- 1 time per month
- 2-3 times per month
- 1 time per week
- 2 times per week
- 3-4 times per week
- 5-6 times per week
- 1 time per day
- 2 or more times per day



Question 39 appears on the next page

Over the past 12 months...

38a. Which fats were usually added to your vegetables **DURING COOKING**? (Please do not include potatoes. Mark as many as apply.)

- |   |  |
|---|--|
| <input type="radio"/> Margarine (including low-fat) | <input type="radio"/> Corn oil                         |
| <input type="radio"/> Butter (including low-fat)    | <input type="radio"/> Canola or rapeseed oil           |
| <input type="radio"/> Lard, fatback, or bacon fat   | <input type="radio"/> Oil spray, such as Pam or others |
| <input type="radio"/> Olive oil                     | <input type="radio"/> Other kinds of oils              |
|   | <input type="radio"/> None of the above                |

39. Now, thinking again about all the cooked vegetables you ate in the past 12 months, how often was some sort of fat, sauce, or dressing added **AFTER COOKING OR AT THE TABLE**? (Please do not include potatoes.)

- NEVER (GO TO QUESTION 40)
- |   |   |
|---|---|
| <input type="radio"/> 1-6 times per year  | <input type="radio"/> 3-4 times per week      |
| <input type="radio"/> 7-11 times per year | <input type="radio"/> 5-6 times per week      |
| <input type="radio"/> 1 time per month    | <input type="radio"/> 1 time per day          |
| <input type="radio"/> 2-3 times per month | <input type="radio"/> 2 times per day         |
| <input type="radio"/> 1-2 times per week  | <input type="radio"/> 3 or more times per day |

39a. Which fats, sauces, or dressings were usually added **AFTER COOKING OR AT THE TABLE**? (Please do not include potatoes. Mark as many as apply.)

- |   |                                      |
|---|--------------------------------------|
| <input type="radio"/> Margarine (including low-fat) | <input type="radio"/> Salad dressing |
| <input type="radio"/> Butter (including low-fat)    | <input type="radio"/> Cheese sauce   |
| <input type="radio"/> Lard, fatback, or bacon fat   | <input type="radio"/> White sauce    |
|   | <input type="radio"/> Other          |

39b. If margarine, butter, lard, fatback, or bacon fat was added to your cooked vegetables **AFTER COOKING OR AT THE TABLE**, how much did you usually add?

- Did not usually add these
- Less than 1 teaspoon
- 1 to 3 teaspoons
- More than 3 teaspoons

39c. If salad dressing, cheese sauce, or white sauce was added to your cooked vegetables **AFTER COOKING OR AT THE TABLE**, how much did you usually add?

- Did not usually add these
- Less than 1 tablespoon
- 1 to 3 tablespoons
- More than 3 tablespoons

Question 40 appears in the next column.

40. Over the past 12 months, how often did you eat sweet peppers (green, red, or yellow)?

- NEVER (GO TO QUESTION 41)
- |   |   |
|---|---|
| <input type="radio"/> 1-6 times per year  | <input type="radio"/> 2 times per week        |
| <input type="radio"/> 7-11 times per year | <input type="radio"/> 3-4 times per week      |
| <input type="radio"/> 1 time per month    | <input type="radio"/> 5-6 times per week      |
| <input type="radio"/> 2-3 times per month | <input type="radio"/> 1 time per day          |
| <input type="radio"/> 1 time per week     | <input type="radio"/> 2 or more times per day |

40a. Each time you ate sweet peppers, how much did you usually eat?

- Less than 1/8 pepper
- 1/8 to 1/4 pepper
- More than 1/4 pepper

41. Over the past 12 months, did you eat fresh tomatoes (including those in salads)?

- NO (GO TO QUESTION 42)
- YES

41a. How often did you eat fresh tomatoes (including those in salads) **WHEN IN SEASON**?

- NEVER
- |   |   |
|---|---|
| <input type="radio"/> 1-6 times per season  | <input type="radio"/> 2 times per week        |
| <input type="radio"/> 7-11 times per season | <input type="radio"/> 3-4 times per week      |
| <input type="radio"/> 1 time per month      | <input type="radio"/> 5-6 times per week      |
| <input type="radio"/> 2-3 times per month   | <input type="radio"/> 1 time per day          |
| <input type="radio"/> 1 time per week       | <input type="radio"/> 2 or more times per day |

41b. How often did you eat fresh tomatoes (including those in salads) **DURING THE REST OF THE YEAR**?

- NEVER
- |   |   |
|---|---|
| <input type="radio"/> 1-6 times per year  | <input type="radio"/> 2 times per week        |
| <input type="radio"/> 7-11 times per year | <input type="radio"/> 3-4 times per week      |
| <input type="radio"/> 1 time per month    | <input type="radio"/> 5-6 times per week      |
| <input type="radio"/> 2-3 times per month | <input type="radio"/> 1 time per day          |
| <input type="radio"/> 1 time per week     | <input type="radio"/> 2 or more times per day |

41c. Each time you ate fresh tomatoes, how much did you usually eat?

- Less than 1/4 tomato
- 1/4 to 1/2 tomato
- More than 1/2 tomato

Question 42 appears on the next page.

Over the past 12 months...

42. How often did you eat lettuce salads (with or without other vegetables)?

- NEVER (GO TO QUESTION 43)
- 1-6 times per year       2 times per week
- 7-11 times per year     3-4 times per week
- 1 time per month         5-6 times per week
- 2-3 times per month     1 time per day
- 1 time per week         2 or more times per day

42a. Each time you ate lettuce salads, how much did you usually eat?

- Less than 1/4 cup
- 1/4 to 1 1/4 cups
- More than 1 1/4 cups

43. How often did you eat salad dressing (including low-fat) on salads?

- NEVER (GO TO QUESTION 44)
- 1-6 times per year       2 times per week
- 7-11 times per year     3-4 times per week
- 1 time per month         5-6 times per week
- 2-3 times per month     1 time per day
- 1 time per week         2 or more times per day

43a. Each time you ate salad dressing on salads, how much did you usually eat?

- Less than 2 tablespoons
- 2 to 4 tablespoons
- More than 4 tablespoons

44. How often did you eat sweet potatoes or yams?

- NEVER (GO TO QUESTION 45)
- 1-6 times per year       2 times per week
- 7-11 times per year     3-4 times per week
- 1 time per month         5-6 times per week
- 2-3 times per month     1 time per day
- 1 time per week         2 or more times per day

44a. Each time you ate sweet potatoes or yams, how much did you usually eat?

- 1 small potato or less than 1/4 cup
- 1 medium potato or 1/4 to 3/4 cup
- 1 large potato or more than 3/4 cup

45. How often did you eat French fries, home fries, hash browned potatoes, or tater tots?

- NEVER (GO TO QUESTION 46)
- 1-6 times per year       2 times per week
- 7-11 times per year     3-4 times per week
- 1 time per month         5-6 times per week
- 2-3 times per month     1 time per day
- 1 time per week         2 or more times per day

45a. Each time you ate French fries, home fries, hash browned potatoes, or tater tots how much did you usually eat?

- Less than 10 fries or less than 1/2 cup
- 10 to 25 fries or 1/2 to 1 cup
- More than 25 fries or more than 1 cup

46. How often did you eat potato salad?

- NEVER (GO TO QUESTION 47)
- 1-6 times per year       2 times per week
- 7-11 times per year     3-4 times per week
- 1 time per month         5-6 times per week
- 2-3 times per month     1 time per day
- 1 time per week         2 or more times per day

46a. Each time you ate potato salad, how much did you usually eat?

- Less than 1/2 cup
- 1/2 to 1 cup
- More than 1 cup

47. How often did you eat baked, boiled, or mashed potatoes?

- NEVER (GO TO QUESTION 48)
- 1-6 times per year       2 times per week
- 7-11 times per year     3-4 times per week
- 1 time per month         5-6 times per week
- 2-3 times per month     1 time per day
- 1 time per week         2 or more times per day

47a. Each time you ate baked, boiled, or mashed potatoes, how much did you usually eat?

- 1 small potato or less than 1/2 cup
- 1 medium potato or 1/2 to 1 cup
- 1 large potato or more than 1 cup

Over the past 12 months...

47b. How often was sour cream (including low-fat) added to your potatoes, EITHER IN COOKING OR AT THE TABLE?

- Almost never or never (GO TO QUESTION 47d)
- About 1/4 of the time
- About 1/2 of the time
- About 3/4 of the time
- Almost always or always

47c. Each time sour cream was added to your potatoes, how much was usually added?

- Less than 1 tablespoon
- 1 to 3 tablespoons
- More than 3 tablespoons

47d. How often was margarine (including low-fat) added to your potatoes, EITHER IN COOKING OR AT THE TABLE?

- Almost never or never
- About 1/4 of the time
- About 1/2 of the time
- About 3/4 of the time
- Almost always or always

47e. How often was butter (including low-fat) added to your potatoes, EITHER IN COOKING OR AT THE TABLE?

- Almost never or never
- About 1/4 of the time
- About 1/2 of the time
- About 3/4 of the time
- Almost always or always

47f. Each time margarine or butter was added to your potatoes, how much was usually added?

- Never added
- Less than 1 teaspoon
- 1 to 3 teaspoons
- More than 3 teaspoons

47g. How often was cheese or cheese sauce added to your potatoes, EITHER IN COOKING OR AT THE TABLE?

- Almost never or never (GO TO QUESTION 48)
- About 1/4 of the time
- About 1/2 of the time
- About 3/4 of the time
- Almost always or always

47h. Each time cheese or cheese sauce was added to your potatoes, how much was usually added?

- Less than 1 tablespoon
- 1 to 3 tablespoons
- More than 3 tablespoons

48. How often did you eat salsa?

- NEVER (GO TO QUESTION 49)
- 1-6 times per year
- 7-11 times per year
- 1 time per month
- 2-3 times per month
- 1 time per week
- 2 times per week
- 3-4 times per week
- 5-6 times per week
- 1 time per day
- 2 or more times per day

48a. Each time you ate salsa, how much did you usually eat?

- Less than 1 tablespoon
- 1 to 5 tablespoons
- More than 5 tablespoons

49. How often did you eat catsup?

- NEVER (GO TO QUESTION 50)
- 1-6 times per year
- 7-11 times per year
- 1 time per month
- 2-3 times per month
- 1 time per week
- 2 times per week
- 3-4 times per week
- 5-6 times per week
- 1 time per day
- 2 or more times per day

49a. Each time you ate catsup, how much did you usually eat?

- Less than 1 teaspoon
- 1 to 6 teaspoons
- More than 6 teaspoons

50. How often did you eat stuffing, dressing, or dumplings?

- NEVER (GO TO QUESTION 51)
- 1-6 times per year
- 7-11 times per year
- 1 time per month
- 2-3 times per month
- 1 time per week
- 2 times per week
- 3-4 times per week
- 5-6 times per week
- 1 time per day
- 2 or more times per day

50a. Each time you ate stuffing, dressing, or dumplings, how much did you usually eat?

- Less than 1/2 cup
- 1/2 to 1 cup
- More than 1 cup

Question 43 appears in the next column.

Question 51 appears on the next page.

Over the past 12 months...

51. How often did you eat chili?

- NEVER (GO TO QUESTION 52)
- |   |   |
|---|---|
| <input type="radio"/> 1-6 times per year  | <input type="radio"/> 2 times per week        |
| <input type="radio"/> 7-11 times per year | <input type="radio"/> 3-4 times per week      |
| <input type="radio"/> 1 time per month    | <input type="radio"/> 5-6 times per week      |
| <input type="radio"/> 2-3 times per month | <input type="radio"/> 1 time per day          |
| <input type="radio"/> 1 time per week     | <input type="radio"/> 2 or more times per day |

51a. Each time you ate chili, how much did you usually eat?

- Less than 1/2 cup  
 1/2 to 1 3/4 cups  
 More than 1 3/4 cups

52. How often did you eat Mexican foods (such as tacos, tostados, burritos, tamales, fajitas, enchiladas, quesadillas, and chimichangas)?

- NEVER (GO TO QUESTION 53)
- |   |   |
|---|---|
| <input type="radio"/> 1-6 times per year  | <input type="radio"/> 2 times per week        |
| <input type="radio"/> 7-11 times per year | <input type="radio"/> 3-4 times per week      |
| <input type="radio"/> 1 time per month    | <input type="radio"/> 5-6 times per week      |
| <input type="radio"/> 2-3 times per month | <input type="radio"/> 1 time per day          |
| <input type="radio"/> 1 time per week     | <input type="radio"/> 2 or more times per day |

52a. Each time you ate Mexican foods, how much did you usually eat?

- Less than 1 taco, burrito, etc.  
 1 to 2 tacos, burritos, etc.  
 More than 2 tacos, burritos, etc.

53. How often did you eat cooked dried beans (such as baked beans, pintos, kidney, blackeyed peas, lima, lentils, soybeans, or refried beans)? (Please don't include bean soups or chili.)

- NEVER (GO TO QUESTION 54)
- |   |   |
|---|---|
| <input type="radio"/> 1-6 times per year  | <input type="radio"/> 2 times per week        |
| <input type="radio"/> 7-11 times per year | <input type="radio"/> 3-4 times per week      |
| <input type="radio"/> 1 time per month    | <input type="radio"/> 5-6 times per week      |
| <input type="radio"/> 2-3 times per month | <input type="radio"/> 1 time per day          |
| <input type="radio"/> 1 time per week     | <input type="radio"/> 2 or more times per day |

53a. Each time you ate beans, how much did you usually eat?

- Less than 1/2 cup  
 1/2 to 1 cup  
 More than 1 cup

Question 54 appears in the next column.

53b. How often were the beans you ate refried beans, beans prepared with any type of fat, or with meat added?

- Almost never or never  
 About 1/4 of the time  
 About 1/2 of the time  
 About 3/4 of the time  
 Almost always or always

54. How often did you eat other kinds of vegetables?

- NEVER (GO TO QUESTION 55)
- |   |   |
|---|---|
| <input type="radio"/> 1-6 times per year  | <input type="radio"/> 2 times per week        |
| <input type="radio"/> 7-11 times per year | <input type="radio"/> 3-4 times per week      |
| <input type="radio"/> 1 time per month    | <input type="radio"/> 5-6 times per week      |
| <input type="radio"/> 2-3 times per month | <input type="radio"/> 1 time per day          |
| <input type="radio"/> 1 time per week     | <input type="radio"/> 2 or more times per day |

54a. Each time you ate other kinds of vegetables, how much did you usually eat?

- Less than 1/4 cup  
 1/4 to 1/2 cup  
 More than 1/2 cup

55. How often did you eat rice or other cooked grains (such as bulgur, cracked wheat, or millet)?

- NEVER (GO TO QUESTION 56)
- |   |   |
|---|---|
| <input type="radio"/> 1-6 times per year  | <input type="radio"/> 2 times per week        |
| <input type="radio"/> 7-11 times per year | <input type="radio"/> 3-4 times per week      |
| <input type="radio"/> 1 time per month    | <input type="radio"/> 5-6 times per week      |
| <input type="radio"/> 2-3 times per month | <input type="radio"/> 1 time per day          |
| <input type="radio"/> 1 time per week     | <input type="radio"/> 2 or more times per day |

55a. Each time you ate rice or other cooked grains, how much did you usually eat?

- Less than 1/2 cup  
 1/2 to 1 1/2 cups  
 More than 1 1/2 cups

55b. How often was butter, margarine, or oil added to your rice IN COOKING OR AT THE TABLE?

- Almost never or never  
 About 1/4 of the time  
 About 1/2 of the time  
 About 3/4 of the time  
 Almost always or always

Question 56 appears on the next page.

Over the past 12 months...

56. How often did you eat pancakes, waffles, or French toast?

- NEVER (GO TO QUESTION 57)
- |   |   |
|---|---|
| <input type="radio"/> 1-6 times per year  | <input type="radio"/> 2 times per week        |
| <input type="radio"/> 7-11 times per year | <input type="radio"/> 3-4 times per week      |
| <input type="radio"/> 1 time per month    | <input type="radio"/> 5-6 times per week      |
| <input type="radio"/> 2-3 times per month | <input type="radio"/> 1 time per day          |
| <input type="radio"/> 1 time per week     | <input type="radio"/> 2 or more times per day |

56a. Each time you ate pancakes, waffles, or French toast, how much did you usually eat?

- Less than 1 medium piece  
 1 to 3 medium pieces  
 More than 3 medium pieces

56b. How often was margarine (including low-fat) added to your pancakes, waffles, or French toast AFTER COOKING OR AT THE TABLE?

- Almost never or never  
 About 1/4 of the time  
 About 1/2 of the time  
 About 3/4 of the time  
 Almost always or always

56c. How often was butter (including low-fat) added to your pancakes, waffles, or French toast AFTER COOKING OR AT THE TABLE?

- Almost never or never  
 About 1/4 of the time  
 About 1/2 of the time  
 About 3/4 of the time  
 Almost always or always

56d. Each time margarine or butter was added to your pancakes, waffles, or French toast, how much was usually added?

- Never added  
 Less than 1 teaspoon  
 1 to 3 teaspoons  
 More than 3 teaspoons

56e. How often was syrup added to your pancakes, waffles, or French toast?

- Almost never or never (GO TO QUESTION 57)  
 About 1/4 of the time  
 About 1/2 of the time  
 About 3/4 of the time  
 Almost always or always

56f. Each time syrup was added to your pancakes, waffles, or French toast, how much was usually added?

- Less than 1 tablespoon  
 1 to 4 tablespoons  
 More than 4 tablespoons

57. How often did you eat lasagna, stuffed shells, stuffed manicotti, ravioli, or tortellini? (Please do not include spaghetti or other pasta.)

NEVER (GO TO QUESTION 58)

- |   |   |
|---|---|
| <input type="radio"/> 1-6 times per year  | <input type="radio"/> 2 times per week        |
| <input type="radio"/> 7-11 times per year | <input type="radio"/> 3-4 times per week      |
| <input type="radio"/> 1 time per month    | <input type="radio"/> 5-6 times per week      |
| <input type="radio"/> 2-3 times per month | <input type="radio"/> 1 time per day          |
| <input type="radio"/> 1 time per week     | <input type="radio"/> 2 or more times per day |

57a. Each time you ate lasagna, stuffed shells, stuffed manicotti, ravioli, or tortellini, how much did you usually eat?

- Less than 1 cup  
 1 to 2 cups  
 More than 2 cups

58. How often did you eat macaroni and cheese?

NEVER (GO TO QUESTION 59)

- |   |   |
|---|---|
| <input type="radio"/> 1-6 times per year  | <input type="radio"/> 2 times per week        |
| <input type="radio"/> 7-11 times per year | <input type="radio"/> 3-4 times per week      |
| <input type="radio"/> 1 time per month    | <input type="radio"/> 5-6 times per week      |
| <input type="radio"/> 2-3 times per month | <input type="radio"/> 1 time per day          |
| <input type="radio"/> 1 time per week     | <input type="radio"/> 2 or more times per day |

58a. Each time you ate macaroni and cheese, how much did you usually eat?

- Less than 1 cup  
 1 to 1 1/2 cups  
 More than 1 1/2 cups

59. How often did you eat pasta salad or macaroni salad?

NEVER (GO TO QUESTION 60)

- |   |   |
|---|---|
| <input type="radio"/> 1-6 times per year  | <input type="radio"/> 2 times per week        |
| <input type="radio"/> 7-11 times per year | <input type="radio"/> 3-4 times per week      |
| <input type="radio"/> 1 time per month    | <input type="radio"/> 5-6 times per week      |
| <input type="radio"/> 2-3 times per month | <input type="radio"/> 1 time per day          |
| <input type="radio"/> 1 time per week     | <input type="radio"/> 2 or more times per day |

Perf

Question 57 appears in the next column

Question 59 appears on the next page

Over the past 12 months...

59a. Each time you ate **pasta salad** or **macaroni salad**, how much did you usually eat?

- Less than 1/2 cup
- 1/2 to 1 cup
- More than 1 cup

60. Other than the pastas listed in Questions 57, 58, and 59, how often did you eat **pasta, spaghetti, or other noodles**?

NEVER (GO TO QUESTION 61)

- 1-6 times per year
- 7-11 times per year
- 1 time per month
- 2-3 times per month
- 1 time per week
- 2 times per week
- 3-4 times per week
- 5-6 times per week
- 1 time per day
- 2 or more times per day

60a. Each time you ate **pasta, spaghetti, or other noodles**, how much did you usually eat?

- Less than 1 cup
- 1 to 3 cups
- More than 3 cups

60b. How often did you eat your **pasta, spaghetti, or other noodles with tomato sauce or spaghetti sauce made WITH meat**?

- Almost never or never
- About 1/4 of the time
- About 1/2 of the time
- About 3/4 of the time
- Almost always or always

60c. How often did you eat your **pasta, spaghetti, or other noodles with tomato sauce or spaghetti sauce made WITHOUT meat**?

- Almost never or never
- About 1/4 of the time
- About 1/2 of the time
- About 3/4 of the time
- Almost always or always

60d. How often did you eat your **pasta, spaghetti, or other noodles with margarine, butter, oil, or cream sauce**?

- Almost never or never
- About 1/4 of the time
- About 1/2 of the time
- About 3/4 of the time
- Almost always or always

61. How often did you eat **bagels or English muffins**?

NEVER (GO TO INTRODUCTION TO QUESTION 62)

- 1-6 times per year
- 7-11 times per year
- 1 time per month
- 2-3 times per month
- 1 time per week
- 2 times per week
- 3-4 times per week
- 5-6 times per week
- 1 time per day
- 2 or more times per day

61a. Each time you ate **bagels or English muffins**, how many did you usually eat?

- Less than 1 bagel or English muffin
- 1 bagel or English muffin
- More than 1 bagel or English muffin

61b. How often was **margarine (including low-fat)** added to your **bagels or English muffins**?

- Almost never or never
- About 1/4 of the time
- About 1/2 of the time
- About 3/4 of the time
- Almost always or always

61c. How often was **butter (including low-fat)** added to your **bagels or English muffins**?

- Almost never or never
- About 1/4 of the time
- About 1/2 of the time
- About 3/4 of the time
- Almost always or always

61d. Each time **margarine or butter** was added to your **bagels or English muffins**, how much was usually added?

- Never added
- Less than 1 teaspoon
- 1 to 2 teaspoons
- More than 2 teaspoons

61e. How often was **cream cheese (including low-fat)** spread on your **bagels or English muffins**?

- Almost never or never (GO TO INTRODUCTION TO QUESTION 62)
- About 1/4 of the time
- About 1/2 of the time
- About 3/4 of the time
- Almost always or always



Question 61 appears in the next column

Introduction to Question 62 appears on the next page.

Over the past 12 months...

61f. Each time cream cheese was added to your bagels or English muffins, how much was usually added?

- Less than 1 tablespoon
- 1 to 2 tablespoons
- More than 2 tablespoons

The next questions ask about your intake of breads other than bagels or English muffins. First, we will ask about bread you ate as part of sandwiches only. Then we will ask about all other bread you ate.

62. How often did you eat breads or rolls AS PART OF SANDWICHES (including burger and hot dog rolls)?

- NEVER (GO TO QUESTION 63)
- 1-6 times per year
- 7-11 times per year
- 1 time per month
- 2-3 times per month
- 1 time per week
- 2 times per week
- 3-4 times per week
- 5-6 times per week
- 1 time per day
- 2 or more times per day

62a. Each time you ate breads or rolls AS PART OF SANDWICHES, how many did you usually eat?

- 1 slice or 1/2 roll
- 2 slices or 1 roll
- More than 2 slices or more than 1 roll

62b. How often were the breads or rolls that you used for your sandwiches white bread (including burger and hot dog rolls)?

- Almost never or never
- About 1/4 of the time
- About 1/2 of the time
- About 3/4 of the time
- Almost always or always

62c. How often was mayonnaise or mayonnaise-type dressing (including low-fat) added to your sandwich bread or rolls?

- Almost never or never (GO TO QUESTION 62e)
- About 1/4 of the time
- About 1/2 of the time
- About 3/4 of the time
- Almost always or always

62d. Each time mayonnaise or mayonnaise-type dressing was added to your sandwich breads or rolls, how much was usually added?

- Less than 1 teaspoon
- 1 to 3 teaspoons
- More than 3 teaspoons

62e. How often was margarine (including low-fat) added to your sandwich bread or rolls?

- Almost never or never
- About 1/4 of the time
- About 1/2 of the time
- About 3/4 of the time
- Almost always or always

62f. How often was butter (including low-fat) added to your sandwich bread or rolls?

- Almost never or never
- About 1/4 of the time
- About 1/2 of the time
- About 3/4 of the time
- Almost always or always

62g. Each time margarine or butter was added to your sandwich breads or rolls, how much was usually added?

- Never added
- Less than 1 teaspoon
- 1 to 2 teaspoons
- More than 2 teaspoons

63. How often did you eat breads or dinner rolls, NOT AS PART OF SANDWICHES?

- NEVER (GO TO QUESTION 64)
- 1-6 times per year
- 7-11 times per year
- 1 time per month
- 2-3 times per month
- 1 time per week
- 2 times per week
- 3-4 times per week
- 5-6 times per week
- 1 time per day
- 2 or more times per day

63a. Each time you ate breads or dinner rolls, NOT AS PART OF SANDWICHES, how much did you usually eat?

- 1 slice or 1 dinner roll
- 2 slices or 2 dinner rolls
- More than 2 slices or 2 dinner rolls



Perf

Question 62c appears in the next column  
Question 63 appears in the next column

Question 64 appears on the next page.

Over the past 12 months...

63b. How often were the breads or rolls you ate white bread?

- Almost never or never
- About 1/4 of the time
- About 1/2 of the time
- About 3/4 of the time
- Almost always or always

63c. How often was margarine (including low-fat) added to your breads or rolls?

- Almost never or never
- About 1/4 of the time
- About 1/2 of the time
- About 3/4 of the time
- Almost always or always

63d. How often was butter (including low-fat) added to your breads or rolls?

- Almost never or never
- About 1/4 of the time
- About 1/2 of the time
- About 3/4 of the time
- Almost always or always

63e. Each time margarine or butter was added to your breads or rolls, how much was usually added?

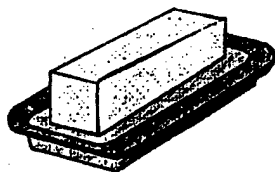
- Never added
- Less than 1 teaspoon
- 1 to 2 teaspoons
- More than 2 teaspoons

63f. How often was cream cheese (including low-fat) added to your breads or rolls?

- Almost never or never (GO TO QUESTION 64)
- About 1/4 of the time
- About 1/2 of the time
- About 3/4 of the time
- Almost always or always

63g. Each time cream cheese was added to your breads or rolls, how much was usually added?

- Less than 1 tablespoon
- 1 to 2 tablespoons
- More than 2 tablespoons



Question 64 appears in the next column.

64. How often did you eat jam, jelly, or honey on bagels, muffins, bread, rolls, or crackers?

NEVER (GO TO QUESTION 65)

- 1-6 times per year
- 7-11 times per year
- 1 time per month
- 2-3 times per month
- 1 time per week
- 2 times per week
- 3-4 times per week
- 5-6 times per week
- 1 time per day
- 2 or more times per day

64a. Each time you ate jam, jelly, or honey, how much did you usually eat?

- Less than 1 teaspoon
- 1 to 3 teaspoons
- More than 3 teaspoons

65. How often did you eat peanut butter or other nut butter?

NEVER (GO TO QUESTION 66)

- 1-6 times per year
- 7-11 times per year
- 1 time per month
- 2-3 times per month
- 1 time per week
- 2 times per week
- 3-4 times per week
- 5-6 times per week
- 1 time per day
- 2 or more times per day

65a. Each time you ate peanut butter or other nut butter, how much did you usually eat?

- Less than 1 tablespoon
- 1 to 2 tablespoons
- More than 2 tablespoons

66. How often did you eat roast beef or steak IN SANDWICHES?

NEVER (GO TO QUESTION 67)

- 1-6 times per year
- 7-11 times per year
- 1 time per month
- 2-3 times per month
- 1 time per week
- 2 times per week
- 3-4 times per week
- 5-6 times per week
- 1 time per day
- 2 or more times per day

66a. Each time you ate roast beef or steak IN SANDWICHES, how much did you usually eat?

- Less than 1 slice or less than 2 ounces
- 1 to 2 slices or 2 to 4 ounces
- More than 2 slices or more than 4 ounces

Question 67 appears on the next page.

Over the past 12 months...

67. How often did you eat turkey or chicken cold CUTS (such as loaf, luncheon meat, turkey ham, turkey salami, or turkey pastrami)? (We will ask about other turkey or chicken later.)

- NEVER (GO TO QUESTION 68)
- |   |   |
|---|---|
| <input type="radio"/> 1-6 times per year  | <input type="radio"/> 2 times per week        |
| <input type="radio"/> 7-11 times per year | <input type="radio"/> 3-4 times per week      |
| <input type="radio"/> 1 time per month    | <input type="radio"/> 5-6 times per week      |
| <input type="radio"/> 2-3 times per month | <input type="radio"/> 1 time per day          |
| <input type="radio"/> 1 time per week     | <input type="radio"/> 2 or more times per day |

67a. Each time you ate turkey or chicken COLD CUTS, how much did you usually eat?

- Less than 1 slice  
 1 to 3 slices  
 More than 3 slices

68. How often did you eat luncheon or deli-style ham? (We will ask about other ham later.)

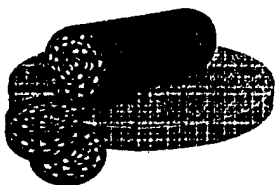
- NEVER (GO TO QUESTION 69)
- |   |   |
|---|---|
| <input type="radio"/> 1-6 times per year  | <input type="radio"/> 2 times per week        |
| <input type="radio"/> 7-11 times per year | <input type="radio"/> 3-4 times per week      |
| <input type="radio"/> 1 time per month    | <input type="radio"/> 5-6 times per week      |
| <input type="radio"/> 2-3 times per month | <input type="radio"/> 1 time per day          |
| <input type="radio"/> 1 time per week     | <input type="radio"/> 2 or more times per day |

68a. Each time you ate luncheon or deli-style ham, how much did you usually eat?

- Less than 1 slice  
 1 to 3 slices  
 More than 3 slices

68b. How often was the luncheon or deli-style ham you ate light, low-fat, or fat-free?

- Almost never or never  
 About 1/4 of the time  
 About 1/2 of the time  
 About 3/4 of the time  
 Almost always or always



Question 69 appears in the next column

69. How often did you eat other cold cuts or luncheon meats (such as bologna, salami, corned beef, pastrami, or others, including low-fat)? (Please do not include ham, turkey, or chicken cold cuts.)

- NEVER (GO TO QUESTION 70)
- |   |   |
|---|---|
| <input type="radio"/> 1-6 times per year  | <input type="radio"/> 2 times per week        |
| <input type="radio"/> 7-11 times per year | <input type="radio"/> 3-4 times per week      |
| <input type="radio"/> 1 time per month    | <input type="radio"/> 5-6 times per week      |
| <input type="radio"/> 2-3 times per month | <input type="radio"/> 1 time per day          |
| <input type="radio"/> 1 time per week     | <input type="radio"/> 2 or more times per day |

69a. Each time you ate other cold cuts or luncheon meats, how much did you usually eat?

- Less than 1 slice  
 1 to 3 slices  
 More than 3 slices

69b. How often were the other cold cuts or luncheon meats you ate light, low-fat, or fat-free cold cuts or luncheon meats? (Please do not include ham, turkey, or chicken cold cuts.)

- Almost never or never  
 About 1/4 of the time  
 About 1/2 of the time  
 About 3/4 of the time  
 Almost always or always

70. How often did you eat canned tuna (including in salads, sandwiches, or casseroles)?

- NEVER (GO TO QUESTION 71)
- |   |   |
|---|---|
| <input type="radio"/> 1-6 times per year  | <input type="radio"/> 2 times per week        |
| <input type="radio"/> 7-11 times per year | <input type="radio"/> 3-4 times per week      |
| <input type="radio"/> 1 time per month    | <input type="radio"/> 5-6 times per week      |
| <input type="radio"/> 2-3 times per month | <input type="radio"/> 1 time per day          |
| <input type="radio"/> 1 time per week     | <input type="radio"/> 2 or more times per day |

70a. Each time you ate canned tuna, how much did you usually eat?

- Less than 1/4 cup or less than 2 ounces  
 1/4 to 1/2 cup or 2 to 3 ounces  
 More than 1/2 cup or more than 3 ounces

70b. How often was the canned tuna you ate water-packed tuna?

- Almost never or never  
 About 1/4 of the time  
 About 1/2 of the time  
 About 3/4 of the time  
 Almost always or always

Question 71 appears on the next page

Over the **past 12 months...**

70c. How often was the canned tuna you ate prepared with mayonnaise or other dressing (including low-fat)?

- Almost never or never
- About 1/4 of the time
- About 1/2 of the time
- About 3/4 of the time
- Almost always or always

71. How often did you eat **GROUND** chicken or turkey? (We will ask about other chicken and turkey later.)

NEVER (GO TO QUESTION 72)

- 1-6 times per year
- 7-11 times per year
- 1 time per month
- 2-3 times per month
- 1 time per week
- 2 times per week
- 3-4 times per week
- 5-6 times per week
- 1 time per day
- 2 or more times per day

71a. Each time you ate **GROUND** chicken or turkey, how much did you usually eat?

- Less than 2 ounces or less than 1/2 cup
- 2 to 4 ounces or 1/2 to 1 cup
- More than 4 ounces or more than 1 cup

72. How often did you eat beef hamburgers or cheeseburgers?

NEVER (GO TO QUESTION 73)

- 1-6 times per year
- 7-11 times per year
- 1 time per month
- 2-3 times per month
- 1 time per week
- 2 times per week
- 3-4 times per week
- 5-6 times per week
- 1 time per day
- 2 or more times per day

72a. Each time you ate beef hamburgers or cheeseburgers, how much did you usually eat?

- Less than 1 patty or less than 2 ounces
- 1 patty or 2 to 4 ounces
- More than 1 patty or more than 4 ounces

72b. How often were the beef hamburgers or cheeseburgers you ate made with lean ground beef?

- Almost never or never
- About 1/4 of the time
- About 1/2 of the time
- About 3/4 of the time
- Almost always or always

Question 73 appears in the next column.

73. How often did you eat ground beef in mixtures (such as meatballs, casseroles, chili, or meatloaf)?

NEVER (GO TO QUESTION 74)

- 1-6 times per year
- 7-11 times per year
- 1 time per month
- 2-3 times per month
- 1 time per week
- 2 times per week
- 3-4 times per week
- 5-6 times per week
- 1 time per day
- 2 or more times per day

73a. Each time you ate ground beef in mixtures, how much did you usually eat?

- Less than 3 ounces or less than 1/2 cup
- 3 to 8 ounces or 1/2 to 1 cup
- More than 8 ounces or more than 1 cup

74. How often did you eat hot dogs or frankfurters? (Please do not include sausages or vegetarian hot dogs.)

NEVER (GO TO QUESTION 75)

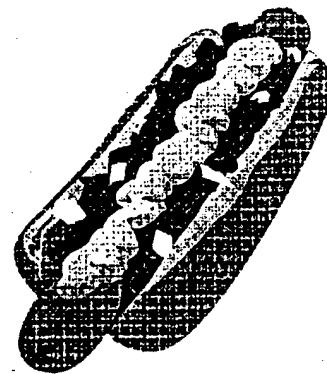
- 1-6 times per year
- 7-11 times per year
- 1 time per month
- 2-3 times per month
- 1 time per week
- 2 times per week
- 3-4 times per week
- 5-6 times per week
- 1 time per day
- 2 or more times per day

74a. Each time you ate hot dogs or frankfurters, how many did you usually eat?

- Less than 1 hot dog
- 1 to 2 hot dogs
- More than 2 hot dogs

74b. How often were the hot dogs or frankfurters you ate light or low-fat hot dogs?

- Almost never or never
- About 1/4 of the time
- About 1/2 of the time
- About 3/4 of the time
- Almost always or always



Question 75 appears on the next page.

Over the past 12 months...

75. How often did you eat beef mixtures such as beef stew, beef pot pie, beef and noodles, or beef and vegetables?

- NEVER (GO TO QUESTION 76)
- 1-6 times per year       2 times per week
- 7-11 times per year     3-4 times per week
- 1 time per month         5-6 times per week
- 2-3 times per month     1 time per day
- 1 time per week          2 or more times per day

75a. Each time you ate beef stew, beef pot pie, beef and noodles, or beef and vegetables, how much did you usually eat?

- Less than 1 cup
- 1 to 2 cups
- More than 2 cups

76. How often did you eat roast beef or pot roast? (Please do not include roast beef or pot roast in sandwiches.)

- NEVER (GO TO QUESTION 77)
- 1-6 times per year       2 times per week
- 7-11 times per year     3-4 times per week
- 1 time per month         5-6 times per week
- 2-3 times per month     1 time per day
- 1 time per week          2 or more times per day

76a. Each time you ate roast beef or pot roast (including in mixtures), how much did you usually eat?

- Less than 2 ounces
- 2 to 5 ounces
- More than 5 ounces

77. How often did you eat steak (beef)? (Do not include steak in sandwiches)

- NEVER (GO TO QUESTION 78)
- 1-6 times per year       2 times per week
- 7-11 times per year     3-4 times per week
- 1 time per month         5-6 times per week
- 2-3 times per month     1 time per day
- 1 time per week          2 or more times per day

77a. Each time you ate steak (beef), how much did you usually eat?

- Less than 3 ounces
- 3 to 7 ounces
- More than 7 ounces

Question 78 appears in the next column

77b. How often was the steak you ate lean steak?

- Almost never or never
- About 1/4 of the time
- About 1/2 of the time
- About 3/4 of the time
- Almost always or always

78. How often did you eat pork or beef spareribs?

- NEVER (GO TO QUESTION 79)
- 1-6 times per year       2 times per week
- 7-11 times per year     3-4 times per week
- 1 time per month         5-6 times per week
- 2-3 times per month     1 time per day
- 1 time per week          2 or more times per day

78a. Each time you ate pork or beef spareribs, how much did you usually eat?

- Less than 4 ribs
- 4 to 12 ribs
- More than 12 ribs

79. How often did you eat roast turkey, turkey cutlets, or turkey nuggets (including in sandwiches)?

- NEVER (GO TO QUESTION 80)
- 1-6 times per year       2 times per week
- 7-11 times per year     3-4 times per week
- 1 time per month         5-6 times per week
- 2-3 times per month     1 time per day
- 1 time per week          2 or more times per day

79a. Each time you ate roast turkey, turkey cutlets, or turkey nuggets, how much did you usually eat? (Please note: 4-8 turkey nuggets = 3 ounces.)

- Less than 2 ounces
- 2 to 4 ounces
- More than 4 ounces

80. How often did you eat chicken as part of salads, sandwiches, casseroles, stews, or other mixtures?

- NEVER (GO TO QUESTION 81)
- 1-6 times per year       2 times per week
- 7-11 times per year     3-4 times per week
- 1 time per month         5-6 times per week
- 2-3 times per month     1 time per day
- 1 time per week          2 or more times per day

Question 81 appears on the next page

Over the past 12 months...

80a. Each time you ate chicken as part of salads, sandwiches, casseroles, stews, or other mixtures, how much did you usually eat?

- Less than 1/2 cup
- 1/2 to 1 1/2 cups
- More than 1 1/2 cups

81. How often did you eat baked, broiled, roasted, stewed, or fried chicken (including nuggets)? (Please do not include chicken in mixtures.)

- NEVER (GO TO QUESTION 82)
- 1-6 times per year
- 7-11 times per year
- 1 time per month
- 2-3 times per month
- 1 time per week
- 2 times per week
- 3-4 times per week
- 5-6 times per week
- 1 time per day
- 2 or more times per day

81a. Each time you ate baked, broiled, roasted, stewed, or fried chicken (including nuggets), how much did you usually eat?

- Less than 2 drumsticks or wings, 1 breast or thigh, or less than 4 nuggets
- 2 drumsticks or wings, 1 breast or thigh, or 4 to 8 nuggets
- More than 2 drumsticks or wings, 1 breast or thigh, or more than 8 nuggets

81b. How often was the chicken you ate fried chicken (including deep fried) or chicken nuggets?

- Almost never or never
- About 1/4 of the time
- About 1/2 of the time
- About 3/4 of the time
- Almost always or always

81c. How often was the chicken you ate WHITE meat?

- Almost never or never
- About 1/4 of the time
- About 1/2 of the time
- About 3/4 of the time
- Almost always or always

81d. How often did you eat chicken WITH skin?

- Almost never or never
- About 1/4 of the time
- About 1/2 of the time
- About 3/4 of the time
- Almost always or always

82. How often did you eat baked ham or ham steak?

- NEVER (GO TO QUESTION 83)
- 1-6 times per year
- 7-11 times per year
- 1 time per month
- 2-3 times per month
- 1 time per week
- 2 times per week
- 3-4 times per week
- 5-6 times per week
- 1 time per day
- 2 or more times per day

82a. Each time you ate baked ham or ham steak, how much did you usually eat?

- Less than 1 ounce
- 1 to 3 ounces
- More than 3 ounces

83. How often did you eat pork (including chops, roasts, and in mixed dishes)? (Please do not include ham, ham steak, or sausage.)

- NEVER (GO TO QUESTION 84)
- 1-6 times per year
- 7-11 times per year
- 1 time per month
- 2-3 times per month
- 1 time per week
- 2 times per week
- 3-4 times per week
- 5-6 times per week
- 1 time per day
- 2 or more times per day

83a. Each time you ate pork, how much did you usually eat?

- Less than 2 ounces or less than 1 chop
- 2 to 5 ounces or 1 chop
- More than 5 ounces or more than 1 chop

84. How often did you eat gravy on meat, chicken, potatoes, rice, etc.?

- NEVER (GO TO QUESTION 85)
- 1-6 times per year
- 7-11 times per year
- 1 time per month
- 2-3 times per month
- 1 time per week
- 2 times per week
- 3-4 times per week
- 5-6 times per week
- 1 time per day
- 2 or more times per day

84a. Each time you ate gravy on meat, chicken, potatoes, or rice, etc., how much did you usually eat?

- Less than 1/8 cup
- 1/8 to 1/2 cup
- More than 1/2 cup

Over the past 12 months...

85. How often did you eat liver (all kinds) or liverwurst?

- NEVER (GO TO QUESTION 86)
- |   |   |
|---|---|
| <input type="radio"/> 1-6 times per year  | <input type="radio"/> 2 times per week        |
| <input type="radio"/> 7-11 times per year | <input type="radio"/> 3-4 times per week      |
| <input type="radio"/> 1 time per month    | <input type="radio"/> 5-6 times per week      |
| <input type="radio"/> 2-3 times per month | <input type="radio"/> 1 time per day          |
| <input type="radio"/> 1 time per week     | <input type="radio"/> 2 or more times per day |

85a. Each time you ate liver or liverwurst, how much did you usually eat?

- Less than 1 ounce  
 1 to 4 ounces  
 More than 4 ounces

86. How often did you eat bacon (including low-fat)?

- NEVER (GO TO QUESTION 87)
- |   |   |
|---|---|
| <input type="radio"/> 1-6 times per year  | <input type="radio"/> 2 times per week        |
| <input type="radio"/> 7-11 times per year | <input type="radio"/> 3-4 times per week      |
| <input type="radio"/> 1 time per month    | <input type="radio"/> 5-6 times per week      |
| <input type="radio"/> 2-3 times per month | <input type="radio"/> 1 time per day          |
| <input type="radio"/> 1 time per week     | <input type="radio"/> 2 or more times per day |

86a. Each time you ate bacon, how much did you usually eat?

- Fewer than 2 slices  
 2 to 3 slices  
 More than 3 slices

86b. How often was the bacon you ate light, low-fat, or lean bacon?

- Almost never or never  
 About 1/4 of the time  
 About 1/2 of the time  
 About 3/4 of the time  
 Almost always or always

87. How often did you eat sausage (including low-fat)?

- NEVER (GO TO QUESTION 88)
- |   |   |
|---|---|
| <input type="radio"/> 1-6 times per year  | <input type="radio"/> 2 times per week        |
| <input type="radio"/> 7-11 times per year | <input type="radio"/> 3-4 times per week      |
| <input type="radio"/> 1 time per month    | <input type="radio"/> 5-6 times per week      |
| <input type="radio"/> 2-3 times per month | <input type="radio"/> 1 time per day          |
| <input type="radio"/> 1 time per week     | <input type="radio"/> 2 or more times per day |

87a. Each time you ate sausage, how much did you usually eat?

- Less than 1 patty or 2 links  
 1 to 3 patties or 2 to 5 links  
 More than 3 patties or 5 links

87b. How often was the sausage you ate light, low-fat, or lean sausage?

- Almost never or never  
 About 1/4 of the time  
 About 1/2 of the time  
 About 3/4 of the time  
 Almost always or always

88. How often did you eat fish sticks or fried fish (including fried seafood or shellfish)?

- NEVER (GO TO QUESTION 89)
- |   |   |
|---|---|
| <input type="radio"/> 1-6 times per year  | <input type="radio"/> 2 times per week        |
| <input type="radio"/> 7-11 times per year | <input type="radio"/> 3-4 times per week      |
| <input type="radio"/> 1 time per month    | <input type="radio"/> 5-6 times per week      |
| <input type="radio"/> 2-3 times per month | <input type="radio"/> 1 time per day          |
| <input type="radio"/> 1 time per week     | <input type="radio"/> 2 or more times per day |

88a. Each time you ate fish sticks or fried fish, how much did you usually eat?

- Less than 2 ounces or less than 1 fillet  
 2 to 7 ounces or 1 fillet  
 More than 7 ounces or more than 1 fillet

89. How often did you eat fish or seafood that was NOT FRIED (including shellfish)?

- NEVER (GO TO THE INTRODUCTION TO QUESTION 90)
- |   |   |
|---|---|
| <input type="radio"/> 1-6 times per year  | <input type="radio"/> 2 times per week        |
| <input type="radio"/> 7-11 times per year | <input type="radio"/> 3-4 times per week      |
| <input type="radio"/> 1 time per month    | <input type="radio"/> 5-6 times per week      |
| <input type="radio"/> 2-3 times per month | <input type="radio"/> 1 time per day          |
| <input type="radio"/> 1 time per week     | <input type="radio"/> 2 or more times per day |

89a. Each time you ate fish or seafood that was not fried, how much did you usually eat?

- Less than 2 ounces or less than 1 fillet  
 2 to 5 ounces or 1 fillet  
 More than 5 ounces or more than 1 fillet



Over the past 12 months...

Now think about all the meat, poultry, and fish you ate in the past 12 months and how they were prepared.

90. How often was oil, butter, margarine, or other fat used to FRY, SAUTE, BASTE, OR MARINATE any meat, poultry, or fish you ate? (Please do not include deep frying.)

NEVER (GO TO QUESTION 91)

- |   |   |
|---|---|
| <input type="radio"/> 1-6 times per year  | <input type="radio"/> 2 times per week        |
| <input type="radio"/> 7-11 times per year | <input type="radio"/> 3-4 times per week      |
| <input type="radio"/> 1 time per month    | <input type="radio"/> 5-6 times per week      |
| <input type="radio"/> 2-3 times per month | <input type="radio"/> 1 time per day          |
| <input type="radio"/> 1 time per week     | <input type="radio"/> 2 or more times per day |

90a. Which of the following fats were regularly used to prepare your meat, poultry, or fish? (Mark all that apply.)

- |   |  |
|---|--|
| <input type="radio"/> Margarine (including low-fat) | <input type="radio"/> Corn oil                         |
| <input type="radio"/> Butter (including low-fat)    | <input type="radio"/> Canola or rapeseed oil           |
| <input type="radio"/> Lard, fatback, or bacon fat   | <input type="radio"/> Oil spray, such as Pam or others |
| <input type="radio"/> Olive oil                     | <input type="radio"/> Other kinds of oils              |
|   | <input type="radio"/> None of the above                |

91. How often did you eat tofu, soy burgers, or soy meat-substitutes?

NEVER (GO TO QUESTION 92)

- |   |   |
|---|---|
| <input type="radio"/> 1-6 times per year  | <input type="radio"/> 2 times per week        |
| <input type="radio"/> 7-11 times per year | <input type="radio"/> 3-4 times per week      |
| <input type="radio"/> 1 time per month    | <input type="radio"/> 5-6 times per week      |
| <input type="radio"/> 2-3 times per month | <input type="radio"/> 1 time per day          |
| <input type="radio"/> 1 time per week     | <input type="radio"/> 2 or more times per day |

91a. Each time you ate tofu, soy burgers, or soy meat-substitutes, how much did you usually eat?

- Less than 1/4 cup or less than 2 ounces  
 1/4 to 1/2 cup or 2 to 4 ounces  
 More than 1/2 cup or more than 4 ounces

Continued on next page in the next column

92. Over the past 12 months, did you eat soups?

NO (GO TO QUESTION 93)

YES



92a. How often did you eat soup DURING THE WINTER?

NEVER

- |   |   |
|---|---|
| <input type="radio"/> 1-6 times per winter  | <input type="radio"/> 2 times per week        |
| <input type="radio"/> 7-11 times per winter | <input type="radio"/> 3-4 times per week      |
| <input type="radio"/> 1 time per month      | <input type="radio"/> 5-6 times per week      |
| <input type="radio"/> 2-3 times per month   | <input type="radio"/> 1 time per day          |
| <input type="radio"/> 1 time per week       | <input type="radio"/> 2 or more times per day |

92b. How often did you eat soup DURING THE REST OF THE YEAR?

NEVER

- |   |   |
|---|---|
| <input type="radio"/> 1-6 times per year  | <input type="radio"/> 2 times per week        |
| <input type="radio"/> 7-11 times per year | <input type="radio"/> 3-4 times per week      |
| <input type="radio"/> 1 time per month    | <input type="radio"/> 5-6 times per week      |
| <input type="radio"/> 2-3 times per month | <input type="radio"/> 1 time per day          |
| <input type="radio"/> 1 time per week     | <input type="radio"/> 2 or more times per day |

92c. Each time you ate soup, how much did you usually eat?

- Less than 1 cup  
 1 to 2 cups  
 More than 2 cups

92d. How often were the soups you ate bean soups?

- Almost never or never  
 About 1/4 of the time  
 About 1/2 of the time  
 About 3/4 of the time  
 Almost always or always

92e. How often were the soups you ate cream soups (including chowders)?

- Almost never or never  
 About 1/4 of the time  
 About 1/2 of the time  
 About 3/4 of the time  
 Almost always or always

Question 92 appears on the next page

Over the past 12 months...

92f. How often were the soups you ate tomato or vegetable soups?

- Almost never or never
- About 1/4 of the time
- About 1/2 of the time
- About 3/4 of the time
- Almost always or always

92g. How often were the soups you ate broth soups (including chicken) with or without noodles or rice?

- Almost never or never
- About 1/4 of the time
- About 1/2 of the time
- About 3/4 of the time
- Almost always or always

93. How often did you eat pizza?

NEVER (GO TO QUESTION 94)

- 1-6 times per year
- 7-11 times per year
- 1 time per month
- 2-3 times per month
- 1 time per week
- 2 times per week
- 3-4 times per week
- 5-6 times per week
- 1 time per day
- 2 or more times per day

93a. Each time you ate pizza, how much did you usually eat?

- Less than 1 slice or less than 1 mini pizza
- 1 to 3 slices or 1 mini pizza
- More than 3 slices or more than 1 mini pizza

93b. How often did you eat pizza with pepperoni, sausage, or other meat?

- Almost never or never
- About 1/4 of the time
- About 1/2 of the time
- About 3/4 of the time
- Almost always or always

94. How often did you eat crackers?

NEVER (GO TO QUESTION 95)

- 1-6 times per year
- 7-11 times per year
- 1 time per month
- 2-3 times per month
- 1 time per week
- 2 times per week
- 3-4 times per week
- 5-6 times per week
- 1 time per day
- 2 or more times per day

Question 95 appears in the next column

94a. Each time you ate crackers, how many did you usually eat?

- Fewer than 4 crackers
- 4 to 10 crackers
- More than 10 crackers

95. How often did you eat corn bread or corn muffins?

NEVER (GO TO QUESTION 96)

- 1-6 times per year
- 7-11 times per year
- 1 time per month
- 2-3 times per month
- 1 time per week
- 2 times per week
- 3-4 times per week
- 5-6 times per week
- 1 time per day
- 2 or more times per day

95a. Each time you ate corn bread or corn muffins, how much did you usually eat?

- Less than 1 piece or muffin
- 1 to 2 pieces or muffins
- More than 2 pieces or muffins

96. How often did you eat biscuits?

NEVER (GO TO QUESTION 97)

- 1-6 times per year
- 7-11 times per year
- 1 time per month
- 2-3 times per month
- 1 time per week
- 2 times per week
- 3-4 times per week
- 5-6 times per week
- 1 time per day
- 2 or more times per day

96a. Each time you ate biscuits, how many did you usually eat?

- Fewer than 1 biscuit
- 1 to 2 biscuits
- More than 2 biscuits

97. How often did you eat potato chips, tortilla chips, or corn chips (including low-fat, fat-free, or low-salt)?

NEVER (GO TO QUESTION 98)

- 1-6 times per year
- 7-11 times per year
- 1 time per month
- 2-3 times per month
- 1 time per week
- 2 times per week
- 3-4 times per week
- 5-6 times per week
- 1 time per day
- 2 or more times per day

Question 98 appears on the next page

Over the **past 12 months...**

97a. Each time you ate **potato chips, tortilla chips, or corn chips**, how much did you usually eat?

- Fewer than 10 chips or less than 1 cup
- 10 to 25 chips or 1 to 2 cups
- More than 25 chips or more than 2 cups

97b. How often were the chips you ate **Wow chips** or other chips made with fat substitute (Clean or Olestra)?

- Almost never or never
- About 1/4 of the time
- About 1/2 of the time
- About 3/4 of the time
- Almost always or always

97c. How often were the chips you ate other **low-fat or fat-free chips**?

- Almost never or never
- About 1/4 of the time
- About 1/2 of the time
- About 3/4 of the time
- Almost always or always

98. How often did you eat **popcorn** (including low-fat)?

- NEVER (GO TO QUESTION 99)
- 1-6 times per year
- 7-11 times per year
- 1 time per month
- 2-3 times per month
- 1 time per week
- 2 times per week
- 3-4 times per week
- 5-6 times per week
- 1 time per day
- 2 or more times per day

98a. Each time you ate **popcorn**, how much did you usually eat?

- Less than 2 cups, popped
- 2 to 5 cups, popped
- More than 5 cups, popped

99. How often did you eat **pretzels**?

- NEVER (GO TO QUESTION 100)
- 1-6 times per year
- 7-11 times per year
- 1 time per month
- 2-3 times per month
- 1 time per week
- 2 times per week
- 3-4 times per week
- 5-6 times per week
- 1 time per day
- 2 or more times per day

99a. Each time you ate **pretzels**, how many did you usually eat?

- Fewer than 5 average twists
- 5 to 20 average twists
- More than 20 average twists

100. How often did you eat **peanuts, walnuts, seeds, or other nuts**?

- NEVER (GO TO QUESTION 101)
- 1-6 times per year
- 7-11 times per year
- 1 time per month
- 2-3 times per month
- 1 time per week
- 2 times per week
- 3-4 times per week
- 5-6 times per week
- 1 time per day
- 2 or more times per day

100a. Each time you ate **peanuts, walnuts, seeds, or other nuts**, how much did you usually eat?

- Less than 1/4 cup
- 1/4 to 1/2 cup
- More than 1/2 cup

101. How often did you eat **energy, high-protein, or breakfast bars** such as **Power Bars, Balance, Clif, or others**?

- NEVER (GO TO QUESTION 102)
- 1-6 times per year
- 7-11 times per year
- 1 time per month
- 2-3 times per month
- 1 time per week
- 2 times per week
- 3-4 times per week
- 5-6 times per week
- 1 time per day
- 2 or more times per day

101a. Each time you ate **energy, high-protein, or breakfast bars**, how much did you usually eat?

- Less than 1 bar
- 1 bar
- More than 1 bar

102. How often did you eat **yogurt** (NOT including frozen yogurt)?

- NEVER (GO TO QUESTION 103)
- 1-6 times per year
- 7-11 times per year
- 1 time per month
- 2-3 times per month
- 1 time per week
- 2 times per week
- 3-4 times per week
- 5-6 times per week
- 1 time per day
- 2 or more times per day

Question 101 appears in the next column.

Question 103 appears on the next page.

Over the past 12 months...

102a. Each time you ate yogurt, how much did you usually eat?

- Less than 1/2 cup or less than 1 container
- 1/2 to 1 cup or 1 container
- More than 1 cup or more than 1 container

103. How often did you eat cottage cheese (including low-fat)?

NEVER (GO TO QUESTION 104)

- 1-6 times per year
- 7-11 times per year
- 1 time per month
- 2-3 times per month
- 1 time per week
- 2 times per week
- 3-4 times per week
- 5-6 times per week
- 1 time per day
- 2 or more times per day

103a. Each time you ate cottage cheese, how much did you usually eat?

- Less than 1/4 cup
- 1/4 to 1 cup
- More than 1 cup

104. How often did you eat cheese (including low-fat; including on cheeseburgers or in sandwiches or subs)?

NEVER (GO TO QUESTION 105)

- 1-6 times per year
- 7-11 times per year
- 1 time per month
- 2-3 times per month
- 1 time per week
- 2 times per week
- 3-4 times per week
- 5-6 times per week
- 1 time per day
- 2 or more times per day

104a. Each time you ate cheese, how much did you usually eat?

- Less than 1/2 ounce or less than 1 slice
- 1/2 to 1 1/2 ounces or 1 slice
- More than 1 1/2 ounces or more than 1 slice

104b. How often was the cheese you ate light or low-fat cheese?

- Almost never or never
- About 1/4 of the time
- About 1/2 of the time
- About 3/4 of the time
- Almost always or always

104c. How often was the cheese you ate fat-free cheese?

- Almost never or never
- About 1/4 of the time
- About 1/2 of the time
- About 3/4 of the time
- Almost always or always

105. How often did you eat frozen yogurt, sorbet, or ices (including low-fat or fat-free)?

NEVER (GO TO QUESTION 106)

- 1-6 times per year
- 7-11 times per year
- 1 time per month
- 2-3 times per month
- 1 time per week
- 2 times per week
- 3-4 times per week
- 5-6 times per week
- 1 time per day
- 2 or more times per day

105a. Each time you ate frozen yogurt, sorbet, or ices, how much did you usually eat?

- Less than 1/2 cup or less than 1 scoop
- 1/2 to 1 cup or 1 to 2 scoops
- More than 1 cup or more than 2 scoops

106. How often did you eat ice cream, ice cream bars, or sherbet (including low-fat or fat-free)?

NEVER (GO TO QUESTION 107)

- 1-6 times per year
- 7-11 times per year
- 1 time per month
- 2-3 times per month
- 1 time per week
- 2 times per week
- 3-4 times per week
- 5-6 times per week
- 1 time per day
- 2 or more times per day

106a. Each time you ate ice cream, ice cream bars, or sherbet, how much did you usually eat?

- Less than 1/2 cup or less than 1 scoop
- 1/2 to 1 1/2 cups or 1 to 2 scoops
- More than 1 1/2 cups or more than 2 scoops

106b. How often was the ice cream you ate light, low-fat, or fat-free ice cream or sherbet?

- Almost never or never
- About 1/4 of the time
- About 1/2 of the time
- About 3/4 of the time
- Almost always or always

Over the past 12 months...

107. How often did you eat cake (including low-fat or fat-free)?

- NEVER (GO TO QUESTION 108)
- |   |   |
|---|---|
| <input type="radio"/> 1-6 times per year  | <input type="radio"/> 2 times per week        |
| <input type="radio"/> 7-11 times per year | <input type="radio"/> 3-4 times per week      |
| <input type="radio"/> 1 time per month    | <input type="radio"/> 5-6 times per week      |
| <input type="radio"/> 2-3 times per month | <input type="radio"/> 1 time per day          |
| <input type="radio"/> 1 time per week     | <input type="radio"/> 2 or more times per day |

107a. Each time you ate cake, how much did you usually eat?

- Less than 1 medium piece  
 1 medium piece  
 More than 1 medium piece

107b. How often was the cake you ate light, low-fat, or fat-free cake?

- Almost never or never  
 About 1/4 of the time  
 About 1/2 of the time  
 About 3/4 of the time  
 Almost always or always

108. How often did you eat cookies or brownies (including low-fat or fat-free)?

- NEVER (GO TO QUESTION 109)
- |   |   |
|---|---|
| <input type="radio"/> 1-6 times per year  | <input type="radio"/> 2 times per week        |
| <input type="radio"/> 7-11 times per year | <input type="radio"/> 3-4 times per week      |
| <input type="radio"/> 1 time per month    | <input type="radio"/> 5-6 times per week      |
| <input type="radio"/> 2-3 times per month | <input type="radio"/> 1 time per day          |
| <input type="radio"/> 1 time per week     | <input type="radio"/> 2 or more times per day |

108a. Each time you ate cookies or brownies, how much did you usually eat?

- Less than 2 cookies or 1 small brownie  
 2 to 4 cookies or 1 medium brownie  
 More than 4 cookies or 1 large brownie

108b. How often were the cookies or brownies you ate light, low-fat, or fat-free cookies or brownies?

- Almost never or never  
 About 1/4 of the time  
 About 1/2 of the time  
 About 3/4 of the time  
 Almost always or always

Question 109 appears in the next column.

109. How often did you eat doughnuts, sweet rolls, Danish, or pop-tarts?

- NEVER (GO TO QUESTION 110)
- |   |   |
|---|---|
| <input type="radio"/> 1-6 times per year  | <input type="radio"/> 2 times per week        |
| <input type="radio"/> 7-11 times per year | <input type="radio"/> 3-4 times per week      |
| <input type="radio"/> 1 time per month    | <input type="radio"/> 5-6 times per week      |
| <input type="radio"/> 2-3 times per month | <input type="radio"/> 1 time per day          |
| <input type="radio"/> 1 time per week     | <input type="radio"/> 2 or more times per day |

109a. Each time you ate doughnuts, sweet rolls, Danish, or pop-tarts, how much did you usually eat?

- Less than 1 piece  
 1 to 2 pieces  
 More than 2 pieces

110. How often did you eat sweet muffins or dessert breads (including low-fat or fat-free)?

- NEVER (GO TO QUESTION 111)
- |   |   |
|---|---|
| <input type="radio"/> 1-6 times per year  | <input type="radio"/> 2 times per week        |
| <input type="radio"/> 7-11 times per year | <input type="radio"/> 3-4 times per week      |
| <input type="radio"/> 1 time per month    | <input type="radio"/> 5-6 times per week      |
| <input type="radio"/> 2-3 times per month | <input type="radio"/> 1 time per day          |
| <input type="radio"/> 1 time per week     | <input type="radio"/> 2 or more times per day |

110a. Each time you ate sweet muffins or dessert breads, how much did you usually eat?

- Less than 1 medium piece  
 1 medium piece  
 More than 1 medium piece

110b. How often were the sweet muffins or dessert breads you ate light, low-fat, or fat-free sweet muffins or dessert breads?

- Almost never or never  
 About 1/4 of the time  
 About 1/2 of the time  
 About 3/4 of the time  
 Almost always or always

111. How often did you eat fruit crisp, cobbler, or strudel?

- NEVER (GO TO QUESTION 112)
- |   |   |
|---|---|
| <input type="radio"/> 1-6 times per year  | <input type="radio"/> 2 times per week        |
| <input type="radio"/> 7-11 times per year | <input type="radio"/> 3-4 times per week      |
| <input type="radio"/> 1 time per month    | <input type="radio"/> 5-6 times per week      |
| <input type="radio"/> 2-3 times per month | <input type="radio"/> 1 time per day          |
| <input type="radio"/> 1 time per week     | <input type="radio"/> 2 or more times per day |

Question 112 appears on the next page.

Over the past 12 months...

111a. Each time you ate fruit crisp, cobbler, or strudel how much did you usually eat?

- Less than 1/2 cup
- 1/2 to 1 cup
- More than 1 cup

112. How often did you eat pie?

NEVER (GO TO QUESTION 113)

- 1-6 times per year
- 7-11 times per year
- 1 time per month
- 2-3 times per month
- 1 time per week
- 2 times per week
- 3-4 times per week
- 5-6 times per week
- 1 time per day
- 2 or more times per day

112a. Each time you ate pie, how much did you usually eat?

- Less than 1/8 of a pie
- About 1/8 of a pie
- More than 1/8 of a pie

The next four questions ask about the kinds of pie you ate. Please read all four questions before answering.

112b. How often were the pies you ate fruit pie (such as apple, blueberry, others)?

- Almost never or never
- About 1/4 of the time
- About 1/2 of the time
- About 3/4 of the time
- Almost always or always

112c. How often were the pies you ate cream, pudding, custard, or meringue pie?

- Almost never or never
- About 1/4 of the time
- About 1/2 of the time
- About 3/4 of the time
- Almost always or always

112d. How often were the pies you ate pumpkin or sweet potato pie?

- Almost never or never
- About 1/4 of the time
- About 1/2 of the time
- About 3/4 of the time
- Almost always or always

112e. How often were the pies you ate pecan pie?

- Almost never or never
- About 1/4 of the time
- About 1/2 of the time
- About 3/4 of the time
- Almost always or always

113. How often did you eat chocolate candy?

NEVER (GO TO QUESTION 114)

- 1-6 times per year
- 7-11 times per year
- 1 time per month
- 2-3 times per month
- 1 time per week
- 2 times per week
- 3-4 times per week
- 5-6 times per week
- 1 time per day
- 2 or more times per day

113a. Each time you ate chocolate candy, how much did you usually eat?

- Less than 1 average bar or less than 1 ounce
- 1 average bar or 1 to 2 ounces
- More than 1 average bar or more than 2 ounces

114. How often did you eat other candy?

NEVER (GO TO QUESTION 115)

- 1-6 times per year
- 7-11 times per year
- 1 time per month
- 2-3 times per month
- 1 time per week
- 2 times per week
- 3-4 times per week
- 5-6 times per week
- 1 time per day
- 2 or more times per day

114a. Each time you ate other candy, how much did you usually eat?

- Fewer than 2 pieces
- 2 to 9 pieces
- More than 9 pieces

115. How often did you eat eggs, egg whites, or egg substitutes (NOT counting eggs in baked goods and desserts)? (Please include eggs in salads, quiche, and souffles.)

NEVER (GO TO QUESTION 116)

- 1-6 times per year
- 7-11 times per year
- 1 time per month
- 2-3 times per month
- 1 time per week
- 2 times per week
- 3-4 times per week
- 5-6 times per week
- 1 time per day
- 2 or more times per day

Over the past 12 months...

115a. Each time you ate eggs, how many did you usually eat?

- 1 egg
- 2 eggs
- 3 or more eggs

115b. How often were the eggs you ate egg substitutes?

- Almost never or never
- About 1/4 of the time
- About 1/2 of the time
- About 3/4 of the time
- Almost always or always

115c. How often were the eggs you ate egg whites only?

- Almost never or never
- About 1/4 of the time
- About 1/2 of the time
- About 3/4 of the time
- Almost always or always

115d. How often were the eggs you ate regular whole eggs?

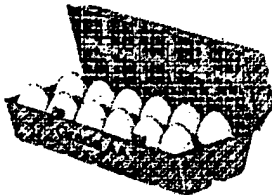
- Almost never or never
- About 1/4 of the time
- About 1/2 of the time
- About 3/4 of the time
- Almost always or always

115e. How often were the eggs you ate cooked in oil, butter, or margarine?

- Almost never or never
- About 1/4 of the time
- About 1/2 of the time
- About 3/4 of the time
- Almost always or always

115f. How often were the eggs you ate part of egg salad?

- Almost never or never
- About 1/4 of the time
- About 1/2 of the time
- About 3/4 of the time
- Almost always or always



Question 117 appears in the next column.

116. How many cups of coffee, caffeinated or decaffeinated, did you drink?

NONE (GO TO QUESTION 117)

- Less than 1 cup per month
- 1-3 cups per month
- 1 cup per week
- 2-4 cups per week
- 5-6 cups per week
- 1 cup per day
- 2-3 cups per day
- 4-5 cups per day
- 6 or more cups per day

116a. How often was the coffee you drank decaffeinated?

- Almost never or never
- About 1/4 of the time
- About 1/2 of the time
- About 3/4 of the time
- Almost always or always

117. How many glasses of ICED tea, caffeinated or decaffeinated, did you drink?

NONE (GO TO QUESTION 118)

- Less than 1 cup per month
- 1-3 cups per month
- 1 cup per week
- 2-4 cups per week
- 5-6 cups per week
- 1 cup per day
- 2-3 cups per day
- 4-5 cups per day
- 6 or more cups per day

117a. How often was the iced tea you drank decaffeinated or herbal tea?

- Almost never or never
- About 1/4 of the time
- About 1/2 of the time
- About 3/4 of the time
- Almost always or always

118. How many cups of HOT tea, caffeinated or decaffeinated, did you drink?

NONE (GO TO QUESTION 119)

- Less than 1 cup per month
- 1-3 cups per month
- 1 cup per week
- 2-4 cups per week
- 5-6 cups per week
- 1 cup per day
- 2-3 cups per day
- 4-5 cups per day
- 6 or more cups per day

118a. How often was the hot tea you drank decaffeinated or herbal tea?

- Almost never or never
- About 1/4 of the time
- About 1/2 of the time
- About 3/4 of the time
- Almost always or always

Question 119 appears on the next page.

Over the **past 12 months...**

119. How often did you add **sugar or honey** to your coffee or tea?

- NEVER (GO TO QUESTION 120)
- Less than 1 time per month
- 1-3 times per month
- 1 time per week
- 2-4 times per week
- 5-6 times per week
- 1 time per day
- 2-3 times per day
- 4-5 times per day
- 6 or more times per day

119a. Each time **sugar or honey** was added to your coffee or tea, how much was usually added?

- Less than 1 teaspoon
- 1 to 3 teaspoons
- More than 3 teaspoons

120. How often did you add **artificial sweetener** to your coffee or tea?

- NEVER (GO TO QUESTION 121)
- Less than 1 time per month
- 1-3 times per month
- 1 time per week
- 2-4 times per week
- 5-6 times per week
- 1 time per day
- 2-3 times per day
- 4-5 times per day
- 6 or more times per day

120a. What kind of **artificial sweetener** do you usually use?

- Equal or aspartame
- Sweet N Low or saccharin

121. How often was **non-dairy creamer** added to your coffee or tea?

- NEVER (GO TO QUESTION 122)
- Less than 1 time per month
- 1-3 times per month
- 1 time per week
- 2-4 times per week
- 5-6 times per week
- 1 time per day
- 2-3 times per day
- 4-5 times per day
- 6 or more times per day

121a. Each time **non-dairy creamer** was added to your coffee or tea, how much was usually used?

- Less than 1 teaspoon
- 1 to 3 teaspoons
- More than 3 teaspoons

121b. What kind of **non-dairy creamer** did you usually use?

- Regular powdered
- Low-fat or fat-free powdered
- Regular liquid
- Low-fat or fat-free liquid

122. How often was **cream or half and half** added to your coffee or tea?

NEVER (GO TO QUESTION 123)

- Less than 1 time per month
- 1-3 times per month
- 1 time per week
- 2-4 times per week
- 5-6 times per week
- 1 time per day
- 2-3 times per day
- 4-5 times per day
- 6 or more times per day

122a. Each time **cream or half and half** was added to your coffee or tea, how much was usually added?

- Less than 1 tablespoon
- 1 to 2 tablespoons
- More than 2 tablespoons

123. How often was **milk** added to your coffee or tea?

NEVER (GO TO QUESTION 124)

- Less than 1 time per month
- 1-3 times per month
- 1 time per week
- 2-4 times per week
- 5-6 times per week
- 1 time per day
- 2-3 times per day
- 4-5 times per day
- 6 or more times per day

123a. Each time **milk** was added to your coffee or tea, how much was usually added?

- Less than 1 tablespoon
- 1 to 3 tablespoons
- More than 3 tablespoons

123b. What kind of **milk** was usually added to your coffee or tea?

- Whole milk
- 2% milk
- 1% milk
- Skim, nonfat, or 1/2% milk
- Evaporated or condensed (canned) milk
- Soy milk
- Rice milk
- Other

Over the past 12 months...

124. How often was **sugar or honey** added to foods you ate? (Please do not include sugar in coffee, tea, other beverages, or baked goods.)

- NEVER (GO TO INTRODUCTION TO QUESTION 125)
- 1-6 times per year
- 7-11 times per year
- 1 time per month
- 2-3 times per month
- 1 time per week
- 2 times per week
- 3-4 times per week
- 5-6 times per week
- 1 time per day
- 2 or more times per day

124a. Each time **sugar or honey** was added to foods you ate, how much was usually added?

- Less than 1 teaspoon
- 1 to 3 teaspoons
- More than 3 teaspoons

The following questions are about the kinds of margarine, mayonnaise, sour cream, cream cheese, and salad dressing that you eat. If possible, please check the labels of these foods to help you answer.

125. Over the past 12 months, did you eat margarine?

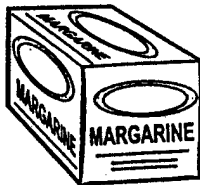
- NO (GO TO QUESTION 126)
- YES

125a. How often was the margarine you ate **regular-fat margarine** (stick or tub)?

- Almost never or never
- About 1/4 of the time
- About 1/2 of the time
- About 3/4 of the time
- Almost always or always

125b. How often was the margarine you ate **light or low-fat margarine** (stick or tub)?

- Almost never or never
- About 1/4 of the time
- About 1/2 of the time
- About 3/4 of the time
- Almost always or always



125c. How often was the margarine you ate **fat-free margarine**?

- Almost never or never
- About 1/4 of the time
- About 1/2 of the time
- About 3/4 of the time
- Almost always or always

126. Over the past 12 months, did you eat butter?

- NO (GO TO QUESTION 127)
- YES

126a. How often was the butter you ate **light or low-fat butter**?

- Almost never or never
- About 1/4 of the time
- About 1/2 of the time
- About 3/4 of the time
- Almost always or always

127. Over the past 12 months, did you eat mayonnaise or mayonnaise-type dressing?

- NO (GO TO QUESTION 128)
- YES

127a. How often was the mayonnaise you ate **regular-fat mayonnaise**?

- Almost never or never
- About 1/4 of the time
- About 1/2 of the time
- About 3/4 of the time
- Almost always or always

127b. How often was the mayonnaise you ate **light or low-fat mayonnaise**?

- Almost never or never
- About 1/4 of the time
- About 1/2 of the time
- About 3/4 of the time
- Almost always or always



Over the past 12 months...

127c. How often was the mayonnaise you ate fat-free mayonnaise?

- Almost never or never
- About 1/4 of the time
- About 1/2 of the time
- About 3/4 of the time
- Almost always or always

128. Over the past 12 months, did you eat sour cream?

NO (GO TO QUESTION 129)

YES

128a. How often was the sour cream you ate regular-fat sour cream?

- Almost never or never
- About 1/4 of the time
- About 1/2 of the time
- About 3/4 of the time
- Almost always or always

128b. How often was the sour cream you ate light, low-fat, or fat-free sour cream?

- Almost never or never
- About 1/4 of the time
- About 1/2 of the time
- About 3/4 of the time
- Almost always or always

129. Over the past 12 months, did you eat cream cheese?

NO (GO TO QUESTION 130)

YES

129a. How often was the cream cheese you ate regular-fat cream cheese?

- Almost never or never
- About 1/4 of the time
- About 1/2 of the time
- About 3/4 of the time
- Almost always or always

129b. How often was the cream cheese you ate light, low-fat, or fat-free cream cheese?

- Almost never or never
- About 1/4 of the time
- About 1/2 of the time
- About 3/4 of the time
- Almost always or always

130. Over the past 12 months, did you eat salad dressing?

NO (GO TO INTRODUCTION TO QUESTION 131)

YES

130a. How often was the salad dressing you ate regular-fat salad dressing (including oil and vinegar dressing)?

- Almost never or never
- About 1/4 of the time
- About 1/2 of the time
- About 3/4 of the time
- Almost always or always

130b. How often was the salad dressing you ate light or low-fat salad dressing?

- Almost never or never
- About 1/4 of the time
- About 1/2 of the time
- About 3/4 of the time
- Almost always or always

130c. How often was the salad dressing you ate fat-free salad dressing?

- Almost never or never
- About 1/4 of the time
- About 1/2 of the time
- About 3/4 of the time
- Almost always or always

The following two questions ask you to summarize your usual intake of vegetables and fruits. Please do not include salads, potatoes, or juices.

131. Over the past 12 months, how many servings of vegetables (not including salad or potatoes) did you eat per week or per day?

- Less than 1 per week
- 1-2 per week
- 3-4 per week
- 5-6 per week
- 1 per day
- 2 per day
- 3 per day
- 4 per day
- 5 or more per day

Over the past 12 months...

132. Over the past 12 months, how many servings of fruit (not including juices) did you eat per week or per day?

- Less than 1 per week
- 1-2 per week
- 3-4 per week
- 5-6 per week
- 1 per day
- 2 per day
- 3 per day
- 4 per day
- 5 or more per day

133. Over the past month, which of the following foods did you eat **AT LEAST THREE TIMES**? (Mark as many as apply.)

- Avocado, guacamole
- Cheeseecake
- Chocolate, fudge, or butterscotch toppings or syrups
- Chow mein noodles
- Croissants
- Dried apricots
- Egg rolls
- Granola bars
- Hot peppers
- Jello, gelatin
- Milkshakes or ice-cream sodas
- Olives
- Oysters
- Pickles or pickled vegetables or fruit
- Plantains
- Pork neckbones, hock, head, feet
- Pudding or custard
- Veal, venison, lamb
- Whipped cream, regular
- Whipped cream, substitute
- NONE

134. For **ALL** of the past 12 months, have you followed any type of vegetarian diet?

NO (GO TO INTRODUCTION TO QUESTION 135)

YES

134a. Which of the following foods did you **TOTALLY EXCLUDE** from your diet? (Mark all that apply.)

- Meat (beef, pork, lamb, etc.)
- Poultry (chicken, turkey, duck)
- Fish and seafood
- Eggs
- Dairy products (milk, cheese, etc.)



The next questions are about your use of fiber supplements or vitamin pills.

135. Over the past 12 months, did you take any of the following types of fiber or fiber supplements on a regular basis (more than once per week for at least 6 of the last 12 months)? (Mark all that apply.)

- NO, didn't take any fiber supplements on a regular basis (GO TO QUESTION 136)
- YES, psyllium products (such as Metamucil, Fiberall, Serutan, Perdiem, Correctol)
- YES, methylcellulose/cellulose products (such as Citrucel, Unifiber)
- YES, Fibercon
- YES, Bran (such as wheat bran, oat bran, or bran wafers)

136. Over the past 12 months, did you take any multivitamins, such as One-a-Day-, Theragran-, or Centrum-type multivitamins (as pills, liquids, or packets)?

NO (GO TO INTRODUCTION TO QUESTION 138)

YES

137. How often did you take One-a-day-, Theragran-, or Centrum-type multivitamins?

- Less than 1 day per month
- 1-3 days per month
- 1-3 days per week
- 4-6 days per week
- Every day

137a. Does your multivitamin usually contain minerals (such as iron, zinc, etc.)?

- NO
- YES
- Don't know

137b. For how many years have you taken multivitamins?

- Less than 1 year
- 1-4 years
- 5-9 years
- 10 or more years



Over the past 12 months...

137c. Over the past 12 months, did you take any vitamins, minerals, or other herbal supplements other than your multivitamin?

NO



Thank you *very much* for completing this questionnaire! Because we want to be able to use all the information you have provided, we would greatly appreciate it if you would please take a moment to review each page making sure that you:

- Did not skip any pages.
- Completely blackened-in each answer, and
- Completely erased any changes you may have made.

YES (GO TO INTRODUCTION TO QUESTION 138.)

These last questions are about the vitamins, minerals, or herbal supplements you took that are NOT part of a One-a-day-, Theragran-, or Centrum-type of multivitamin.

Please include vitamins taken as part of an antioxidant supplement.

138. How often did you take Beta-carotene (NOT as part of a multivitamin in Question 137)?

NEVER (GO TO QUESTION 139)

- Less than 1 day per month
- 1-3 days per month
- 1-3 days per week
- 4-6 days per week
- Every day

138a. When you took Beta-carotene, about how much did you take in one day?

- Less than 10,000 IU
- 10,000-14,999 IU
- 15,000-19,999 IU
- 20,000-24,999 IU
- 25,000 IU or more
- Don't know

138b. For how many years have you taken Beta-carotene?

- Less than 1 year
- 1-4 years
- 5-9 years
- 10 or more years

Question 139 appears in the next column.

139. How often did you take Vitamin A (NOT as part of a multivitamin in Question 137)?

NEVER (GO TO QUESTION 140)

- Less than 1 day per month
- 1-3 days per month
- 1-3 days per week
- 4-6 days per week
- Every day

139a. When you took Vitamin A, about how much did you take in one day?

- Less than 8,000 IU
- 8,000-9,999 IU
- 10,000-14,999 IU
- 15,000-24,999 IU
- 25,000 IU or more
- Don't know

139b. For how many years have you taken Vitamin A?

- Less than 1 year
- 1-4 years
- 5-9 years
- 10 or more years

140. How often did you take Vitamin C (NOT as part of a multivitamin in Question 137)?

NEVER (GO TO QUESTION 141)

- Less than 1 day per month
- 1-3 days per month
- 1-3 days per week
- 4-6 days per week
- Every day

140a. When you took Vitamin C, about how much did you take in one day?

- Less than 500 mg
- 500-999 mg
- 1,000-1,499 mg
- 1,500-1,999 mg
- 2,000 mg or more
- Don't know

140b. For how many years have you taken Vitamin C?

- Less than 1 year
- 1-4 years
- 5-9 years
- 10 or more years

Question 141 appears on the next page.

# Nashville Men's Health Study

Vanderbilt University Medical Center  
Nashville, TN

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For the Department of Defense Grant entitled 'Molecular Markers of Estrogen Metabolism and Progression from High-Grade Prostatic Intraepithelial Neoplasia (HGPIN) to Prostate Cancer'

Please answer the questions below . We realize you may not know all of the answers to these questions, but please do the best you can and be as accurate as possible. It is OK to ask your friends or family for help, and you may refuse to answer any question.

All your information will be confidential, and used only for research.

Remember to bring this questionnaire to us at your clinic appointment. If you have any questions, or need another questionnaire, call Sandra Motley RN at 615-936-3418

Subject #

Subject Initials

Your Name: \_\_\_\_\_

Today's Date: \_\_\_\_\_

**First, a few questions about your date of birth, education, race, and occupation**

1. Date of Birth: Month \_\_\_\_\_ Day \_\_\_\_\_ Year \_\_\_\_\_ Age \_\_\_\_\_

2. What is your current marital status? (Select only one.)

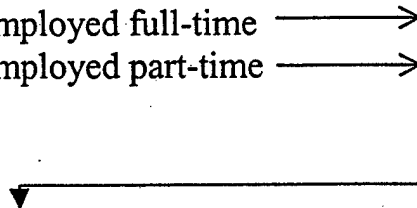
- Married
- Living with a partner
- Widowed
- Divorced
- Separated
- Single, never married and not living with a partner

3. How much school have you completed? (Select only one)

- 8<sup>th</sup> grade or less
- More than 8<sup>th</sup> grade and less than high school
- High school
- Some College or a junior college degree (Associates, RN, etc )
- College (BA, BS, BSN, etc.)
- More than college completed (MA, MS, PhD, MD, JD, etc)

4. Are you presently employed? (Select only one.)

- No, \_\_\_\_\_ → **GO TO Question #6**
- Yes, employed full-time \_\_\_\_\_ →
- Yes, employed part-time \_\_\_\_\_ →



5. If employed, how do you classify your job? (Select only one.)

- Skill or craft
- Machine operator
- Manual Labor
- Sales
- Scientific / Technical
- Service
- Clerical or office
- Professional, managerial, or administrative
- Performer, composer, or entertainer

6. Have you ever worked with or around cadmium (battery manufacturing, welding, yellow paints, etc.)

- No - **GO TO Question # 7**
- Yes

↓  
If Yes, what type of job? \_\_\_\_\_

How Long? \_\_\_\_\_

7. What best describes the race of each of your parents: ✓ one box for each parent

	White	African-American	Hispanic	Asian	Native-America	Other
Mother						
Father						

If you answered 'OTHER', please specify your parent's race:

Mother \_\_\_\_\_

Father \_\_\_\_\_

8. What type of Health Insurance do you have? (Circle One)

- a. Medicare
- b. Medicaid/TennCare
- c. HMO
- d. PPO
- e. Conventional / Indemnity
- f. Combination / POS / Open end HMO
- g. None
- h. Other \_\_\_\_\_

**A few questions about tobacco use.**

9. Have you smoked at least 5 packs or 100 cigarettes, cigars, or pipes during your lifetime?

- No - **GO TO QUESTION #15**
- Yes

If Yes, please answer #10 - #14

10. How old were you when you started smoking? \_\_\_\_\_ years old.

11. What did you smoke most (Select one only)?

- Cigarette
- Cigar
- Pipe

12. Do you currently smoke?

- Yes
- No

13. If you do not currently smoke, how old were you when you stopped smoking on a regular basis?

\_\_\_\_\_ years old.

14. Now, or during the time you smoked regularly, how many cigarettes, cigars or pipefuls do you usually smoke:

On an average WEEKDAY (Monday - Friday )? \_\_\_\_\_

On an average WEEKEND (Saturday - Sunday)? \_\_\_\_\_

**Now we want to ask several questions about your family, and your family's health history.**

15. Were you adopted?

- No
- Yes

16. Were you a twin, triplet, or other multiple birth?

- No - **GO TO Question # 19**
- Twin
- Triplet or other multiple birth

17. Were you identical twins, triplets, etc?

- Yes
- No

18. Was your twin or any of the others male?

- Yes - How Many Males? \_\_\_\_\_
- No

19. How many brothers do you have? *Please include only blood-related brothers with the same father and mother, and include all deceased brothers.*

\_\_\_\_\_ brothers (both living and deceased)


20. How many brothers does your mother have?

\_\_\_\_\_ brothers (both living and deceased)

21. How many brothers does your father have?

\_\_\_\_\_ brothers (both living and deceased)


22. Have any of your close male relatives ever had prostate cancer?

- I Don't Know
- No – **GO TO Question # 24**
- Yes 

23. If Yes, which relatives:

- Father
- Brother
- Son
- Uncle
- Grandfather

24. Have any of your close female relatives ever had breast cancer?

- I don't Know
- No – **GO TO QUESTION # 26**
- Yes 


25. If Yes, which relatives:

- Father's Mother
- Mother's Mother
- Mother
- Sisters
- Aunts

**Now some questions about prostate cancer screening.**

26. Have you ever had a PSA test (blood test to check for prostate cancer)?

No – *Go to Question #28*

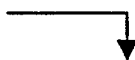
Yes 

27. If Yes, how long ago did you last have a PSA test?

- Less than 1 year ago
- 1 to 2 years ago
- 3 to 5 years ago
- More than 5 years ago

28. Have you ever had a rectal exam (that is, an exam in which the doctor checks your lower rectum with a finger)?

No – *GO TO Question # 30*

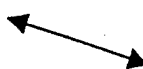
Yes 

29. If Yes, how long ago did you last have a rectal exam?

- Less than 1 year ago
- 1 to 2 years ago
- 3 to 5 years ago
- More than 5 years ago


**Now several questions about your height and weight.**

30. What is the tallest you have ever been (without shoes)?

\_\_\_\_\_ feet \_\_\_\_\_ inches 

31. How old were you when you were this tall? \_\_\_\_\_ years old.

32. How much did you weigh when you were born? If you are not sure, please provide your best guess:

\_\_\_\_\_ pounds \_\_\_\_\_ ounces  Unsure 

**Please check this box if you can not provide a birth weight**

33. Did you weigh less than 5 ½ pounds

- Yes
- No
- Unsure

34. Did you weigh 9 pounds or more

- Yes
- No
- Unsure

35. How much did you weigh at each of the following times?

a. Age 18 years: \_\_\_\_\_ pounds

b. Age 30 years: \_\_\_\_\_ pounds

c. Age 50 years: \_\_\_\_\_ pounds

d. 5 years ago: \_\_\_\_\_ pounds

36. What has been the most you have ever weighed? \_\_\_\_\_ pounds.

37. How old were you when you reached this maximum adult weight?  
\_\_\_\_\_ years old.

**A few questions about how you are doing at this time.**

38. Below is a list of statements. By circling one (1) number per line, please indicate how true each statement has been for you during the past 7 days.

	Not at all	A little bit	Some- what	Quite a bit	Very much
<b>I am able to work (Include work at home)</b>	0	1	2	3	4
<b>My work (and work at home) is fulfilling</b>	0	1	2	3	4
<b>I am able to enjoy life</b>	0	1	2	3	4
<b>I have accepted my illness (if ill)</b>	0	1	2	3	4
<b>I am sleeping well</b>	0	1	2	3	4

39. Please list all the prescription medications you currently use, as well as how often you take each medication (for example: 1/day).

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40. Please list all non-prescription medications, vitamin/mineral supplements, or other herbal supplements you use, and how often.

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41. Did anyone help you complete this questionnaire:

- Yes - If Yes, who helped? (wife, friend, etc) \_\_\_\_\_
- No

**Nashville Men's Health Study  
Physical Activity Assessment Interview**

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Subject #   
Month Day Year

Subject Initials

Date

**Occupational Activity Module**

**Current Occupation:** I'd like to start by asking about your current work status.

**1. Do you work outside the home, either for pay or as a regular volunteer?**

- No – GO TO Question # 7
- Yes

**2. What is your main occupation or volunteer activity?**

\_\_\_\_\_

**3. How long have you had this job? \_\_\_\_\_ years**

**4. {Classify this job: Circle the most appropriate number to fit this job, ask subject if need clarification on job details}**

- 1 – low activity - White collar, clerical, driving, sales
- 2 – moderate activity - plumbing, carpentry, farming, etc.
- 3 – high-activity - Dock work, construction, sports, sweating

**5. When you are at this work place, how often do you do the following things?**

	Never	Seldom	Some times	Often	Always
sit...	1	2	3	4	5
stand...	1	2	3	4	5
walk...	1	2	3	4	5
lift heavy objects	1	2	3	4	5
am tired...	1	2	3	4	5
sweat...	1	2	3	4	5

6. In comparison with others of my own age I think my work is physically  
much heavier      heavier      as heavy      lighter      much lighter

### **CURRENT HOUSEHOLD ACTIVITY**

Some questions about the activities you did in your home last week

7. Did you do light household work (dusting, washing dishes, mending/sewing)?
0. Never
  1. Sometimes (only when partner or help not available)
  2. Mostly (sometimes assisted by partner)
  3. Always (alone or with partner)
8. Did you do heavy housework (washing floors, windows, carry trash)?
0. Never
  1. Sometimes (only when partner or help not available)
  2. Mostly (sometimes assisted by partner)
  3. Always (alone or with partner)
9. For how many persons do you keep house, including self  
(fill in '0' if you answered 'never' to 7 and 8) \_\_\_\_\_
10. How many rooms did you keep clean, including kitchen, bedroom, garage, cellar, bathroom, attic, etc.  
(fill in '0' if you answered 'never' in 7 and 8)
0. Never do housekeeping
  1. 1 - 6 rooms
  2. 7 - 9 rooms
  3. 10 or more rooms
11. For the rooms that you clean, on how many floors are these rooms?  
\_\_\_\_\_ floors
12. Did you prepare warm meals yourself, or did you assist in preparing?
0. Never
  1. Sometimes (once or twice a week)
  2. Mostly (3 - 5 times a week)
  3. Always (more than 5 times a week)

13. How many flights of stairs did you walk on a typical day (one flight of stairs is 10 steps)?

0. I never walk stairs
1. 1 - 5
2. 6 - 10
3. More than 10

14. If you went somewhere in your hometown, what kind of transportation did you use?

0. I never go out
1. Car
2. Public transportation
3. Bicycle
4. Walking

15. How often did you go out for shopping?

0. Never or less than once a week
1. Once a week
2. Twice a week
3. Every day

16. If you went out for shopping, what kind of transportation did you use?

0. I never go out shopping
1. Car
2. Public transportation
3. Bicycle
4. Walking

#### LEISURE TIME ACTIVITY

17. Did you play a sport or exercise last week?

- No – GO TO Question # 20
- Yes

18. Most Frequent Sport: \_\_\_\_\_  
Hours/week \_\_\_\_\_  
Months per Year \_\_\_\_\_

19. Next Frequent Sport: \_\_\_\_\_  
 Hours per week \_\_\_\_\_  
 Months per Year \_\_\_\_\_

20. Did you have other physically active activities last week?  
 No – GO TO Question #23  
 Yes

21. Most frequent activity: \_\_\_\_\_  
 Hours per week \_\_\_\_\_  
 Months per Year \_\_\_\_\_

22. Next frequent Activity: \_\_\_\_\_  
 Hours/week \_\_\_\_\_  
 Months per Year \_\_\_\_\_

23. During Leisure time: *(circle single most appropriate response)*

	Never	Seldom	Some times	Often	Always
I sweat	1	2	3	4	5
I play a sport	1	2	3	4	5
I watch television	1	2	3	4	5
I walk	1	2	3	4	5
I cycle	1	2	3	4	5

24. How many minutes do you walk or cycle per day to and from work, school, and shopping?  I do not work

< 5      5-15      15-30      30-45      > 45 minutes per day

25. Do you regularly attend (at least 2 times per month) a religious service?  
 Yes       No

26. How many hours a day did you usually watch television? \_\_\_ hours/day

27. In comparison to others, my physical activity during leisure time is.....  
 Much      more      more      the same      less      much less

**Thank you for completing this Questionnaire**

**Thank you for completing  
this questionnaire!**

**Please Bring it back to us !**

**Nashville Men's Health Study**  
**Interview Checklist**

Subject #	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Subject Initials	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

- \_\_\_ Answer questions about study
- \_\_\_ Review eligibility
- \_\_\_ Consent form read and signed by subject and witness
- \_\_\_ Study ID Labels on all documents
- \_\_\_ Review medications/vitamins
- \_\_\_ Copy of consent form to subject
- \_\_\_ Diet history
- \_\_\_ Physical activity
- \_\_\_ Give subject diet report
- \_\_\_ Weigh
- \_\_\_ Height
- \_\_\_ Sitting height
- \_\_\_ Hips
- \_\_\_ Waist
- \_\_\_ Purple blood
- \_\_\_ Red blood
- \_\_\_ Urine collected
- \_\_\_ Collect mailed questionnaire

Subject #   
 Subject Initials

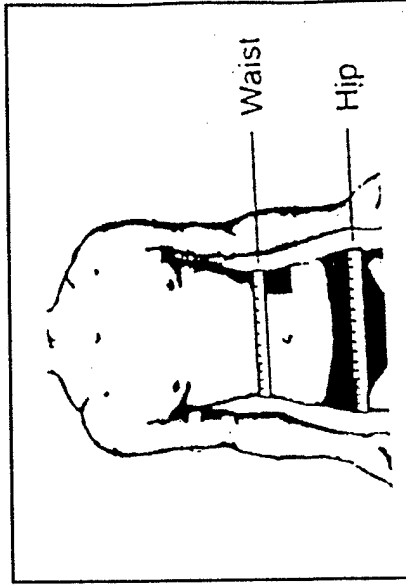
## Nashville Men's Health Study Body Measurement

Date: \_\_\_/\_\_\_/\_\_\_ m d y y Time: \_\_\_:\_\_\_ (\_\_\_ a.m.) or (\_\_\_ p.m.) <check one>

Measurements should be made without shoes and minimal clothing, such as underwear.

Weight: \_\_\_ lbs Height: \_\_\_ ft \_\_\_ /4 inches Sitting Height: \_\_\_ /4 inches

- 1) Waist: \_\_\_ /2 inches Hips: \_\_\_ /2 inches  
 2) Waist: \_\_\_ /2 inches Hips: \_\_\_ /2 inches  
 3) Waist: \_\_\_ /2 inches Hips: \_\_\_ /2 inches



**Instructions:**

- Use Gulich II tape measure, with sensing meter. Tape must be horizontal & not twisted
- Waist: Measure at 2" above the navel. Narrowest part of the torso (see diagram)
- Hips: Maximum posteria extension of buttocks
- Weight: Electronic scale, calibrated, no shoes
- Height: No shoes; heels together; eyes straight ahead; compress hair
- Sitting Height: Subject sits. Length from chair to top of head

# Nashville Men's Health Study Biospecimen Collection

Subject #   
 Subject Initials

**Blood:** Draw 2 tubes of blood (1 purple top EDTA and 1 red top serum).  
 Draw red tube first.

Sample Obtained      Date Drawn      Time Drawn  
 \_\_\_ Yes \_\_\_ No    \_\_\_ / \_\_\_ / \_\_\_    \_\_\_ A.M. \_\_\_ P.M.

Tubes Drawn:      Name of Person drawing sample:  
 \_\_\_ Purple \_\_\_ Red

Comments:  
 \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_

Urine: Aliquot 9 aliquots: Discard remainder

Sample Obtained:      Date:      Time:  
 \_\_\_ Yes \_\_\_ No    \_\_\_ / \_\_\_ / \_\_\_    \_\_\_ A.M. \_\_\_ P.M.

Number of Aliquots      Name of Person Aliquoting  
 \_\_\_ Aliquots

Comments:  
 \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_

Processing Lab

Date Blood Delivered      Time:      Delivered Samples:      # Aliquots      Time in Freezer      Freezer Box #      Freezer Shelf #  
 \_\_\_ / \_\_\_ / \_\_\_    \_\_\_ : \_\_\_ AM \_\_\_ PM    \_\_\_ Purple    \_\_\_ Purple    \_\_\_ AM \_\_\_ PM

Initial for Receipt:      Time:  
 \_\_\_ : \_\_\_ AM \_\_\_ PM

Date Urine Delivered:      Time:  
 \_\_\_ / \_\_\_ / \_\_\_    \_\_\_ : \_\_\_ AM \_\_\_ PM

\_\_\_ Urine    \_\_\_ Urine    \_\_\_ AM \_\_\_ PM

Subject #   
 Subject Initials   
 Date \_\_\_\_\_

**Nashville Men's Health Study  
 Pathology & Prostate Cancer Screening History**

Clinics:  Vanderbilt  VA  Meharry  Other (specify other) \_\_\_\_\_

**Blood Analysis:**

Date	Clinic	PSA (ng/ml)	Free- PSA	PPA	Testosterone	Estradiol	SHBG	Other

**DRE History:**

Date	Clinic	Conclusion (negative, positive, suspicious)	Asymmetry	Induration	Nodularity	Firmness

**Nashville Men's Health Study  
Pathology (cont.)**

Subject #

Subject Initials

Date \_\_\_\_\_

**Ultra Sound Results:**

Date	Clinic	Conclusion (negative, positive, suspicious)	Volume

**Biopsy History:**

Date	Clinic	# Cores Left	# Cores Right	Total Cores	*Conclusion

\*Conclusion Options: Benign, Low-grade PIN, High-grade PIN, Suspicious, Invasive/CAP

**Nashville Men's Health Study  
Pathology (cont.)**

Subject # <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
Subject Initials <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
Date _____

**HGPIN**  
 Yes \_\_\_\_\_  
 No \_\_\_\_\_

**Zone**  
 \_\_\_\_\_ Peripheral  
 \_\_\_\_\_ Transition  
 \_\_\_\_\_ Both

**Distribution**  
 \_\_\_\_\_ Focal  
 \_\_\_\_\_ Multifocal  
 \_\_\_\_\_ Extensive

**Invasive Cancer:**  
 Yes \_\_\_\_\_  
 No \_\_\_\_\_

T	N	M

Score	Sum

**BPH**  
 Yes \_\_\_\_\_  
 No \_\_\_\_\_

**Zone**  
 \_\_\_\_\_ Peripheral  
 \_\_\_\_\_ Transition  
 \_\_\_\_\_ Both

**Distribution**  
 \_\_\_\_\_ Focal  
 \_\_\_\_\_ Multifocal  
 \_\_\_\_\_ Extensive

February 20, 2003

«FirstName» «LastName»  
«Address1»  
«City» «State» «PostalCode»

Dear Mr. «LastName»,

You are invited to join the Nashville Men's Health Study. Prostate cancer is the most commonly diagnosed cancer in the United States, and we need your help to understand why prostate cancer is so common in Tennessee. To complete this study and to better understand the causes of prostate cancer, we have been given permission to contact men who recently received medical tests for prostate cancer at Vanderbilt or the VA.

The United States government has funded this research study, because so many men have prostate cancer and we do not understand why. It will be difficult to prevent prostate cancer or improve prostate cancer treatment without understanding the causes of this disease.

Even though you may not have prostate cancer, we need your participation. Your information will help us figure out how those men who have prostate cancer may differ from those men who do not have prostate cancer. In giving us your answers, you may be helping other men your own age and younger. You can make an important difference in helping to prevent prostate cancer by being involved in this study.

An interviewer from Vanderbilt University will be calling you. You have the right to decline this call. This introductory telephone call will take about 5 minutes, and we may ask you to visit our office at a convenient time to collect additional information. The interviewer will tell you more, and answer questions.

Cancer research relies on people to participate. We look forward to talking with you in the next couple of weeks. If you have any questions, please call Sandra Motley at 615-936-3418.

We are excited about this study and hopeful that you will participate.

Sincerely,

---

Dr. Joseph Smith  
Professor and Chair of Urologic Surgery  
Vanderbilt University

---

Dr. Jay H. Fowke  
Assistant Professor of Medicine  
Vanderbilt University

### **Why Prostate Cancer Research?**

Prostate cancer is the most common cancer diagnosis in the United States. Men living in the Southern United States are more likely to be diagnosed with prostate cancer than men living in other regions.

### **Why this study?**

The Molecular Markers of Prostate Cancer Study is funded by Department of Defense (U.S. Army) through Vanderbilt University to study the possible role of hormones and diet in prostate disease.

### **Who Is Eligible**

The study is open to men who are at least 50 years of age, received medical care at Vanderbilt, and live in Middle Tennessee.

### **What will be asked of Participants?**

Study participants will come in for a visit to our office at Vanderbilt. Each participant will provide a blood and urine sample, and fill-out a questionnaire. We will measure your weight and height, and ask you about the foods you usually eat. This visit will take about 1 hour, and we can schedule this meeting for a time of day convenient for you.

### **Location**

Clinic visits will be held in the Clinical Research Center at Vanderbilt located in Medical Center North on the 3rd floor. Visitor parking is available next to this building.

### **What are the benefits of Participating?**

As a participant in the study, you will have the opportunity to contribute to important research on preventing prostate cancer. Other people may receive future benefits from your participation. You may receive a summary of your information, and there will be no cost to you.

### **More Information**

#### **Please call:**

**Saundra Motley RN**

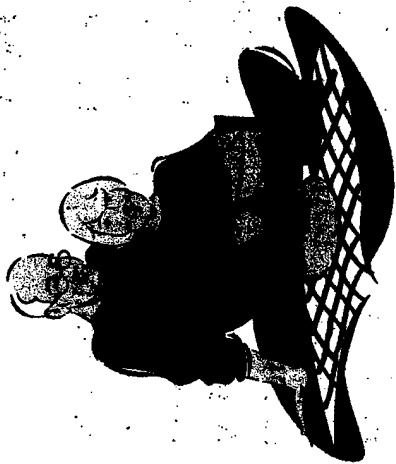
**Project Coordinator**

**Center for Health Services  
Research**

**(615) 936-3418**

#### **E-mail:**

**Saundra.Motley@Vanderbilt.edu**



**Why does Prostate Cancer  
Affect So Many People in  
Tennessee?**

# ***Nashville Men's Health Study***



**NMHS Study by**

**Jay H. Fowke, PhD, MPH**

**Principal Investigator**

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Nashville Men's Health Study  
Telephone Script for Identification

*For the Department of Defense Grant entitled 'Molecular Markers of Estrogen Metabolism and Progression from High-Grade Prostatic Intraepithelial Neoplasia (HGPIN) to Prostate Cancer'*

**(Greeting: Record who answers phone / man or woman)**

My name is \_\_\_\_\_, and I am calling from Vanderbilt University Medical Center.

May we speak with (subject's name), please?

**(If not available):** That's fine. Is there a better time to call?

**(Ask for better time to call back, record time, and call back at that time. Start at beginning of script.)**

I hope I haven't taken too much of your time. Have a great (day/evening).  
Thanks again. **(Hang-up)**

**(If Subject comes to telephone: repeat introduction)**

Did you receive the letter I mailed you last week?

**(If No,  
Confirm address. Tell him you will send letter immediately, and will call again next week. Thank subject. Hang-up.)**

We are conducting a study to understand how diet and physical activity may affect men's health and cancer risk. We are identifying men who have prostate cancer, as well as men who do not have prostate cancer. This telephone call will take only a few minutes, and I would like to tell you a little more about this study to see if you may be interested in taking part?

**If no time, (either thank the participant for his time or enquire when would be a better time to call her back. Also record in the verification table of the ACCESS database the appropriate response and time to call back)**

**Otherwise, continue:**

The findings of this study will be important because very little is known about what causes prostate cancer. Many lifestyle choices, including eating habits and physical activity levels, may be very important risk markers of prostate cancer. ***{Be ready to answer a few questions here- on published study results & role of estrogen in BC}.***

We would like to schedule an appointment with our research nurse at our Vanderbilt clinic. This appointment may be scheduled at a time most convenient for you. During this visit, our nurse will measure your weight, height, and the circumference of your waist and hips. She will ask you several questions about the types of foods you usually eat, and about your activities.. After the interview, we will ask you to provide a urine sample and a blood sample. We estimate this visit will take about 1 hour. You will be given a summary of your dietary intake information, and this study will not cost you any money.

All of this information will be used for research purposes only, and all information will be kept confidential. No one other than the professors conducting the study will have access to your answers or the blood or urine samples. It is your decision whether or not you want to participate. Your participation will not benefit you or affect your healthcare, but may help other men in Tennessee by helping find the causes of prostate cancer.

Would you be interested in taking part in this study to investigate the causes of prostate cancer?

***(If no, thank the participant for his time):***

That's fine. Thank you for your time and have a nice day. Good-bye.

***(If Yes)***

That's great. We appreciate your willingness to participate.

In order to qualify for this study, you must be at least 50 years of age, you must not have benign prostatic hypertrophy (BPH) (symptoms include weak or interrupted urine flow, painful urination, blood in urine, pelvic pain), you must have never been treated for prostate cancer, and you must not be taking any medications, such as Lupron or other drugs, that affects steroid or hormone levels. Do you think you qualify for this study?

***(If YES to any question:) Thank you for your time. Unfortunately, you are ineligible for this study because..... Thank you again. Good bye.***

***(If NO to all questions: subject eligible. Continue)***

It appears that you are eligible to take part in this research study. When would be a good time for you to do the interview- we will need about 1 hour.

(Begin schedule protocol: Name, address, date of visit, time of visit. Record all information, record telephone number)

**Result of Recruitment:**

- 1: recruited**
- 2: not interested**
- 3: ill**
- 4: no time**
- 5: no transportation**
- 6: other: \_\_\_\_\_**

I will send you a map a directions, as well as information about who to call if you need to re-schedule this appointment. If you have any questions before you receive my letter, feel free to call 615-936-2903. Sandra, our research nurse, will be expecting you. Don't for get to bring your parking ticket to this meeting for validation.

On behalf of the entire Nashville Men's Health Study research staff, I would like to thank you for participating in this study. Have a nice afternoon.

**Answering Machine Protocol**

Hello, my name is \_\_\_\_\_ and I'm calling from Vanderbilt University Medical Center about a research study we are conducting. I will try to call back later. Thanks.

January 21, 2003

«Title» «FirstName» «LastName»  
«Address1»  
«City» «State» «PostalCode»

Dear «Title» «LastName»,

I am writing to thank you for taking part in our research study. As a participant in this study, your time and involvement was important to the success of our project. We plan to share the results of the study as soon as it is possible for us to do so.

I am enclosing the results of your dietary questionnaire. This is a summary of your average daily intake, based on your response to the dietary questions.

I have enjoyed meeting and working with you on the Nashville Men's Health Study. Please let me know if you have any questions by calling and leaving a message.

Sincerely,

Saundra Motley RN  
Project Coordinator  
Nashville Men's Health Study  
Vanderbilt University  
Telephone # 936-3418  
Saundra.Motley@Vanderbilt.edu

Dr. Jay H. Fowke  
Principal Investigator  
Nashville Men's Health Study  
Assistant Professor of Medicine  
Vanderbilt University

PI: Jay H. Fowke, Ph.D.

Date: November 4, 2002

Title: Molecular Markers of Estrogen Metabolism and Progression from High-Grade Prostatic Intraepithelial Neoplasia (HGPIN) to Prostate Cancer

Institution: Vanderbilt University Medical Center

Vanderbilt University Institutional Review Board  
Proposal for Research Using Human Subjects

Consent for Research Study

This consent form applies to all men undergoing diagnostic tests for prostate cancer.

Name of subject \_\_\_\_\_ Age \_\_\_\_\_

The following information is provided to inform you about the research project and your participation in the study. Please read this form carefully. Please feel free to ask any questions you may have about this study and the information given below. You will be given an opportunity to ask questions, and your questions will be answered. You will be given a copy of this consent form.

**1. Purpose of the study.**

You are asked to participate in this study because you recently received a test for prostate cancer. The study investigates the role of hormones in prostate cancer development. Hormones, such as estrogens and androgens, cause prostate cells to grow and divide, potentially contributing to the formation of a prostate cancer. We have received funding from the Department of Defense (U.S. Army) to investigate how these hormones could influence prostate cancer formation. We will enroll men with prostate cancer and men without prostate cancer, and compare the amounts of these hormones between these groups. This study may help us to understand why some men develop prostate cancer while others do not, and to develop new approaches to prevent prostate cancer.

**2. Description of the procedures to be followed and approximate duration of the study.**

We will ask you to visit our office at Vanderbilt University Medical Center for about 1 hour. This office visit can be scheduled for a day convenient to you. During this visit, we will collect a sample of blood (about 5 teaspoons) in the usual way, by inserting a needle into a vein in your arm. We will use this blood sample to determine levels of the hormones that are thought to be important in modifying prostate cancer risk, and we will identify enzymes responsible for breaking-down these hormones. We will collect a small (about 3 ounce) urine sample. This urine sample will be used to determine the levels of additional hormones that are excreted from your body in your urine. Our blood and urine measurements may be affected by tobacco, weight, diet, and perhaps other factors. If you use tobacco, it is important these urine and blood samples be collected at least 2 hours after your last cigarette, cigar, or pipe. We will measure your weight, height, the circumference of your waist and hips, and we will ask you about the types of foods you typically eat and your exercise habits. We will give you a summary of your dietary information when it is possible to do so.

In summary, your research office visit will include:

- A blood sample
- A urine sample
- Weight and height measurements
- Questions about your diet and activities
- Waist and Hip Measurements

Your medical records will be reviewed to determine eligibility. The project coordinator will collect demographic, medication, and pathology information.

At this interview, we will give you a questionnaire that contains questions about several topics such as your education, job, and date of birth. This questionnaire will require about 20 minutes, and we will ask you to complete the questionnaire at home and mail it back to us in a postage-paid envelope, which we provide.

PI: Jay H. Fowke, Ph.D.

Date: November 4, 2002

Title: Molecular Markers of Estrogen Metabolism and Progression from High-Grade Prostatic Intraepithelial Neoplasia (HGPIN) to Prostate Cancer

Institution: Vanderbilt University Medical Center

Vanderbilt University Institutional Review Board  
Proposal for Research Using Human Subjects

Consent for Research Study

You may be removed from the study if you are found to be no longer eligible in the study or if you are unwilling or unable to provide the information we request.

**3. Possible discomforts, inconveniences, and/or risks**

Drawing blood may hurt slightly, and you might have a black and blue mark. Occasionally a person may become dizzy or faint when blood is drawn and there is a rare possibility of infection or temporary nerve damage. You may collect your urine sample in a nearby bathroom for privacy. There should be no risk or discomfort when we measure your weight or height, ask questions about your diet or physical activities.

If you are injured as a direct result of participating in this research project, you will be provided with medical care at no cost to you for that injury. You will not receive any injury compensation, only medical care. This is not a release of your legal rights, and you should discuss this with investigators before enrolling.

All questionnaires and other information you provide will be kept confidential. Documents will be stored in locked rooms and cabinets, accessible only to the study investigators. A study ID number will be assigned to each volunteer, and all your documents will be labeled only with this study ID number. Only the project manager and principal investigator will be able to break this code. Our analysis compares groups of study participants, and no information about an individual study participant will be released or reported. The documents will be shredded and destroyed when they are no longer needed for research purposes, and always no longer than 20 years from collection.

**4. Benefits resulting from this study**

There are no direct benefits to you for participating in this study. Other than what is specifically stated in this consent form, there is no compensation. The knowledge gained from your participation in this research may help further our understanding of how to prevent or treat prostate cancer.

**5. Alternative procedures**

You may choose not to take part in this study. You may choose not to answer certain questions or may contact the principal investigator at 615-936-2903 if later you decide to have your samples or questionnaires destroyed.

**6. Contact information:**

If you should have any questions about this research study, please feel free to contact Dr. Jay H. Fowke at 615-936-2903. For additional information about giving consent or your rights as a participant in this study, please feel free to contact the Vanderbilt University Institutional Review Board Office at (615) 322-2918 or toll free at (866-224-8273). If you are participating in a research project at the VA Medical Center, please contact the Research and Development office at (615) 327-5346.

NOV 07 2002

OCT 03 2003

PI: Jay H. Fowke, Ph.D.

Date: November 4, 2002

Title: Molecular Markers of Estrogen Metabolism and Progression from High-Grade Prostatic Intraepithelial Neoplasia (HGPIN) to Prostate Cancer

Institution: Vanderbilt University Medical Center

Vanderbilt University Institutional Review Board  
Proposal for Research Using Human Subjects

Consent for Research Study

**7. Sample Donation**

One risk of donating samples for genetic research may be the release of information (for example your name) that could link you to the stored samples and/or the results of the tests run on your samples. The release of this information that identifies you could cause problems with insurance or future employment. There are many safeguards in place to prevent the release of information from this study.

All samples obtained for this study will be assigned a study ID number. The key to the study ID number will be kept in a locked file in the investigator's office. Only the Principal Investigator (Dr. Jay H. Fowke) and the study coordinator will have access to the code and information that identifies you as a being in this study. The results of tests run on your samples will not be recorded in your records and neither you, nor your doctor will be told of the results. No one else, including relatives, doctors, employers or insurance companies will be allowed to view your test results.

Your blood and urine samples will be used only for research and will not be sold or used directly to produce products that could be sold for money. The cells, proteins, DNA or other materials from your samples, as well as the results of genetic testing and other data about you, may be shared with other researchers for research purposes. Personal information may also be shared (such as your age, sex and illness) but the samples will not be labeled with your name, address or other information that would identify you. All information will be coded to maintain your privacy. At the end of the study, the codes used to identify your samples will be destroyed. There will be no cost to you for any of the tests your samples are used for. You will not be paid to have these tests performed.

These blood and urine samples will be used to investigate the relationship between hormones and hormone metabolism in prostate cancer. However, cancer research often advances in unexpected directions, and the DNA from your samples may also be used in future studies for purposes that are currently unknown. These future studies most likely will be related to prostate cancer, but it is possible these studies may be related to other diseases. The samples you donate will be destroyed when they are no longer needed, and always within 20 years of collection.

There is a chance that the samples that you are donating under this study may have some commercial value, however no commercial value is anticipated. Should your donated samples lead to the development of a commercial product, Vanderbilt University will own it and may take action to patent and license the product. Vanderbilt does not intend to provide you with any compensation for your participation in this study nor for any future value that the sample you have given may be found to have. You will not receive any notice of future uses of your samples.

OCT 03 2002

PI: Jay H. Fowke, Ph.D.

Date: November 4, 2002

Title: Molecular Markers of Estrogen Metabolism and Progression from High-Grade Prostatic Intraepithelial Neoplasia (HGPIN) to Prostate Cancer  
Institution: Vanderbilt University Medical Center

Vanderbilt University Institutional Review Board  
Proposal for Research Using Human Subjects

Consent for Research Study

Please check Yes or No, and sign to indicate that you have freely given consent for sample donation. You may continue to participate in this study regardless of which level of participation you choose.

My blood sample may be used for genetic testing in association with this prostate cancer study.

Yes       No

My blood sample may be stored for future genetic research in prostate cancer.

Yes       No

My blood/tissue sample may be stored/shared for future genetic research involved with other medical conditions (for example, diabetes, heart disease, etc).

Yes       No

We may contact you again in the future and ask you to participate in other studies. If you are contacted, you will be presented with a form much like this one that will explain the research and ask for your consent to participate.

---

Participant Signature for Sample Donation

PI: Jay H. Fowke, Ph.D.

Date: November 4, 2002

Title: Molecular Markers of Estrogen Metabolism and Progression from High-Grade Prostatic Intraepithelial Neoplasia (HGPIN) to Prostate Cancer  
Institution: Vanderbilt University Medical Center

Vanderbilt University Institutional Review Board  
Proposal for Research Using Human Subjects

Consent for Research Study

Your rights as a volunteer:

Your participation in this study is voluntary, and you may choose not to participate. You are not waiving your legal rights, or releasing any agent from liability or negligence. You are also free to withdraw from this study at any time. Withdrawal or refusal to participate will not prejudice your health care.

In the event new information becomes available that may affect the risks or benefits associated with this study or your willingness to participate in it, you will be notified so that you can make an informed decision whether or not to continue your participation in this study.

Efforts will be made to keep the personal information in your research record private and confidential but absolute confidentiality cannot be guaranteed. Your personal information may be disclosed if required by law. The U.S. Army Medical Research and Material Command reserves the right to audit the records of this study for quality assurance and protocol compliance.

**STATEMENT BY PERSON AGREEING TO PARTICIPATE IN THIS STUDY**

I have read this consent form. All my questions have been answered, and I freely and voluntarily choose to participate. I understand that I may withdraw at any time.

The material contained in this consent form has been explained to me verbally. All my questions have been answered, and I freely and voluntarily choose to participate. I understand that I may withdraw at any time.

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature of Volunteer

\_\_\_\_\_  
Address of Volunteer

Consent obtained by:

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Printed Name and Title

NOV 07 2002

OCT 03 2002

Subject Name: \_\_\_\_\_

Date: \_\_\_\_\_

Title of Study: Nashville Men's Health Study

Principal Investigator: Jay H. Fowke, PhD

VAMC: Nashville

The following information is provided to inform you about the research study and your participation in it. Please read the form and feel free to ask any questions you may have about the information provided below. You will be given the opportunity to ask questions and have your questions answered before making a decision to participate in this study. You will be given a copy of this consent form.

**PURPOSE OF THE STUDY**

You are asked to participate in this study because you recently received a test for prostate cancer. The study investigates the role of hormones in prostate cancer development. Hormones, such as estrogens and androgens, cause prostate cells to grow and divide, potentially contributing to the formation of a prostate cancer. We have received funding from the Department of Defense (U.S. Army) to investigate how these hormones could influence prostate cancer formation. We will enroll men with prostate cancer and men without prostate cancer, and compare the amounts of these hormones between these groups. This study may help us to understand why some men develop prostate cancer while others do not and to develop new approaches to prevent prostate cancer.

**DESCRIPTION OF THE PROCEDURES AND APPROXIMATE DURATION OF THE STUDY**

We will ask you to visit our office at Vanderbilt University Medical Center for about 1 hour. This office visit can be scheduled for a day convenient to you. During this visit, we will collect a sample of blood (about 5 teaspoons) in the usual way, by inserting a needle into a vein in your arm. We will use this blood sample to determine levels of the hormones that are thought to be important in modifying prostate cancer risk, and we will identify enzymes responsible for breaking-down these hormones. We will collect a small (about 3 ounce) urine sample. This urine sample may be used to determine the levels of additional hormones that are excreted from your body in your urine. Our blood and urine measurements may be affected by tobacco, weight, diet, and perhaps other factors. If you use tobacco, it is important that this urine sample be collected at least 2 hours after your last cigarette, cigar, or pipe. We will measure your weight, height, the circumference of your waist and hips, and we will ask you about the types of foods you typically eat and your exercise habits. We will give you a summary of your dietary information when it is possible to do so.

SUBJECT'S IDENTIFICATION (I.D. plate of given name - last, first, middle)

VA FORM  
JAN 1990 10-1086

IRB Approval Date: \_\_\_\_\_

*NOV 07 2002*

IRB Expiration Date: \_\_\_\_\_

*OCT 03 2003*

IRB Chair Initials: \_\_\_\_\_

*UHF*

Subject Name: \_\_\_\_\_

Date: \_\_\_\_\_

Title of Study: Nashville Men's Health Study

Principal Investigator: Jav H. Fowke, PhD

VAMC: Nashville

Your medical records will be reviewed to determine eligibility. The project coordinator will collect demographic, medication, and pathology information.

At this interview, we will give you a questionnaire that contains questions about several topics such as your education, job, and date of birth. This questionnaire will require about 20 minutes, and we will ask you to complete the questionnaire at home and mail it back to us in a postage-paid envelope, which we provide.

You may be removed from the study if you are found to be no longer eligible in the study or if you are unwilling or unable to provide the information we request.

In summary, your research office visit will include:

- A blood sample
- A urine sample
- Weight and height measurements
- Questions about your diet and activities
- A questionnaire to take home, and mail back to us

**DESCRIPTION OF THE DISCOMFORTS, INCONVENIENCES, AND/OR RISKS**

Drawing blood may hurt slightly, and you might have a black and blue mark. Occasionally a person may become dizzy or faint when blood is drawn and there is a rare possibility of infection or temporary nerve damage. You may collect your urine sample in a nearby bathroom for privacy. There should be no risk or discomfort when we measure your weight or height, ask questions about your diet or physical activities.

All questionnaires and other information you provide will be kept confidential. Documents will be stored in locked rooms and cabinets, accessible only to the study investigators. A study ID number will be assigned to each volunteer, and all of your documents will be labeled only with this study number. Only the project manager and the principal investigator will be able to break this code. Our analysis compares groups of study participants, and no information about an individual study participant will be released or reported. The documents will be shredded and destroyed when they are no longer needed for research purposes, and always no longer than 20 years from collection.

Subject's Initials \_\_\_\_\_

*NOV 0 2002 Inv.*

*OCT 08 2003*

*LMGR*

Subject Name: \_\_\_\_\_

Date: \_\_\_\_\_

Title of Study: Nashville Men's Health Study

Principal Investigator: Jay H. Fowke, PhD

VAMC: Nashville

For study participants who are veterans:

As a veteran subject you will not be required to pay for any treatment received as a research subject, which is being done solely for the purpose of this research study. However, your insurance carrier will be billed for all routine care and clinical procedures, if applicable. If you are in a "priority group # 7 veteran category" you are subject to making a co-payment as indicated by a means test. Your doctor should be able to provide you with this information or refer you to the appropriate individual for any questions you may have. As a veteran, you will receive medical care and treatment for injuries suffered as a result of participating in a VA research program in accordance with Federal Law. You will incur no additional charges for additional medical care that may result from injury or complications that are a direct result of your participation in this study.

ANTICIPATED BENEFITS RESULTING FROM STUDY PARTICIPATION

There are no direct benefits to you for participating in this study. Other than what is specifically stated in the consent form, there is no compensation. The knowledge gained from your participation in this research may help others, by furthering our understanding of how to prevent or treat prostate cancer.

ALTERNATIVE PROCEDURES/OTHER TREATMENT AVAILABLE

You may choose not to take part in this study. Your participation is entirely voluntary. You can refuse to participate now or you can withdraw from this study at any time after giving your consent without affecting your healthcare/services or other rights. This will not interfere with your regular medical treatment, if you are a patient. You may choose not to answer certain questions or may contact the principal investigator at 615-936-2903 if later you decide to have your samples or questionnaires destroyed.

CONTACT INFORMATION

If you should have any questions about this research study, please feel free to contact Dr. Jay H. Fowke at 615-936-2903. For additional information about giving consent or your rights as a participant in this study, please feel free to contact the Vanderbilt University Institutional Review Board Office at (615) 322-2918 or the Research and Development Office at (615) 327-5346.

Subject's Initials \_\_\_\_\_

Subject Name: \_\_\_\_\_

Date: \_\_\_\_\_

Title of Study: Nashville Men's Health Study

Principal Investigator: Jay H. Fowke, PhD

VAMC: Nashville

**RESEARCH RESULTS**

In the event new information becomes available that may affect the risks and/or benefits associated with this study or your willingness to participate in it, you and your physician will be notified so you can make a decision whether or not to continue your participation in this study. If results of this study are reported in medical journals or at meetings, you will not be identified by name, or by any other means without your specific consent.

**CONFIDENTIALITY AND PRIVACY**

Your rights of privacy will be maintained in the following manner. Your medical records will be maintained according to this medical center's requirements. All information obtained about you during the research study will be kept as confidential as legally possible and will be accessible only to the investigators, the sponsor (when applicable), and any appropriate government agency. Research records, like any other hospital records, may be inspected by federal regulatory authorities, including the Food and Drug Administration (FDA), state regulatory authorities, and legally authorized parties.

**STORING SAMPLES AND GENETIC SCREENING OF STORED SAMPLES**

The purpose of this part of the study is to store for future use samples of your blood to look for genetic factors (DNA) that may cause or relate to prostate cancer or other conditions or illnesses. This blood sample is the same sample described in section 2 above.

One risk of donating samples for genetic research may be the release of information (for example your name) that could link you to the stored samples and/or the results of the tests run on your samples. The release of this information that identifies you could cause problems with insurance or future employment. There are many safeguards in place to prevent the release of information from this study. All samples obtained for this study will be assigned a study ID number. The key to the study ID number will be kept in a locked file in the investigator's office. Only Dr. Jay H. Fowke and the study coordinator will have access to the code and information that identifies you as a being in this study. The results of tests run on your samples will not be recorded in your records and neither you, nor your doctor will be told of the results. No one else, including relatives, doctors, employers or insurance companies will be allowed to view your test results.

Subject's Initials \_\_\_\_\_

NOV 07 2002

OCT 03 2003

*LMJR*

Subject Name: \_\_\_\_\_

Date: \_\_\_\_\_

Title of Study: Nashville Men's Health Study

Principal Investigator: Jay H. Fowke, PhD

VAMC: Nashville

Your blood and urine samples will be used only for research and will not be sold or used directly to produce products that could be sold for money. The cells, proteins, DNA or other materials from your samples, as well as the results of genetic testing and other data about you, may be shared with other researchers for research purposes. Personal information may also be shared (such as your age, sex and illness) but the samples will not be labeled with your name, address or other information that would identify you. All information will be coded to maintain your privacy. At the end of the study, the codes used to identify your samples will be destroyed. There will be no cost to you for any of the tests your samples are used for. You will not be paid to have the tests performed.

These blood and urine samples will be used to investigate the relationship between hormones and hormone metabolism in prostate cancer. However, cancer research often advances in unexpected directions, and the DNA from your samples may also be used in future studies for purposes that are currently unknown. These future studies most likely will be related to prostate cancer, but it is possible these studies may be related to other diseases. The samples you donate will be destroyed when they are no longer needed, and always within 20 years of collection.

There is a chance that the samples that you are donating under this study may have some commercial value. No commercial value is anticipated. Should your donated samples lead to the development of a commercial product, Vanderbilt University will own it and may take action to patent and license the product. Vanderbilt does not intend to provide you with any compensation for your participation in this study nor for any future value that the sample you have given may be found to have. You will not receive any notice of future uses of your samples.

Subject's Initials \_\_\_\_\_

Subject Name: \_\_\_\_\_

Date: \_\_\_\_\_

Title of Study: Nashville Men's Health Study

Principal Investigator: Jay H. Fowke, PhD

VAMC: Nashville

Please check Yes or No and sign your name, indicating you have freely given your answers and consent:

My blood/tissue sample may be used for genetic testing in association with this study.

Yes       No

My blood/tissue sample may be stored/shared (if applicable) for future genetic research in prostate cancer.

Yes       No

My blood/tissue sample may be stored/shared (if applicable) for future genetic research involved with other medical conditions (for example, obesity, diabetes, cancer, heart disease, Alzheimer's disease, etc).

Yes       No

Subject's Initials \_\_\_\_\_

Subject Name: \_\_\_\_\_

Date: \_\_\_\_\_

Title of Study: Nashville Men's Health Study

Principal Investigator: Jay H. Fowke, PhD

VAMC: Nashville

**STATEMENT OF PERSON AGREEING TO PARTICIPATE IN THIS RESEARCH STUDY**

I have read ( ) this consent form or have had it read to me ( ).

\_\_\_\_\_ has explained the study to me and all of my questions have been answered. I have been told of the risks or discomforts and possible benefits of the study. I have been told of other choices of treatment available to me.

If I do not take part in this study, my refusal to participate will involve no penalty or loss of rights to which I am entitled. I may withdraw from this study at any time without penalty or loss of VA or other benefits to which I am entitled.

I have been told my rights as a research subject, and I voluntarily consent to participate in this study. I have been told what the study is about and how and why it is being done. All my questions have been answered.

I will receive a signed copy of this consent form.

\_\_\_\_\_  
Subject's Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature of Subject's Representative\*/Relationship

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature of Witness

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature of Investigator

\_\_\_\_\_  
Date

\*Only required if subject not competent.

Subject's Initials \_\_\_\_\_

## **Informed Consent**

Informed consent is a process, not just a document that human subjects sign. The process of obtaining informed consent must comply with the requirements of 45 CFR 46.116. The documentation of informed consent must comply with 45CFR 46.117. Information will be presented to enable persons to voluntarily decide whether or not to participate as a research subject. Explanation will be designed to educate the participant in terms that they can understand. The written presentation of information is used to document the basis for consent and for the subjects' future reference. Informed consent is not an isolated point in time that ends upon the subject signing the form. The process of informed consent continues during the entire relationship of the participant to the research project.

### **Procedure:**

- The consent form used will have date of IRB approval
- The informed consent will be obtained at Visit 1, the in-person interview
- Make sure the participant is comfortable
- Consider the educational and emotional state of the participant
- Provide adequate time for the participant to consider the information
- Confidentiality
- Written approval of release of information
- Explain the study to the participant including:

#### **Clinical protocols**

- Urine sample
- Blood sample

#### **Questionnaires**

- Dietary History
- Activity

#### **Measurement procedures**

- Answer participant questions
- Sign Consent
- Provide participant with copy of signed document
- Original to be kept in patient study file

## **Patient Identification and Confidentiality**

### **Confidentiality**

Throughout the study, standard measures to ensure privacy and information on study subjects will be maintained. Subjects will be informed that all information will be confidentially held, and assured that data will be used only for statistical purposes. Individuals will not be identified in the analysis. No data beyond what is stated in the informed consent will be sought without authorization from the subject or next of kin. Information on hospitalization or illness will not be sought from hospitals or doctors without a signed medical release from the subject. No information on any individual will be released to anyone other than study personnel without the written approval of the individual or, where appropriate, the next of kin or physician in the case of a life-threatening situation. All study personnel will be instructed not to discuss any cases with persons other than study personnel.

### **Identification Protocols**

Each patient will be assigned a numerical identification number for confidentiality purposes. The patient's initials will also be part of the ID#  
The numbers will be assigned in sequence 001,002,003, and so on  
Patients will retain the same number throughout the study

All specimen will have NMHS =Nashville Men's Health Study  
All specimen will have the patient ID# and an alpha code  
All Specimens will have a letter on the label to indicate source

U=urine  
G=Genetic  
S=Serum and Blood Clots

Duplicate of label will be placed on Biospecimen Collection Form

Example ID # 001 XYZ U would denote patient 1, Urine  
All specimens would be labeled using this identification system

## ADVERSE EVENTS

### Introduction

Only subjects with ongoing doctor/patient relationships will be used in this study. Patients will continue their usual care with their physician(s). Telephone numbers for the study PI and study coordinator will be given to the subject. Any problems discovered by the study team will be discussed at an appropriate level with the patient sufficient to affect referral to the patient's primary care physician who will also be informed after written consent by the patient.

Adverse event is defined as any unfavorable and unintended sign, symptom, or disease temporally associated with the use of a treatment or procedure regardless of whether it is considered related to the treatment or procedure. Examples of adverse events are:

- Death
- A Life-Threatening Condition
- A Cancer
- A PERSISTENT OR SIGNIFICANT DISABILITY/INCAPACITY (substantial disruption of one's ability to conduct normal life functions)
- A Hospitalization (includes an overnight stay, regardless of length of stay, even if the hospitalization is a precautionary measure for continued observation)
- *Prolonged* an existing inpatient hospitalization. NOTE: Hospitalization for a pre-existing condition, which has not worsened, does not constitute a serious experience.
- A congenital anomaly/birth defect (in offspring of subject taking the product, regardless of time of diagnosis)
- An overdose (whether accidental or intentional)

Throughout the study, we will closely monitor for adverse events. Side effects are monitored in several ways.

- Participants have the telephone numbers of the project coordinator and the principal investigator, and are encouraged to call if necessary.
- Participants also may e-mail study personnel.
- Participants will be instructed to write-down any side effects or unusual events, and bring these notes to a clinic visit

All project staff consult with the principal investigator and physician co-investigator about all side effects reported by subjects. All potential side effects are rated as mild, moderate, or severe. The project coordinator handles minor side effects, after consultation with the PI and Co-I. Moderate or severe events will be recorded on a adverse event form. This form includes a summary of the adverse clinical event, an assessment of the likelihood that the event was due to protocol, and a statement of action taken. These forms remain as part of the participant's file. The PI and physician Co-I will be responsible for stopping the study if needed. The intervention phase, last only for the clinic visit in which blood is drawn.

Adverse events will be reported to the Vanderbilt IRB as required by protocol.

## **Questionnaires**

### **Identification Protocols**

To maintain confidentiality and to meet HIPPA standards of PHI, the patient will be identified by use of an ID#. Each patient will be assigned a numerical identification number for confidentiality purposes. The patient's initials will also be part of the ID#. The numbers will be assigned in sequence 001,002,003, and so on. Patients will retain the same number throughout the study.

Example ID # 001 XYZ would denote patient 1

All questionnaires will have the patient identification number.

Assigning a birth date of 06/01 and the patient's year of birth for age analysis will protect patient age information.

### **Procedure**

A questionnaire will be provided to subjects either at the clinic visit or mailed to their home prior to the dietary interview. It is designed to collect basic demographic and health information, such as age, race, occupation, and family history of cancer and physical activity. It is possible that subjects may need to ask spouses or family members for help in recalling this information, and therefore accuracy may be improved by providing participants a few days to complete this mailed questionnaire. Additionally, completion of the questionnaire at the subject's home decreases the time of the interview. Subjects will be asked to return the questionnaire in a postage paid envelope or bring to the interview session. Up to three reminder calls will be placed to the subject in the event that the subject does not return the questionnaire promptly, and subjects will be provided the additional options of returning the questionnaire in person or having a research associate pick it up at their home or place of business.

Habitual physical activity will be measured using a modified version of the Baecke index, designed to capture the physical activities of older people. This questionnaire includes questions that cover three components of physical activity: physical activity at work, sports during leisure time, and physical activity during leisure time excluding sports.

Habitual dietary intake will be measured by interview to capture a wide range of usual eating patterns, cooking practices, supplements, herbs, and vegetables during the past year. The FFQ is the Diet History Questionnaire developed at the NIH and recently validated against alternative questionnaires and assessment approaches.

The diet questionnaires are administered by in person interview. During the interview, the research nurses asked whether or not the participant eats a certain food, and the frequency that food is consumed. Similarly, each activity is asked. Paper versions of these questionnaires were included in this protocol for the review, however subjects will not see this paper version. Men, in general, do not complete dietary questionnaires as reliably as women, and therefore an in-person interview for these difficult questionnaires is necessary to obtain reliable information.

## **Peripheral venous blood**

### **Identification**

To maintain confidentiality and to meet HIPPA standards of PHI, the patient will be identified by use of an ID#. Each patient will be assigned a numerical identification number for confidentiality purposes. The patient's initials will also be part of the ID#. The numbers will be assigned in sequence 001,002,003, and so on. Patients will retain the same number throughout the study.

Example ID # 001 XYZ would denote patient 1  
All specimens would be labeled using this identification system

Peripheral venous blood will be collected using standard sterile procedures.

One 5ml (ethylenediamine-tetraacetic acid or EDTA) will be for a source of DNA

Two 5 ml (no anticoagulants) will be collected for radioimmunoassay for E2 (Serum estradiol)

The EDTA tube of blood will be transported to the PHG DNA core lab in room 518 Light Hall for DNA extraction. Contact: Cara Sutcliffe , ext 6-2744

The remaining two 5 ml vials of blood will be allowed to clot and centrifuged. The serum will be pipetted into a maximum of 9 equal amounts in 1.8 crovials. The remaining clots will also be retained and frozen at -80 degrees.

The specimens will be transported and analyses will be conducted at the Molecular Epidemiologic Research Laboratory directed by Dr. Quiyin Cai located at the Vanderbilt-Ingram Cancer Center. Dr. Fritz Parl in Medical Pathology at Vanderbilt University will oversee estrogen analysis on blood and urine specimens.

The biospecimens collected in this protocol will be stored frozen for up to 20 years, and additional laboratory tests may be performed on remaining biospecimens in order to further explain our study results or to develop subsequent protocols. At the end of this period, samples will be destroyed, and all paper documents will be shredded and destroyed.

## **Urine Collection**

### **Identification**

To maintain confidentiality and to meet HIPPA standards of PHI, the patient will be identified by use of an ID#. Each patient will be assigned a numerical identification number for confidentiality purposes. The patient's initials will also be part of the ID#. The numbers will be assigned in sequence 001,002,003, and so on. Patients will retain the same number throughout the study.

Example ID # 001 XYZ would denote patient 1  
All specimens would be labeled using this identification system

A urine sample at least about 20 mls, will be collected. Two ml aliquots of urine will be dispensed into each of nine labeled (ID #) freezer tubes and stored at -80°C until assayed for estrogen. Urinary 2HE, 4HE, and 16HE metabolite levels will be measured. Smoking participants will be asked not to smoke for a two-hour period prior to the visit, to reduce the impact of aromatic hydrocarbon exposure on estrogen metabolism.

### **Procedure**

#### **Preparation:**

- 9-1.8ml cryovials vials
- Specimen box
- Labels
- Permanent markers
- Biohazard Bags

At the clinic visit, participants will be given:

- Urine containers

### **Urine Processing**

- Urine specimens will be stored in CRC refrigerator
- Specimens will be processed after participant visit
- All specimen's will be labeled with date, participant ID #
- 1-2 ml aliquots of the urine sample will be pipetted into each of 9-labeled cryovials.
- Vials will be placed in specimen box for storage
- Remaining specimen will be discarded
- Study staff will then transport specimens to Dr. Qiuyin Cai MRB II, 618, ext # 6-1351
- Date, time and location of sample in the freezer will be recorded on the specimen log
- Samples will be stored at -80° C.
- Urine specimens will be stored until ready for analysis.

## Measurement Protocols

### Procedure

Collect data at 1 time-point during the study:

Body circumferences will be measured at initial clinic visit. Height and weight will be collected. A sitting height will also be collected.

Body mass index (weight (kg)/height (m)<sup>2</sup>) and the waist-to-hip ratio will be calculated. Body mass index (BMI) is a measure of body fat based on height and weight that applies to both adult men and women. Inches will be converted into millimeters and pounds into kilograms.

#### Height:

1. Height will be measured at initial clinic visit.
2. Height will be measured with out shoes and recorded in inches

#### Sitting Height:

1. Sitting height gives a measure of the trunk. It is a measurement of the distance from the highest point on the head to the base-sitting surface. Height measurement can vary throughout the day, being higher in the morning, so should be measured at a consistent time of day.
2. The subject sits with both feet on the floor, the lower back and shoulders straight and in alignment looking straight ahead. The height is measured form the surface of the chair to the highest point on the head.

#### Body weight:

1. Body weight will be measured at initial clinic visit.
2. Weight without shoes will be measured using calibrated scales and recorded in pounds

Participant's hip and waist circumferences will be measured in light clothing using a Gullick 2 tape measure. The circumference measures will be collected twice, and repeated if disparity between these two measures is greater than 10%.

1. Patient should be wearing loose fitting clothing.
2. Patient should be standing and breathing quietly with legs together and arms at sides leaving enough room to get the tape measure around the body

#### Waist:

- a. Measure the torso one inch above the navel even if this is not the usual waist line. Be sure that the tape is snug and horizontal and measure from the side. Make sure that fingers are not under the tape measure
- b. Record the first measure to the nearest half inch. If the measure is equal to a quarter inch,  $\frac{1}{4}$  or  $\frac{3}{4}$ , then round downward
- c. Remove the tape measure and begin again for the second measurement.

- d. Record the second measurement in the same manner as the first. If the two measurements are not within one inch of each other, then the entire process should be repeated and the two new measurements recorded

**Hips:**

- e. Measure the hips at the largest spot between the waist and thighs. This can be found by sliding the tape measure up and down. Be sure that the tape is snug and horizontal and measure from the side. Make sure that fingers are not under the tape measure
- f. Record the first measure to the nearest half inch. If the measure is equal to a quarter inch,  $\frac{1}{4}$  or  $\frac{3}{4}$ , then round downward
- g. Remove the tape measure and begin again for the second measurement.
- h. Record the second measurement in the same manner as the first. If the two measurements are not within one inch of each other, then the entire process should be repeated and the two new measurements recorded.